



PM Formalisation of Micro food processing Enterprises Scheme

HANDBOOK ON

FOOD SAFETY AND STANDARDS



**Prepared for Food Processing EDP Training for Credit Linked Subsidy
Beneficiaries Under PMFME Scheme**

**Food Processing EDP Training for Credit Linked Subsidy
Beneficiaries Under PMFME Scheme**

Training Handbook on

Module 8: Food Safety and Standards

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Chapter I

Food Regulatory Compliances

1.1 Introduction

In the past few years we all are experiencing that, the Food Industry is getting highly regulated and are mandatorily made to comply with certain requirements. These requirements are mainly concerning towards the safety and quality of food product that is to be served or made available in the market for their intended use by the target consumers.

All over the world it is being ensured that the food what the citizens of the nation are consuming is safe enough. Team of experts and specialist in the field of food processing sectors are continuously working towards framing regulatory guidelines and food standards which are aligned to international level. These regulatory frameworks structured for food industry regulates handling, manufacturing, storage, distribution and sale of food products, so as to maintain safety and quality in supply chain.

The regulatory frameworks need to get regularly updated while considering the following;

- Increased Consumer Awareness on Food Quality
- Increased Non-compliance to Quality
- Increased Global Trade
- Emerging Risks
- New Technologies



Regulatory Compliance

Definition: A regulatory compliance is a procedure where the supplied food product meets all the requirements in the form of directives, regulations, and standards stated by any regulatory body.

These sets of act, rules or regulations are essentially developed to protect the interest of a nation, its citizens and other businesses. In India the food supply is regulated by FSSAI, BIS, Legal Metrology, Tea Board etc. The main intention to have a food product compliance, is quality assurance. The product has to meet two most important compliances one is formulation compliance and another one is labelling compliance. The formulation compliance meets the quantitative requirements for ingredients and additives which are used to manufacture the product. Whereas, the labelling compliance is to provide true information of the product and make consumer aware about what they are purchasing.

Regulatory Non-Compliance

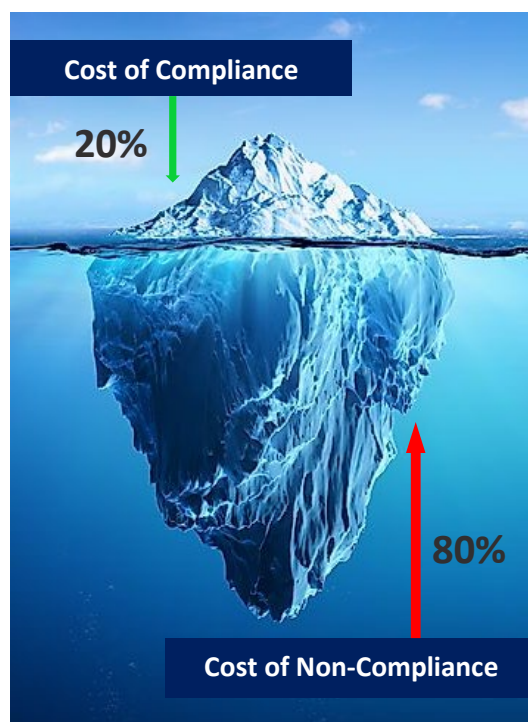
Definition: It is an intentional or unintentional gesture of disregarding the Act, Rules, Regulation or any advisories from a competent authority or Government who acts as the regulatory body of a particular business sector.

Non-compliance often results in legal punishment and penalties, including fines. It is also evident that the cost associated with non-compliance is much higher than the cost of compliance. To understand this in a better way, a case study is discussed below.

A food business operator is manufacturing a food product and supplying it throughout the country. It was observed that there are lot of non-compliance associated with the product under business. Even it was reported a food poisoning outbreak due to consumption of this food product.

These non-compliances and looking at the severity of the risk, the food business operator was charged with legal penalties and fines. Also, the business was asked for product recall too. Therefore, the cost to the non-compliance (CNC) came almost 5 times to the cost of compliance (CoC).

One can correlate this situation with an Iceberg. Where, the visible part is always small and that creates an ignorance about the hidden large portion. The larger portion of non-compliance cost also includes a hidden cost like; cost associated with business disruption, revenue loss, loss of customer trust and reduced consumer base etc.



Hence, it is always better to comply with rules and regulation stated by the regulatory bodies. A comprehensive compliance system of FSSAI includes surveillance and inspections for both domestic and imported food products.

1.2 Food Control System

It has become an important aspect to control and manage the food hazards and associated risk. To achieve this a food control system to meet predetermined objectives; concerning to food quality and safety is needed.

A national food control system means an activity which ensures that food available within a country is safe, wholesome and fit for human consumption, conforms to food safety and quality requirements and is honestly and accurately labelled as prescribed by the law.

Food Control System is an integration of a mandatory regulatory approach with preventive and educational strategies that protect the whole food chain. When establishing a food control system, a Risk Analysis approach has to be taken under consideration. Risk analysis must be the foundation on which food control policy and consumer protection measures are based.

Risk Analysis is a process approach which includes three phases, viz. Risk Assessment, Risk Management and Risk Communication.

Risk assessment - a scientifically based process consisting of the following steps:

- (i) Hazard identification
- (ii) Hazard characterization
- (iii) Exposure assessment and
- (iv) Risk characterization

Risk management - the process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed selecting appropriate prevention and control options.

Risk communication - the interactive exchange of information and opinions throughout the risk analysis process concerning hazards and risks, risk related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

An improved understanding of the risk based approach and growing awareness about the impact of food safety on public health and national economies, has led many countries, to make significant changes to their food control systems, in recent years. Governments around the world are constantly evolving legislation to ensure the food consumed by their citizens is safe.

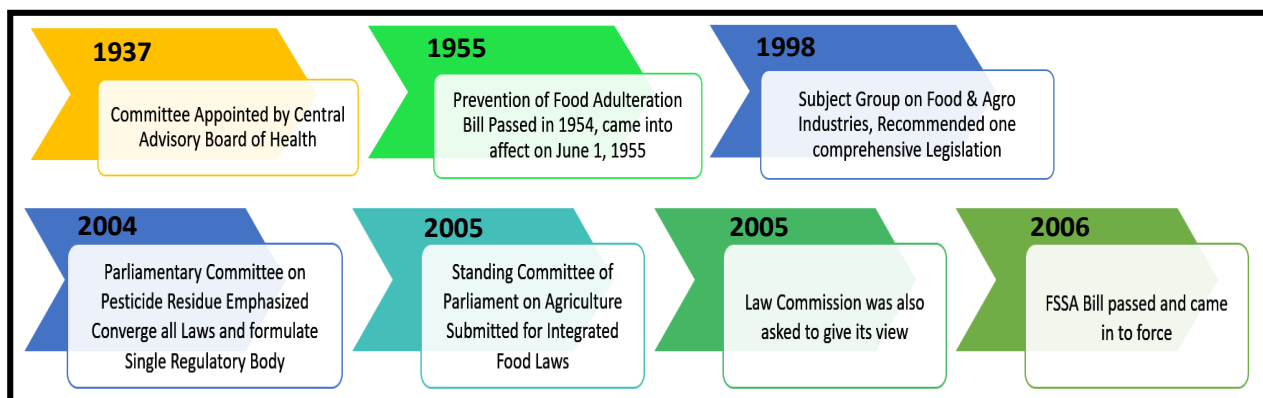
1.3 Food Safety and Standards Act and Food Authority

In India various acts & orders were there to handle food related issues. These all acts and orders were governed by various Ministries and Departments. Earlier the food supply was regulated by following acts and orders which were sector specific and more concerning towards specific objectives.

1. Prevention of Food Adulteration Act, 1954
2. Fruit Products Order, 1955
3. Meat Food Products Order, 1973
4. Vegetable Oil Products (Control) Order, 1947
5. Edible Oils Packaging (Regulation) Order 1988
6. Solvent Extracted Oil, Deoiled Meal, and Edible Flour (Control) Order, 1967
7. Milk and Milk Products Order, 1992
8. Any other order concerning to food under the Essential Commodity Act, 1955

But to keep track on all the rules and regulations made thereunder these act it massive task for a Food Business Operators (FBO). Also, there was a lot of confusion as to which authority one should report to. Therefore, to harmonize all the systems, the FSS Act was brought into place.

Timeline of Food Laws in India and Genesis of FSSAI



The main intention was to shift from multi-level to a single line of control with focus on self-compliance rather than a pure regulatory regime. To achieve this these all seven acts/orders were repealed and consolidated into single act called, **Food Safety and Standard Act, 2006**. The act was officially implemented on August 5, 2011.

Under this act it was also an aim to establish a single reference point for all matters relating to food safety and standards, which will work as an independent statutory authority. By this a regulatory body called **Food Safety and Standards Authority of India (FSSAI)** was established, which is the current Food Control System for India. The head office of FSSAI is situated at Delhi with 4 regional offices located in Delhi, Mumbai, Kolkata and Chennai.

1.4 Functions of FSSAI

Food Safety and Standards Authority of India (FSSAI) is an autonomous statutory body established under FSS Act, 2006. Ministry of Health & Family Welfare, Government of India is the administrative Ministry of FSSAI.

The Food Authority i.e. FSSAI and the State Food Safety Authorities shall be responsible for the enforcement of this Act. These authorities shall monitor and verify that the relevant requirements of law are fulfilled by food business operators at all stages of food business.

The FSSAI performs following functions, so as to achieve a goal of ensuring the availability of safe and wholesome food for human consumption.

1. Framing of Regulations to lay down the Standards and guidelines in relation to articles of food and specifying appropriate system of enforcing various standards thus notified.
2. Laying down mechanisms and guidelines for accreditation of certification bodies engaged in certification of food safety management system for food businesses.
3. Laying down procedure and guidelines for accreditation of laboratories and notification of the accredited laboratories.
4. To provide scientific advice and technical support to Central Government and State Governments in the matters of framing the policy and rules in areas which have a direct or indirect bearing of food safety and nutrition.
5. Collect and collate data regarding food consumption, incidence and prevalence of biological risk, contaminants in food, residues of various, contaminants in foods products, identification of emerging risks and introduction of rapid alert system.
6. Creating an information network across the country so that the public, consumers, Panchayats etc. receive rapid, reliable and objective information about food safety and issues of concern.
7. Provide training programmes for persons who are involved or intend to get involved in food businesses.
8. Contribute to the development of international technical standards for food, sanitary and phyto-sanitary standards.
9. Promote general awareness about food safety and food standards.

The Food Authority is assisted by Scientific Committees and Panels in setting standards and the Central Advisory Committee in coordinating with enforcement agencies.

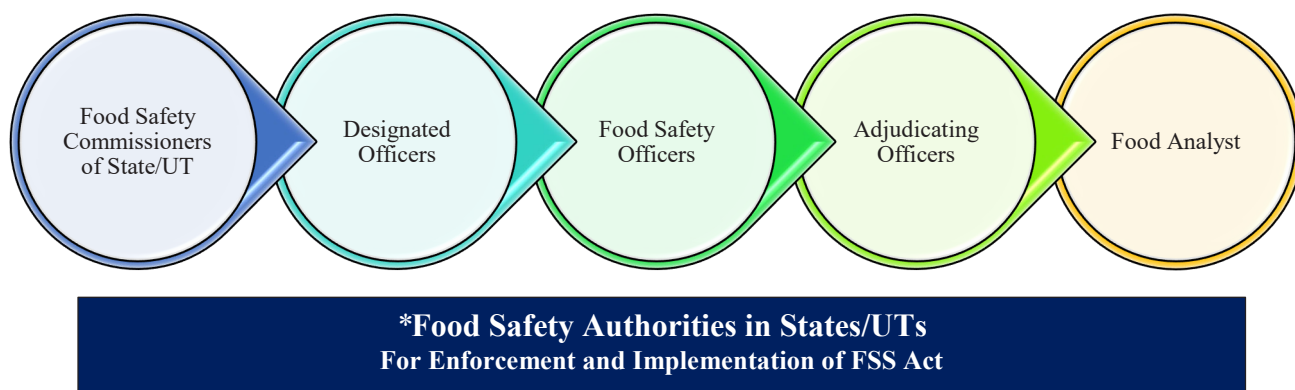
1.5 Enforcement System of FSSAI

Enforcement of FSS Act is nothing but responsibility of ensuring compliance by the FBO’s to the rules and regulations of this act. The enforcement is undertaken on the basis of surveillance, monitoring, inspection and random sampling of food products carried out by the Officials of Food Safety Departments.

Food Safety and Standards Authority of India and State Food Authorities are jointly responsible for implementation & enforcement of FSS Act, 2006. The details are provided under Section 29 of FSS Act, 2006.

The Food Authority and the State Food Safety Authorities monitors and verifies that the relevant requirements of law are fulfilled by FBO’s at all stages of food business. The authorities also maintain a system of control and other activities as appropriate to the circumstances, including public communication on food safety and risk, food safety surveillance and other monitoring activities covering all stages of food business. The Food Authority provides policy interventions, direction and coordination at national level, where the State and Union Territory Authorities conduct food safety enforcement at the field level.

Even more the primary responsibility of ensuring compliance rests with the States and UTs. States/UT Governments have appointed Commissioners of Food Safety, notified Adjudicating Officers, Designated Officers and Food Safety Officers for their respective jurisdictions to perform various functions mandated under the Act. The enforcement is primarily undertaken by all Food Safety Commissioners of State/UT along with Designated Officers and Food Safety Officers. Along with this the Adjudicating Officers and Food Analyst also support the enforcement activities.



**The functions and enforcement responsibilities of these appointed authorities are provided in the Chapter VII - ENFORCEMENT OF THE ACT of the Food Safety and Standard Act, 2006.*

1.6 Important Provisions in FSS Act, 2006

Various provisions which are applicable for Food Business Operators who are in an activity of manufacture, storage, distribution, sale and import of food are given in twelve chapters of the FSS Act. These provisions are not applicable to any farmer or fisherman or farming operations or crops or livestock or aquaculture, and supplies used or produced in farming or products of crops produced by a farmer at farm level or a fisherman in his operations.

Chapter IV of the FSS Act, 2006 covers **General Provisions as to Articles of Food** whereas, the Chapter V deals with **Provisions Relating to Import of Articles of Food**. These provisions are given in different sections of this act (i.e. Section 19 to Section 25) as given below.

Section 19. Use of food additive or processing aid

No article of food shall contain any food additive or processing aid unless it is in accordance with the provisions of this Act and regulations made thereunder.

Section 20. Contaminants, naturally occurring toxic substances, heavy metals, etc.

No article of food shall contain any contaminant, naturally occurring toxic substances or toxins or hormone or heavy metals in excess of such quantities as may be specified by regulations.

Section 21. Pesticides, veterinary drugs residues, antibiotic residues and microbiological counts

(1) No article of food shall contain insecticides or pesticides residues, veterinary drugs residues, antibiotic residues, solvent residues, pharmacological active substances and micro-biological counts in excess of such tolerance limit as may be specified by regulations.

(2) No insecticide shall be used directly on article of food except fumigants registered and approved under the Insecticides Act, 1968 (46 of 1968).

Section 22. Genetically modified foods, organic foods, functional foods, proprietary foods, etc.

No person shall manufacture, distribute, sell or import any novel food, genetically modified articles of food, irradiated food, organic foods, foods for special dietary uses, functional foods, nutraceuticals, health supplements, proprietary foods and such other articles of food which the Central Government may notify in this behalf.

Section 23. Packaging and labelling of foods.

(1) No person shall manufacture, distribute, sell or expose for sale or despatch or deliver to any agent or broker for the purpose of sale, any packaged food products which are not marked and labelled in the manner as may be specified by regulations. Provided that the labels shall not contain any statement, claim, design or device which is false or misleading in any particular concerning the food products contained in the package or concerning the quantity or the nutritive value implying medicinal or therapeutic claims or in relation to the place of origin of the said food products.

(2) Every food business operator shall ensure that the labelling and presentation of food, including their shape, appearance or packaging, the packaging materials used, the manner in which they are arranged and the setting in which they are displayed, and the information which is made available about them through whatever medium, does not mislead consumers.

Section 24. Restrictions of advertisement and prohibition as to unfair trade practices.

(1) No advertisement shall be made of any food which is misleading or deceiving or contravenes the provisions of this Act, the rules and regulations made thereunder.

(2) No person shall engage himself in any unfair trade practice for purpose of promoting the sale, supply, use and consumption of articles of food or adopt any unfair or deceptive practice including the practice of making any statement, whether orally or in writing or by visible representation which –

- (a) falsely represents that the foods are of a particular standard, quality, quantity or grade-composition;
- (b) makes a false or misleading representation concerning the need for, or the usefulness;
- (c) gives to the public any guarantee of the efficacy that is not based on an adequate or scientific justification thereof: Provided that where a defence is raised to the effect that such guarantee is based on adequate or scientific justification, the burden of proof of such defence shall lie on the person raising such defence.

Section 25. All imports of articles of food to be subject to this Act.

(1) No person shall import into India –

- (i) any unsafe or misbranded or sub-standard food or food containing extraneous matter;
- (ii) any article of food for the import of which a licence is required under any Act or rules or regulations, except in accordance with the conditions of the licence; and
- (iii) any article of food in contravention of any other provision of this Act or of any rule or regulation made thereunder or any other Act.

(2) The Central Government shall, while prohibiting, restricting or otherwise regulating import of article of food under the Foreign Trade (Development and Regulation) Act, 1992 (22 of 1992), follow the standards laid down by the Food Authority under the provisions of this Act and the Rules and regulations made thereunder.

1.7 FSSR Compliance

Food Safety and Standards Rules & Regulations (FSS Act, 2006 & FSS Regulations, 2011) are mandatory and must be complied in order to achieve ultimate objective of national food safety. Under this act, FSSR means regulation which includes rules and orders issued by FSSAI, that can be utilized as guidelines for conduct of food business and proper implementation of the act. The regulations, and revisions of these regulations in the form of compendium can be accessed from the FSSAI portal. Compendium encompasses all amendments to the individual regulations notified in the Gazette of India for the purpose of providing ready reference to food business operators and consumers.

Every food business operator has to comply with these below mentioned regulations, concerning to their business conduct.

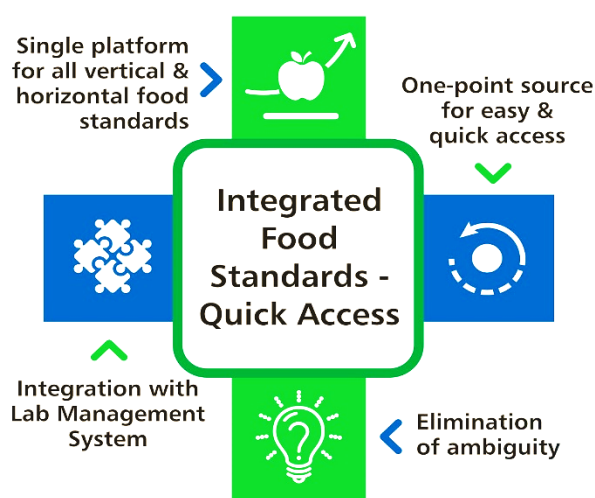
1. FSS (Licensing and Registration of Food Businesses) Regulation, 2011
2. FSS (Food Products Standards and Food Additives) Regulation, 2011
3. FSS (Prohibition and Restriction of Sales) Regulation, 2011
4. FSS (Contaminants, Toxins and Residues) Regulation, 2011
5. FSS (Laboratory and Sampling Analysis) Regulation, 2011
6. FSS (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016
7. FSS (Food Recall Procedure) Regulation, 2017
8. FSS (Import) Regulation, 2017
9. FSS (Approval for Non-Specific Food and Food Ingredients) Regulation, 2017
10. FSS (Organic Food) Regulation, 2017
11. FSS (Alcoholic Beverages) Regulation, 2018
12. FSS (Fortification of Food) Regulation, 2018
13. FSS (Food Safety Auditing) Regulation, 2018
14. FSS (Advertising and Claims) Regulation, 2018
15. FSS (Packaging) Regulation, 2018
16. FSS (Foods for Infant Nutrition) Regulations, 2020
17. FSS (Labelling and Display) Regulations, 2020
18. FSS (Ayurveda Aahara) Regulations, 2022
19. FSS (Vegan Foods) Regulations, 2022

1.8 Concept of Food Standards

The regulatory compliance of any FBOs will largely be evaluated based on the standards framed by FSSAI. Framing of food standards depends upon various factors like emerging new technologies, changes in processing and preservation technologies, new risks associated with food and additives, and also advancement in food assessment methods.

FSSAI lays down science-based standards for articles of foods, and to regulate their manufacture, storage, distribution, sale and import, to ensure safe and wholesome food for human consumption.

FSSAI has developed a system- **Integrated Food Standard (IFS) Quick Access**, integrating all Food Safety Standards and Regulations. IFS system would facilitate a user to access the information relating to all permitted food additives; HS Code; Food Category Code; contaminants, pesticide residues, metallic contaminant, product-specific quality standards; licensing and imports related requirements.



Food standards are broadly classified into Horizontal Standards and Vertical Standards.

Horizontal standards

- Standards applicable to multiple industries and they are more general in nature
- Common standards for multiple food
- Regulations covering these standards
 - *Food Safety and Standards (Contaminants, Toxins and Residues) Regulation, 2011*
 - *Food Safety and Standards (Labelling and Display) Regulations, 2020*

E.g.: Limit of Aflatoxin for All articles of food 30 µg/kg, and Veg and Non-veg Logo on Label

Vertical standards

- Standards that apply to a particular industry or to particular operations and practices
- Identity standards for specific food
- Regulations covering these standards
 - *Food Safety and Standards (Food Products Standards and Food Additives) Regulation, 2011*
 - *Food Safety and Standards (Vegan Foods) Regulations, 2022*

E.g.: TSS of Tomato Puree should not be less than 9% and that of Tomato Paste not less than 25%

1.9 Duties & Obligations of Food Business Operators (FBO) under FSS Act, 2006

Under the Section 26 (Responsibilities of the Food business operator) of Chapter VI of the Food Safety and Standard Act, 2006 it is a duty of every food business operator to comply and perform following responsibilities concerning towards the food safety.

- (1) Every food business operator shall ensure that the articles of food satisfy the requirements of this Act and the rules and regulations made thereunder at all stages of production, processing, import, distribution and sale within the businesses under his control.
- (2) No food business operator shall himself or by any person on his behalf manufacture, store, sell or distribute any article of food –
 - (i) *which is unsafe; or*
 - (ii) *which is misbranded or sub-standard or contains extraneous matter; or*
 - (iii) *for which a licence is required, except in accordance with the conditions of the licence; or*
 - (iv) *which is for the time being prohibited by the Food Authority or the Central Government or the State Government in the interest of public health; or*
 - (v) *in contravention of any other provision of this Act or of any rule or regulation made thereunder.*
- (3) No food business operator shall employ any person who is suffering from infectious, contagious or loathsome disease.
- (4) No food business operator shall sell or offer for sale any article of food to any vendor unless he also gives a guarantee in writing in the form specified by regulations about the nature and quality of such article to the vendor. Provided that a bill, cash memo, or invoice in respect of the sale of any article of food given by a food business operator to the vendor shall be deemed to be a guarantee under this section, even if a guarantee in the specified form is not included in the bill, cash memo or invoice.
- (5) Where any food which is unsafe and is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment within a specified time, it is found that there is no evidence that the rest of the batch, lot or consignment is unsafe

Along with this, it is the responsibility of any FBO to obtain Licence/Registration for their food business under this act, while complying to general hygienic and sanitary practices given in the Schedule 4 of Licensing and Registration Regulation 2011.

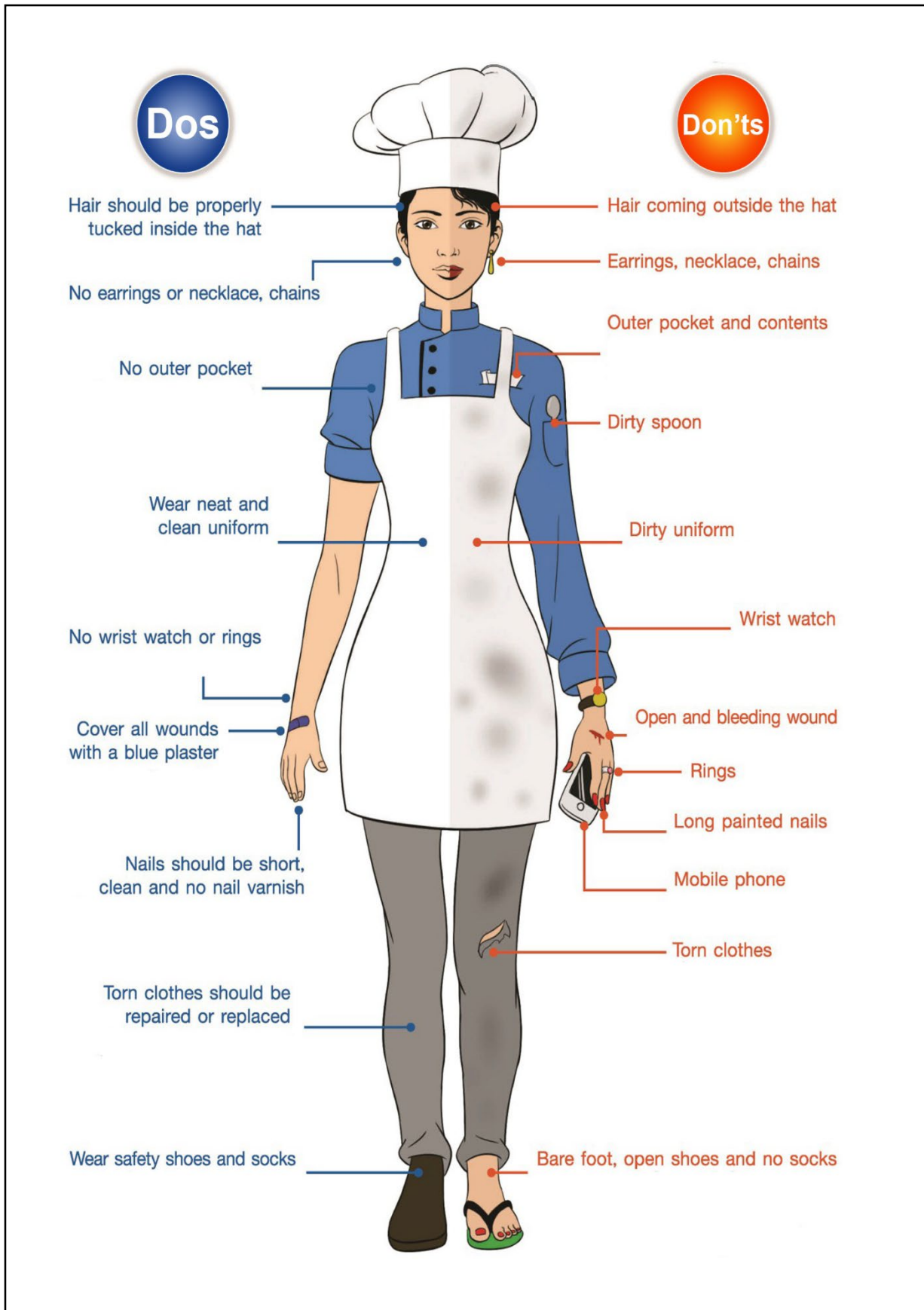
1.10 Do’s & Don’ts for FBOs

Risk associated with contamination of food is still not under control globally. The outbreaks like food borne illness, food poisoning and food intoxication has resulted in health and economic losses. Looking at its impact on consumer health it has become a matter of concern for the Food Safety and Standard Authority of India (FSSAI). For this, FSSAI has provided an advisory for the chefs and food handlers, more specifically concerning about hygiene and safety in food business. The advisory, states guidelines that to be followed at each and every stage of food processing, like procurement of raw material, pre-preparation, preparation, storage and distribution etc.

The following Do’s and Don’ts are to be followed by any FBO to achieve food safety.

Do’s	Don’ts
<ol style="list-style-type: none"> 1. Take bath daily before reporting to work. 2. Wear clean and protective clothing, clean aprons, hand gloves, and head wear appropriately 3. Wash hands with soap and clean (potable) water; before & after work; after handling chemicals or contaminated materials; etc. 4. Keep food premises clean, well ventilated, and no water stagnation is allowed. 5. Carefully inspect raw material for freshness and quality before purchasing. 6. Procure packaged products from FSSAI licensed/registered vendors only. 7. Use clean (potable) water for washing, food preparation, drinking, cleaning of utensils, etc. 8. Use equipment & utensils etc. of food-grade quality. 	<ol style="list-style-type: none"> 1. Do not Handle food when sick. 2. Do not work or prepare on dirty surface 3. Do not prepare or sell food in an area prone to pollution such as effluent water, heavy smoke, hazardous waste and more. 4. Do not store hazardous substances such as fuel, chemicals, etc. near the food preparation area. 5. Do not use loose oil or spices. 6. Do not keep food at room temperature for more than 4 hours. 7. Do not resell leftover food the next day. 8. do not keep the waste bins open

Pictorial guidelines for maintaining personal hygiene in food premises is as given below.



Chapter II

Licensing/Registration of FBO

2.1 Introduction

Food Safety and Standard Authority of India has reinforced rules and regulations for food business operators. The Act has made mandatory provisions for FBO and regulation of manufacturing, storage, sale, & distribution process to ensure utmost food safety and hygiene. Amongst these regulation, the foremost important regulation that any food business operator should comply is Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011. According to this regulation, it has been made mandatory by FSSAI that, every food business operator involved in the manufacturing, processing, sale of food products and storage distribution must compulsorily obtain FSSAI Registration or License. Functioning without a valid food license or registration is a punishable offence for FBOs as per FSS Act, 2006, and they will not be able to continue their business operation.

A business with license or registration, will get a 14-digit numeric registration or a license number that is printed on all the food packages that the business is manufacturing.

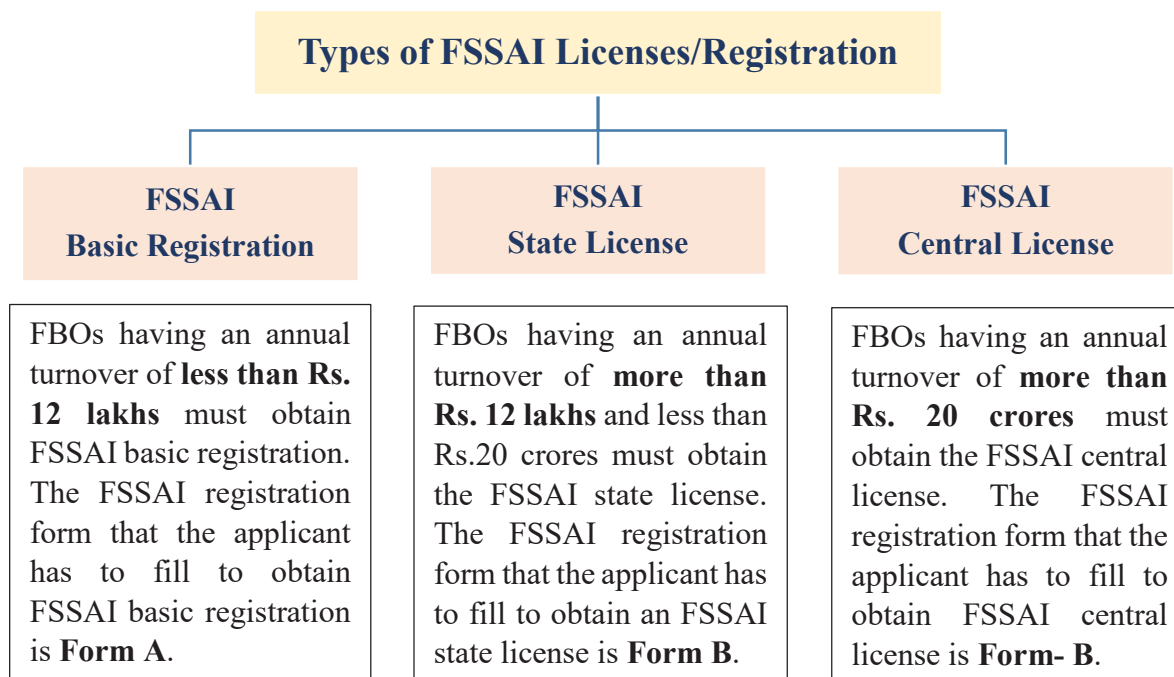


Obtaining license or registration is a mandatory first step before starting any food business operation in India. Along with this, holding a license and registration for a food business brings certain advantages, like;

- As it is a mandatory requirement of Food Authority, FBOs have to comply with this. Failure to do so will attract penalties which cost more than the fee required pay to obtain license/registration.
- It generates trust amongst the consumer and creates strong brand recognition among the target end-users and public at large. It also enables businesses to attract more customers
- FBO's will be able to use FSSAI logo, which can build a goodwill among the customers. Also, it increases the competitiveness of business to that with those business which don't have licence/registration and hence improves creditability of the business.
- It offers legal stability to the business as well as opens financial channels for business expansion, that otherwise is lacking in unregistered counterparts
- It also supports the FBO to ensure about food safety

2.2 Types of Licenses and Registration

The type of FSSAI license or registration is based on the Kind of Business, turnover and installation capacity of production. The business registration with FSSAI is categorised into three types.



Under the Schedule 3 of the Food Safety and Standards (Licensing and Registration of Food Businesses), Regulations 2011, fee to be paid for Grant/ Renewal of Registration / License is given. The fee concerning towards manufacturing unit is as mentioned in table given below.

Sr. No.	Type of License/Registration	Fee per annum (in. Rs.)
1.	Registration	100
2.	License issued by Central Licensing Authority	7500
3.	License issued by State Licensing Authority:	
	Manufacturer/Miller with capacity above 1MT per day Production or 10,001 to 50,000 LPD of milk or 501 to 2500 MT of milk solids per annum	5000
	Manufacturer/Miller with capacity below 1 MT of Production or 501 to 10,000 LPD of milk or 2.5 MT to 500 MT of milk solids per annum	3000
4.	Any other Food Business Operator	2000
*Duplicate copy of Registration or License - 10% of the applicable fee to be paid <i>The payment for the fee shall be made by the Food Business Operator through Bank draft or online transfer or treasury chalan or any other suitable means as specified by the Licensing Authority.</i>		

2.3 Kind of Businesses (KOBs) and their eligibility to obtain Licence/Registration

It is necessary to check the eligibility of the business to understand whether the business needs to obtain registration or license (if license then whether state licence or central license).

To check the business eligibility one can click on the link <https://foscoc.fssai.gov.in/business-eligibility>. A webpage detailing about Kind of Business, Eligibility Criteria, type of license or registration along with fees to be paid will get reflected. Details about kind of business eligible for registration or license is given below.

Eligibility for Applying to obtain FSSAI Registration

Petty food business operators are eligible to apply for FSSAI registration. Petty Food Business category included the following;

Those who manufacture or sell food items either themselves or via a retailer, hawker, itinerant vendor or a temporary stall owner. Those who distribute food, which also includes, in any religious or social gathering except a caterer. Other food businesses including small scale or cottage industry or such other industries relating to food business or tiny food businesses with an annual turnover not exceeding Rs. 12 lakhs and those whose:

- Processing Units including repackers, but other than milk and milk products and meat and meat products, with production capacity of food not exceeding 100 kg or 100 litre per day.
- Procurement or handling and collection of milk is up to 500 litres of milk per day or up to 2.5 metric ton (MT) of milk solids per annum.
- Vegetable oil processing units, including units producing vegetable oil by the process of solvent extraction, oil expeller unit and refineries with a turnover of up to 100 kg or 100 litre per day.
- Meat processing units with a production of more than 100 kg per day or 30 MT per day.
- Slaughtering capacity is 2 large animals or 10 small animals or 50 poultry birds per day or less.
- Cold storage including the Storage Excluding Controlled Atmosphere+ Cold as well as cold and refrigerated storage and cold storage which is temperature controlled, each having a turnover of up to Rs 12 lakhs per annum.
- Wholesalers, retailers, distributors, and suppliers with an annual turnover of up to Rs 12 lakhs.
- Dhaba owners and other food vending establishments along with clubs and canteens having up to Rs 12 lakhs turnover per annum.
- Hotels and Restaurants with a turnover of up to Rs 12 lakhs per annum. Transporters with an annual turnover of up to Rs 12 lakhs.

Eligibility for Applying to obtain FSSAI State Licence

A state licence is for food business operators that do not classify as petty food businesses. The eligibility for food business operators for a State FSSAI Licence includes the following;

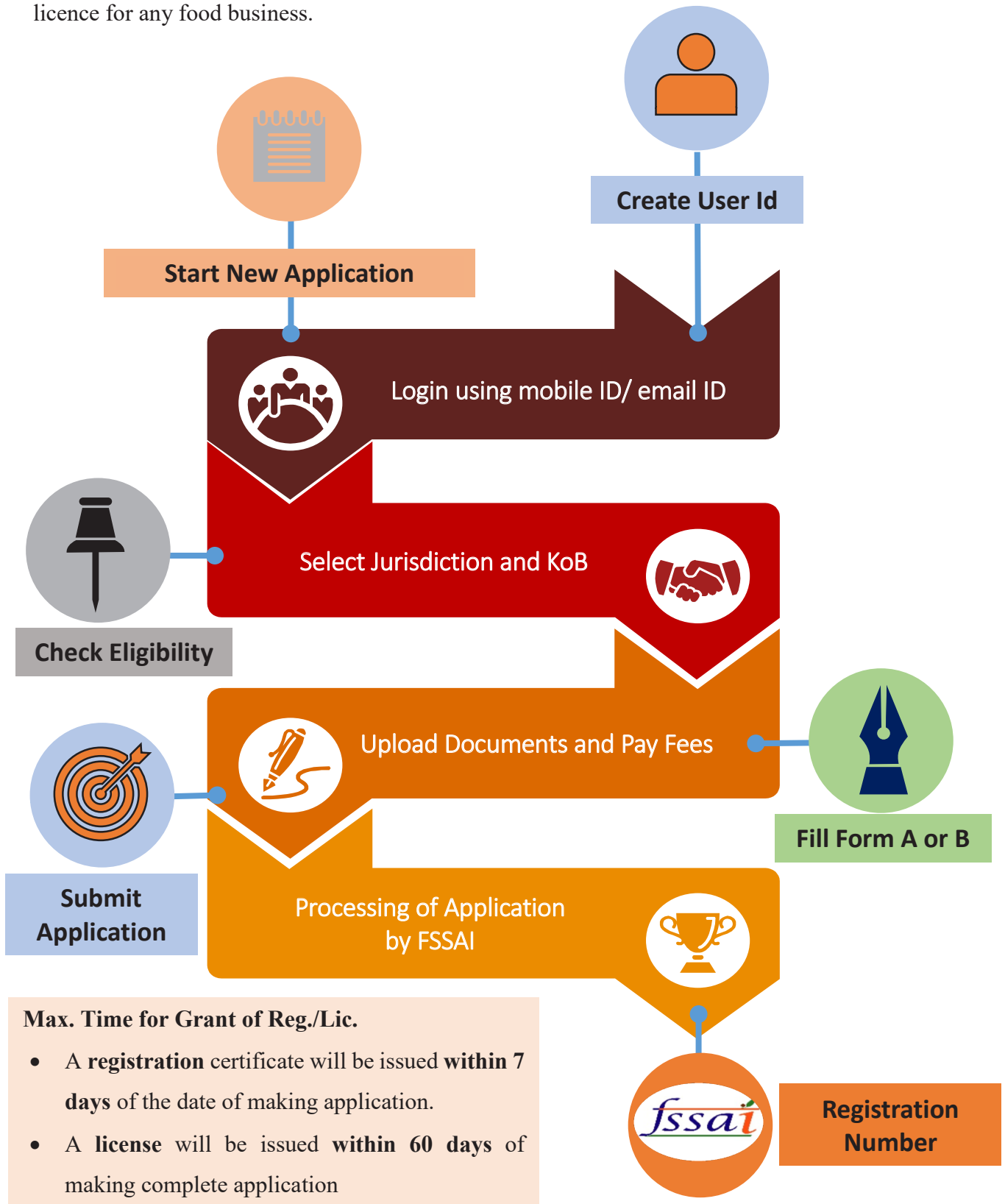
- Dairy units, including milk chilling units that are equipped to handle or process milk from 501 litres per day (LPD) to 50,000 LPD or 2.5 million tons (MT) to 2,500 MT of milk solids per annum.
- Vegetable oil processing units and also units that vegetable oil by the process of solvent extraction and refineries, which include oil expeller unit that produces up to 2 MT per day or have an annual turnover of Rs 12 lakh and above.
- Slaughtering units that have a capacity in case of large animals of more than 2 and up to 50; for small animals capacity more than 10 and up to 150 and for poultry birds capacity more than 50 and up to 1000 per day.
- Meat processing units that have a capacity of upto 500 kg of meat per day or of 150 MT per annum.
- All food processing units which even includes relabellers and repackers that have a capacity of more than 100 kg or 100 litre and up to 2 MT per day and includes all grains, pulses and cereals milling units.
- Storage businesses excluding that which have controlled atmosphere and cold, that have a capacity of up to 50,000 MT. For storages that are cold and refrigerated, the eligibility criteria is, a capacity of more than 10,000 MT and for storages that have cold and controlled atmosphere too, the eligibility capacity is more than 10,000 MT.
- Wholesalers that have an annual turnover of up to 30 crores.
- Retailers, distributors, suppliers as well as caterers with a turnover of up to 20 crores per annum.
- Dhaba owners, or owners of other food vending establishments as well as clubs and canteens that have an annual turnover of 12 lakhs.
- Hotels that have a minimum of 3-star rating and below 5-star.
- Restaurants that have a turnover of up to Rs 20 crores.
- Marketers that have a turn over annually of 20 crores.
- Transporters having minimum 100 vehicles/wagons, or an annual turnover of up to 30 crores.

Eligibility for Applying to obtain FSSAI Central Licence

- Dairy units including milk chilling units equipped to handle or process more than 50,000 litres of liquid milk/day or 2500 MT of milk solid per annum.
- Vegetable oil processing units and units producing vegetable oil by the process of solvent extraction and refineries including oil expeller unit having installed capacity more than 2 MT per day.
- All slaughter houses equipped to slaughter more than 50 large animals or 150 or more small animals including sheep and goats or 1000 or more poultry birds per day.
- Meat processing units equipped to handle or process more than 500 kg of meat per day or 150 MT per annum.
- All food processing units other than mentioned under (I) to (IV) including relabellers and repackers having installed capacity more than 2 MT/day except grains, cereals and pulses milling units.
- 100 % Export Oriented Units.
- All Importers importing food items including food ingredients and additives for commercial use.
- All food business operators manufacturing any article of food containing ingredients or substances or using technologies or processes or combination thereof whose safety has not been established through these regulations or which do not have a history of safe use or food containing ingredients which are being introduced for the first time into the country.
- Food Business Operator operating in two or more states.
- Food catering services in establishments and units under Central Government Agencies like Railways, Air and airport, Seaport, Defence etc.

2.4 Basic flow chart for Obtaining Registration/Licence

Below is the schematic representation of process for obtaining a registration certificate of licence for any food business.



2.5 Food Safety Compliance System (FoSCoS)


One can apply to obtain license or registration through an online portal called FoSCoS. Details about the portal along with the screenshots (Source: <https://foscos.fssai.gov.in/>) are given below, for better understanding the portal fields and to facilitate the use of the port while making an application.



About FoSCoS

Food Safety Compliance System (FoSCoS) is an enhanced version of Food Licensing and Registration System (FLRS) which was launched in 2012 for issuance of FSSAI Licenses and Registration. It is a PAN-India IT platform for food safety regulatory needs also. It also integrates with other platforms of FSSAI as well as GST, PAN, MCA etc. further ease out the processes for businesses and also ensure a 360 degree profiling of businesses.

Standardized Food Products 
View all FSSAI Standardized Products Clubbing of variants of products

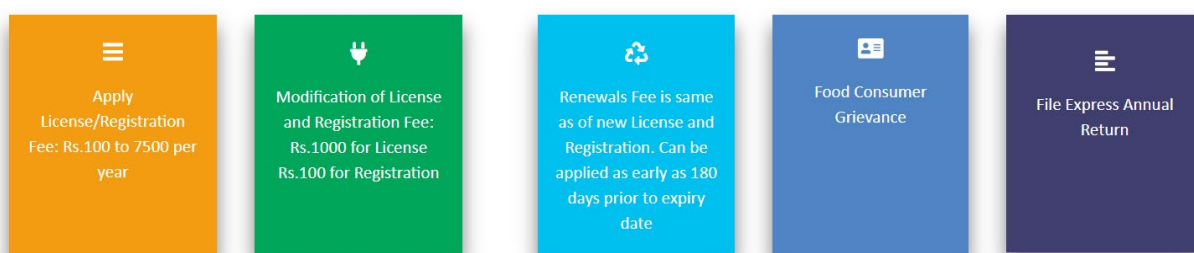
Eligibility of your food business 
View all Eligibility Criteria Details

Under this field you can search for the list of standardized products as per the food category system, and you will get know about under which category your product falls.

You can check eligibility of your food processing business using this filed. Based on Kind of Business you will be able know about whether your business needs registration or license.



Once you click on first tab (i.e. Track Application), you will be able to fill your application number and after entering the captcha you will be able to know about status of your application.



Amongst these five colored squares, the first yellow colored tab is to apply for obtaining License/Registration. Once you click on it you get lead towards the further process for application.

<p>DOCUMENTS REQUIRED</p> <p>NEW/RENEWAL/MODIFICATION OF LICENSE</p> <p>NEW REGISTRATION</p> <p>FEE STRUCTURE</p>	<p>ADDITIONAL INFORMATION</p> <p>ANNUAL RETURN</p> <p>FORM D-1</p> <p>Importer</p> <p>Exporter</p> <p>INSPECTION CHECKLIST</p> <p>CONDITION OF LICENSE</p>	<p>FSS ACT, 2006</p> <p>FSS RULES, 2011</p> <p>FSS REGULATIONS</p> <p>GAZETTE NOTIFICATION</p> <p>ADVISORIES/ORDERS</p>	<p>USEFUL LINKS</p> <p>FoSTaC</p> <p>Audit Management System</p> <p>FOOD SAFETY MITRA</p> <p>Notified Food Laboratories</p> <p>Data Statistics</p> <p>More Links</p>
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At the bottom of the web page different links are provided for required documents, forms as well as the links which lead you towards the Act, Regulations and different notification published by FSSAI. The red colored square mark denotes about tabs, on which if you click will state the list of documents required to be uploaded while filling the application for License/Registration.

Apply for New License/Registration



Apply For
License/Registration



Apply For
License/Registration
[Railways]



Apply For
License/Registration
[Airport/Seaport]

On the previous page we have seen about the yellow tab for application process. Once you click on the yellow tab, these three squares will get reflected on your screen. Red one is for Applying to obtain License or Registration for Manufacturing Units.

Select the state where premises is located for which License/Registration will be obtained.

Once you click on red tab, you observe a field, seeking information about the State in which you want to start your Manufacturing Unit. By using the scroll down option you can select any State.

Manufacturer
Trade/Retail
Food Services
Central Govt. Agencies
Head Office

General Manufacturing ⊖

Manufacturers / Processors other than dairy units, vegetable oil processing units, slaughtering units and meat processing units.

Repacking means packing of food product into different sizes with labelling after doing minimal processing as required like sorting, grading, sieving etc. from wholesale packages. The food product is not manipulated & the composition or formulation is not affected or changed

- More than 2 MT/day. **No grains, cereals and pulses milling units**
- All grains, Cereals & Pulses milling units without any ceiling on quantity and/or other Food Businesses more than 100Kg/Litre upto 2 MT/day
- Turnover not exceeding Rs. 12 lakhs and whose production capacity of food does not exceed 100 kg/ltr per day

Once you select the State and proceed, you will be asked to provide information about your kind of business to check the business eligibility. In Manufacturing sections, different sections are given which are specific for particular food sector. In the section of General Manufacturing Unit three options are given which are based on the capacity or turnover of the business. You have select the Kind of Business (KoB) by clicking the small white circles and click of proceed tab for eligibility check.

Clear Selected KOBs

Proceed

Cancel

2.6 Steps to obtain License / Registration for Food Business

Below are the screen shots stating the Kind of Business and their eligible license category. If you check the business type which has a turnover less than Rs. 12 Lakh, your eligible license category is **Registration**. So for such kind of business you need apply for obtaining registration by filling the **Form “A”**. If you click on options other than this you will be required to obtain either a State License or Central License, by filling the **Form “B”**.

S.No	Kind of Business	License Category
1	Manufacturer - General Manufacturing	Registration


[Click here to apply for Registration for all businesses](#)


Form "A"
 [See [Regulation 2.1.1](#) and [Regulation 2.1.7](#)]
 Application for Registration under Food Safety and Standards Act, 2006


S.No	Kind of Business	License Category
1	Manufacturer - General Manufacturing	State License


[Click here to apply for State License for all businesses](#)


Form "B" : Application for License / Renewal of license under Food Safety and Standards Act, 2006

-  **Premises Detail**

-  **Product Selection**

-  **Communication Details**

-  **Required Document**

-  **Payments**

While filling the Form B to obtain a License for you Food Business, you have to fill the information in concern sections. In Premises Details, you have to provide details about Business Location, Address of Manufacturing Unit and Corresponding Details, etc. In Product Selection section, you have to select the Product Category and List of Products that you are going to manufacture in your Unit. After providing Communication Details, you need to upload the required documents and pay the fee.

Once you fill all the required details you have to save and submit your application. On successfully submission of application form you will receive a 14 Digit Registration Number that you use for further communication and by using it you can track your application status too.

2.7 Conditions of License

All Food Business Operators shall ensure that the following conditions are complied with at all times during the course of its food business.

The Food Business Operators shall:

1. Display a true copy of the license granted (Form C) at all times at a prominent place in the premises.
2. Give necessary access to Licensing Authorities or their authorised personnel to the premises.
3. Inform Authorities about any change or modifications in activities /content of license.
4. Employ at least one technical person to supervise the production process.
5. Ensure that no product other than the product indicated in the license/registration is produced in the unit.
6. Maintain factory's sanitary and hygienic standards and worker's Hygiene as specified in the Schedule - 4 according to the category of food business
7. Maintain daily records of production, raw materials utilization and sales separately.
8. Ensure that the source and standards of raw material used are of optimum quality.
9. Food Business Operator shall not 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.
10. Ensure Clean-In-Place systems (wherever necessary) for regular cleaning of the machine & equipments.
11. Ensure testing of relevant chemical and/or microbiological contaminants in food products in accordance with these regulations as frequently as required on the basis of historical data and risk assessment to ensure production and delivery of safe food through own or NABL accredited /FSSAI notified labs at least once in six months.
12. Ensure that as much as possible the required temperature shall be maintained throughout the supply chain from the place of procurement or sourcing till it reaches the end consumer including chilling, transportation, storage etc.
13. The manufacturer/importer/distributor shall buy and sell food products only from, or to, licensed/registered vendors and maintain record thereof.
14. Furnish periodic annual return (1st April to 31st March), within upto 31st May of each year. For collection/ handling/ manufacturing of Milk and Milk Products half yearly returns also to be furnished as specified (1st April to 31st September before 30th November and 1st October to 31st March).

2.8 Best practices to be followed while applying for Registration/License

FBOs may face trouble sometimes why applying for obtaining license and registration for their business. This may happen due to negligence, confusion and being uninformed about the process. Hence, a basic yet needful guidance, providing detailed information about each document based on the Kind of Business (KOB) is very much required. Below are some key best practices that one should follow to overcome eleventh hour rush and make the application process smooth.

General guidelines while applying for a license:

- Never rush while applying, this may create Typographical errors
- Always submit a legible and clear document
- Photocopied documents shall be self-attested
- Submit the updated document
- Never provide fake information
- Always compare all documents and check for uniformity in data. E.g. Address, Name etc.
- Never submit a fabricated or forged document, this may lead to rejection of application
- Before applying for any License, try to go through the KOB Eligibility Document
- Stick with the eligibility document as a mistake may stand your application rejected
(<https://foscos.fssai.gov.in/assets/docs/KindofBusinessEligibilityLatest.pdf>)
- Understand the Product Standards and Regulations. This also helps to understand the KOB.
- Check the updated list of documents for respective KOBs.
- Refer the link (<https://foscos.fssai.gov.in/home-document>) for state specific documents (if any)
- Documents in the list with an asterisk symbol, shall be submitted on letter head.
- If the Authority reverts the query, try to resolve at the earliest this will expedite the procedure
- A FBO's premise shall have only one FSSAI License or Registration on which any number of Kind of Businesses (KoB) can be endorsed.
- If you encounter with any queries, you may contact the FoSCoS helpline 1800112100 or helpdesk foscos@fssai.gov.in
- If you face any difficulty try to get help from a Food Safety Mitra (Digital Mitra)

2.9 List of documents and guidelines for obtaining registration/license

One can find the list of documents from FoSCoS portal also, but for ease of the beneficiaries in application process an indicative list of documents is provided below.

List of documents applicable for all sort of KOB: (Common documents irrespective of KOBs)

1. List of Directors/Partners/ Proprietor/Executive Members of Society/Trust with full address and contact details with nomination of authorized signatory.
*Mention their Full Name, Contact Details and address on the letterhead firm.
2. Photo I.D and address proof issued by Government authority of Proprietor/Partner/Director(s)/ Authorized Signatory.
*A proof with an address being mentioned on it. Aadhar suffices the requirement.
3. Proof of possession of premises. (Sale deed/ Rent agreement/ Electricity bill, etc.)
 - a. Exact address as being mentioned on the Application.
 - b. Latest Document if available.
 - c. If the Proof of premise is not in the name of Firm or Authorized personals of the firm, the proof of premise shall be accompanied by a No Objection Certificate.
 - d. If the Proof of premise is in Regional Language, while applying for Central License can be submitted along with the Self-Attested Translation of the same.
4. Partnership Deed/ Self Declaration for Proprietorship/ Memorandum & Articles of Association towards the constitution of the firm / Copy of certificate obtained under Coop Act-1861/ Multi State Coop Act-2002 in case of Cooperative.
*Proprietorship Firm shall submit a self-declaration as per format:
(<https://fssai.gov.in/PDF/SelfDeclarationforProprietorship.pdf>)
5. Form IX: Nomination of Person as per Clause 2.5 of FSS Rules, 2008:
 - a. Not required for a Proprietorship Firm.
 - b. The name of the nominee shall be the same both in Form IX and Form B.
 - c. The document shall be signed by the nominee and then signed by the authorized personnel.
6. Recall Plan:
 - a. Submit detailed Recall plan along with the details of the Recall Management Team.
 - b. Refer the below link for further clarification
(https://fssai.gov.in/upload/uploadfiles/files/Guidelines_Food_Recall_28_11_2017.pdf)

List of documents applicable for all sort of manufacturing business

1. Blueprint/layout plan of the processing unit showing the dimensions in meters/square meters and operation-wise area allocation
 - a. Legible and clear Layout
 - b. Mention the dimensions in meters/square meters
 - c. State operation-wise area allocation (Production, Quality, Storage, etc.)
 - d. Name and address of premises mentioned on the blueprint and matching with form B
2. Name and List of Equipments and Machinery along with the number, installed capacity and horsepower used
 - a. Number of each equipment
(If different products are made in same premise, make separate lists of equipment for each product)
 - b. Installed capacity (MT per Day or MT per Hr)
 - c. Horsepower used.
 - d. Note: Capacity declared in application should be justifiable/ matching with machinery.
3. Water Analysis Report:
 - a. IS 10500 test of products with water as an ingredient/IS 14543 for Packaged Drinking Water and Mineral Water and similar products wherever standards apply.
 - b. Report shall not be older than 6 months.
 - c. Test report shall be from a FSSAI recognized and NABL accredited laboratory.
 - d. The Lab shall have both Biological and Chemical as a scope of testing from NABL.
 - e. Sample shall be drawn by the Authorized representative lab and Name of the representative shall be mentioned on the report.
 - f. An opinion regarding the conformance of the sample with the IS 10500/IS 14543 (as required) shall be there on the report.
 - g. Note: If water is not an ingredient, it shall be justified and a self-declaration regarding that shall be submitted.
4. Production unit photograph
 - a. The photographs of Entrance with Board, Processing lines, Laboratory (If any).
 - b. Note: Preferably, compile all photographs into a single pdf not exceed the limit of 3MB.
5. Repacker Declaration and NOC for both Repacker and Relabeller from the Manufacturer
(*Only applicable for Repacker business*)
 - a. Submit a Repacker declaration
<https://foodlicensing.fssai.gov.in/PDF/DeclarationforFBO.pdf>
 - b. A NOC from the Manufacturer of the product on their letterhead with license copy attached.

6. NOC from CGWA for FBO who draws Groundwater (*Wherever applicable*)

7. Ingredient and Additive Statement

(*Only for KOB-Proprietary Food & KOB-Food or Health Supplements and Nutraceuticals*)

(<https://foscoss.fssai.gov.in/public/assets/docs/FLRS2016002691.pdf>)

a. *KOB-Proprietary Food*

- i. Furnish generic name of the product. Not the Brand name
- ii. Quote nearest food category as per Food Safety & Standards Regulation (FSSR)
- iii. Quote FSSR reference of ingredients and limit of additives used (If So)
- iv. Specify names of flavours
- v. Name of the product mentioned in form b should be the same as that of attachment.
- vi. Different products shall have separate entries

**Example of Statement of Ingredient and Additives for Proprietary Food is given on page no. 33 as ready reference*

b. *KOB-Food or Health Supplements and Nutraceuticals*

- i. Refer the Draft FSS (Nutra) 2022. This draft regulation is operationalized by order.
- ii. Write the specific name of the product and type of product
- iii. Quote nearest food category of the article as per FSSR.
- iv. Quote FSSR reference for every ingredient.
- v. State an actual component used as a source of vitamin/ minerals.
- vi. Enter the corresponding schedule and serial number against every ingredient and additives
- vii. State exact portion or part of Botanical used
- viii. If adding, specify Names and types of Flavours
- ix. Specify the QUANTITY of nutrients added wherever applicable and it shall not exceed the recommended daily allowance as specified in the Nutraceutical regulations.
- x. If available, furnish purity of ingredients.

***Example of Statement of Ingredient and Additives for products under category 13 is given on page no. 33 as ready reference*

**Example of Statement of Ingredient and Additives for Proprietary Food*

Statement of Ingredients and Additives

*(To be printed on Letterhead and duly signed and sealed)
(An Example for Proprietary Food)*

Name of the Proprietary Food: Dosa Batter

Nearest Category of the Product: 6.6 (Refer Food Category System mentioned in FSS (FPS&FA regulation, 2011)

Name of the Nearest Category: Batters (Refer Food Category System mentioned in FSS (FPS&FA regulation, 2011)

Statement of Ingredient:

S. No	Name of Ingredient	Reference
1	Rice	2.4.24
2	Urad Dal	2.4.26
3	Water	2.10.8
4	Iodised Salt	Schedule I of FSS (Fortification of Food) 2018

Statement of Additives:

(When Additives are not there, there is no need to mention the same)

S. No	Name of Additive	Quantity added per Kg	Limit	Reference
-	-	-	-	-

***Example of Statement of Ingredient and Additives for products under category 13*

Statement of Ingredients and Additives

*(To be printed on Letterhead and duly signed and sealed)
(An Example for Category 13 Foods)*

Name of the Product: Multivitamin Capsule (Specific name of the product with the format as well)

Nearest Category of the Product: 13.6 (Refer Food Category System mentioned in FSS (Nutra regulation, 2022)-Draft

Name of the Nearest Category: Health Supplement

(Refer Food Category System mentioned in FSS (Nutra regulation, 2022)-Draft

Statement of Ingredient:

S. No	Name of Ingredient	Reference	Quantity added	Limit/RDA
1	Vitamin C (L-Ascorbic Acid)	7(i) of Schedule I of FSS (Nutra) Draft	60 mg	80 mg/Day
2	Vitamin B12 (Hydroxocobalamine)	6(ii) of Schedule I of FSS (Nutra) Draft	2.00 mcg	2.2 mcg/ Day

Statement of Additives:

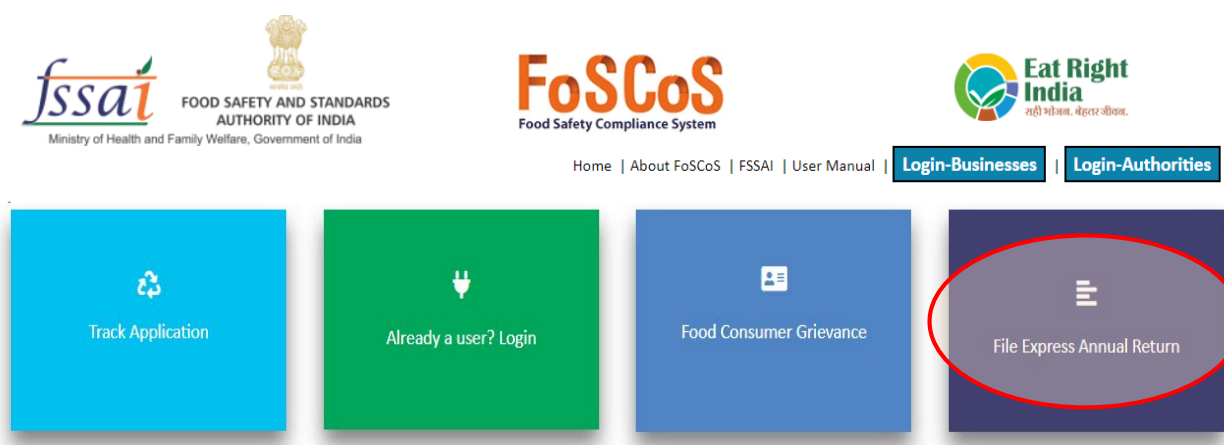
(When Additives are not there, there is no need to mention the same)

S. No	Name of Additive	Quantity added per Kg	Limit	Reference
1	HPMC	3 mg	GMP	31 of List of food additives to be used in formats such as tablets, capsules and syrups

2.10 Filing of Annual Return

As per the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, it has made mandatory that, every manufacturer and importer who has been issued a license shall submit annual return on or before 31st May of each year, electronically or in physical form (form D-1) as may be prescribed by the concerned Food Safety Commissioner, in respect of each class of food products handled by him during the previous financial year.

Provided however that every licensee engaged in manufacturing of milk and/or milk products shall file half yearly returns for the periods 1st April to 30th September and 1st October to 31st March of every financial year in the form D-2. Such returns will be filed within a month from the end of the period.



A user manual for filling annual return is made available on the following link.

<https://foscos.fssai.gov.in/assets/docs/User%20manual%20of%20File%20Annual%20Return.pdf>

A separate return shall be filed for every license issued under the Regulations, irrespective of whether the same Food Business Operator holds more than one license.

Fine System: Any delay in filing return beyond 31st May of each year shall attract a penalty of Rs. 100 per day of delay for delay till the date of filling the return. The maximum penalty that can be levied shall not exceed 5 times the annual fees.

- Filing the returns is applicable to every FBO has a business turnover of more than Rs.12 lakhs, or FBO importing, selling, manufacturing, exporting, storing, distributing, handling or transporting any type of food product, or FBO involved in the manufacturing and distribution of milk.
- Fast-food joints, Restaurants, Grocery stores and Canteens are exempted from filing the FSSAI annual return.

2.11 On-Time Renewal of Registration and License

A Registration or license granted under these Regulations shall be valid and subsisting, unless otherwise specified, for a period of 1 to 5 years as chosen by the Food Business Operator, from the date of issue of registration or license subject to remittance of fee applicable for the period and compliance with all conditions of license.

It is therefore necessary to renew the registration or license, not later than 30 days prior to the expiry date as indicated in the registration certificate or license. An application for the renewal of a registration or license granted can be made by filling the Form A (for Registration) or Form B (for License) of Schedule 2, as the case may be.



A user manual for applying for renewal is made available on the following link.

<https://foscoss.fssai.gov.in/assets/docs/HowtoapplyRenewal.pdf>

The Registration or License shall continue to be in force till such time that the orders are passed on the renewal application which in no case shall be beyond 30 days from the date of expiry of registration or license.

Fine System:

Any renewal application filed beyond the period mentioned under Regulation 2.1.7 (2) above but before the expiry date, shall be accompanied by a late fee of Rs 100 per day for each day of delay.

- Any Registration or license for which renewal has not been applied for within the period mentioned in Regulation 2.1.7 (2) or 2.1.7 (4) above shall expire and the Food Business Operator shall stop all business activity at the premises. The Food Business Operator will have to apply for fresh Registration or license as provided in Regulation 2.1.1 and 2.1.3 as the case may be, if it wants to restart the business.
- Food Business Operator having valid certificate of an accredited food safety auditor or from an agency accredited by Food Authority or any other organisation notified by food Authority for this purpose will not be normally required to be inspected before renewal of license. Provided that Designated Officer may order an inspection before renewal if considered necessary for reasons to be recorded in writing.

Instant Renewal of License/Registration

As per the order of FSSAI dated 11.01.2023, that the renewal of license or registration will be granted instantly, without any scrutiny by the food authority, subject to following;

- i. No change in existing details of the food business
- ii. The validity of renewal for License will be only 1 year and for registration 1-5 year as chosen by the FBO

FBO's are required to self-declare the compliance to the points of inspection checklist at the time of renewal. Also, ensure that the annual returns with penalties (if any) has been filed by the FBO. There shall not be late fee of Rs. 100 per day levied if the renewal application is made in the last 30 days prior to expiry. Even the window for renewal will be available as early as 180 days prior to license/registration validity expiry date.

2.12 Concept of Modifications of license or registration

Food Business Operators shall ensure that the Registering or Licensing Authority always has up-to-date information on their food business establishments. It is therefore necessary to inform Authorities about any change or modifications in activities /content of license.

FBOs shall inform about any modifications or additions or changes in product category, layout, expansion, closure, or any other material information based on which the license was granted and such information shall be conveyed before the changes occur.

Any change that alters the information contained in the license certificate shall require an approval or endorsement in license prior to start of business with such changes.

The screenshot shows the FSSAI FoSCoS portal interface. At the top, there are logos for FSSAI, the Government of India, FoSCoS, and Eat Right India. Below the logos are navigation links: Home, About FoSCoS, FSSAI, User Manual, Login-Businesses, and Login-Authorities. The main navigation menu has three options: 'Apply for New License/Registration', 'Apply for Renewal without Sign in', and 'Modification of License and Registration', which is circled in red. Below the menu, a form titled 'Kindly select the details you want to change:' has three checkboxes. The first two are unchecked, and the third, 'Selection of Standardised Products by existing manufacturing license holders (Window is opened till 30th June 2021 without fee)', is checked. A callout box on the left explains that users can select any one of three changes.

The Food Business Operator shall submit the original license to the Licensing Authority along with a fee equivalent to one-year license fee for effecting necessary changes. The licensing Authority may approve and issue an amended license incorporating such changes in activities within 30 days from the date of receipt of such information.

While approving the afore mentioned changes the concerned registering or Licensing Authority shall take into account the feasibility of carrying on the business and the legal and other relevant aspects of the desired modifications or additions or changes in activities and, if required, may order an inspection of the premises before granting the approval.

Instant Modification of License

As per the order dated 29 Dec, 2022, the food authority has decided to modify the license instantly subject to following conditions;

- Instant modification is applicable for addition of any standardized products except the products from High Risk Food Categories
- This provision will be available only for existing licensed manufacturers only
- Modification fee shall be same

Chapter III

Packaging and Labelling Requirements for FBO

3.1 Introduction to Food Packaging

Apart from manufacturing the product in any food processing industry, it is very much important to package it in a suitable packaging material. This will maintain the quality and integrity of product till it reaches the consumer for its intended use.

Below are some definitions which are important to know by any FBO.

- **Package or container:** A pre-packaged box, bottle, casket, tin, barrel, case, pouch, receptacle, sack, bag, wrapper or such other things in which an article of food is packed
- **Packaging material:** Materials such as cardboard, paper, glass, metal, plastic, multi-layer packaging material used for packaging of food products
- **Primary food packaging:** Packaging material in direct contact with food products
- **Secondary food packaging:** Packaging material which encloses the primary food packaging and does not come in direct contact with food products
- **Tertiary packaging:** A wrapping, Container or Box which is used to protect manufactured goods for shipping or storing.
- **Multilayer/Composite Food Packaging:** Food packaging material composed of two or more layers of same or different types of packaging materials.
- **Food Grade Packaging:** Material made of substances which are safe and suitable for their intended use, and shall not endanger human health or result in unacceptable change in the composition of the food or organoleptic characteristics.



Types of Packaging Materials



Primary Packaging



Secondary Packaging



Tertiary Packaging

3.2 Packaging Requirements for FBOs

The requirements about packaging of any food that is being manufactured by any Food Business Operator (FBO) are given in a regulation called, Food Safety and Standards (Packaging) Regulation, 2018. Every food business operator has to comply with these requirements so as to maintain quality and safety in supply chain.

Below are the general requirements stated in the regulation.

- Every food business operator shall ensure that the packaging material used shall be in accordance with these regulations. Where Indian Standards are not available, then relevant International Standards may be complied by the FBO.
- Any material which comes in direct contact with food or likely to come in contact with food used for packaging, preparation, storing, wrapping, transportation and sale or service of food shall be of food grade quality.
- Packaging materials shall be suitable for the type of product, the conditions provided for storage and the equipment for filling, sealing and packaging of food as well as transportation conditions.
- Packaging materials shall be able to withstand mechanical, chemical or thermal stresses encountered during normal transportation. In case of flexible or semi-rigid containers, an overwrap packaging may be necessary.
- Food products shall be packed in clean, hygienic and tamper-proof package or container.
- The sealing material shall be compatible with the product and the containers as well as the closure systems used for the containers.
- Tin containers once used, shall not be re-used for packaging of food.
- Plastic containers of capacity 5 litre and above and Glass bottles, which are reused for packaging of food, shall be suitably durable, easy to clean or disinfect.
- Printing inks for use on food packages shall conform to IS: 15495.
- Printed surface of packaging material shall not come into direct contact with food products.
- Newspaper or any such material shall not be used for storing and wrapping of food.
- In case of multilayer packaging the layer which comes in direct contact with food or layers likely to come in contact with food shall meet the requirements of packaging materials specified in Schedule I, II and III of these regulations.
- The materials listed in Schedule I, II and III of these regulations shall be compatible with their intended use as a packaging material so as not to alter the quality and safety of the food product.
- Every food business operator shall obtain the certificate of conformity issued by NABL accredited laboratory against these regulations for the packaging material which comes in direct contact with food or layers likely to come in contact with food to be used.

Along with this Specific Requirements for Primary food packaging is also given in the regulation. List of Standards for specific packaging material are given in Schedule III of this act. The packaging material being used by the FBO has to comply with these standards. Some of the standards are as given below;

- IS 10146 - Specification for Polyethylene
- IS 10142 - Specification for Polystyrene
- IS 10151 - Specification for Polyvinyl Chloride (PVC)
- IS 10910 - Specification for Polypropylene and its copolymers
- IS 12252 - Specification for Polyalkylene Terephthalates (PET & PBT)
- IS 14636 - Specification for Flexible Packaging Materials
- IS 2508 - Specification for Polyethylene Films and Sheets

To have a better understanding about the complementary nature and suitability of packaging material, a list of suggestive packaging materials which may be used for packaging of food products falling under the specified categories is provided in Schedule – IV of this regulation.

3.3 Labelling Requirements for FBOs

The requirements for labelling of pre-packaged foods and display of essential information on the package label are prescribed in the Food Safety and Standards (Labelling and Display) Regulations, 2020. Below are some definitions which are important any FBO for easy implementing the requirements.

Assorted Pack: Any package or container containing multiple units of different food products intended and displayed for retail sale and complies with the general labelling requirement.

Retail Pack or Retail Unit: The packages which are intended for sale to ultimate consumer for the purpose of consumption of the food contained therein.

Best Before Date: The date which signifies the end of the period under any stated storage conditions during which the food product shall remain fully marketable and shall retain any specific qualities for which tacit or express claims have been made, and beyond that date, the food may still be perfectly safe to consume, though, its quality may have diminished. However, the product shall not be sold if any stage the product become unsafe.

Date of Manufacture: The date on which the food products becomes the product as described.

Date of Packaging: The date on which the food product is placed in the immediate container in which it will be ultimately sold.

Use by Date or Expiry Date: The date, which signifies the end of the estimated period under any stated storage conditions, after which the product may not remain safe and the food product probably will not have the quality of safety attributes normally expected by the consumers and the food, shall not be sold or distributed for human consumption.

Front of Pack: A part of the package that faces forward (in the principal field of vision) and is typically the first thing a consumer will see when they look at the product.

Principal Display Panel: The part of the container/package which is intended or likely to be displayed or presented or shown or examined by the customer under normal and customary conditions of display, sale or purchase of the food article contained therein.

Labelling: Any written, printed or graphic matter that is present on the label, accompanies the food or is displayed near the food.

Lot Number or Code Number or Batch Number: The identification mark depicted shown on the label by the use of numeral or alphabet or combinations thereof, brief preceded by “Lot number” or “code number” or “batch number” or any unique identification marks such as Batch No., B. No., L. No., Lot No., Code, LN, CN or BN, B No by which the food can be traced in manufacture and identified in distribution.

3.4 General Requirements for Labelling to be complied by FBO

- Every pre-packaged food shall be labelled with information as required under these regulations unless otherwise provided
- When a food product is sold through e-commerce or any other direct selling means, the mandatory requirements of the label as given in these regulations shall be provided to the consumer through appropriate means before sale except ‘batch number/ lot number, best before, use by date, expiry date, date of manufacturing/ packing
- Pre-packaged food shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect
- Any information or pictorial device written, printed, or graphic matter may be displayed on the label provided that it is not in conflict with the requirements of these regulations
- The particulars of declaration required under these Regulations to be specified on the label shall be in English or Hindi in Devnagri Script. Provided that nothing herein contained shall prevent the use of any other language in addition to the language required under this regulation: Provided further that the information provided in such other language shall not contradict the information on the label in the English or Hindi
- Label on pre-packaged foods shall be applied in such a manner that it will not become separated from the container
- Contents on the label shall be clear, unambiguous, prominent, conspicuous, indelible and readily legible by the consumer under normal conditions of purchase and use;
- Where a package is provided with an outside container or wrapper and such container or wrapper is displayed for retail sale, it shall also contain all the declarations which are required to appear on the package except where such container or wrapper itself is transparent and the declarations on the package(s) are easily readable through such outside container or wrapper.

In addition to general requirements as given above, it is also mandatory for FBO to provide following information on the label of every package.

(1) The Name of Food: Every package of food shall carry name of the food which indicate the true nature of the food contained in the package, on the Front of Pack

(2) List of Ingredients: Except for single ingredient foods, a list of ingredients shall be declared on the label in the following manner.

(a) The list of ingredients shall contain an appropriate title, such as the term “Ingredients/List of Ingredients”.

(b) The name of ingredients used in the product shall be listed in descending order of their composition by weight or volume, as the case may be at the time of its manufacture.

(c) A food additive carried over into a food in an amount sufficient to perform a technological function in that food as a result of the use of raw material or other ingredients in which the additives were used shall be included in the list of ingredient.

(d) A specific name shall be used for ingredients in the list of ingredients.

(e) Where an ingredient is itself the product of two or more ingredients, such a compound ingredient shall be declared, by their specific names.

(f) Added water shall be declared in the list of ingredients except in cases where water forms part of an ingredient, such as, brine, syrup or broth, used in the compound food and so declared in the list of ingredients: Provided that water or other volatile ingredients evaporated in the course of manufacture need not be declared; Provided further that in case of dehydrated or condensed food, which are intended to be reconstituted by addition of water, the ingredients in such reconstituted food shall be declared in descending order of weight or volume as the case may be, and shall contain a statement such as “Ingredients of the product when prepared in accordance with the directions on the label”.

(g) The ingoing percentage of an ingredient (including compound ingredients or categories of ingredients), by weight or volume as appropriate, at the time of manufacture, shall be disclosed for foods sold as a mixture or combination where the ingredient.

(3) Nutritional information

(a) For the purposes of these regulations, nutritional information is a description intended to inform the consumer of nutritional properties of the food and the following definitions shall be applicable:

(b) Nutritional Information per 100g or 100ml or per single consumption pack of the product and per serve percentage (%) contribution to Recommended Dietary Allowance calculated on the basis of 2000kcal energy, 67 g total fat, 22 g saturated fat, 2 g trans-fat, 50 g added sugar and 2000 mg of sodium (5 g salt) requirement for average adult per day, shall be given on the label containing the following:

(i) energy value (kcal);

(ii) the amounts of,

(A) Protein (g);

(B) Carbohydrate (g) and Total Sugars (g), added sugars (g);

(C) Total fat (g), saturated fat (g), trans fat (other than naturally occurring trans-fat) (g) and cholesterol (mg)

(4) Declaration regarding Vegetarian or Non-Vegetarian Nature of Food

(a) Every package of **Non-Vegetarian Food** containing ingredients including food additives, processing aids of animal origin shall bear a declaration to this effect made by a symbol and colour code as stipulated below. The symbol shall consist of a brown colour filled triangle inside a square with brown outline having the sides not less than the minimum size specified in the regulation.



Provided where any article of food contains egg only as Non-Vegetarian ingredient, the manufacturer, or packer or seller may give declaration to this effect in addition to the said symbol.

(b) Every package of **Vegetarian Food** containing ingredients including food additives, processing aids of plant origin shall bear a declaration to this effect by a symbol and colour code as stipulated below. The symbol shall consist of a green colour filled circle inside a square with green outline having the diameter not less than the minimum size specified in the regulation.



(5) Declaration regarding Food Additives

Functional classes for food additives shall be declared together with the specific name(s) or recognized International Numbering System (INS) as specified in Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011 in the list of the ingredients.

(6) Declaration of name and complete address

- (a) The name and complete address of the brand owner, whether or not, he himself is the manufacturer, marketer, packer or bottler, as the case may be, shall be declared on the label. Such name and address shall be preceded by the qualifying words “Manufactured by (Mfg. by, Mfd. by)” or “Marketed by (Mkt. by)” or “Manufactured & Marketed by” or “Packed & Marketed by” as the case may be
- (b) Where an article of food is imported into India, the package of food shall also carry the name and complete address of the importer in India.

(7) FSSAI logo and license number

(The FSSAI logo and license number under the Act shall be displayed on the label of the food package in contrast color to the background as below.



(8) Net quantity, Retail Sale Price and Consumer Care details

Declaration and manner of declaration of Net quantity, Retail Sale Price and Consumer Care details shall be as provided in Legal Metrology Act, 2009 (1 of 2010) and the Rules made there under.

(9) Lot/Code/Batch Identification

A batch number or code number or lot number shall be declared on the label.

(10) Date Marking

Date of manufacture or packaging and Expiry/Use by shall be declared on the label.

Expression “Best before” may also be used as optional or additional information.

(11) Labelling of Imported Foods

Labelling requirements for imported products shall be governed by the Food Safety and Standards (Import) Regulations, 2017 in addition to the requirement mentioned in these regulations.

(12) Country of Origin for Imported Foods

- (a) The country of origin of the food shall be declared on the label of food imported into India.
- (b) When a food undergoes processing in a second country which changes its nature, the country in which the processing is performed resulting in change in HS Code at the 6-digit level shall be considered to be the county of origin for the purposes of labelling.

(13) Instructions for use

Instructions for use, including reconstitution, where applicable, shall be included on the label, to ensure proper utilization of the food or where such food requires directions for reasons for health and safety (e.g. ‘Refrigerate after opening’).

(14) Declaration regarding Food allergen: The foods and ingredients which are known to cause allergy shall be declared separately as

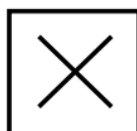
Contains..... (Name of allergy causing ingredients)

Provided that in case presence of ingredients due to cross contamination which are known to cause allergy may be declared separately as

May Contains..... (Name of allergy causing ingredients)

(15) Specific Symbolic Representations:

- (a) Every package of food material sold in retail but which is **Not Meant for Human Consumption** example Pooja water, Ghee for Diya, Oil for Pooja etc. shall bear a declaration to this effect by a symbol as stipulated below. The symbol shall consist of a black colour cross inside a square with black outline having the sides of square not less than the minimum size specified in the regulation.



(b) Every package of **Food Fortified** as per FSS (Fortification of Foods) Regulations, 2018, shall carry the words “**Fortified with (name of the fortificant)**” and the logo, as specified below, on the label. It may also carry a tag line “**Sampoorna Poshan Swasth Jeevan**” under the logo.




**Fortified with
SAMPOORN POSHAN
SWASTH JEEVAN**

(c) Every package of certified **Organic Food** as per Food Safety and Standards (Organic Foods) Regulations, 2017 shall carry the logo as specified.



Jaivik Bharat

(d) Any food that has undergone the process of irradiation (**Irradiated Foods**) provided under regulation 2.13 of Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, shall bear the **Radura logo** in green colour and following declaration on the label,

<p>PROCESSED BY RADIATION</p>  <p>Name of the Product: Purpose of Radiation Processing: Operating License No. : Batch Identification No. (BIN) (as provided by facility): Date of Processing.....”</p>
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3.5 General principles of Advertising and Claims

FSSAI has finalised the regulation called, Food Safety and Standards (Advertising and Claims) Regulation, 2018, pertaining to claims and advertisements by food business operators in respect of their food products. These regulations are aimed at establishing fairness in claims and advertisements of food products and make food businesses accountable for such claims /advertisements so as to protect consumer interests.

Below are some of the definition under this regulation.

- **Advertisement:** Any audio or visual publicity, representation or pronouncement made by means of any light, sound, smoke, gas, print, electronic media, internet or website and includes through any notice, circular, label, wrapper, or other document
- **Claim:** Any representation which is printed, oral, audio or visual and states, suggests, or implies that a food has particular qualities relating to its origin, nutritional properties, nature, processing, composition or otherwise
- **Equivalence claims:** Claims that attempt to promote the equality in value, amount and importance of one food attribute to another
- **Health claim:** Any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health
- **Nutrient function claim:** Claims which describes the physiological role of the nutrient in growth, development and normal functions of the body
- **Other function claim:** Claims that describes the specific beneficial effects of the consumption of foods or their constituents, in the context of the total diet or normal functions or biological activities of the body, which relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health
- **Reduction of disease risk claims:** Claims that state, suggest or imply that consumption of such foods or food constituents, in the context of total diet, reduce the risk of developing a disease or health related condition
- **Nutrition claim:** Any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins, minerals and other permitted listed nutrients
- **Non-addition claims:** Any claim that an ingredient or additive has not been added to a food, either directly or indirectly and the ingredient or additive is one whose presence or addition is permitted in the food and which consumers would normally expect to find in the food

Every food business operator and marketer while advertising and publishing or disseminating marketing communication meant for promotion or sale of any article of food including labelling claims shall comply with the following general principles, as stated in Food Safety and Standards (Advertising and Claims) Regulations, 2018.

1. Claims must be truthful, unambiguous, meaningful, not misleading and help consumers to comprehend the information provided.
2. Claims shall not encourage or condone excess consumption of a particular food.
3. Claims shall not state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients as required by the body.
4. Where the claim benefit is related to or dependent on the method of preparation of the food the same shall be provided on the label.
5. Reduction of disease risk claims shall specify the number of servings of the food per day for the claimed benefit.
6. The claim that a food has certain nutritional or health attributes shall be scientifically substantiated by validated methods of characterising or quantifying the ingredient or substance that is the basis for the claim.
7. Where the meaning of a trade mark, brand name or fancy name containing adjectives such as “natural”, “fresh”, “pure”, “original”, “traditional”, “authentic”, “genuine”, “real”, appearing in the labelling, presentation or advertising of a food is such that it is likely to mislead the consumer as to the nature of the food, in such cases a disclaimer shall be mentioned prominently on the front of pack of the label stating that – “*This is only a brand name or trademark, or fancy name and does not represent its true nature; (relevant one may be chosen as applicable)”
8. All disclaimers related to a claim shall be conspicuous and legible.
9. Notwithstanding the mandatory declaration of Food Safety and Standards Authority of India logo and license number as per Food Safety and Standards (Packaging and Labelling) Regulations, 2011, no claim or promotion of sale, supply, use and consumption of articles of foods shall be made using Food Safety and Standards Authority of India logo and license number.
10. Advertisements shall also not undermine the importance of healthy lifestyles.
11. Advertisements for food or beverages shall not be promoted or portrayed as a meal replacement unless otherwise specifically permitted as a meal replacement under any other Regulations made under Food Safety and Standards Act, 2006 (34 of 2006)
12. Claims in advertisements shall be consistent with information on the label of the food or beverage.
13. No advertisement shall be made for food products which is deceptive to the consumers.
14. Every declaration which is required to be made on advertisements under these regulations shall be conspicuous and legible.

Chapter IV

Introduction to HACCP and FSMS Certification

4.1 Introduction to FSMS

Unsafe food is a threat to human health and economies globally. Therefore, ensuring food safety is a public health priority and an essential step to achieving food security. Effective food safety and quality control systems are key not only to safeguarding the health and well-being of people, but also to fostering economic development and improving livelihoods by promoting access to domestic, regional and international markets.

To provide assurance of food safety, food businesses must implement an effective; Food Safety Management System (FSMS). The FSMS is based on *Hazard Analysis and Critical Control Point (HACCP)* and suitable *Pre-Requisite Programmes (PRPs)*.

This actively controls the hazards throughout the food chain starting from food production till final consumption, and provides assurance to business operator as well as to the consumer about quality and safety requirements.

As per the condition of license under FSS (Licensing & Registration of Food Businesses) Regulations 2011, every food business operator (FBO) applying for licensing must have a documented FSMS plan and comply with schedule 4 of this regulation. The compliance to the Schedule 4 requirements introduces the concept of FSMS based on implementation of PRPs.

A systematic approach to the identification, evaluation, and control of food safety hazards. To understand the concept of HACCP and FSMS, it very much necessary to know about PDCA Cycle.

4.2 PDCA (Plan Do Check Act) Cycle

PDCA is an improvement cycle based on the scientific method of proposing a change in a process, implementing the change, measuring the results, and taking appropriate action. It also is known as the Deming Cycle after W. Edwards Deming, who introduced the concept in Japan in the 1950s. The PDCA cycle has four stages:

1. Plan — Determine goals for a process and needed changes to achieve them.
2. Do — Implement the changes.
3. Check — Evaluate the results in terms of performance.
4. Act — Standardize and stabilize the change depending on the results.



4.3 Important Definitions to know

Below are some important definitions that one should know before understanding the HACCP.

1. CCP Decision Tree: A sequence of questions to assist in identifying a CCP.
2. Control: Manage the conditions of an operation to maintain compliance with established criteria.
3. Control Measure: Any action or activity that can be used to prevent, eliminate or reduce a significant hazard.
4. Control Point: Any step at which biological, chemical, or physical factors can be controlled.
5. Corrective Action: Procedures followed when a deviation occurs.
6. Criterion: A requirement on which a judgement or decision can be based.
7. Critical Control Point: A step at which essentially a control can be applied
8. Critical Limit: A maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP
9. Deviation: Failure to meet a critical limit.
10. HACCP Plan: The written procedures to be followed based upon the principles of HACCP.
11. HACCP System: The result of the implementation of the HACCP Plan.
12. HACCP Team: The group of people who are responsible for developing, implementing and maintaining the HACCP system.
13. Hazard: A biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.
14. Hazard Analysis: The process of collecting and evaluating information on hazards associated with the food under consideration.
15. Monitor: To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.
16. Prerequisite Programs: Foundation for HACCP which including GMP's, GHPs, etc.
17. Severity: The seriousness of the effect(s) of a hazard.
18. Step: A point, procedure, operation or stage in the food system from primary production to final consumption.
19. Validation: That element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards.
20. Verification: Those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan.

4.4 HACCP (Hazard Analysis and Critical Control Point)

It is defined as systematic approach to the identification, evaluation, and control of food safety hazards. It is designed for use in all segments of the food industry from growing, harvesting, processing, manufacturing, distributing, and merchandising to prepare food for consumption. Prerequisite programs such as current Good Manufacturing Practices (GMP) are an essential foundation for the development and implementation of successful HACCP plans.



Food safety systems based on the HACCP principles have been successfully applied in food processing plants, retail food stores, and food service operations. HACCP is based on the seven principles which includes hazard analysis, CCP identification, establishing critical limits, monitoring procedures, corrective actions, verification procedures, and record-keeping and documentation. Under such systems, if a deviation occurs indicating that control has been lost, the deviation is detected and appropriate steps are taken to re-establish control in a timely manner to assure that potentially hazardous products do not reach the consumer.

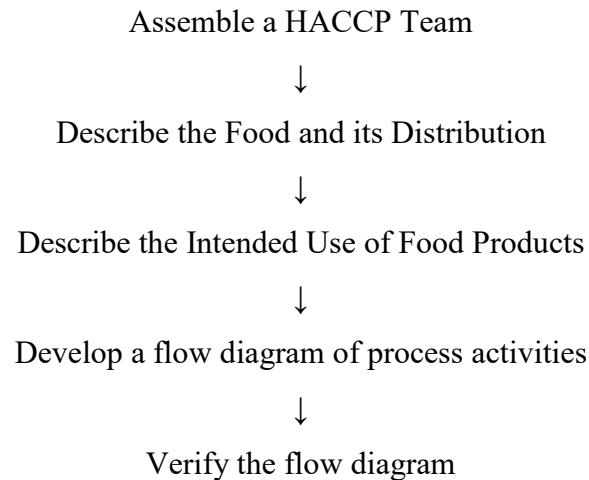
4.5 Preliminary requirements for HACCP Plan

To implement HACCP system in any food industry, a clear flow chart of all the activities right from raw material selection to storage of finished product is required. The purpose of a flow diagram is to provide a clear, simple outline of the steps involved in the process. The scope of the flow diagram must cover all the steps in the process which are directly under the control of the establishment.

In addition, the flow diagram can include steps in the food chain which are before and after the processing that occurs in the establishment. Before implementing the HACCP plan in the food industry, the first task is to assemble the HACCP team consisting of individuals who have specific knowledge and expertise appropriate to the product and process. The team should also include local personnel who are involved in the operation as they are more familiar with the variability and limitations of the operation.

4.6 Steps in Developing HACCP Plan

HACCP plan includes all the activities that are to be performed for implementing the quality and safety management system in food industry. This includes following steps.



The HACCP team should include representatives from all the sections of food industry, i.e. from inventory management, production, marketing etc. The team first describes the food and its mode of distribution in market. This consists of a general description of the food, ingredients, and processing methods whether the food is to be distributed frozen, refrigerated, or at ambient temperature. The intended consumers will get identified and their intended use will also get discussed. A flow process chart for the processing line to which the HACCP plan has to be implemented will get chalked-out. An on-site review of this flow chart will get verified the accuracy and completeness of the flow diagram. Once the HACCP plan is developed, it will get implemented by following 7 principles those are described in brief below.

4.7 Seven Principle of HACCP

Below are the 7 HACCP principles through which the food safety management system will get implemented.

Principle 1: Conduct a hazard analysis.

Principle 2: Determine the critical control points (CCPs).

Principle 3: Establish critical limits.

Principle 4: Establish monitoring procedures.

Principle 5: Establish corrective actions.

Principle 6: Establish verification procedures.

Principle 7: Establish record-keeping and documentation procedures.

Principle 1: Conduct a hazard analysis

This involves listing the steps in the process and identifying where significant hazards are likely to occur. The HACCP team will focus on hazards that can be prevented, eliminated or controlled by the HACCP plan. A justification for including or excluding the hazard is reported and possible control measures are identified.

Principle 2: Determine the critical control points (CCPs)

A critical control point (CCP) is a point, step or procedure at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to acceptable levels. The HACCP team will use a CCP decision tree to help identify the critical control points in the process. A critical control point may control more than one food safety hazard or in some cases more than one CCP is needed to control a single hazard. The number of CCP's needed depends on the processing steps and the control needed to assure food safety.

Principle 3: Establish critical limits

A critical limit (CL) is the maximum and/or minimum value to which a quality or safety parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level. The critical limit is usually a measure such as time, temperature, water activity (aw), pH, weight, or some other measure that is based on scientific literature and/or regulatory standards.

Principle 4: Establish monitoring procedures

Monitoring procedures are meant for measurement of the critical limit at each critical control point. Monitoring procedures should describe how the measurement will be taken, when the measurement is taken, who is responsible for the measurement and how frequently the measurement is taken during production.

Principle 5: Establish corrective actions

Corrective actions are the procedures that are followed when a deviation in a critical limit occurs. This usually includes identification of the problems and the steps taken to assure that the problem will not occur again.

Principle 6: Establish verification procedures

These are the activities other than monitoring, that validates the HACCP plan and its operation. The HACCP team may identify activities such as auditing of CCP's, record review, prior shipment review, instrument calibration and product testing as part of the verification activities.

Principle 7: Establish record-keeping and documentation procedures

Documenting and recording the information can be used to prove the quality assurance and safety.

4.8 FSMS Certification

FSMS Certification is a procedure to verify that the essential principles of food safety are applicable throughout the food chain (including primary production through to the final consumer), to achieve the goal of ensuring that food is safe and suitable for human consumption. FSMS certification is voluntary and is applicable to all organizations in the food chain, regardless of size and complexity.



After getting FSMS certification, the food industry will acquire confidence in performing business tasks as producing, processing, retailing food products for both domestic and export markets. The certification to food industry can help organizations maintain legal compliance, satisfy customers, improve their brand reputation and more. It also helps in building trust between consumers and producers, and ensure integrity of food supply chain. The labels and certification marks on packaged products help a consumer to recognise trustworthy food products easily. Certification and the logo are being used important marketing tools and supports the business in improving the competitiveness.

Certification Process

The FSMS certification of any food business can be get done from any certification bodies. The certification process is basically divided into 5 steps.

1. Application for certification to the certification bodies
2. Preliminary Audit of premises by the certification body for preparedness of industry
3. Certification Audit or Main Audit for verifying the conformance to the requirements
4. Issuing Certificate upon meeting with the certification requirements
5. Surveillance Audit to assess the clients continued to the compliance
6. Certification Maintenance is updating the certificate for certain changes if any

Chapter V

FSSAI Initiatives for Promoting Safe and Wholesome Food

5.1 Introduction

Apart from the regulatory functions of FSSAI which has been made mandatory under the Food Safety and Standards (FSS), Act 2006, such as setting science-based, globally benchmarked standards for food, ensuring credible food-testing and compliance to these standards through surveillance and enforcement activities. These activities involve a wide range of initiatives and programmes. These initiatives aim to promote both the demand for and the supply of safe and healthy food in a sustainable way. Let's have a quick view on these initiatives and movements of FSSAI.

5.2 EAT RIGHT INDIA MOVEMENT

This is the most popular and very important initiative of FSSAI. It is the main aim of Food Safety and Standards Act, 2006, and ultimately FSSAI, to ensure availability of safe and wholesome food for the people in India. Inspired by

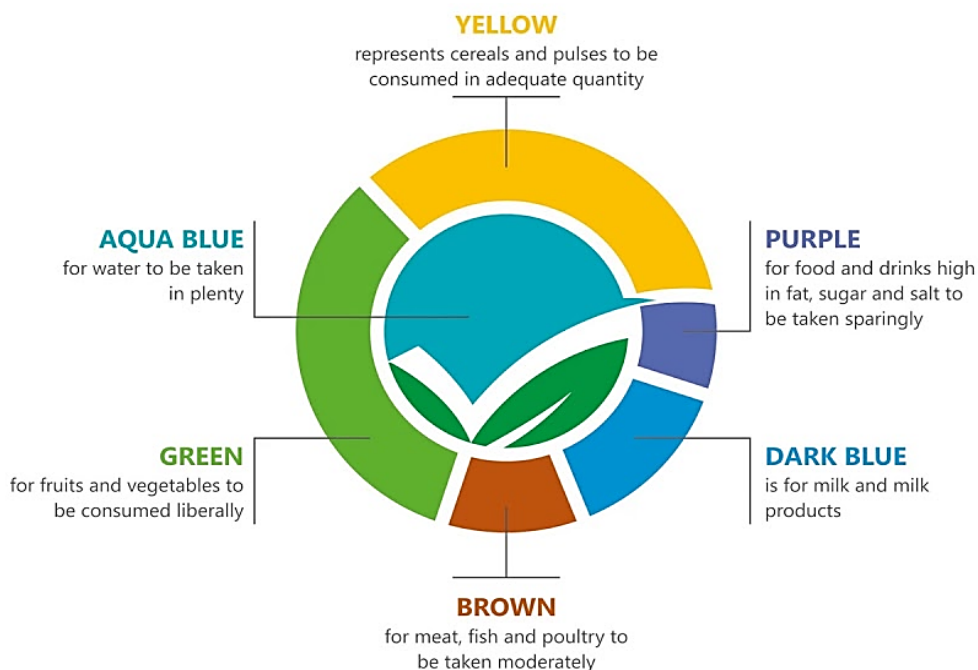


the focus on preventive and promotive healthcare in the National Health Policy 2017 and flagship programmes like Ayushman Bharat, POSHAN Abhiyaan and Swachh Bharat Mission, FSSAI has embarked on a large-scale effort to transform the country's food system in order to provide people safe, healthy and sustainable food through the “**Eat Right India**” movement.

This movement is not merely a concept or an abstract thought. It is an action oriented program driven by a judicious mix of regulatory, capacity-building and empowerment measures with series of flagship programmes and initiatives. The main objectives of this movement is to improve the public health, combat negative nutritional trend and fight with lifestyle diseases.

The Eat Right India movement is started on 10th July 2018, and works for ensuring safe, healthy and sustainable food. The Tag line of this initiative is, “*Sahi Bhojan Behetar Jeevan*”.

The image provided below gives information about the logo of Eat Right India.



The key themes of the Eat Right India movement are operated through six strategic priorities.

These are as given below.

- i. Robust standards and code of practices
- ii. Credible food testing and effective surveillance
- iii. Strengthened compliance, enforcement and emergency response
- iv. Strong culture of self – compliance
- v. Promoting healthy diets and sustainability
- vi. Empowered consumers



5.3 FOOD SAFETY MITRA

Realizing the need to assist small FBOs in obtaining licensing/registration, training and hygiene rating, FSSAI has launched Food Safety Mitra Scheme (FSM) in the year 2019. Food Safety Mitra will be an individual, professionally trained and certified by FSSAI who assists in compliances related to FSS Act, Rules & Regulations.



Website: <https://fssai.gov.in/mitra/>

The Food Safety Mitra will work for following job roles.

Digital Mitra: To assist FBO in their compliances on online portals of FSSAI.

The Digital Mitra will assist in following;

- *Filing of new application for License/Registration*
- *Further online correspondence regarding queries raised by Authorities*
- *Filing application for Modification of License/Registration*
- *Filing of Annual Returns / Declarations*
- *Filing Applications for Approval of Product/Label/Advertisement Claims*
- *Filing appeal for revocation of Suspended License/Registration*

Trainer Mitra: To train FBOs regarding the Food Safety Act, Regulations and implementation.

The Trainer Mitra will assist in following;

- *Conducting training of Food Safety Supervisors under FoSTaC*
- *Conducting training at Eat Right Campus*
- *Conducting training of Food Safety Personnel in Business on demand*

Hygiene Mitra: To do Hygiene Ratings of FBOs.

The Hygiene Mitra will assist in following;

- *Hygiene auditing of FBO outlets as per prescribed guidelines*
- *Help FBOs with implementation of hygiene guidelines*
- *Train Food Safety Supervisors and Food Handlers - Safe and hygienic food handling practices*

Through this multi layered ecosystem, responsive to the needs of FBOs, FSSAI aims to create a last mile self-driven & self-employed compliance structure.

5.4 SAFE AND NUTRITIOUS FOOD (SNF)

Food Safety and Standards Authority of India (FSSAI) has undertaken several initiatives under the umbrella of ‘Safe and Nutritious Food’ (SNF) for citizen guidance and behavioural change in every sphere at home, school, workplace or eating out.

- i) SNF@Home ii) SNF@School iii) SNF@Workplace iv) SNF@Eatout

The SNF portal i.e. www.snfportal.in serves as an online resource centre containing information pertaining to this initiative with access to resource materials developed by FSSAI, interactive guides on understanding food safety and nutrition and a gateway for everyone to participate in these initiatives through partnerships. It includes awareness materials such as the Pink Book (Home Kitchen), DART Book (Simple Test for Food Adulterants), Yellow Book (School Children’s) and Orange Book (Workplaces).



5.5 DETECT ADULTERATION WITH RAPID TEST (DART)

Adulteration is an intentional addition of substances which is prohibited to be added into the food which will make the food unsafe for human consumption. These adulterants are incorporated into to the food to enhance the colour, appearance, texture, weight etc. To find out the adulterants added in the foods we are consuming in our daily life, FSSAI has released a [Detect Adulteration with Rapid Test \(DART\)](#) booklet is a compilation of more than 50 quick tests for detection of adulterants at household levels. By using this manual, the consumers can easily test the food products by themselves regardless of sophisticated laboratory analysis environment.



These tests also include sensory evaluation tests for establishing authentication of food products. DART depicts the differences between pure and adulterated food product through pictorial representations.

The book covers simple test for detecting the adulterants in food. The tests are as simple that any person can conduct them at any place and it does not require any sophisticated analytical facility and chemicals as such.

5.6 FOOD FORTIFICATION

Food Fortification Resource Centre is setup by FSSAI to eliminate Hidden Hunger from wide communities of people in the world. This centre helps to promote large-scale fortification of food across India. Hidden Hunger is the deficiency of micronutrients in the food we consume which leads to serious health risks. To eliminate this, foods have been fortified with additional vitamins and minerals to enhance their bio - availability.



In simple, Fortification is the addition of key vitamins and minerals such as Iron, Iodine, Zinc and Vitamins A & D to staple foods such as rice, wheat, oil, milk and salt to supplement and improve their nutritional content. These nutrients may or may not have been originally present in the food before processing or may have been lost during processing.

Food Fortification has a high benefit-to-cost ratio. It requires an initial investment to purchase both the equipment and the vitamin and mineral premix, but the overall costs of fortification are extremely low. Even when all program costs are passed on to consumers, the price increase is approximately by 1-2%, which is less than the normal price variation.

Fortified Foods by FSSAI



Wheat Four Fortified with Iron, Folic Acid, Vitamin B12



Salt Double Fortified with Iodine and Iron



Rice Fortified with Iron, Folic Acid, Vitamin B12



Milk Fortified with Vitamin A and Vitamin D

5.7 REPURPOSE USED COOKING OIL (RUCO)

This is an initiative of FSSAI to reduce the consumption of used cooking oil in the daily foods we consume on domestic as well as commercial basis to avoid diverse health effects. RUCO enable the collection of used cooking oil to biodiesel and also sets mandatory limit of Total Polar Compounds (TPC).



Website: <https://eatrightindia.gov.in/ruco/>

The TPC limit in used cooking oil should not exceed 25 % as per the prescribed standards. If the TPC limit is beyond 25 % the vegetable oil is not suitable for use by the FBO. It also ensures safe handling and disposal of UCO by Food Business Operators and issued standardised methods and operating procedures for the handling and disposal of UCO.

This initiative is started behind the fact that the repeated frying of oil leads to change in physiochemical and sensory properties of oils. Therefore, RUCO helps to limit the use of frying by using same cooking oil to decrease the level of Total Polar Compounds in used oil.

To ensure that Used Cooking Oil (UCO) is neither directly used in the food preparation nor re-enter food chain, it has been notified that all FBOs whose consumption of edible oil for frying is more than 50 Litre per day shall maintain record about oil usage and disposal. It is recommended to collect and dispose the UCO by the agencies authorised by FSSAI or Commissioner of Food of States/UTs.

It is the responsibility of the FBOs enrolled in the RUCO initiative to collect used UCO safely in a collecting drums provided by authorise collecting agencies, and dispose it to authorised Non-Food Production (NFP) Units such as Bio-diesel and Soap Manufacturers, for making the use of UCO as feedstock by these Units. The UCO aggregators/collection agencies that are registered with these NFP Units will collect the UCO from FBOs.

5.8 TRANS – FAT FREE INDIA

Trans fats are bad fats, which should not be consumed as part of our diet. They are the worst type of fats as they raise the bad cholesterol [Very low density lipoprotein (VLDL) and low density lipoprotein-cholesterol (LDL-c)] and lowers the good cholesterol [high density lipoprotein-cholesterol (HDL-c)] in our body. Trans fats have been linked to heart diseases, overweight/obesity, high blood pressure, diabetes and some types of cancers. The sources of trans fat can be Natural or Artificial. Natural trans fats are also called ruminant trans fats, as they are present in small quantities in meat and dairy products obtained from ruminant animals such as cows, sheep and cattle.

When removing the trans-fat associated with partially hydrogenated oils from shortenings, margarines, pan oils, topical oils, etc., there are several options available depending on the application and desired functionality.

These may include:

- Natural High-Stability Oils
- Commodity oils like Palm blends
- Fully hydrogenated oils (FHOs)
- Inter Esterified oils
- High-oleic oils

On the demand side, FSSAI has launched a mass media campaign “Heart Attack Rewind”- a 30-second Public Service Announcement (PSA) which aims to create awareness about the harmful effects of trans fat by the following ways listed below

- Reducing acceptability of industrially produced (IP) trans-fat in foods
- Building public support for government action to eliminate IP trans-fat
- Leading consumers to the FSSAI website to seek more information about trans fat

5.9 FOOD SAFETY ON WHEELS (FSWs)

FSWs were initiated by FSSAI to provide mobile food testing facilities to impart confidence amongst consumers that food is safe and nutritious to consume. It is mainly intended to address the lack of testing infrastructure in the remote areas to furnish the elementary analytical needs of the consumers.



5.10 JAIVIK BHARAT

Organic foods are products of holistic agricultural practices focusing on bio-diversity, soil health, chemical free inputs etc. with an environmentally and socially responsible approach that have been produced in accordance with organic production standards. Now-a-days organic foods are in increasing demand and trend among the people because of its irreplaceable health benefits.



In this case it is essential to distinguish organic products from inorganic products placed in the market. For ease of consumers to identify certified organic products FSSAI has launched Jaivik Bharat, a unique logo which is intended to identify organic products from non – organic ones. This logo represents both the certification of National programme for Organic Production (NPOP) and Participatory Guarantee System (PGS). The Indian Organic Integrity Database serves as a single point of reference for accessing the information on organic foods for the consumers.

5.11 FOOD SAFETY TRAINING AND CERTIFICATION (FoSTaC)

Food Safety Training & Certification is a large scale training programme for the food business operators. All food businesses having Central Licences or State Licenses should have at least one trained and certified food safety supervisor for every 25 food-handlers or part thereof on all their premises.



Website: <https://fostac.fssai.gov.in/index>

The food safety supervisors will be certified & trained under FoSTaC.

There are 16 courses in three levels, i.e. Basic, Advanced & Special.

Objective:

- To enhance the availability of skilled/ trained manpower in the food industry.
- Creating an improved environment of self-compliance to FSS Act, Rules and Regulations by the responsible Food Businesses.
- Bringing a behavioural change and inculcating a culture of Food safety in the country.

5.12 CLEAN STREET FOOD HUB (CSFH)

An initiative by FSSAI to ensure health, hygiene and safety standard of street food for all consumers and to upgrade existing food street across the country and provide safe and hygienic local eating experience, FSSAI with support of state government bodies has framed benchmarks for basic hygiene and sanitary requirements for upgrading the existing infrastructures of food streets across the country. Currently there are 144 potential clean street food hubs has been certified by the authority. Under this Food Safety Display Boards have been introduced to inform the consumers about the food safety and sustainability.

5.13 BLISSFUL HYGIENIC OFFERING TO GOD (BHOG)

BHOG is a large scale initiative to transform the country's food system to ensure safe, healthy and sustainable food for all the devotees at the Places of Worship (PoW).

PoW are a very important part of Indian society and food served in these places is regarded as pure and sacred but food safety also needs to be implemented. FSSAI has, therefore, initiated Project BHOG (Blissful Hygienic Offering to God) to encourage all Places of Worship (PoW) to adopt and maintain food safety and hygiene in the preparation of Prasad.



All the PoW that distribute Prasad, including vendors that sell Prasad in the vicinity of the PoW, are henceforth required to obtain FSSAI license/ registration and they also need to follow the sanitary and hygiene practices as per food safety and Standards regulations.

The FSSAI aims to create awareness among the PoW through Project BHOG to discourage malpractices related to food served as Prasad, langar, etc. and to ensure regulatory compliance.

Training of food handlers and vendors inside and outside the PoW premises are an integral part of the BHOG initiative. On a pilot basis, the FSSAI has carried out training programmes in Maharashtra and Tamil Nadu along with trainers from Association of Food Scientists and Technologists of India (AFSTI) with the support of State Governments.

Chapter VI

Food Quality Testing and GLP

6.1 Introduction

Food is a major determinant of health, nutritional status and productivity of the population. It is, therefore, essential that the food we consume is wholesome and safe. Food safety and quality are important at the home level, but are critical in large scale food production and processing, and also where food is freshly prepared and served.

Food Quality refers to attributes that influence a product's value to consumers. This includes both negative attributes such as spoilage, contamination, adulteration, food safety hazards as well as positive attributes such as colour, flavour, texture. It is therefore a holistic concept integrating factors such as nutritional traits, sensorial properties (colour, texture, shape, appearance, taste, flavour, odour), social considerations, safety.

Food safety means assurance that food is acceptable for human consumption according to its intended use. Safety is a preliminary attribute and precursor of quality. In order to ensure that foods are safe and of good quality, across the world various governments and international bodies have laid down food standards that manufacturers/suppliers are expected to adhere to.

6.2 Food Quality Testing

Testing of food is very important to ensure about food quality and food safety before it gets distributed for the consumption or its intended use. For this the food is analysed for various quality as well as safety parameters, as stated in the regulations of FSS Act, 2006.

Food analysis is the discipline which deals with the development, application and study of analytical procedures for characterizing the properties of foods and their constituents. The analytical procedures are used to provide information about a wide variety of different characteristics of foods, including their composition, structure, physicochemical properties and sensory attributes.

This information is critical to our rational understanding of the factors that determine the properties of foods, as well as to our ability to economically produce foods that are consistently safe, nutritious and desirable and for consumers to make informed choices about their diet.

6.3 Purpose of Food Quality Testing

Food products are analysed in all of the sectors of the food industry including food manufacturers and ingredient suppliers as well.

The various purposes that foods are analysed are as below.

- A. Government Regulations and Recommendations
- B. Food Safety
- C. Quality Control

A. Government regulations and recommendations

The regulations and recommendations are designed,

- to maintain the general quality of the food supply
- to ensure the food industry provides consumers with foods that are wholesome and safe
- to inform consumers about the nutritional composition of foods so that they can make knowledgeable choices about their diet
- to enable fair competition amongst food companies
- to eliminate economic fraud

The Food Business Operators are made mandatory to comply with these regulations by following certain requirements as mentioned below.

- Food Standards
- Nutritional Labelling
- Food Authenticity
- Food Inspection and Grading

Food Standards

Effective food standards and control systems are required to integrate quality into every aspect of food production and service, to ensure the supply of hygienic, wholesome food as well as to facilitate trade within and between nations. Government agencies have specified a number of voluntary and mandatory standards.

Mandatory Standards:

- Standards of Identity* specifies the type and amounts of ingredients that certain foods must contain if they are to be called by a particular name on the food label.
- Standards of Quality* specifies minimum requirements for different product characteristics
- Standards of Fill-of-Container* states about how full a container must be

Voluntary Standards:

- Standards of Grade*

Food products are graded according to their quality *e.g.* from standard to excellent.

Specification of the grade of a food product on the label is voluntary

Nutritional Labelling

Regulations pertaining to the nutritional labelling of foods has made it mandatory for almost all food products to have standardized nutritional labels. One of the major reasons for introducing these regulations was so that consumers could make informed choices about their diet. Nutritional labels state the total calorific value of the food, as well as total fat, saturated fat, cholesterol, sodium, carbohydrate, dietary fibre, sugars, protein, vitamins, calcium and iron.

Food Authenticity

The price of certain foods is dictated by the quality of the ingredients that they contain. There are many instances in the past where manufacturers have made false claims about the authenticity of their products in order to get a higher price. It is therefore important to have analytical techniques that can be used to test the authenticity of certain food components, to ensure that consumers are not the victims of economic fraud and that competition among food manufacturers is fair.

Food Inspection and Grading

Food laboratories are routinely analyses the properties of food products to ensure that they meet the appropriate laws and regulations. As an essential part of the food safety ecosystem, FSSAI has created a network of 232 laboratories to fulfill its mandate on food testing and analysis.

B. Food Safety

One of the most important reasons for analysing foods from both the consumers and the manufacturers standpoint is to ensure that they are safe. It would be economically disastrous, as well as being rather unpleasant to consumers, if a food manufacturer sold a product that was harmful or toxic. A food may be considered to be unsafe because it contains harmful microorganisms (e.g., Listeria, Salmonella), toxic chemicals (e.g., pesticides, herbicides) or extraneous matter (e.g., glass, wood, metal, insect matter). It is therefore important that food manufacturers do everything they can to ensure that these harmful substances are not present, or that they are effectively eliminated before the food is consumed.

C. Quality Control

The food industry is highly competitive and food manufacturers are continually trying to increase their market-share and profits. To do this they must ensure that their products are of higher quality, less expensive, and more desirable than their competitors. Ideally, a food manufacture wants to take the raw ingredients, process them in a certain way and produce a product with specific desirable properties. Unfortunately, the properties of the raw ingredients and the processing conditions vary from time to time which causes the properties of the final product to vary, often in an unpredictable way.

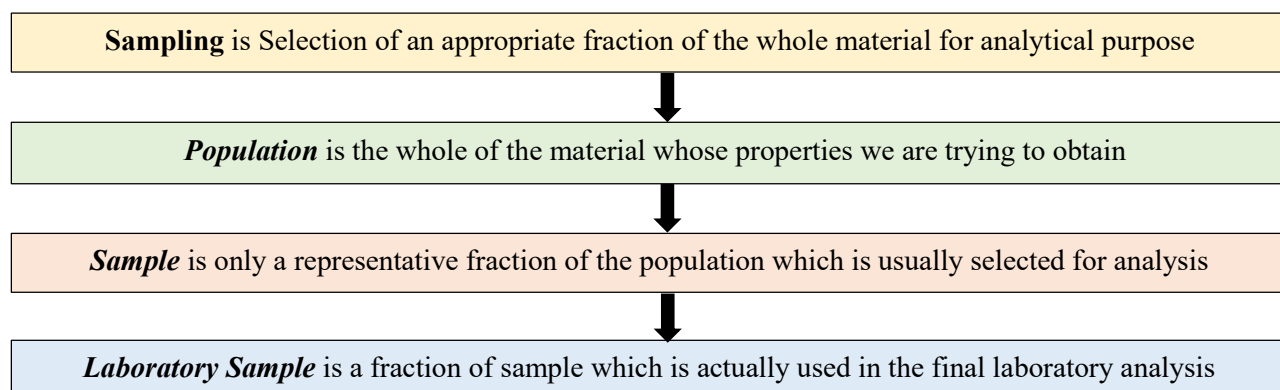
To meet these rigorous standards food manufacturers, need analytical techniques to analyse food materials,

- Before the manufacturing process (*i.e. Characterization of raw materials*)
- During the manufacturing process (*i.e. Monitoring quality during processing*)
- After the manufacturing process (*i.e. Characterization of final product*)

6.4 Sampling of Food for Food Quality Testing

A food analyst often has to determine the characteristics of a large quantity of food material. Analysing every part of the material to obtain an accurate measure of the property of interest, is practically impossible. Hence, a sampling technique is very much necessary to make the product quantity into analysable amount. It is a normal practice to select a fraction of the whole material for analysis, and to assume that its properties are representative of the whole material.

The sample selection and the amount of sample to be selected depends upon analytical techniques. The analytical techniques may be either *Destructive (Consumes Sample)* or *Non-Destructive (Retains the sample)*. Below is flow of sampling procedure to convert the food product batch into a laboratory sample to be used for analysis.



6.5 Food Testing Laboratory

Food testing laboratories plays a vital role in Food Safety and Standards Act, 2006. Food Analytical Laboratory is a critical and integral part of supply of safe and quality food. For analyzing the food products and to check the compliance, Food Authority (*i.e. FSSAI*) has categorized food laboratories based on their purpose or scope of work. The analysis of sample has to be carried out through FSSAI Recognized Laboratory or NABL Accredited Laboratory.

FBO's should check the scope of the Laboratory before submitting their samples for analysis. Scope of laboratory is nothing but the approved list of products / parameters that the laboratory is able to perform the analysis for. Report obtained from laboratory whose scope does not include your product will not be get considered by Food Authority for meeting the compliance for obtaining the license or registration certificate.

FSSAI has categorized the approved and notified laboratories as;

i. Primary food laboratories

The Food Authority notifies food laboratories and research institutions accredited by National Accreditation Board for Testing and Calibration Laboratories or any other accreditation agency for the purposes of carrying out analysis of samples by the Food Analysts

ii. Referral food laboratories

The Food Authority recognizes referral food laboratories for the purposes of carrying out analysis of appeal samples. Presently there are 20 referral food laboratories

iii. National Reference Laboratories

FSSAI has recognized National Reference laboratory (NRL) to set up a country wide standard for routine procedures, validation of such standard procedure / testing methods, development of new methods and ensuring proficiency in testing across the food laboratories with special reference to the risks or food categories. Either a primary food laboratory or a referral food laboratory can be considered for declaration as a NRL.

6.6 Good Laboratory Practices (GLP)

Good laboratory practices are accepted methods to carry out activities or operations in a laboratory. These practices help the authorities and laboratory organizations in ensuring safety in performing the food analysis. They also have a positive influence on the quality of the test result.

A Good Laboratory Practice (GLP) process is an important component of all Quality Programs of food industry. It includes a set of principles that provides the framework within which the laboratory is planned, performed, monitored, reported and archived. It is applicable in all aspects of a laboratory including; implementing, validating and maintaining the laboratory compliance.

The GLP of any food laboratory should focus on Quality and Integrity of analytical data. The standard ISO/IEC 17025:2005, is used to for accreditation of laboratory. The basic principles of GLP are as given below.

- Test facility organization and personnel
- Quality Assurance Program
- Analytical and Instrumentation Facilities
- Apparatus, Materials and Reagents
- Test System
- Test methods and Reference Standards
- Standard Operating Procedures (SOPs)
- Performance of Test/Study
- Reporting of Test Results
- Storage and Retention of Records and materials

Chapter VII

Schedule 4 Requirements and Plant Layout

7.1 Introduction to Schedule 4

Food is susceptible to contamination and adulteration, and are perishable in nature. Looking at the need of providing safe, clean, wholesome food for the better health and welfare of the consumer of the country, it has been recommended to maintain basic sanitary and hygienic conditions in food establishments etc. Any food business operator, being in an activity of handling, processing, manufacturing, storing, distributing the food products should conform to the sanitary and hygienic requirement, food safety measures and other standards as specified in the **Schedule 4** of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011.

Schedule 4 provides guidelines about General Hygienic and Sanitary practices to be followed by Food Business operators. It comprises of 5 parts as mentioned below.

<p style="text-align: center;">Part - I</p> <p>General Hygienic and Sanitary practices to be followed by Petty Food Business Operators applying for Registration</p>	<p style="text-align: center;">Part - II</p> <p>General Requirements on Hygienic and Sanitary Practices to be followed by all Food Business Operators applying for License</p>
<p style="text-align: center;">Part - III</p> <p>Specific Hygienic and Sanitary Practices to be followed by FBOs engaged in manufacture, processing, storing and selling of Milk and Milk Products</p>	<p style="text-align: center;">Part - IV</p> <p>Specific Hygienic and Sanitary Practices to be followed by FBOs engaged in manufacture, processing, storing and selling of Meat and Meat Products</p>
<p style="text-align: center;">Part - V</p> <p>Specific Hygienic and Sanitary Practices to be followed by Practices to be followed by Food Business Operators engaged in Catering / Food Service Establishments</p>	

**Prior to approval or grant of License/Registration to Food Business, an inspection of the units may get directed by the Registering or Licensing Authority. The inspection should confirm that the FBOs has complied with all the measures and requirements as stated in Schedule 4.*

7.2 Food Plant Design

Plant design refers to the overall aspects of a manufacturing industry / processing facility. In this chapter a detailed explanation about General Requirements on Hygienic and Sanitary Practices to be followed by all Food Business Operators which are critical to ensure food safety is given.

Location and Surroundings

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



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.). The premises to conduct food business for manufacturing should have adequate space for manufacturing and storage to maintain overall hygienic environment.



**Details about plant layout, its types and a basic reference layout is given in point number 7.3, 7.4 and 7.5 of this chapter.*

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



- 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.



- Adequate control measures should be in place to prevent insects and rodents from entering the processing area from drains. 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. The mesh or the screen should be of such type which can be easily removed for cleaning. No spraying shall be done during the conduct of business, but instead fly swats/ flaps should be used to kill spray flies getting into the premises.

Equipment and Containers

- 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).



- 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 to ensure freedom from growth of mould/ fungi and infestation. Such utensil or container shall not be used for any other purpose.
- All equipments shall be placed well away from the walls to allow proper inspection

- 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.



- 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.

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



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

- Containers used to hold cleaning chemicals and other dangerous substances shall be identified and stored separately to prevent malicious or accidental contamination of food. If required, a waste water disposal system / effluent treatment plant shall be put in place.

Facilities

- *Water supply*

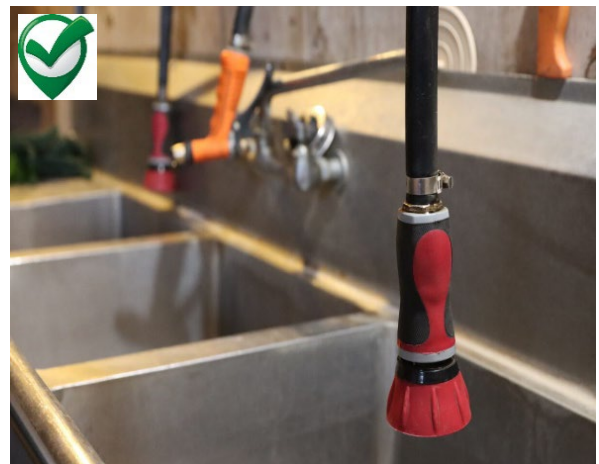
The water used in the manufacturing shall be potable and if required chemical and bacteriological examination of the water shall be done at regular intervals at any recognized laboratory. Continuous supply of potable water shall be ensured in the premises.

In case of intermittent water supply, adequate storage arrangement for water used in food or washing shall be made. Water storage tanks shall be cleaned periodically and records of the same shall be maintained in a register.

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

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.

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



- *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.



- *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.



- *Drainage and waste disposal*

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.



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. 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.

- *Personnel facilities and toilets*

Proper hand washing and drying facility 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 shall be suitably located so that they do not open directly into food processing, handling or storage areas.

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. Rest and refreshments rooms shall be separate from food process and service areas.

- *Personal Hygiene*

Persons suffering from infectious diseases shall not be permitted to work. Any cuts or wounds shall remain covered at all time and the person should not be allowed to come in direct contact with food.



All food handlers shall keep their finger nails trimmed, clean and wash their hands with soap, or detergent and water before commencing work and every time after using toilet.



All food handlers should avoid wearing, false nails or other items or loose jewellery that might fall into food and also avoid touching their face or hair.

Eating, chewing, smoking, spitting and nose blowing shall be prohibited within the premises especially while handling food.

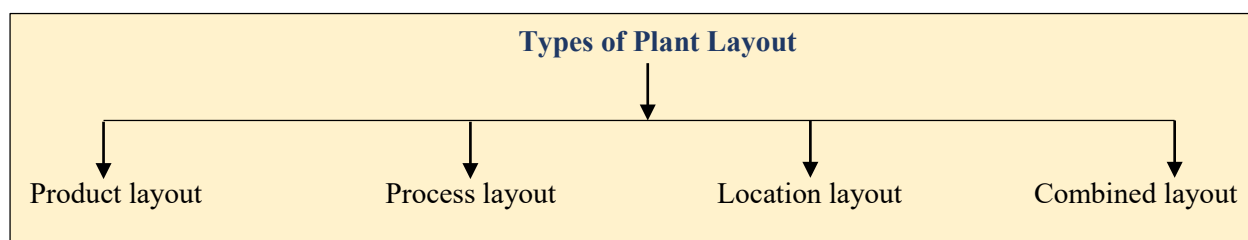
7.3 Plant Layout

Plant layout refers to the arrangement of physical facilities such as machines, equipment, tools, furniture etc. in such a manner so as to have quickest flow of material at the lowest cost and with the least amount of handling in processing the product from the receipt of raw material to the delivery of the final product. The objectives of Plant Layout are as below.

- Helps in proper and efficient utilization of available floor space.
- Supports the transportation of work from one point to another point without any delay.
- Facilitates in proper utilization of production capacity.
- It also reduces material handling costs.
- Utilization of labor becomes efficient.
- It helps reduce accidents.
- It provides the volume and product flexibility.
- There is an ease of supervision and control.
- It provides the employee safety and health.
- It allows an easy maintenance of machines and plant.
- It helps in improving the productivity.

7.4 Types of Plant Layout

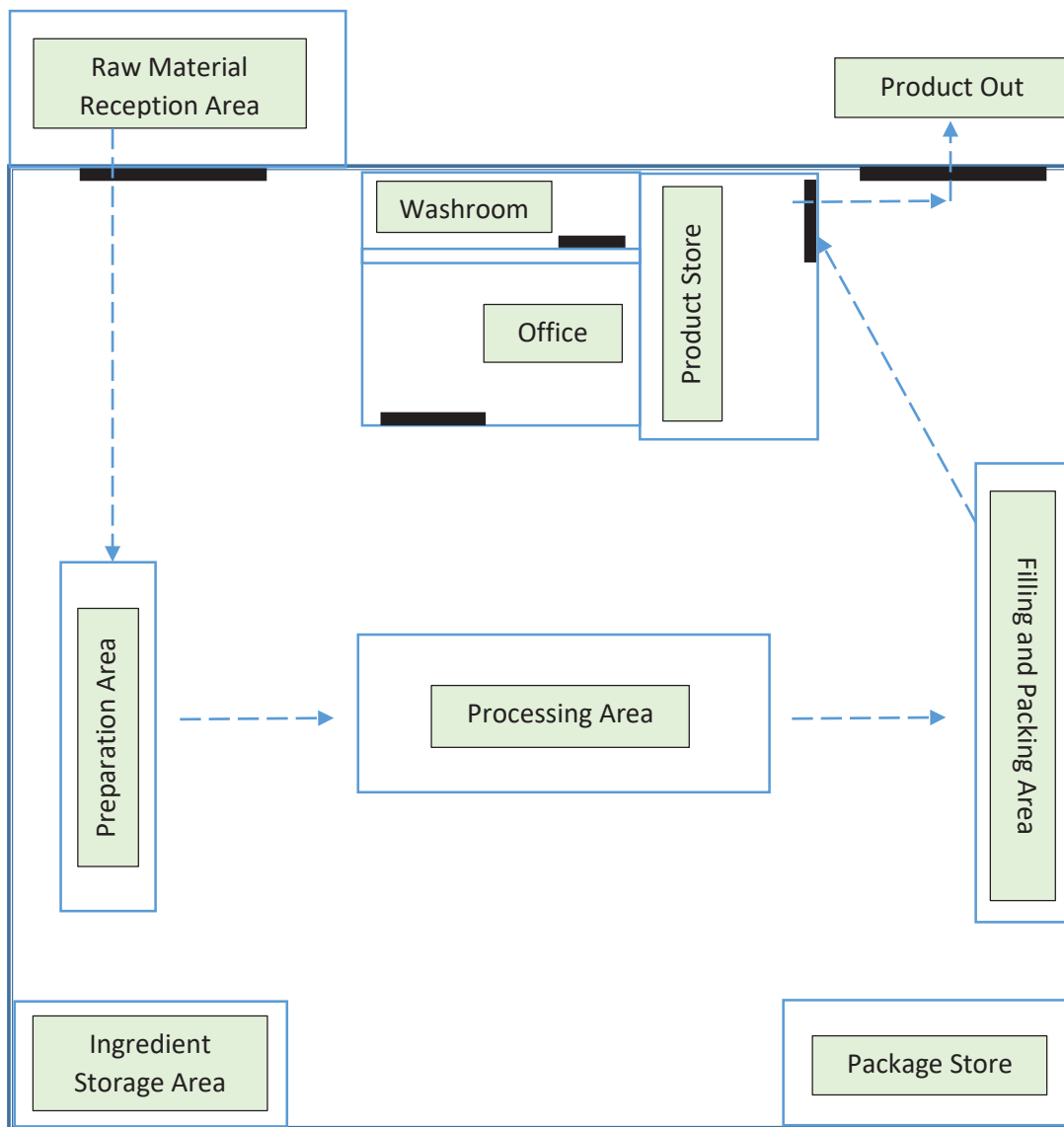
There are four types of Plant Layout which helps in achieving the objectives of plant layout.



- A. Product layout:** The machines and equipment's are arranged in one line depending upon the sequence of operations of the required product without any backtracking or deviation.
- B. Process Layout:** The machines of a similar type are arranged together at one place. Used for batch production and preferred when products are standardized and produced in small quantity.
- C. Location Layout:** The size of the job is bulky and heavy which involves the movement of manpower and machines to the product which remains stationary.
- D. Combined Layout:** It is the combination of process and product layout where several products are produced in repeated numbers with no likelihood of continuous production

7.5 Food Processing Building Design

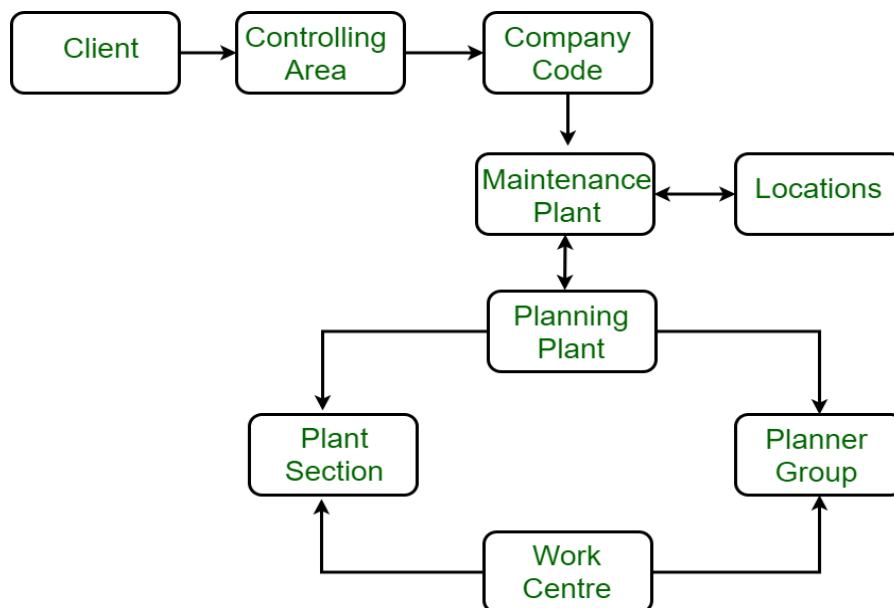
A general layout or plant design of a food processing unit is shown in the image given below. The main objective while designing the plant layout is that the raw material and finished products should not come in contact. It can be achieved by having a unidirectional flow of processing activities in the plant. Along with this care has to be taken to avoid crossing of processing lines or stages which ultimately may lead to cross contamination of food. The pre-processing, processing and post-processing section in the plant has to be clearly identified and a special attention is to be given for the section where hygiene is necessary.



A Basic Food Processing Plant Layout

7.6 Plant Maintenance

Plant Maintenance is a type of module that provide an integrated solution which supports the operational needs of an enterprise-wide system. The main objective is to minimize the loss of production time due to any equipment failure and keeps all the assets in proper working conditions. It helps in quality and product improvement. The major advantage in this are reduction of breakdown losses, quality defects, maintenance cost and increases in net quality profits and the disadvantage is increasing investment in diagnostics equipment, staff training and vice versa.



Organization Structure of Plant Maintenance

7.7 Major Sub-systems of a Plant Maintenance

1. Preventive Maintenance Control: It enables the organization to lower repair cost by avoidance of down time, machine breakage and process variability. It also provides planning, scheduling and control of facilities.
2. Equipment Tracking: An equipment is a useful thing which needs to be protect and monitor. Its cost constitutes the single largest expenditure of an organization.
3. Component Tracking: Components are the subsets of larger equipment and also it deserves same amount of cost control expenditure. It enables expenditure managers to identify components with repair problems.
4. Plant Maintenance Calibration Tracking: It allows organizations to fully use their investments in the plant maintenance module.
5. Plant Maintenance Warranty Claims Tracking: It is an administrative system to provide control of all items covered by manufacturer and vendor warranties. It includes the ability to establish the type and length of warranty.

7.8 Cleaning & Sanitation of Equipment and Premises

Detailed cleaning program shall be developed indicating specific areas to be cleaned, cleaning frequency, procedure, equipment, cleaning material and method. Equipment and utensils used in the food product manufacturing 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. Appropriate facilities for the cleaning and disinfecting of equipment's and instruments and wherever possible cleaning in place (CIP) system shall be adopted. CIP (cleaning in place) facilities can be adopted for cleaning and disinfecting of equipment and instruments. For cleaning of disassembled equipment, utensils and containers, a separated and identified cleaning area shall be provided with adequate potable water supply, drainage system and cleaning agents. Equipment and containers for waste, by-products and inedible or dangerous substances, shall be specifically identifiable and suitably constructed.

Containers used to hold cleaning chemicals and other dangerous substances shall be identified and stored separately to prevent malicious or accidental contamination of food. If required, a waste water disposal system / effluent treatment plant shall be put in place.

7.9 Preventive & Corrective Maintenance

The preventive maintenance programmes shall include all devices used to monitor and/or control food safety hazards. Corrective maintenance shall be carried out in such a way that production on adjoining lines or equipment is not at risk of contamination. Maintenance requests which impact product safety shall be given priority. A request for replacement by a permanent repair shall be included in the maintenance schedule. Lubricants and heat transfer fluids shall be food compatible where there is a risk of direct or indirect contact with the product. The procedure for releasing maintained equipment back to production shall include clean up, sanitizing, where specified in process sanitation procedures, and pre-use inspection. Local area PRP requirements shall apply to maintenance areas and maintenance activities in process areas. 8. Maintenance personnel shall be trained in the product hazards associated with their activities.

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PM Formalisation of Micro food processing Enterprises Scheme

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