

11. Hygiene & FSSAI Standards

Yashi Srivastava

INTRODUCTION TO FOOD SAFETY

- I. Food Safety means assurance that food is acceptable for human consumption according to its intended use.
- II. Food Safety Management System means the adoption of Good Manufacturing Practices, Good Hygienic Practices, Hazard Analysis and Critical Control Point and such other practices as may be specified by regulation, for the food business.
- III. Food Safety Hazard means biological, chemical or physical agent in food, or condition of food, with the potential to cause an adverse health effect. There are majorly four types of hazards

Food Hazards

a. Physical Hazards

Any foreign object (inanimate) found in the food or a naturally occurring object (metal, hard plastic), that poses a hazard is called a 'Physical Contamination or Hazard'.

Common Physical Hazards include:

- Glass
- Chipped pieces from equipment
- Metal shavings from equipment's, cans, foils etc.
- Stapler pins
- Blades
- Plastic or chipped pieces of disposables
- Lint and threads
- Band- aids
- Hair
- Finger nails
- Jewellery pieces

b. Chemical Hazards

Naturally occurring and process induced chemical substances that can cause a food borne illness are called a 'Chemical Contaminant or Hazard'.

Natural Chemical Contaminants include:

- Biological toxins
- Mycotoxins (aflatoxin, ochratoxin etc.)

Process Induced Chemical Contaminants include:

- Toxic metals in the processing set up or supply chain
- Pesticides, Colorants
- Cleansing products and sanitizers
- Equipment lubricants
- Chemical Food Additives, Preservatives
- Packaging materials-migration of residues from packaging material to oil.
- Adulteration with other oils or mineral oil

c. Biological Hazards

Biological hazards are organisms, or substances produced by organisms, that pose a threat to human health. They are a major concern in food processing because they cause most food borne illness outbreaks. Major biological hazards include –

- Bacteria ex: Salmonella spp., Enterohaemorrhagic Escherichia coli, Listeria monocytogenes, Staphylococcus aureus, Clostridium botulinum,
- Yeast & Mold ex: Candida, Aspergillus sp., Helicospodium

Biological Hazards Causes -

1. Food Borne Infections – This result when a person consumes food containing pathogens; which grow in the human intestine and cause discomfort or disease. Typical symptoms of a ‘food borne Infections’ do not appear immediately.
2. Food Borne Intoxications - This result when a person consumes food containing toxins in it; that cause discomfort or disease. Typical symptoms of a ‘food borne Intoxication’ appear quickly. Food Borne toxin are mediated infections, that result when a person consumes food containing toxins produced by the pathogens in it; which grow in the human intestine and produce toxins that cause discomfort or disease.

Conditions favouring growth of Microorganisms

FAT TOM Conditions	Definition
Food	Food borne Microorganisms draw nutrients from Potentially hazardous foods
Acidity	Food borne Microorganisms grow well between the pH range of most foods
Temperature	Microorganisms grow well between the temperature range of 5 ^o C – 60 ^o C, most commonly known as the 'Danger Zone'
Time	Microorganisms need sufficient time to grow; when exposed to the 'Danger Zone'
Oxygen	Microorganisms require oxygen in free or combined state; to favor their growth
Moisture	Microorganisms require moisture to grow and is measured in the form of 'Water Activity (Aw)'

FOOD SAFETY REGULATIONS

To provide assurance of food safety, Food businesses must implement an effective Food Safety Management System (FSMS) based on Hazard Analysis and Critical Control Point (HACCP) and suitable pre- requisite programmes by actively controlling hazards throughout the food chain starting from food production till final consumption

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. Schedule 4 introduces the concept of FSMS based on implementation of Good Manufacturing Practices (GMP) and Good Hygiene Practices (GHP) by food businesses.

Schedule 4: Part-II

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

The establishment in which food is being handled, processed, manufactured, packed, stored, and distributed by the food business operator and the persons handling them should conform to the sanitary and hygienic requirement, food safety measures and other standards as specified below.

It shall also be deemed to be the responsibility of the food business operator to ensure adherence to necessary requirements

1. LOCATION AND SURROUNDINGS

Manufacturing / processing / packaging premises shall be located away from sources of pollution like open drains, garbage yards, industries that emit fumes or gases and dense vegetation.

In order to avoid contamination from external sources such as odor, pests, dust etc., appropriate measures shall be taken to protect the processing area from environmental contamination. Processing area shall not have direct access to any residential area.

2. LAYOUT & DESIGN OF FOOD ESTABLISHMENT PREMISES

a) Outside the food production premise

Layout & Design of the food production unit should be uni directional to prevent backward flow of materials during processing. This is required in order to prevent cross contamination.

b) Inside the food production premise

1. Floors, ceilings and walls of the establishment must be made of impervious material. They should be smooth and easy to clean with no flaking paint or plaster and maintained in a sound condition to minimize accumulation of dirt, condensation & growth of moulds
2. The doors in the establishment shall be made of smooth and non-absorbent surfaces and they shall be easy to clean and disinfectant. Doors can be fitted with automatic closing spring, strip or air curtain.
3. The floor shall have adequate and proper drainage with appropriate slope and they should be easy to clean and disinfect. The drainage shall flow in a direction opposite to the direction of food preparation area to avoid contamination.
4. The drains should be covered to prevent insects and rodents from entering the processing area.
5. The windows, doors & all other openings to outside environment in the establishment shall be well screened with wire-mesh or insect- proof screen to protect the premise from pests. The doors shall be fitted with automatic closing

springs to keep them closed at all times and also the mesh should be easy to remove & clean to avoid accumulation of dust & dirt.

3. EQUIPMENT & CONTAINERS

During preparation / handling / processing / storage of food products like flour, sugar, dairy based products, spices, bakery ingredients, dry fruits, cereals & grains, oilseed, refined oil, etc. certain equipment's e.g. scoops, spoons, cooking vessels, containers, tanks, silos, hoppers, pipes, packaging machines, filters, etc. come into contact with food.

All these food contact surfaces shall be:

- made up of non-corrosive / rust free material
- smooth, free from any grooves
- easy to clean and maintain
- non-toxic and non-reactive
- of food grade quality

Generally, food grade stainless steel or galvanized iron material is preferred as it complies with the above requirements.

- All the equipment's used during food preparation, handling & packaging (if any) shall be designed, located and fabricated to facilitate easy cleaning and shall be kept away from impure air and dust.
- Every utensil or container containing food products 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.
- No utensil or container used for the manufacturing of food items shall be kept in any place in which such utensil or container be contaminated and thereby render the food noxious.
- All equipment shall be kept clean, repaired and maintained in sound condition all the time.
- All measuring instruments / equipment like temperature gauges, pressure gauges, weighing balances, etc. shall be calibrated periodically for correct measurement.

4. FACILITIES

6. **Water Supply:** Water used in cleaning of equipment's / containers / cooking vessels shall be potable and shall not introduce any hazards or contaminate the food products. Clean and safe water storage facilities shall be provided. Steam, if used for heating of any food material shall be generated from potable water. If non-potable water is used anywhere in cleaning of containers / areas which are not in use for food processing / handling / storage, then the concerned pipeline shall be identified as such or differentiated from potable water.
7. **Drainage and waste disposal:** Waste generated during processing like spillage of products, bleaching earth, spent wash, de-gummed oil, ash from boiler, etc. shall be collected regularly and such collected waste shall be stored in such a manner that it will not contaminate the food process and storage area inside / outside the environment of the premises. Waste generated in processing area shall be collected in dustbins and dustbins shall be provided with lid, identified to a specific area and cleaned regularly.

Collected waste shall periodically be handed over to a local waste-collecting body or disposed of in an appropriate manner that will not cause any hazards.

An Effluent treatment plant if required shall be set up as per the Environment Pollution Control Board.

8. **Personnel facilities and toilets:** Personal facilities include hand washing and drying system with potable water supply, adequate and separate lavatories and changing facilities. Hand wash facilities shall be provided with hot or cold running water with self-closing / or elbow operated tap, soap solution, hand drying system / towel and disinfectant. Adequate number of separate clean toilets for males and females, refreshment rooms and changing rooms shall be provided at suitable locations and these shall not have direct access to the process / storage area.

To generate awareness in food handlers, display boards for 'Do and Don't', personal hygiene, personal behavior and good manufacturing practices shall be put up at prominent places with pictorial information and instructions in an understandable language or the local language.

9. Air quality and ventilation system shall be designed and constructed so that air does not flow from contaminated areas to clean areas. Ventilation is especially important at workstations devoted to raw-material handling, processing, storage, etc.

10. Lighting: Adequate lighting facility shall be provided to enable the food handlers to operate in a hygienic manner. Lighting shall be protected / covered to prevent contamination due to accidental breakages.

CLEANING AND MAINTENANCE OF EQUIPMENT

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 containers that come in contact with food products and used for its handling, storage, processing & packaging 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). MS (Mild Steel powder coated) Tanks and pipelines should be preferably avoided and replaced with SS (Stainless Steel).
- 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.
- 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 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.
- All items, fittings and equipment's that touch or come in contact with food must be kept in good condition in a way that enables them to be kept clean and wherever necessary, to be disinfected.
- Lubricants and heat transfer fluids shall be food grade where there is a risk of direct or

Dos and Don'ts

- Never store chemicals near food, food storage areas or any tools or equipment that will touch food. Keep them under lock in a designated area only for cleaning tools and chemicals.
- Never leave chemicals on or near a food preparation area. That includes on top of counters, stoves, etc.
- Do not store chemicals above food prep areas, kitchen sinks or drain boards.
- Store chemicals in their originally labelled containers and make sure they are closed properly.
- Never use food storage containers to store, transport or mix chemicals.
- Always read the instructions on the label before use, even if it's a product you use regularly. You don't want to accidentally use the product in the wrong area or use it incorrectly.
- Use safety posters or graphics to warn employees about chemical safety precautions. In businesses where language barriers could be a problem, create materials that are either bilingual or use pictures that don't require further descriptions.

- Always spray chemicals holding the spray nozzle away from you.
- Never mix two different chemicals together.
- Always wear protective gloves and goggles when recommended.

Preventive & Corrective Maintenance

Preventive maintenance programmes shall be in place.

- 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.
- Temporary fixes shall not put product safety at risk. 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.
- Maintenance personnel shall be trained in the product hazards associated with their activities

5. FOOD OPERATIONS & CONTROL

Procurement of raw materials

While procuring and receiving the raw material, the food handler shall ensure that –

1. Raw materials shall be purchased from reliable and known suppliers. As per Condition of license, every manufacturer, distributor or supplier selling an article

of food to manufacturing shall give either separately or in the bill, cash memo or label a warranty in Form E. i.e. Form of Guarantee.

2. It shall conform to all the Regulations and standards laid down under the Food Safety & Standard Act, 2006.
3. Records of raw materials & source of procurement shall be maintained in a register for inspection.
4. All raw materials should be checked for visible deterioration & off- odour and for any foreign matter.
5. If material is received in tankers (for e.g. milk, oil, water, etc.), it should be checked for seal integrity and mostly dedicated tankers shall be used.
6. No raw material or ingredient thereof shall be accepted if it is known to contain parasites, undesirable micro-organisms, pesticides, veterinary drugs or toxic items or decomposed or extraneous substances, which would not be reduced to an acceptable level by normal sorting and/or processing.
7. Raw materials should be purchased in quantities that correspond to storage/preservation capacity of the establishment.
8. Packaged raw material must be checked for 'expiry date'/ 'best before'/ 'use by date, packaging integrity and storage conditions.

STORAGE OF RAW MATERIALS & FOOD

After receiving and accepting the raw material, there comes the need of storage. The storage facilities shall be designed and constructed to avoid cross - contamination during storage, permit adequate maintenance and cleaning and shall avoid pest access and accumulation. Cold Storage facility shall be provided for food that requires being stored below 5°C.

While designing the storage room, segregation shall be there for raw, processed, packaging, rejected, returned or recalled food items, allergen material & distinguishably marked and secured products (hardware & cleaning chemicals). The storage area for raw food shall be separate from the area of work-in-progress, processed, cooked and packaged products.

Also, the containers made of non-toxic materials shall be provided for storage of raw materials, work-in-progress and finished / ready to serve products.

While procuring and receiving the raw material, the food handler shall ensure that –

1. Storage instructions over food packaging should be followed.
2. Temperature and humidity requisite for respective food materials / products shall be maintained, to enhance shelf life.
3. FIFO (First In First Out) & FEFO (First Expire First Out) stock rotation system as applicable, shall be followed in storage areas, work-in-progress and processed/cooked or packaged food products.
4. The food materials shall be stored on racks / pallets, well above the floor level and away from the wall.

Production

A detailed food safety plan & hygiene requirement to be followed for the manufacturing / processing of different food products.

Transportation

1. Transportation vehicles, tankers, conveyances, and containers shall be maintained in a state of good repair, cleanliness, and condition consistent with requirements given in relevant specifications.
2. Where the same vehicles, conveyances, and containers are used for food and non-food products, cleaning shall be carried out between loads & No petroleum or hazardous chemicals tankers shall be engaged for Food items transportation.
3. Bulk containers shall be dedicated to food use only. Where required by the organization, bulk containers shall be dedicated to a specified material.
4. Bulk tankers, deliveries tankers shall be sealed with plastic / metal seals with numbered seals & thread or lead seals should be restricted.

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

6. MANAGEMENT & SUPERVISION

A detailed Standard Operating Procedure (SOP) for the processing of food as well as its packing, dispatch and storage shall be developed. A standard operating procedure, or SOP, is a living document showing technical instructions of how to perform a routine or repetitive task. SOPs aim to achieve efficiency, quality output and uniformity of performance, while reducing miscommunication and failure to comply with establishment requirements. The SOP should be based on 5W's & 1H (i.e. why, when, what, where, who & how)

A good standard operating procedure –

- Should provide all information necessary to perform a task
- It is usually specific to the equipment used for the procedure
- Should be detailed
- Should be standalone
- Should provide quality information
- Should provide references

The technical managers and supervisors shall have appropriate qualifications, knowledge and skills on food hygiene principles and practices.

As per the condition of FSSAI license – The Food Business Operator shall employ at least one technical person to supervise the production process.

The person supervising the production process shall possess at least a degree in science with Chemistry/ Bio-chemistry/ Food and nutrition/ Microbiology or a degree or diploma in Food Technology/ Dairy Technology/ Dairy Microbiology/ Dairy chemistry/ Dairy engineering/ Oil technology/ Veterinary science / Hotel management & technology or any degree or diploma in any other discipline related to the specific requirement of the business from a recognized university or institute or equivalent.

It should be ensured that SOPs help handle, store, and process, prepare and display the food products safely and correctly and that the lot or batch can be easily traced and recalled if necessary.

7. FOOD TESTING FACILITY

A well-equipped laboratory for physical, microbiological and chemical analysis shall be in place inside the premise of establishment. In case of any suspicion or possible contamination, food materials shall be tested before dispatch by the Food Business Operator.

If there is no in house laboratory facility, then regular testing shall be done through an accredited lab notified by FSSAI. In case of complaints received and if so required, the company shall voluntarily do the testing either in the in-house laboratory or an accredited lab or lab notified by FSSAI. As per the condition of FSSAI license – Food Business Operator shall 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 /FSSA notified labs at least once in six months.

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8. AUDIT, DOCUMENTATION & RECORDS

1. A periodic audit of the whole system according to the SOP shall be done.
2. Appropriate records of raw material receipt, stock of existing RM, production, storage, distribution, service, laboratory test results, cleaning and sanitation, pest control and product recall shall be kept.
3. The records shall be retained for a period of one year or till the shelf-life of the product, whichever is more.

9. SANITATION AND MAINTENANCE OF ESTABLISHMENT PREMISES

PEST CONTROL

A pest is any living organism that causes damages or discomfort, or transmits or produces diseases.

1. The establishment shall have a nominated person to manage pest control activities and/or deal with appointed expert contractor.
2. Pest management programmes shall be documented and shall identify target pests, and address plans, methods, schedules, control procedures and, where necessary, training requirements.
3. Programmes shall include a list of chemicals which are approved for use in specified areas of the establishment to be get listed in agreement.
4. Food establishment, including equipment and building shall be kept in good repair to prevent pest access and to eliminate potential breeding sites. Holes, drains and other places where pests are likely to gain access shall be kept in sealed condition or fitted with mesh / grills / claddings or any other suitable means as required and animals, birds and pets shall not be allowed to enter into the food establishment areas/ premises.
5. Food materials shall be stored in pest-proof containers stacked above the ground and away from walls.
6. Pest infestations shall be dealt with immediately and without adversely affecting the food safety or suitability. Treatment with permissible chemical, physical or biological agents, within the appropriate limits, shall be carried out without posing a threat to the safety or suitability of food. Records of pesticides / insecticides used along with dates and frequency shall be maintained.

7. Animals, birds and pets shall not be allowed to enter into the food establishment areas/ premises.
8. In order to control the settlement of pests in the surroundings (i.e. not to provide them place of refuge and feed resources) it is necessary to maintain a non-attractive environment which includes:
 - Isolated storage of unutilized materials, pallets and machines, without contact with the walls and buildings.
 - Design and maintenance of external spaces, including:
 - Elimination of holes and spaces in waste land with high vegetation.
 - Regular cutting of grass lawns
 - The elimination of stagnant water.
 - The absence of rags, papers, plastic films and other detritus abandoned on the ground.
9. Tidying and cleaning of technical buildings (machine shop, boiler room, refrigeration rooms, and electrical cabinets) to avoid rodent settlement.
10. Mosquito nets at window and suitable screens on access doors.
11. Rigorous management of waste containers, which include:

MONITORING AND DETECTION

Pest-monitoring programmes shall include the placing of detectors and traps in key locations to identify pest activity. A map of detectors and traps shall be maintained. Detectors and traps shall be designed and located so as to prevent potential contamination of materials, products or facilities.

The Major Pest includes – (Informative purpose)

12. Cockroaches
13. Rodents (mice, rats, squirrels etc.)
14. Flies
15. Stored product pests (Flour beetle, sawtooth grain beetle, cigarette beetle, Indian meal moth etc.)

10. PERSONAL HYGIENE

No personnel suffering from a disease shall be allowed to enter into any food handling area. Any person suffering from a disease shall immediately report illness to the management and medical examination of a food handler shall be carried out immediately.

All personnel shall be medically examined once in a year and a record signed by a registered medical practitioner shall be maintained. All the personnel shall be compulsorily inoculated against the enteric group of diseases and a record shall be maintained. In case of an epidemic, all workers are to be vaccinated irrespective of the scheduled vaccination.

Medical examination to be concluded -

1. Physical examination
2. Eye Test
3. Skin examination
4. *Compliance with schedule of vaccine to be inoculated against enteric group of diseases
5. Any test required to confirm any communicable or infectious disease which the person suspected to be suffering from on clinical examination

Note - * Vaccine to be inoculated against enteric group of diseases, shall be decided by the medical practitioners according to the list as declared by the municipal corporation of that area.

BEHAVIOURAL & PERSONAL CLEANLINESS

Personal cleanliness of food handlers is the most important link in preventing foodborne illness. These personal hygiene habits shall become a part of their behaviour.

1. All food handlers shall wear suitable clean protective clothing, head covering, face mask, gloves and footwear.
2. Food handlers shall always wash their hands with soap and clean potable water, disinfect their hands and then dry with hand drier or clean cloth towel or disposable paper.
3. Food handlers shall always wash their hands at the beginning of food handling activities immediately after handling raw food or any contaminated material,

tools, equipment or work surface, where this could result in contamination of other food items or after using the toilet.

4. No Food handlers shall be engaged in smoking, spitting, chewing, sneezing or coughing over any food and eating in food preparation and food service areas.
5. The food handlers should trim their nails and hair periodically.
6. Food Handlers shall avoid certain hand habits such as scratching nose, running finger through hair, rubbing eyes, ears and mouth, scratching beard, scratching parts of bodies etc. When unavoidable, hands should be effectively washed before resuming work after such actions.
7. Street shoes inside the food preparation area should not be worn while handling & preparing food.
8. Food handlers should not handle soiled currency notes/cards to avoid cross contamination.

Visitor Management

1. Generally, visitors should be discouraged from going inside the food handling areas.
2. Visitors when entering food manufacturing, cooking, preparation and storage or handling areas shall wear protective clothing, footwear.
3. Visitors shall adhere to the personal hygiene provisions as mandate for food handlers.

11. PRODUCT INFORMATION AND CONSUMER AWARENESS

All packaged food products shall carry a label and requisite information as per provisions of FSS Act, 2006 and Regulations made there under. (Please refer

<http://www.fssai.gov.in/home/fss-legislation/fss-regulations.html>

Labelling General Requirement -

Every pre-packaged food shall carry a label containing information as required hereunder unless otherwise provided, namely -

1. The particulars of declaration required under these Regulations to be specified on the label shall be in English or Hindi in Devanagari script; Provided that nothing

herein contained shall prevent the use of any other language in addition to the language required under this regulation.

2. Pre-packaged food shall not be described or presented on any label or in any labelling manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.
3. Labels in pre-packaged foods shall be applied in such a manner that they will not become separated from the container.
4. Contents on the label shall be clear, prominent, indelible and readily legible by the consumer under normal conditions of purchase and use.
5. Where the container is covered by a wrapper, the wrapper shall carry the necessary information or the label on the container shall be readily legible through the outer wrapper and not obscured by it.
6. License number shall be displayed on the principal display panel in the following format

Labelling of Pre-packaged Foods

In addition to the General Labelling requirements specified above every package of food shall carry the following information on the label, namely -

- Name of the food
- List of ingredients in descending order
- Nutritional information
- Declaration regarding veg or non-veg
- Declaration regarding food additives
- Name and complete address of manufacturer or packer
- Net content by weight or volume
- Date of Manufacture / Packing
- Lot / Code / Batch identification
- Best Before Date
- Instructions for use
- Importer details and Country of origin for imported products

12. TRAINING

1. All food handlers shall be aware of their role and responsibility in protecting food from contamination.
2. Food handlers shall have the necessary knowledge and skills which are relevant to food processing / manufacturing, packing, storing and serving.
3. All food handlers shall be trained in food hygiene and food safety aspects along with personal hygiene requirements.
4. Periodic assessments of the effectiveness of training, awareness of safety requirements and competency level shall be made.
5. Training programmes shall be routinely reviewed and updated wherever necessary.

FSSAI STANDARDS & REGULATIONS

Section 92 (1) of Food Safety and Standards Act, 2006 empowers the Food Authority to make regulations/standards in consistent with this Act and Rules made there under. After the enactment of the FSS Act, 2006 FSSAI has drafted six principal regulations through extensive consultation and deliberations/ meetings with various stakeholders. These regulations have been notified in the gazette of India on 1st August, 2011 and came into force on 5th August, 2011.

The Food Safety & Standards Act 2006 is Act to consolidate the laws relating to food and to establish the Food Safety and Standards Authority of India for laying down science based standards for articles of food and to regulate their manufacture, storage distribution, sale and import, to ensure availability of safe and wholesome food for human consumption and for matters connected therewith or incidental thereto.

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, De-oiled Meal and Edible Flour (Control) Order, 1967
7. Milk and Milk Products Order, 1992
8. Any order under Essential Commodities Act, 1955 relating to food.

Total 21 Regulations.

Six principal regulations were notified in the gazette of India on 1st August, 2011 and came into force on 5th August, 2011.

5 New regulations were notified in 2016 & 2017.

Another 11 regulations were added between 2018 & 2020.

Regulation-1

Licensing and Registration of Food Businesses (Regulation, 2011)

- This regulation came in force on 5th August, 2011
- Subject to Regulation, no person shall commence any food business unless he possesses a valid license
- Sanitary and hygienic requirements for food manufacturer/ processor/handler

Regulation-2

Licensing and Registration of Food Businesses (Regulation, 2011)

- This standard describes product and provide specification of every ingredient.
- This regulation provides detailed standards of various food products, It prescribes the limits of various food additives used across different food groups; and lays down microbiological requirement for different foods. It essentially consists of physical, chemical and microbiological standards of different foods.

Regulation-3

Prohibition and Restriction of Sales (Regulation, 2011)

- This regulation gives a guidelines defined which product has restriction for sale or not allowed to sale.

Regulation-4

Packaging and Labeling (Regulation, 2011)

- This standard is about packaging and labeling requirement.
- Mandatory printing articles.
- With the growing concern over the health risks that are involved in the consumption of packaged food, the FSSAI is now stringent on the regulatory norms related to FSSAI packaging and labelling requirements.

Regulation-4

Contaminants, Toxins and Residues (Regulation, 2011)

- This regulation provide information on maximum residual limits of Contaminants, Toxins and Residues.
- Prescribes that the chemicals as described in the monograph of Indian Pharmacopoeia when used in food shall not contain metal contaminants beyond the limit prescribed therein.

Regulation-5

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- Prescribes that the chemicals as described in the monograph of Indian Pharmacopoeia when used in food shall not contain metal contaminants beyond the limit prescribed therein.

Regulation-6

Laboratory and Sampling Analysis (Regulation, 2011)

- This regulation provide procedure of sampling and analysis along with sample size of various article of food.

Regulation-7

Food or Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical Purpose, Functional Foods and Novel Food, (Regulations, 2016)

- These regulations cover eight categories of Functional foods, namely, Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Specialty food containing plant or botanicals, Foods containing Probiotics, Foods containing Prebiotics and Novel Foods.

Regulation-8

Food Recall Procedure (Regulation, 2017)

- These regulations shall apply to the food or food products that are determined or prima facie considered unsafe and/or as may be specified by the Food Authority from time to time.
- Recall can be defined as an action to remove food products from market at any stage of the food chain, including that possessed by consumer, which may pose a threat to the public health or food that violate the Act, or the rules or regulations made there under.

Regulation-9

Import (Regulation, 2017)

- This regulation describe about Licensing of Food Importers.
- Clearance of Imported Food by the Food Authority.
- Section 25 of the Food Safety & Standard Act, 2006, stipulates that all imports of articles of food are subject to the provisions of the Act. Selective sampling & testing of food articles on the basis of risk profiling done by FSSAI is implemented at the Customs ICEGATE.

Regulation-10

Approval for Non-Specific Food and Food Ingredients (Regulation, 2017)

This regulation describe process for approval of novel food, food not having specification laid down in FSSR, 2011.

In the new regulation, FSSAI has defined Non-specified food as “any food other than proprietary food or food ingredients, including additives, processing aids and enzymes for which standards have not been specified in any regulation made under the Act.”

Regulation-11

Organic Food (Regulation, 2017)

- These Regulations recognizes two systems of certification i.e. Participatory Guarantee System (PGS) implemented by Ministry of Agriculture and Farmers Welfare and National Programme for Organic Production (NPOP) implemented by Ministry of Commerce and Industry.
- These regulations ensure integrity of the Organic Food products, and help in controlling unscrupulous practices in the market.

Regulation-12

Alcoholic Beverages (Regulation, 2018)

- Specifying the standards for Alcoholic beverages namely Distilled Alcoholic Beverage, Wines and, Beer.
- It also specifies the specific requirement for labelling of Alcoholic Beverages in addition to the labelling requirements of FSS (Packaging and Labelling) Regulations, 2011.
- The specific labelling requirements are declaration of alcohol content, labeling of standard drink, not to contain any nutritional information, no health claim, restriction on words ‘non-intoxicating’ or words implying similar meaning on label of beverage containing more than 0.5 per cent alcohol by volume, Labelling of wine, Allergen warning, statutory warning etc.

Regulation-13

Fortification of Food (Regulation, 2018)

- Food Fortification is a scientifically proven, cost-effective, scalable and sustainable global intervention that addresses the issue of micronutrient deficiencies.
- This regulation is for fortifying staples namely Wheat Flour and Rice (with Iron, Vitamin B12 and Folic Acid), Milk and Edible Oil (with Vitamins A and D) and Double Fortified Salt (with Iodine and Iron) to reduce the high burden of micronutrient malnutrition in India.
- The '+F' logo has been notified to identify fortified foods.

Regulation-14

Food Safety Auditing (Regulation, 2018)

- To strengthen the food safety surveillance system, FSSAI has envisaged audits of Food Business Operators through Private Auditing Agencies.
- In order to cultivate and foster the growth of compliance culture, FSSAI is enabling compliance through private recognised Auditing Agencies.
- Food Safety Audits will reduce the regulatory Food Safety Inspections conducted by Central or State Licensing Authorities.
- Satisfactory Audits will lead to less frequent regulatory inspections by Central or State Licensing Authority except the regulatory sampling. This will strengthen food safety surveillance system and encourage self-compliance while at the same time assuring safe food to the consumers.

Regulation-15

Recognition and Notification of Laboratories (Regulation, 2018)

- Food Testing and analysis is an essential part of the food safety ecosystem to assure that the food is safe to consume.
- For the same, FSSAI recognizes and notifies NABL accredited food laboratories under Section 43 of FSS Act, 2006.
- FSSAI is also recognizing foreign laboratories to reduce the time in clearance of food consignments at ports.
- FSSAI approved notified laboratories as National Reference Laboratories (NRLs) and as ancillary facility of NRLs (ANRLs) for specific purpose.

Regulation-16

Advertising and Claims (Regulation, 2018)

- 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.
- As per these regulations, firms running food businesses cannot use words or phrases such as natural, fresh, original, traditional, authentic, genuine, real on the food labels, barring some exceptions.
- Such restrictions are primarily aimed at restricting an open-ended use of these words by food businesses on frivolous grounds

Regulation-17

Packaging (Regulation, 2018)

- The General Requirements have been laid down regarding packaging materials used for packing food.
- The Regulations lay down specific requirements regarding the materials and substances that are intended to come in contact with food products.
- This describes the specification of material which can be used as a packing material of food article.

Regulation-18

Recovery and Distribution of Surplus food (Regulation, 2019)

- To establish a uniform national regulation to protect organizations and individuals when they donate food in good faith.
- To encourage the donation of food and grocery products to non-profit organizations for distribution to needy individuals.
- This describes about how surplus food can be distributed, considering both food safety and food wastage.

Regulation-19

Safe food and balanced diets for children in school (Regulation, 2020)

- It provides the fundamental idea and makes clear what foods are healthy and what is not healthy for school children to consume.
- Responsibilities of School Authority to ensure safe food and balanced diets on school premises.
- Promotion of safe food and balanced diet in and around school campus.
- Food marketing and advertisement and selling to children in school.

Regulation-20

Foods for Infant Nutrition (Regulation, 2020)

- This regulation include standards for Infant formula for special medical purpose especially food for infants inborn with Errors of Metabolism (IEM).
- Standards for Premature infant milk substitutes, Lactose-free and Lactose and sucrose free infant milk substitutes under infant formula for special medical purposes.
- There are also standards for food for infants based on traditional food ingredients.

Regulation-21

Labelling and Display (Regulation, 2020)

- These regulations prescribe the labelling requirements of pre-packaged foods and display of essential information on premises where food is manufactured, processed, served and stored.
- Food service establishments with central license or outlets at 10 or more locations will have to mention the calorific value (in kcal per serving and serving size) against the food items displayed on the menu cards or boards or booklets.
- Proposed colour-coded labelling which was intended to enable consumers to identify products that are high in fat, salt and sugar (HFSS) products.
- Functional classes for food additives shall be declared together with the specific name(s) or recognized International Numbering System (INS) as specified in FSS (Food Product Standards and Food Additives) Regulations, 2011 in the list of the ingredients.

WEIGHTS & MEASURES ACT

The Standard of Weights and Measures Act, 1976 was enacted to establish standards of weights and measures, to regulate inter-state trade or commerce

in weights, measures and other goods which are sold or distributed by weight, measure or number, and to provide for matters connected therewith or incidental thereto.

- The Legal Metrology Act 2009 has come into effect after its publication in the Official Gazette on the 14th January 2010.
- It replaces The Standards of Weights and Measures Act, 1976 and the Standards of Weights and Measures (Enforcement) Act, 1985.
- Appointment of Government approved Test Centers for verification of weights and measures.
- Companies to nominate a person who will be held responsible for breach of provisions of the Act
- simplified definition of "Packaged Commodity"
- More stringent punishment for violation of provisions are some of the new features of the Act.

The Legal Metrology (Packaged Commodities) Rules, 2011

Rule 2(h) of Packaged Commodities Rules 2011 defines "Principal Display Panel" in relation to a package, means the total surface area of the package where the information required under these rules are to be given in the following manner, namely;

- all the information could be grouped together and given at one place; or
- the pre-printed information could be grouped together and given in one place and on line information grouped together in other place;

Mandatory declarations

- Name and address of the manufacturer/ packer/ importer;
- Common or generic name of the commodity;
- Net quantity;
- Month and year of manufacture/ pack/ import
- Retail sale price in the form of Maximum Retail Price Inclusive of all taxes;
- Consumer care details;
- Country of origin.

Packaged Commodities covered under the Rules

While certain provisions are applicable for all packaged commodities there are certain rules that do not apply to certain kinds of commodities. Chapter II of the Rules, for example, deal with packages that are meant for retail sale, these provisions would not be applicable to certain kind of commodities.

Beyond the obvious, these rules would not be applicable for products meant for institutional or industrial consumers, i.e. those institutions who directly purchase from the manufacturer for use by the said institution OR consumers who buy the products directly from the manufacturer for use in that industry.

For example, a hospital buying packaged paint directly from paint company would amount to an institutional consumer, and the products would not require the declarations that otherwise are required had the products been sold in retail market.

Further, commodities which contain quantity of more than 25 kg or 25 litres (50 respectively in case cement and fertilizers) are exempted from the specific requirements of retail packages.

Additionally, the Rules do not apply to certain packages even if they satisfy all other criteria if:

- 1) The package is sold by weight or measure and amounts to less than 10 ml or 10 gm (provided the product is not tobacco); or
- 2) Package contains fast food items and is packed by hotels/restaurant/similar body; or
- 3) Contains scheduled drugs and non-scheduled drugs covered by the Drugs (Price Control) Order, 1995; or
- 4) Agricultural farm produce in packages above 50 kgs; or

Thread which is sold in the form of coil to handloom weavers.