Chapter 8: Food Safety Law: Safe Food from Farm Gate to Plate

• Overview of food safety law and regulations
  ▪ Brief historical perspective- from PFA to FSS Act.
  ▪ Objectives, Mandate and Scope of FSS Act & Authority
  ▪ Organizational structure with Roles and Responsibilities
  ▪ Other regulatory bodies dealing with food

• Risk analysis
  ▪ Risk Assessment
  ▪ Risk Management
  ▪ Risk Communication

• Food standards – Ingredients and additives
  ▪ Standard setting process
  ▪ Types of Standards
  ▪ Harmonization

• Food Safety by Kind of Business
  ▪ Schedule IV requirements and its significance
  ▪ FSMS Guidance Documents
  ▪ Third party auditing
  ▪ Hygiene rating and Right place to eat scheme
  ▪ FoSTaC

• Domestic compliance
  ▪ Licensing and Registration
  ▪ State level regulatory structure
  ▪ Active and Passive Surveillance

• Food imports regulations
  ▪ Import clearance process
  ▪ Testing facilities

• Food traceability
  ▪ Meaning of Food recall
  ▪ Food Recall regulations and its implementation
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Overview of food safety law and regulations

The Food Safety and Standards Authority of India (FSSAI) is an autonomous body established under the Ministry of Health and Family Welfare. The FSSAI has been established under the Food Safety and Standards (FSS) Act, 2006 which is a consolidating statute related to food safety and regulation in India.

Brief historical perspective - from PFA to FSS Act.

Till 1954, several food laws were in force in different States of the country. There was considerable variance in the standards and rules for food and its trade under these laws leading to interference in the inter-provincial trade. In 1950, the Constitution of India empowered the Central Government for making legislation on food adulteration, as the subject was included in the concurrent list of the Indian Constitution. Thereafter, a Central legislation called the Prevention of Food Adulteration (PFA) Act was enacted by Government of India in 1954 which came into effect in 1955. The Act repealed all laws existing at that time in States concerning food adulteration.

Subsequently, to control the manufacture, sale and distribution of a number of food products including enforcement of sanitary and hygienic practices of the establishments where these products were manufactured, the Government of India promulgated various orders under the Essential Commodities Act, 1955, which included:

- The Vegetable Oil Products (Control) Order, 1947
- The Fruit Products Order, 1955
- The Solvent Extracted Oil, De oiled Meal, and Edible Flour (Control) Order, 1967
- The Meat Food Products Order, 1973
- The Milk and Milk Products Order, 1992
- The Edible Oils Packaging (Regulation) Order, 1998

These orders were administered by different Ministries of Government of India and over a period of time, this led to a state of multiplicity of food standards (often overlapping and sometimes contradictory to one another) and enforcement agencies. This created confusion among food businesses, consumers, traders, manufacturers and investors and hampered the growth of a modern food processing sector in the country as well as fixation of safety standards. Realizing how inadequate these Acts and Orders were proving, the Prime Minister’s Council of Trade and Industry in 1998 recommended enactment of a comprehensive legislation of food subsuming all the present food laws to modernize the food sector and ensure safety of food. In 2004, the Joint Parliamentary Committee (JPC) emphasized that all the present food laws should be converged and there should be just one regulatory body for the whole of India. The Food Standards and Safety Bill, 2005 was passed by both the Houses of Parliament after extensive discussions, consultations with stakeholders and forging a consensus on contentious issues and received assent of the
President of India on 23rd August 2006. It was thereafter published in the Gazette of India (Extraordinary) Part I, Section 1 dated 24th August, 2006. The Food Safety and Standards (FSS) Act, 2006 repealed the PFA Act and all the six Orders stated above.

Objectives, Mandate and Scope of FSS Act and Authority

The objective of the FSS Act, 2006 is to make available safe and wholesome food to the public, in keeping with changing needs and requirements. The Act also aimed to establish Food Safety and Standards Authority of India (FSSAI), as the single reference point for all matters relating to FSS Act, Regulations and enforcement, by moving from multi-level, multi-departmental control to a single line of command.

The major areas of departure of FSS Act from PFA act are:

a. Food safety is the primary responsibility of the Food Business Operator (FBO) as he knows best how the food is manufactured and how safety can be compromised.

b. Risk assessment must form the basis of standard setting. The regulator needs to monitor the latest scientific development in the food sector, emerging safety issues across the world and anticipate safety risks before they actually hit.

c. FBOs at various stages in the food chain need to adhere to applicable safety and hygienic practices as contamination can occur at any point in the food chain. Certification of food safety processes or safety audits become important to ensure food safety.

d. Transparency in setting standards wherein stakeholders are provided with reasonable time to give suggestions on proposed regulations as well as sufficient time to FBOs to make necessary changes in their processes to adopt the new regulations.

e. FBOs have a clear means of contesting the findings of government food laboratories by appealing to accredited referral laboratories.

Two years later, FSSAI was established under the administrative control of Ministry of Health and Family. The mandate assigned to FSSAI is a) to develop science based standards for food and b) to regulate and monitor the manufacture, processing, storage, distribution, sale and import of food, so as to ensure the availability of safe and wholesome food for human consumption. The Food Safety and Standards Rules, 2011 were notified vide Gazette Notifications dated 5th May, 2011. Six principal regulations were notified and came into force on 1st August 2011 - Food product standards and food additives, Contaminants, toxins & residues, Packaging and labelling, Licensing and registration of FBOs, Prohibition and restriction on sales, Laboratory and sample analysis.

All kinds of food whether unprocessed/semi-processed/processed foods are covered under the scope of the FSS Act. It also includes all kinds of substances and water that is used in the preparation of food. It is important to mention that, the Act considers live animals or products of agriculture, horticulture or animal husbandry as food only when it has already passed on from the hands of a farmer. Thus, all activities throughout the food value chain, after primary production through distribution to retail and catering are under
the ambit of the Act. The Act does not discriminate between a small hawker or a huge FBO and makes it mandatory for everyone handling food to keep it safe and fit for human consumption. Therefore, this Act is applicable to every person who is in the food business.

**Organizational structure with Roles and Responsibilities**

Food Authority is the apex body under FSS Act, and a single reference point related to food safety and standards in the country. It comprises of a Chairperson and 22 members, of which at least one-third are women representing various relevant Ministries and Departments such as Agriculture, Commerce, Consumer Affairs, Food Processing, Health, Legislative Affairs and other stakeholders representing farmers, scientists & technologists, small scale enterprises and consumer bodies. The Food Authority is assisted by Scientific Committee and various Scientific Panels in setting standards of food products and by the Central Advisory Committee (CAC) in coordinating with enforcement agencies. State/District level steering committees assist, aid or advise on any matter concerning food safety in a State/UT.

The Chairperson and Chief Executive Officer of FSSAI are appointed by the Central Government. The CEO is responsible for the day to day administration of the Food Authority and draws up work programme of the Authority in consultation with CAC and is responsible for implementing the work programme and decisions of the food authority. The CEO exercises the power of Commissioner of Food safety while dealing with matters relating to food safety of such articles.

The governing structure of FSSAI is depicted in Figure 1.
The role of the Food Authority as prescribed under FSS Act is as under:

a. To specify food quality and safety standards and guidelines for food articles

b. To specify food labelling standards including claims on health, nutrition, special dietary uses and food category systems

c. To specify appropriate system of enforcement

d. To lay down methods of sampling, analysis and exchange of information among enforcement bodies

e. To lay down mechanisms and guidelines for recognition of accredited certification bodies engaged in FSMS auditing/certification.

f. To ensure quality control of imported food.

g. To provide scientific advice and technical support to central / state governments in matters of framing the policy and rules in areas relating to food safety and nutrition, in implementation of food safety crises management procedures, for improving cooperation with international organisations

h. To create an information network across the country to disseminate reliable and objective information on food safety and issues of concern including introduction of rapid alert system to all its stakeholders

i. To provide training programs in food safety and standards for persons who intend to become involved in businesses

j. Contribute and promote co-ordination of work on food standards undertaken by international governmental and non-governmental organisations.

Decentralized regulatory delivery (Centre vs State role)

India is a vast country with a population of over 1.3 billion and the sheer magnitude of food safety enforcement is a challenging task. The Food Authority and the State Food Authorities jointly share this responsibility. While the Food Authority provides policy intervention through notification of various food safety regulations and direction and coordination at National level, States/UTs conduct enforcement at the field level to verify compliance by FBOs to food standards. FSSAI provides support in the form of imparting training and capacity building of the enforcement staff of States/UTs. The Food Safety Authority in States/UTs is headed by the Commissioners of Food Safety for efficient implementation of FSS Act, Rules and Regulations made thereunder. All Commissioners of Food Safety are members of CAC. The CAC ensures close cooperation between Food Authority and State enforcement agencies. The CAC advises the Food Authority on its work programme, prioritization of work, identifying potential risks and pooling of knowledge. The organisational structure at the State level is described in Figure 2. Details about the testing labs and offices at the regional levels is given in Figure 3.
Figure 8.2: Organizational Structure at the State Level

Figure 8.3: Regional Laboratories and Offices
**Other regulatory bodies dealing with food**

**Bureau of Indian Standards (BIS)** is the National Standards Body of India, functioning under the aegis of Ministry of Consumer Affairs, Government of India for harmonious development of the activities of standardization, conformity assessment and quality assurance of goods, articles, processes, systems and services.

BIS has its Headquarters at New Delhi and 5 Regional Offices (ROs) which are at Kolkata (Eastern), Chennai (Southern), Mumbai (Western), Chandigarh (Northern) and Delhi (Central). There are 22 branch offices under the Regional Offices which offer certification services to the industry and serve as effective link between State Governments, industries, technical institutions, consumer organizations etc. of the respective region.

BIS is engaged in formulating Indian Standards in various technology areas and service sectors under the Bureau of Indian Standards Act, 2016 by a process of consultation involving Government and regulatory bodies, consumers, manufacturers, technologists, scientists and testing laboratories, through duly constituted technical committees comprising of Sectional Committees, Subcommittees and Panels which deal with specific group of subjects. In the Food and Agriculture sector, BIS has formulated over 2150 Indian standards covering food product and equipment specifications, test methods and hygiene codes covering the entire feed and food chain from farm to fork.

BIS does not make Technical Regulations. However, there are technical regulations which make compliance to BIS standards mandatory. Technical regulations are issued by various Departments/Ministries of Government of India.

BIS also operates a product certification scheme by which it grants licenses to manufacturers covering practically every industrial discipline. Though the BIS product certification scheme is essentially voluntary in nature, Government of India, in public interest (for example public health and safety, security, infrastructure requirements, mass consumption) has enforced mandatory BIS certification on various products through various Quality Control Orders or under Regulations issued from time to time under various Acts. In the food sector, FSSAI through the FSS (Prohibition and Restriction of Sales) Regulations, 2011, has made BIS certification mandatory for manufacture, sale and distribution of twelve food products for human consumption covering packaged waters, infant foods, milk powders and condensed milk.

The **Export Inspection Council (EIC)** is the official export–certification body of India which ensures quality and safety of products exported from India. The Export Inspection Council (EIC) functions under the Ministry of Commerce and has a mandate to ensure that products notified under the Export (Quality Control and Inspection) Act, 1963 meet the requirements of the importing countries in respect of their quality and safety.

This assurance is provided through certification of export commodities either by a consignment-wise inspection or quality assurance systems (in process quality control and self-certification) in the exporting units or through installation of food safety management in the food processing units. EIC has its 5 field offices ‘Export Inspection Agencies (EIAs)’ and a network of 30 sub offices backed by NABL accredited laboratories at various places. EIC provides mandatory certification for various food items namely fish and fishery products, dairy product, honey, egg products, meat and meat products, poultry meat...
products and meat by-products, feed additives and pre-mixtures, while other food and non-food products are certified on voluntary basis.

Agricultural and Processed Food Products Export Development Authority (APEDA) and Marine Products Export Development Authority (MPEDA) also function under Ministry of Commerce, Government of India. The main work of these Authorities is to promote the export, assure the quality of the product as per international standards, formulate the standards for export, etc.

APEDA is mandated with the responsibility of export promotion and market development of agricultural commodities and processed foods. The products under the purview of APEDA includes fresh fruits and vegetables, floriculture, processed foods, meat, poultry, milk and other livestock products, food grain, cereals, seeds and allied products. In addition, it has the responsibility to monitor the import of sugar.

APEDA has its Headquarters at New Delhi and 5 Regional Offices and 13 virtual offices which perform the functions of APEDA, make registration and financial assistance schemes etc. available to entrepreneurs / prospective exporters.

MPEDA regulates exports and market promotion of marine products outside India. It is mandated to take all measures required for ensuring sustained, quality seafood exports from the country including carrying out inspection of marine products, implementation of financial assistance schemes for infrastructure development for better preservation and modernized processing, fixing standards, specifications, and imparting trainings to fishermen, fish processing workers, aquaculture farmers and other stakeholders in the respective fields related to fisheries. MPEDA has its Headquarters at Kochi, Kerala and has 11 Regional Offices and 14 sub-regional divisions.

The **Directorate of Marketing and Inspection (DMI)** is an attached Office of the Department of Agriculture, Cooperation and Farmers Welfare under Ministry of Agriculture & Farmers Welfare. It was set up in 1935 to implement the agricultural marketing policies and programmes in the country with a view to safeguard the interests of farmers as well as the consumers. It implements the provisions of the **Agricultural Produce (Grading & Marking) Act, 1937**. Standards notified as per the provisions of the Act are popularly called AGMARK Standards. These standards differentiate between quality and 2-3 grades are prescribed for each commodity. Grades help farmers to get prices for agricultural commodities as per the quality produced by them and consumers get the desired quality.

The DMI is implementing the scheme of certification of agricultural commodities for domestic trade and export. The Scheme is voluntary. For blended edible vegetable oils and fat spreads, certification under AGMARK is mandatory as per provisions in The Food Safety and Standards Act and regulations, 2006.
Risk Analysis

Risk Analysis is an internationally accepted and systematic approach to examine and assess public health and safety risks associated with food and to formulate, implement and communicate risk management decisions. Risk analysis is comprised of three interrelated components—risk assessment, risk management and risk communication.

It is widely recognized that risk analysis must form the basis for a food regulator in developing new food standards, evaluating proposed changes to existing food standards, for monitoring and surveillance activities, assessing new food processing practices, considering emerging food safety issues and ultimately help in taking necessary action.

Risk Assessment

Risk assessment – is the scientific evaluation of known or potential adverse health effects resulting from human exposure to food-borne hazards. The evaluation must be based on data which is of high quality, is credible and objective (e.g. toxicological studies, relevant human studies, laboratory-based studies, exposure studies, surveillance studies etc.). The process consists of the following steps:

**Step 1 - Hazard identification:** “Could this food or anything in it be harmful?” Risk assessors collect and review scientific data and identify biological or chemical hazards in food.

**Step 2 - Hazard characterization:** “What effects do the hazards cause?” Risk assessors evaluate scientific data to determine whether evidence is strong enough to demonstrate that a substance has the potential to cause harm and the nature of the harm.

**Step 3 - Exposure assessment:** “Who may be harmed and what level of exposure may be harmful?” Experts estimate how much of the food or ingredient consumers in general, population groups (e.g. infants, children, adults) or sub-populations (e.g. vegetarians, vegans) are likely to be exposed to under real-life conditions, where both dose and duration are considered. The exposure must be evaluated to determine if a hazard presents an actual risk (step 4). With increased exposure, the risk also increases.

**Step 4 - Risk characterization:** “How likely is it that people will be exposed at a level that can cause harm in real life?” The level of exposure that can cause harm is compared to the actual level of exposure that someone would experience in real life. If the exposure level is higher than that which causes harm, there may be a safety concern for consumers in general or for specific groups.

Risk Management

Risk management – is the process of weighing policy alternatives in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers, and, if needed, selecting appropriate prevention and control measures.
A range of risk management options are available to FSSAI as risk managers for preventing or reducing health risks associated with food. These options can be regulatory i.e. those specified in the Regulations, such as end product standards or outcome-based standards or non-regulatory, such as industry codes of practice, guidelines or information campaigns. While taking such measures, the social and economic aspects are also considered in addition to the scientific risk assessment.

Risk Communication

Risk communication – FSSAI is responsible for risk communication, which is a two-way process and involves sharing the information internally with risk analysis team and with external stakeholders including general public in an open and transparent way including the explanation of risk assessment findings and the basis of risk management decisions. Risk communication is also important to help bridge the gap which sometimes exists between the scientific assessment and consumers’ perceptions of risk.

As per the Food Safety and Standards (Food Recall Procedure) Regulations, 2017, the Food Authority may publicise the recall when it is of the opinion that the public needs to be alerted about a health hazard or that clarification of the situation needs to be made to allay public worries. In cases of public health emergencies, the Food Authority may, depending on the available evidence, alert the public before a decision on recall has been reached.

The Food Authority is planning to establish a web-based facility titled ‘Food Recall portal’ on its website with a unique identification number assigned to each recall for monitoring and to provide information to the consumers about such recall.

FSSAI established a **Food Safety Knowledge Assimilation Network (FSKAN)** portal in 2017 for building a scientific community for collation of knowledge and expertise at one place and to provide an electronic forum for scientific consultation as well as exchange of scientific information and coordination of research activities across the country. These serve as a resource for FSSAI when required to be consulted for particular purpose related to food safety.

FSKAN has provided a platform for wider exposure of identified concern areas/ issues across various food sectors leading to a more synchronized and targeted research in the country, avoided duplication in research and also in formulation and execution of joint projects in areas where gaps or uncertainty in risk assessment for food safety exist. FSKAN has helped FSSAI in strengthening its capacity to manage food safety risks and ensuring rapid access to information during food safety events.

Food standards – Ingredients and Additives

The basic purpose of establishing food standards is protection of public health and risk, promoting fair trade in food, prevent misleading or deceptive products and enable
consumers to make informed choices by providing adequate information. It is important that such standards should be uniform nationally so that FBOs in all parts of the country have only one set of requirements to be complied with and hence a level playing field.

**Standard setting process**

The entire process of standard setting is carried out in a transparent manner involving all stakeholders. FSSAI has constituted scientific bodies, namely the Scientific Committee and subject specific Scientific Panels comprising of eminent independent subject experts/scientists. The Scientific Committee comprises of Chairpersons of all Scientific Panels and six independent experts, responsible for providing consistent opinion to Food Authority while harmonizing working methods of Scientific Panels. The Committee provides opinions on cross industry and sectoral issues and covers areas that are unique and not covered under the competence of the Scientific Panels.

The scientific risk assessment and setting of standards is carried out on the basis of latest developments in food science along with various factors like emergence of new additives, changes in processing technology, identification of new risks associated with metallic contaminants, residues of veterinary drugs, microbiological contaminants, nutritional aspects, advances in analytical methods etc.

Formulation of standards of any article of food involves several stages (Figure 4). After recommendation by the Scientific Panel and validation by the Scientific Committee, a standard is approved by the Food Authority and by Ministry of Health and Family Welfare. Thereafter, a draft notification is issued for inviting public comments for a period of 60 days. The comments received are then considered by the relevant Scientific Panel and after approvals of the Scientific Committee, Food Authority and the Ministry, the standard is finally notified as either an amendment to an existing regulation or a new/revised regulation.

![Figure 8. 4: Stages for Formulation of Food Standards](image-url)
Types of Standards

Food Standards can be broadly categorized into –

**Horizontal Standards**- Horizontal Standards cut across food categories and primarily relate to food safety covering limits for various contaminants (chemical and biological), toxins in food and also requirements for packaging, labelling and claims. These are covered under FSS (Contaminants, Toxins and Residues) Regulations, 2011, under Appendix B of FSS (Food Product Standards and Food Additives) Regulations, 2011 and FSS (Packaging and Labelling) Regulations, 2011.

**Vertical Standards**- Vertical Standards mainly include identity and compositional standards of specific food products and are covered under FSS (Food Product Standards and Food Additives) Regulations, 2011 and under FSS (Health Supplements, Nutraceuticals, Foods for Special Dietary Use, Foods for Special Medical Purpose, Functional food and Novel food) Regulations, 2016.

Harmonization

Harmonization of Indian food standards with global standards is one of the principles mandated under the FSS Act. Standards set by FSSAI are based on international best practices and all efforts are made to harmonize with Codex to promote international trade and higher levels of food safety. Wherever, suitable and appropriate, codex standards are considered for adoption with or without modifications provided they are in line with domestic industry and consumer practices.

Food Safety by Kind of Business

FSSAI recognizes that the responsibility for the supply of food that is safe, healthy and nutritious is shared along the entire food chain - by all involved with the production, processing, trade and consumption of food, as food can be contaminated at any step in the food chain unless effective controls are not put in place. This approach encompasses the whole food chain from primary production to final consumption and the stakeholders include farmers, food processors, transport operators, distributors (wholesale and retail) and consumers. One weak link can make the whole food chain collapse. This necessitates the adoption of practices in food production, post-harvest treatment, processing and handling that reduce the risk of microbiological, chemical and physical hazards from entering the food chain (or controlling at source, if feasible). There are some cases in which the hazard simply cannot be removed from foodstuffs, for example, those hazards involving chemical contaminants. The adoption of sound practices along the food chain – based on the principles defined in Good Agricultural Practices (GAP) and Good Manufacturing Practices (GMP) – are the keys to discharging this responsibility along the food chain.

Keeping this in view, FSSAI has laid down detailed sanitary and hygienic practices that should be followed by FBOs irrespective of their position in the food chain in order to ensure food safety. These practices are commonly called as Schedule 4 requirements (provided under Schedule 4 of FSS (Licensing and Registration of Food Business) Regulations, 2011). Compliance to these practices must be ensured by FBOs in the same way as compliance to standards of end product.


**Schedule IV requirements and its significance**

To provide assurance of food safety, FBOs should strive to 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.

Every licensed FBO must have a documented Food Safety Management System (FSMS) plan and is required to comply with Schedule 4 of FSS (Licensing and Registration of Food Business) Regulation, 2011. Schedule 4 introduces the concept of FSMS based on implementation of Good Manufacturing Practices (GMP) and Good Hygiene Practices (GHP) by food businesses and is divided into five parts as given in Table 1.

**Table 8.1: General Requirements under Schedule**

<table>
<thead>
<tr>
<th>Schedule 4</th>
<th>General Requirements</th>
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<tbody>
<tr>
<td>Part 1</td>
<td>General hygienic and sanitary practices to be followed by food business operators applying for registration - Petty food operators and Street food vendors</td>
</tr>
<tr>
<td>Part 2</td>
<td>General hygienic and sanitary practices to be followed by food business operators applying for license - Manufacturing/ processing/ packaging/ storage/distribution</td>
</tr>
<tr>
<td>Part 3</td>
<td>General hygienic and sanitary practices to be followed by food business operators applying for license - Milk and milk products</td>
</tr>
<tr>
<td>Part 4</td>
<td>General hygienic and sanitary practices to be followed by food business operators applying for license - Slaughter house and meat processing</td>
</tr>
<tr>
<td>Part 5</td>
<td>General hygienic and sanitary practices to be followed by food business operators applying for license - Catering</td>
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Recently, FSSAI has introduced a web-based real time inspection platform for FSOs called **Food Safety Compliance through Regular Inspection & Sampling (FoSCoRIS)**. Based on the risk score of the food business the frequency of inspections is decided, and the inspections are allotted to FSOs by Designated Officers (DOs) through this application, making the application transparent and efficient. This platform enables verification of physical inspection taking place with features like geotagging, time-stamping and real time data collection. It can be used via hand-held devices and FSOs can upload the findings of the inspection of FBOs on the application which in turn helps to digitize inspection reports. This system is envisaged to ease sample collection and forwarding, traceability and, control the quality of compliances.

**FSMS Guidance Documents**

A series of sector specific Food Safety Management System (FSMS) Guidance Documents have been developed with the help of domain experts with the intent to provide implementation guidance to food businesses (especially the small and medium
businesses) involved in manufacturing, packing, storage and transportation to ensure that critical food safety related aspects are addressed throughout the supply chain.

These documents are primarily based on Schedule 4 of FSSs (Licensing & Registration of Food Businesses) Regulation, 2011. The documents are recommendatory in nature and provide the basic knowledge and criteria for implementation of Hazard Analysis and Critical Control Point (HACCP) system by the food businesses. Inspection checklists for FBOs to audit their facility and operations are also included in these documents. The FBOs can evaluate themselves based on the indicative scoring. Also, these documents provide important templates and forms to facilitate the FBOs to maintain the records. These include mandatory forms as prescribed by FSSAI and templates for maintaining records of processes critical for food safety

**Third party auditing**

To strengthen the food safety surveillance system, FSSAI has developed a framework for conduct of food safety audits of FBOs to ensure compliance to sanitary and hygienic requirements, through Recognized Auditing Agencies as per FSS (Food Safety Auditing) Regulations, 2018. It is envisaged to use food safety audits as an alternate to regulatory inspections by Central or State FSOs thereby leading to less frequent regulatory inspections except for regulatory sampling. This will strengthen food safety system and encourage self-compliance while at the same time assuring safe food to the consumers.

**Hygiene rating and Right Place to Eat Scheme**

Hygiene Rating and Right Place to Eat Scheme has been initiated by FSSAI recently under Project Serve Safe, with the intent of ensuring that consumers make informed choices while eating out and encouraging food businesses to showcase and improve their food hygiene standards.

Hygiene Rating reflects the standards of food hygiene found on the date of inspection by the local authority or recognized third party audit agency. This is a voluntary scheme applicable to food businesses supplying food directly to consumers either on or off the premises and food businesses are rated based on food hygiene and safety conditions found at the time of inspection.

Right Place to Eat is a distinguishing mark granted to Food Businesses with hygiene rating of 4 or more, to encourage FBOs in promoting nutrition, and to bring about behavioral change in consumers by making them aware of healthy choices and giving them access to such options.
Food Safety Training & Certification (FoSTaC) is a large scale training and capacity development programme initiated by FSSAI for training of food handlers working in the food businesses at supervisor level, to ensure that the establishments in which food is being handled, processed, manufactured, stored, distributed, conform to the food safety requirements. Once trained the food handlers are certified as “Food Safety Supervisor”. There are 16 FOSTAC courses in three levels, Basic, Advanced and Special covering all sectors of the food business. This initiative was started with the aim to enhance the availability of skilled manpower in order to ensure better implementation and self-compliance to FSS Regulations.

The training is imparted through empanelled training partners and master trainers. FoSTaC began in 2017 and has turned into a nationwide training ecosystem for food business operators. FSSAI has been successful in empanelling several institutes as training partners. FSSAI has mandated that all food businesses having Central Licences or State Licences should have at least one trained and certified food safety supervisor for every 25 food-handlers on all their premises.

Domestic compliance

Licensing and Registration

As per FSS Act, every FBO in the country is required to be licensed/ registered under FSSAI. The licensing and registration procedure and requirements are regulated by FSS (Licensing and Registration of Food Business) Regulations, 2011. Food Licensing and Registration system (FLRS) is an online system to facilitate FBOs in India to apply for License/ Registration certificate and for tracking their applications during processing.

Registration is meant for petty food manufacturers that includes petty retailer, hawker, itinerant vendor or a temporary stall holder or small or cottage scale industry having annual turnover up to 12 lacs. All food businesses having income more than this limit are required to take a license. The process of registration has been outlined in figure 5.
The eligibility criteria for Licensing is according to whether one wants a State or Central License:

**State License-**

- Food Businesses with Annual Turnover between 12 lakhs and 20 crores.
- All grain, cereal and pulses milling units irrespective of turnover.

**Central License-**

- Food Businesses with Annual Turnover more than 20 crores.
- Operating business in two or more States.
- Food business covered under Schedule 1 of FSS (Licensing and Registration of Food Businesses) Regulations, 2011.
The process of licensing is outlined in figure 6.

**Figure 8.6: Licensing Process**

**State level regulatory structure**

The Food Safety Authority in States/UTs is headed by the Commissioners of Food Safety for efficient implementation of FSS Act, rules and regulations made thereunder. The framework for food safety enforcement machinery in the State as provided under the FSS Act primarily comprises of Designated Officer, Food Safety Officer, Adjudicating officer and Food Analyst (Figure 7).
Commissioners of Food Safety are responsible for ensuring an effective implementation of standards and other requirements under the FSS Act, conduct surveys of industrial units to ascertain compliance of such units to standards under the Act, sanction prosecution for offences, prohibit in the interest of public health, the manufacture, storage, distribution and sale of any article of food and also organize training for officials under the State Food Authority.

Designated Officers (DO) are appointed by Commissioner of Food Safety for every district of a State and are in-charge of food safety administration for that district. Designated Officer is the Licensing Authority who can issue or cancel the License of Food Business Operator (FBO). They have the power to prohibit the sale of any article of food, recommend to the Commissioner of Food Safety for sanction to launch prosecutions, maintain record of all inspections made by FSO and action taken by them in the performance of their duties and to investigate any complaint.

Food Safety Officers (FSO) are the representatives of the Food Authority at the ground level and interact directly with the FBOs and thus are the backbone of the entire food safety compliance structure. They are required to inspect all licensed units as frequently as may be prescribed by the DO, to verify/satisfy that conditions of licenses are being complied, report to the DO, procure sample, send for analysis in case of contravention, surveillance, investigate any complaint and to recommend issue of improvement notices to FBOs based on the results of inspections.

Adjudicating Officer (AO) plays a crucial role in enforcement of the Food Law. They have the powers of a civil court for the purposes of the Act and all the proceedings before him are deemed to be judicial proceedings. The AO can issue direction to person found guilty of an offence, for taking corrective action to rectify the mistake or destruction of such article of food. He can also direct the offender to pay compensation to victim or representative of victim in case of injury or death of consumer. He can order for cancellation of license, re-call of food from market as well as forfeiture of establishment and property.
Active and Passive Surveillance

Food Safety Surveillance is a system that collects data regarding all types of contaminants with the purpose of timely identification of food safety hazards that are significant. It can provide relevant data for risk assessment and standards setting. The objective of food safety surveillance is to ensure that the food supplied in the market is safe. Without an effective surveillance system, the consumer can be exposed to a variety of hazards including contaminants, toxins and residues in food. In absence of data, it is not possible to assess the present state and magnitude of the problem. The reports received from surveillance activities are compiled and if any surveillance sample fails due to non-conformity then enforcement sampling may be executed and action for prosecution may be initiated.

Two types of surveillance activities are carried out by FSSAI – Active Surveillance and Passive Surveillance. **Active surveillance** comprises of food safety surveys conducted by FSSAI or the State Food Authorities. It provides the most accurate and timely data on food safety parameters. Such type of surveillance includes National level surveillance, State specific surveillance, Seasonal surveillance, Special surveillance during festivals, Commodity specific surveillance etc.

**Passive surveillance** is a system by which FSSAI receives reports from FBOs or other sources (hospitals, medical care practitioners, research institutions) on contaminants in food products. It is a relatively inexpensive strategy to cover large areas and provides critical information for monitoring community health.

Food imports regulations

FSSAI has the mandate to regulate import of food into the country and ensure that it is safe and wholesome for human consumption. The import procedure and requirements are governed primarily by the FSS (Import) Regulations, 2017. No imports of food article are permitted in India without a valid import license from the Central Licensing Authority of FSSAI.

The major food commodities being imported in India are oil and fats, pulses, fruits and nuts, vegetables, cereals, sugars and sugar confectionery, coffee, tea, spices and beverages. Top exporting countries exporting food commodities to India are Australia, Indonesia, Ukraine, USA, Canada, Brazil and Myanmar.

Import clearance process

FSSAI has its presence at six locations through its own Authorised Officers at Chennai, Kolkata, Mumbai, Delhi, Cochin and Tuticorin covering 20 points of entry. Further, at other Point of Entries throughout the country, FSSAI has notified Customs officials as Authorised Officers for the purpose of regulating food imports. FSSAI has in place an online Food Import Clearance System (FICS), integrated with the customs ICE-GATE (Indian Customs Electronic Commerce/Electronic Data interchange Gateway) under SWIFT (Single Window Interface for Facilitating Trade). The consignment of food articles is referred to FSSAI for clearance by Customs Authorities through FICS.
Thereafter, the food consignments are subject to scrutiny of documents, visual inspection, sampling and testing in FSSAI notified laboratories in order to determine whether they conform to the safety and quality standards laid down under various FSS Regulations.

To expedite the clearance process of imports, Risk Management System (RMS) has been introduced under SWIFT which scrutinizes the application and if the sampling is required; the BOE is referred to FSSAI through FICS or else cleared through green channel. FSSAI has mapped a total of 1470 ITC-HS Codes pertaining to articles of food or food additives with the Customs-ICEGATE. These HS Codes have been subdivided into High Risk or Low-Risk food items based on safety. Further, dual use items have also been identified and if end use is food then the dual use items are referred to FSSAI for clearance.

**Testing facilities**

A laboratory is required under Import regulations to complete the analysis and upload the test report in FICS within five days of receipt of the sample with conclusive opinion about the product tested as conforming or non-conforming. For testing of food import consignments through a transparent and expeditious process, NABL accredited laboratories have been notified by FSSAI throughout the country.

If the samples are found conforming, then a No Objection Certificate (NOC) is generated and if not conforming then Non-Conforming Report (NCR) is generated rejecting the clearance of food consignments. The same is communicated to Customs-ICEGATE through FICS. A system of sending the sample to referral labs exists as in the case of domestic compliance when the sample fails in the notified laboratory. FSSAI has also notified Referral labs for re-testing of appeal samples of the Importers. Animal Quarantine and Plant Quarantine Departments under the Ministry of Agriculture also take samples separately in case of certain food items marked by Customs for their NOC.

Special dispensation for rectification of labels is provided for imported packaged food consignments under Import Regulations, 2017. The Import Regulations also provides for issuance of Provisional NOC in respect of consignments of fresh fruits and vegetables which are perishable in nature with shelf life of less than 7 days or consignments of food which require special storage conditions (refrigerated conditions like frozen or chilled food products) or consignment of pre-packaged retail food products, subject to satisfactory visual inspection and without waiting for the result of testing from the notified laboratory. The consignment can thereafter be moved to the warehouse of the importer. However, the products cannot be released into the domestic market without issuance of NOC which is based on the analysis report. In the event of a non-conformance report, the importer is responsible for moving the consignment back to customs jurisdiction and comply with the requirement of re-export or destruction as decided by AO.
Food traceability

Meaning of Food recall

Food Recall means 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 violates the FSS Act. Recall of food product is in the common interest of the industry, the government and the consumer. A food recall may be initiated as a result of a report or complaint from a variety of sources – manufacturers, wholesalers, retailers, government agencies and consumers.

Food recall regulations and implementation

The FBOs are strictly liable for any article of food which is unsafe under the FSS Act. The FSS (Food Recall) Regulations provides guidance to the FBOs for food recall procedures whereby an FBO is required to immediately inform the competent authorities and co-operate with them, if the food which he has placed in the market is unsafe for the consumers. The regulations also mandate the FBO to establish an effective and efficient follow-up action/ post-recall report system.

A traceability system is an effective tool with which FBOs can trace food throughout the food chain. The FBO is required to have as a minimum a documented one-step-back/one-step forward traceability approach. Small FBOs with limited distribution may not be required to have a fully documented traceability system in place and may rely solely on their purchasing and sale records to act as their traceability record. In the context of a food recall, the objectives of traceability are to:

a. Identify uniquely a lot/batch/consignment of food in a way that allows tracing of the physical flow of the food forwards through the food chain to the immediate customer and tracing of the physical flow of raw materials backwards to the immediate supplier.

b. Create and maintain accurate traceability records that can be provided within a short time period when needed for recall or at the request of the competent authorities.

Summary

- The Food Safety and Standards (FSS) Act, 2006 repealed the PFA Act and all the six Orders under Essential Commodities Act, 1955.

- The mandate assigned to FSSAI is a) to develop science based standards for food and b) to regulate and monitor the manufacture, processing, storage, distribution, sale and import of food, so as to ensure the availability of safe and wholesome food for human consumption.
• The FSS Rules came into effect on 5 August 2011 with the notification of six principal regulations on Food product standards, Contaminant, toxins & residues, Packaging and labelling of food, Licensing and registration of FBOs, Prohibition and restriction of sales, Laboratory and sampling.

• Food Authority provides policy intervention through notification of various food safety regulations, provides direction and coordination at National level, States/UTs conduct enforcement at the field level to verify compliance by FBOs to food standards.

• The Food Safety Authority in States/UTs is headed by the Commissioners of Food Safety for efficient implementation of FSS Act, rules and regulations made thereunder.

• Other regulatory bodies dealing with food include BIS, EIC, APEDA, MPEDA and DMI.

• FSSAI assess risks through its Scientific Panel, Scientific Committee and FSKAN. After scientific risk assessment, FSSAI manages risk and take measures which are regulatory (i.e., provisions in the regulations, end products standards), or non-regulatory (such as industry codes of practice, guidelines or information campaigns). While taking such measures, the social and economic aspects are also considered in addition to the scientific risk assessment. FSSAI communicates risks through issuing advisories, social media channels at both central and state level.

• The basic purpose of establishing food standards is protection of public health and risk, promoting fair trade in food, prevent misleading or deceptive products and enable consumers to make informed choices by providing adequate information. Food standards can be broadly classified as Horizontal and Vertical Standards. These need to be harmonized with International standards.

• FSSAI has laid down detailed sanitary and hygienic practices that should be followed by FBOs irrespective of their position in the food chain in order to ensure food safety. These practices are commonly called as Schedule 4 requirements (provided under Schedule 4 of FSS (Licensing and Registration of Food Business) Regulations, 2011).

• Hygiene Rating and Right Place to Eat Scheme has been initiated by FSSAI recently under Project Serve Safe, with the intent of ensuring that consumers make informed choices while eating out and encouraging food businesses to showcase and improve their food hygiene standards.

• Food Safety Training & Certification (FoSTaC) is a large scale training and capacity development programme initiated by FSSAI for training of food handlers working in the food businesses at supervisor level, to ensure that the establishments in which food is being handled, processed, manufactured, stored, distribute conform to the food safety requirements.

• As per FSS Act, every FBO in the country is required to be licensed/ registered under FSSAI. Registration is meant for petty food manufacturers that includes petty retailer, hawker, itinerant vendor or a temporary stall holder or small or cottage
scale industry having annual turnover up to 12 lacs. All food businesses having income more than this limit are required to take a license.

- Every licensed FBO must have a documented Food Safety Management System (FSMS) plan and is required to comply with Schedule 4 of FSS (Licensing and Registration of Food Business) Regulation, 2011.

- FSSAI has the mandate to regulate import of food into the country and ensure that it is safe and wholesome for human consumption. No imports of food article are permitted in India without a valid import license from the Central Licensing Authority of FSSAI. It is done through an online Food Import Clearance System (FICS).

- Food Recall means 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 violates the FSS Act.

Keywords

**Quality Standards:** The standards framed, based upon the intrinsic properties of Agricultural or Food Commodities

**Mandatory:** Such provisions which are compulsory or binding to comply.

**FoSTaC:** Food Safety Training and Certification, a large-scale training and capacity building programme for food handlers

**FOSCORIS:** Food Safety compliance through Regular Inspections and Sampling, a web-based system to verify compliance to food safety and hygiene standards by food businesses as per regulatory requirements.

**FLRS:** Food Licensing and Registration System, an online system to facilitate FBOs in India to apply for License/ Registration certificate and for tracking their applications during processing.

**FICS:** Food Imports Clearance System, an online system of FSSAI for imported food clearance

**FSKAN:** Food Safety Knowledge Assimilation Network, a scientific community for collation of knowledge and expertise and for coordination of research activities across the country.

Exercises

1. What is the objective and mandate of FSSAI?
2. Describe the structure and roles of Food Authority.
3. How does FSSAI ensure food safety at central and state level?
4. Describe the bodies/organisation other than FSSAI responsible for food safety.
5. Explain the process of standards setting.
6. Explain the eligibility criteria for State and Central License.
7. Give a brief note about FoSTaC.
8. How does FSSAI ensure the safety of imported Foods?
9. What are the salient features of FOSCORIS?

References