



CHAPTER 1

**Food Safety, the FSS Act,
Rules and Regulations**

A. Food Safety

1. Food Safety is important for maintaining overall health and well being. The Food Safety & Standards Act, 2006 defines Food Safety as an “assurance that food is acceptable for human consumption according to its intended use.” Food Safety ensures that food is safe for human consumption and involves handling, preparation, and storage of food in ways that prevent food borne illness. Food safety considerations include the origins of food including the practices relating to food labelling, food hygiene, food additives and contaminants, as well as policies on biotechnology and food and guidelines for the management of import and export, inspection and certification systems for foods.
2. Food Safety is important to prevent microbes and contaminants from getting into foods and water. Microbes or contaminants not only cause diseases to human beings, but they also destroy valuable nutrients in the food. Millions of people fall ill every year and may die as a result of consuming unsafe food. Proper food preparation can prevent most of the food borne diseases. Infections caused due to consumption of unsafe food have a bigger impact on populations with poor & fragile health, infants, elderly, etc., and are usually more severe & may be fatal.
3. There are various opportunities for food contamination to take place. Food supply chain involves a range of stages including on farm production, harvesting, processing, storage, transportation, distribution, etc. before it reaches the consumers and hence opportunities for food contamination increase. Further, Globalization of food business is making the food supply chain longer and complicates food-borne disease outbreak investigation and product recall in case of emergency.
4. Food contamination has far reaching effects beyond direct public health consequences - it undermines food exports, tourism, livelihoods of food handlers and economic development, both in developed and developing countries.
5. Food safety is multi- sectoral and multidisciplinary. To improve food safety, a multitude of different professionals need to work together, making use of the best available science and technologies. Different governmental departments and agencies, encompassing public health, agriculture, education and trade, collaborate and communicate with each other and engage with civil society including consumer groups.
6. Food safety is a shared responsibility between governments, industry, producers, academia, and consumers. Everyone has a role to play. Achieving food safety is a multi-sectoral effort requiring expertise from a range of different disciplines - toxicology, microbiology, parasitology, nutrition, health economics, and human and veterinary medicine. Local communities, women's groups and school education also play an important role. Consumers must be well informed on food safety practices. People should make informed and wise food choices and adopt adequate behaviours. They should know common food hazards and how to handle food safely, using the information provided in food labelling.

B. Unsafe Food

- (a) The Food Safety & Standards Act, 2006 defines Unsafe Food as an article of food whose nature, substance or quality is so affected as to render it injurious to health:-
- (i) by the article itself, or its package, which is composed, whether wholly or in part, of poisonous or deleterious substance; or
 - (ii) by the article consisting, wholly or in part, of any filthy, putrid, rotten, decomposed or diseased animal substance or vegetable substance; or
 - (iii) by virtue of its unhygienic processing or the presence in that article of any harmful substance; or
 - (iv) by the substitution of any inferior or cheaper substance whether wholly or in part; or
 - (v) by addition of a substance directly or as an ingredient which is not permitted; or
 - (vi) by the abstraction, wholly or in part, of any of its constituents; or
 - (vii) by the food article being so coloured, flavoured or coated, powdered or polished, as to damage or conceal the article or to make it appear better or of greater value than it really is; or
 - (viii) by the presence of any colouring matter or preservatives other than that specified for that article of food; or
 - (ix) by the article having been infected or infested with worms, weevils, or insects; or
 - (x) by the food article being prepared, packed or kept under insanitary conditions; or
 - (xi) by the article being misbranded or sub-standard or food containing extraneous matter; or
 - (xii) by the food article containing pesticides and other contaminants in excess of quantities specified by regulations.

C. The Food Safety & Standards Act 2006

(i) Background

1. Prior to Food Safety and Standards Act, 2006, there was multiplicity of food laws, food related legislation was fragmented and there was lack of uniformity in approach and effect. Moreover, there were various Ministries/ organizations/ agencies for standard setting and enforcement of different sectors of food. As a result, there were varied quality/safety standards with rigidness. The existing laws on food failed to match the rapid evolution of food related technologies and advancement in production, storage, distribution, sale, etc. There were few laboratories with poor laboratory infrastructure coupled with thin spread of manpower, and other resources non-conducive to effective fixation of standards. There was poor information dissemination to consumer level.
2. It is in this background that the need for a single law with single regulatory body at national level on all food safety and related matters was felt to ensure holistic approach, uniformity and effective implementation. The Central Government declared its intention in this behalf in the Budget Speech in 2002. The work pertaining to consolidation of various Acts/ Orders governing food was entrusted to the Ministry of Food Processing Industries, who piloted the Food Safety and Standards Bill, 2005 which was finally enacted as the Food Safety and Standards Act, 2006 by the Parliament and the same was published in the Gazette of India (Extraordinary) Part II, Section 1 on 24th August, 2006 after receiving assent of the President on 23rd August, 2006. The Food Safety and Standards Act, 2006 was enacted as a consolidated Act and the following food acts and orders were

- (a) Prevention of Food Adulteration Act, 1954
 - (b) Fruit Products Order, 1955
 - (c) Meat Food Products Order, 1973
 - (d) Vegetable Oil Products (Control) Order, 1947
 - (e) Edible Oils Packaging (Regulation) Order, 1998
 - (f) Solvent Extracted Oil, De-oiled Meal, and Edible Flour (Control) Order, 1967
 - (g) Milk and Milk Products Order, 1992
 - (h) Any other order under Essential Commodities Act, 1955 relating to food
3. The FSS Act was a result of extensive consultations with various stakeholders and series of discussions/ deliberations in the Inter-Ministerial Group and Standing Parliamentary Committee meetings and its clearance from the Group of Ministries. The Ministry of Health and Family Welfare was finally designated as the Administrative Ministry for the purposes of the FSS Act, 2006.

(ii) Salient Features of the FSS Act, 2006

1. The Food Safety and Standards Act, 2006 marks a shift from a multi-level to a single line of control with focus on self-compliance rather than a pure regulatory regime. It envisages regulation of manufacture, storage, distribution, sale and import of food to ensure availability of safe and wholesome food for human consumption and for consumers connected therewith. It provides for establishment of FSSAI as a single reference point for all matters relating to food safety, standards and wholesome/ nutritious foods, regulations and enforcement.
2. The Act extends to the whole of India and provides for uniform licensing/ registration regime across the Centre and the States. It also offers Integrated response to strategic issues like Novel foods, genetically modified foods, international trade etc. The some of salient features the Act may be summarized as under:-
 - (a) Decentralisation of licensing for food products. It empowers States to issue Registration and State License.
 - (b) Effective, transparent and accountable regulatory framework. It has well defined functions, powers and responsibilities of various food authorities, bodies and committees.
 - (c) Emphasises on gradual shift from regulatory regime to self compliance.
 - (d) Regulation of food imported in the country
 - (e) Provision for food recall.
 - (f) Surveillance
 - (g) Envisages large network of food laboratories.
 - (h) New justice dispensation system for fast track disposal of cases.
 - (i) Provision for graded penalties.
 - (j) Consistency between domestic and international food policy measures without reducing safeguards to public health and consumer protection

(k) The act emphasizes on training and awareness program regarding food safety for business operators, consumers and regulators.

(iii) Parts of the FSS Act, 2006

The FSS Act, 2006 is organised through a total of 12 Chapters. A brief description of these chapters is given below:

Chapter-I: Preliminary

This section consists of the Short Title, extent and commencement, Declaration as to expediency of control by the Union, and Definitions.

Chapter-II: Food Safety and Standards Authority of India

This Chapter, containing Sections 4 to 17, provides for establishment of the Food Safety and Standards Authority of India, terms and conditions of appointment and removal of Chairman and the members and their terms of office and other conditions, Officers and other employees of the Food Authority, Functions of the Chief Executive Officer, establishment of the Central Advisory Committee and its functions, establishment of Scientific Panels and the Scientific Committee and the procedure for the Scientific Committee and the Scientific Panels. The chapter further details the duties and functions of the Food Authority to regulate and monitor the manufacture, processing, distribution, sale and import of food. It also provides for the procedures for conduct of meetings of the Food Authority, transaction of business at its meetings and procedure of voting by Members, etc.

Chapter -III: General Principles of Food Safety

Comprising only Section 18, this chapter contains provisions on the general principles of Food Safety, factors to be taken into account while framing regulations or specifying the Standards under the Act, and the principles to be observed in administration of the Act by the Central Government, the Food Authority, the State Government and other agencies, while enforcing or implementing the provisions of the Act. The said authorities shall be guided by the general principles of Food Safety such as risk analysis, risk assessment, risk management, risk communication, transparent public consultation, protection of consumer interests, etc. It empowers the Food Authority to notify other general principles from time to time as per the requirements.

Further, it stipulates that the provisions of this Act shall not apply to any farmer, or fisherman or farming operations or crops or livestock or aquaculture, and supplies used or produced in farming or products of crops produced by a farmer at farm level or a fisherman in his operations.

Chapter -IV: General provisions as to articles of food

Comprising of Sections 19 to 24, this chapter stipulates that no article of food shall contain contaminants, naturally occurring toxic substances or toxins or hormone or heavy metals, insecticides, pesticides, veterinary drugs residues, antibiotic residues, solvent residues, pharmacological active substances and micro-biological counts in excess of such quantities as may be specified by the regulations. Section 19 prohibits use of food additives or processing aids other than those prescribed under the Standards/ regulations. Section 22 places a restriction on various categories of food, which are not in accordance with the standards prescribed under the regulations.

Section 23 deals with the subject of packaging and labelling requirements of food. Section 24 places restrictions on

misleading advertisements and prohibits use of unfair trade practices. It also provides that packaged food product shall be marked and labelled as specified. It prohibits deceptive practices to mislead the public regarding the standards, quality, quantity, usefulness or giving of any guarantee of the efficacy that is not based on an adequate or scientific justification thereof.

Chapter- V: Provisions Relating to Import

Containing only Section 25, this chapter mandates that all imports of articles of food are subject to the provisions of the Act. It provides that no person shall import into India any article of food in contravention of the Act or any rules and regulations made thereunder. It also provides that the Central Government shall, while prohibiting, restricting or otherwise regulating import of articles of food under the Foreign Trade (Development and Regulation) Act, 1992 follows the standards laid down by the Food Authority under the provisions of this Act.

Chapter -VI: Special Responsibilities as to Food Safety

This chapter, containing Sections 26 to 28, provides for the responsibilities of the food business operator to ensure that the articles of food satisfy the requirements of the Act and the rules and regulations made thereunder at all stages of production, processing, import, distribution and sale within the businesses under his control. Section 27 deals with the liabilities of the manufacturers, distributors and sellers of articles of food if they do not conform to the food safety requirements of the Act and the rules and regulations made thereunder. Section 28 spells out the Food Recall procedures and the responsibilities of a Food Business Operator to withdraw the Food from market in case the same is non-compliant with the provisions of the Act and the regulations framed thereunder.

Chapter -VII: Enforcement of the Act

Sections 29 to 42 of the Act comprised in this Chapter deal with the enforcement related provisions including the responsibilities of the Food Authority and the State Food Authorities. Provisions for appointment of Commissioner of Food Safety of the State, licensing and registration of food business, improvement notices, prohibition orders, emergency prohibition notices and orders, notification of food poisoning, appointment of the Designated Officer, Food Safety Officer and their powers, liabilities, powers of search, seizure, prosecution and procedure thereof, and the provision for a purchaser to have the food analysed are contained in these sections.

Chapter - VIII: Analysis of Food

Sections 43 to 47 included in this chapter contain the provisions relating to recognition and accreditation of laboratories, research institutions and referral food laboratories, food analyst, functions of the food analyst and the provisions for sampling and analysis of food.

Chapter - IX: Offences and Penalties

This chapter, consisting of Sections 48 to 67, deals with various offences and penalties for selling food not of the nature or substance or quality demanded, sub-standard food, misbranded food, misleading advertisements, for food containing extraneous matter, for unhygienic or unsanitary processing, for possessing adulterant. The chapter contains provisions for punishment for unsafe food, for interfering with seized items, for false information, for obstructing or impersonating a Food Safety Officer, for carrying out a business without license and compensation in case of injury or death of a consumer.

Chapter - X: Adjudication and Food Safety Appellate Tribunal

Comprising of Sections 68 to 80, this chapter authorises the state governments to notify the adjudicating officer in the district. It defines the powers to compound offences, the powers of the designated officers, establishment of the Food Safety Appellate Tribunals and the procedures and powers of the Tribunal. The chapter bars the jurisdiction of courts in the matters in which the adjudicating officer or Tribunal is empowered by the act. The act provides that the courts can try the cases summarily. The Act also provides for the special courts and public prosecutors for the offences related to the food.

Chapter -XI: Finance, Accounts, Audit and Reports

The Chapter contains Sections 81 to 84 requiring the Food Authority to prepare an Annual Budget showing the estimated receipts and expenditure of the Food Authority. The Central Government shall make grants of such some of money as it deems fit. It provides that the Food Authority shall maintain proper accounts and an annual statements of accounts. The Food Authority is required to prepare an Annual Report, which is to be laid before each House of Parliament.

Chapter -XII: Miscellaneous

This chapter, containing Sections 85 to 101, empowers the Central Government to issue directions to Food Authority, State Governments and obtain reports and returns. The chapter gives over riding effect of this Act over all other food related laws. It empowers the Central Government to make rules and the Food Authority to make regulations. The chapter also gives State Governments powers to make rules and the procedure for rewards and the procedure for recovery of penalties imposed.

Schedules:

There are two Schedules given at the end of the Act. While the First Schedule contains the five zones into which all the States and UTs have been grouped, the Second Schedule contains the Act and various orders which stand repealed with the coming into force of this Act.

There are other laws like BIS and AGMARK relating to Food. These laws are covered at Annexure-I.

D. Food Safety and Standards Rules, 2011

The Food Safety and Standards Act, 2006 under Section 91 empowers the Central Government to make rules by notification in the Official Gazette, for carrying out the provisions of the FSS Act. Such rules may provide for all or any of the following matters, namely:-

- (a) salary, terms and conditions of service of Chairperson and Members other than ex officio Members under subsection (2) and the manner of subscribing to an oath of office and secrecy under sub-section (3) of section 7;
- (b) qualifications of Food Safety Officer under sub-section (1) of section 37;
- (c) the manner of taking the extract of documents seized under sub-clause (8) of section 38;
- (d) determination of cases for referring to appropriate courts and time-frame for such determination under sub-section (4) of section 42;
- (e) qualifications of Food Analysts under section 45; 61

- (f) the manner of sending sample for analysis and details of the procedure to be followed in this regard under subsection (1) of section 47;
- (g) the procedure to be followed in adjudication of cases under sub-section (1) of section 68;
- (h) qualifications, terms of office, resignation and removal of Presiding Officer under sub-section (4), the procedure of appeal and powers of Tribunal under sub-section (5) of section 70;
- (I) any other matter relating to procedure and powers of Tribunal under clause
- (g) of sub-section (2) of section 71;
- (j) the fee to be paid for preferring an appeal to the High Court under subsection (1) of section 76;
- (k) form and time of preparing budget under sub-section (1) of section 81;
- (l) form and statement of accounts under sub-section (1) of section 83;
- (m) the form and time for preparing annual report by Food Authority under sub-section (1) of section 84; and
- (n) any other matter which is required to be, or may be, prescribed or in respect of which provision is to be made by rules by the Central Government.

In exercise of the powers conferred by the Act, the Central Government notified the Food Safety and Standards Rules in 2008 regulating the salaries, allowances and other services of Chairperson and Members other than ex officio Members of Food Authority. Subsequently Central Government came up with comprehensive Food Safety and Standards Rules 2011 to regulate various subject given under Section 91 of the Act.

E. The Food Safety and Standards Regulations, 2011

- (a) The Food Safety and Standards Act, 2006 under Section 92 provides that the Food Authority may, with the previous approval of the Central Government and after previous publication, by notification, make regulations consistent with this Act and the rules made thereunder to carry out the provisions of this Act. Such regulations may provide for all or any of the following matters, namely:-
 - (i) salaries and other conditions of service of officers and other employees of the Food Authority under sub-section (3) of section 9;
 - (ii) rules of procedure for transaction of business under subsection (5) of section 11;
 - (iii) other functions of the Central Advisory Committee under sub-section (2) of section 12, 62
 - (iv) procedure of Scientific Committee and Panels under subsection (4) of section 15;
 - (v) notifying standards and guidelines in relation to articles of food meant for human consumption under sub-section (2) of section 16;
 - (vi) procedure to be followed by Food Authority for transaction of business at its meetings under sub-section (1) of section 17;
 - (vii) making or amending regulations in view of urgency concerning food safety or public health under clause (d) of sub-section (2) of section 18;
 - (viii) limits of additives under section 19;
 - (ix) limits of quantities of contaminants, toxic substance and heavy metals, etc., under section 20;

- (x) tolerance limit of pesticides, veterinary drugs residues, etc, under section 21;
 - (xi) the manner of marking and labelling of foods under section 23;
 - (xii) form in which guarantee shall be given under sub-section (4) of section 26;
 - (xiii) conditions and guidelines relating to food recall procedures under subsection (4) of section 28;
 - (xiv) regulations relating to functioning of Food Safety Officer under subsection (5) of section 29;
 - (xv) notifying the registering authority and the manner of registration; the manner of making application for obtaining license, the fees payable therefore and the circumstances under which such license may be cancelled or forfeited under section 31;
 - (xvi) the respective areas of which the Designated Officer shall be in-charge for food safety administration under subsection (1) of section 36;
 - (xvii) procedure in getting food analysed, details of fees etc., under sub-section (1) of section 40; 63
 - (xviii) functions, procedure to be followed by food laboratories under sub-section (3) of section 43;
 - (xix) procedure to be followed by officials under sub-section (6) of section 47;
 - (xx) financial regulations to be adopted by the Food Authority in drawing up its budget under sub-section (2) of section 81;
 - (xxi) issue guidelines or directions for participation in Codex Meetings and preparation of response to Codex matters; and
 - (xxii) any other matter which is required to be, or may be, specified by regulations or in respect of which provision is to be made by regulations.
- (b) In exercise of the powers conferred by the Act, the Food Authority has from time to time brought out a number of Regulations to regulate the subjects mentioned in Section 92 of the FSS Act. Some important Regulations are given below:
- (i) Food Safety and Standards Authority of India Business Transaction Regulations, 2010
 - (ii) Food Safety and Standards (Licensing and Registration of Food Businesses) Regulation, 2011
 - (iii) Food Safety and Standards (Food Product Standards and Food Additives) Regulation, 2011
 - (iv) Food Safety and Standards (Prohibition and Restriction on Sales) Regulation, 2011
 - (v) Food Safety and Standards (Packaging and Labelling) Regulation, 2011
 - (vi) Food Safety and Standards (Laboratory and Sampling Analysis) Regulation, 2011
 - (vii) Food Safety and Standards (Food or Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical Purpose, Functional Foods and Novel Food) Regulations, 2016
 - (viii) Food Safety and Standards (Food Recall Procedure) Regulation, 2017
 - (ix) Food Safety and Standards (Import) Regulation, 2017