

Author:

[E-mail✉ Taeko Suzuki](mailto:taeko.suzuki@nishimura-asahi.com)

[E-mail✉ Varsha Bhattacharya](mailto:varsha.bhattacharya@nishimura-asahi.com)

[E-mail✉ Makoto Sugitani](mailto:makoto.sugitani@nishimura-asahi.com)

1. Introduction

Food safety is regulated by a number of laws in India, both statutory and case law. India has a quasi-federal governmental system, which was established under the Constitution of India in 1950 (“**Constitution**”), wherein law-making can be undertaken by the federal parliament (which is the central legislature; “**Parliament**”) or state legislatures, or both, depending on the subject matter.¹ Adulteration, trade, commerce, production, supply, and distribution of food, are matters on the Concurrent List,² which means that both the Parliament and state legislatures can pass laws on these matters.^{3 4}

The main statute, which was passed with a view to consolidating food safety laws in India, is the Food Safety and Standards Act, 2006. However, certain aspects continue to be governed by other laws, such as the Indian Penal Code, 1908; the Consumer Protection Act, 2019; and even a constitutional guarantee to a fundamental right to food under the right to life and personal liberty in the Constitution. These are discussed in further detail below.

2. Key laws governing food safety

(1) Food Safety and Standards Act, 2006 (“FSSA”)

The FSSA was enacted by the Parliament in 2006 with a two-fold objective:⁵

- a. To consolidate various existing laws on food safety in India. The FSSA repealed 8 (eight) erstwhile laws related to food safety⁶ and constitutes a comprehensive legal code on the subject;⁷ and
- b. To establish a national regulatory body, the Food Safety and Standards Authority of India (“**FSSAI**”), as the authority for food safety and quality in India. The FSSAI is authorised to regulate and monitor the manufacturing, processing, storage, distribution, sale, and importation of food for the purpose of ensuring the availability of safe and wholesome food for human consumption. It is tasked with establishing science-based standards for articles of food, and also is responsible for promoting

¹ Article 246, read in conjunction with Schedule VII, the Constitution.

² Items 18 and 33, List III, Schedule VII, the Constitution.

³ Article 246(2), the Constitution.

⁴ Generally, in the case of a conflict between Parliament-made and state-made law, the former prevails (Article 254, the Constitution).

⁵ Preamble, the FSSA.

⁶ Section 97, read in conjunction with the Second Schedule, the FSSA.

⁷ The FSSA also has the effect of overriding other food-related laws (Section 89, the FSSA).

awareness of food safety in the country.

The Food Safety and Standards Rules, 2011,⁸ promulgated under the FSSA, set forth an enforcement mechanism for the statute (such as designation of officers, their functions, and procedures to be followed), including a mechanism for adjudication and appeals.

Apart from these rules, more than twenty subordinate regulations have been promulgated under the FSSA,⁹ governing different aspects of laws relating to food, ranging from licensing and registration of food businesses,¹⁰ food product standards and additives,¹¹ items prohibited from sale,¹² rules for contaminants, toxins, and residues,¹³ regulations for health supplements,¹⁴ organic food,¹⁵ alcoholic beverages,¹⁶ advertising,¹⁷ packaging,¹⁸ etc. Some of the other key regulations include the Food Safety and Standards (Food Recall Procedure) Regulations, 2017; Food Safety and Standards (Import) Regulations, 2017; Food Safety and Standards (Food Safety Auditing) Regulations, 2018; Food Safety and Standards (Food for Infant Nutrition) Regulations, 2020; and Food Safety and Standards (Safe food and balanced diets for children in school) Regulations, 2020.

Regulations have also been promulgated to regulate certain aspects of the operation of the FSSAI.¹⁹

The FSSA defines “food”²⁰ as:

“any substance, whether processed, partially processed, or unprocessed, which is intended for human consumption,”

which includes:

- “Primary food” (defined as a product of agriculture or horticulture or animal husbandry and dairying or aquaculture in its natural form, resulting from the growing, raising, cultivating, picking, harvesting, collecting, or catching by a person other than a farmer or fisherman);²¹

⁸ Promulgated under Section 91, the FSSA.

⁹ Promulgated under Section 92, the FSSA.

¹⁰ Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011.

¹¹ Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011.

¹² Food Safety and Standards (Prohibition and Restriction of Sales) Regulations, 2011.

¹³ Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011.

¹⁴ Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016.

¹⁵ Food Safety and Standards (Organic Food) Regulations, 2017.

¹⁶ Food Safety and Standards (Alcoholic Beverages) Regulations, 2018.

¹⁷ Food Safety and Standards (Advertising and Claims) Regulations, 2018.

¹⁸ Food Safety and Standards (Packaging) Regulations, 2018.

¹⁹ Food Safety and Standards Authority of India (Transaction of Business at its Meetings) Regulations, 2010; Food Safety and Standards Authority of India (Procedure for Transaction of Business of the Central Advisory Committee) Regulations, 2010; Food Safety and Standards Authority of India (Salary, Allowances and Other Conditions of Service of Officers and Employees) Regulations, 2013; Food Safety and Standards Authority of India (Transaction of Business and Procedure for the Scientific Committee and Scientific Panel) Regulations, 2016; and Food Safety and Standards Authority of India (Recruitment and Appointment) Regulations, 2018.

²⁰ Section 3(j), the FSSA.

²¹ Section 3(zk), the FSSA.

- Genetically modified or engineered food or food containing such ingredients;
- Infant food;
- Packaged drinking water;
- Alcoholic drinks;
- Chewing gum; and
- Any substance, including water, used in food during its manufacture, preparation, or treatment,

but does not include:

- Animal feed;
- Live animals (unless prepared or processed for placement on the market for human consumption);
- Plants prior to harvest;
- Drugs and medicinal products;
- Cosmetics; or
- Narcotic or psychotropic substances.

The FSSA authorizes the central government to declare any other article as food by notification. It also defines the term “food safety” as an “*assurance that food is acceptable for human consumption according to its intended use.*”²²

The FSSA imposes certain general and specific obligations spanning across different facets of food production and distribution:

a. General obligations and prohibitions

- The FSSA prohibits the use of food additives, processing aids, contaminants, pesticides, etc. in a manner other than as prescribed under the FSSA, read in conjunction with the relevant regulations.
- It prohibits the manufacture, distribution, sale, or importation of any “novel food” (further discussed below), “genetically engineered or modified food,” “irradiated food,” “organic food,” “food for special dietary use(s),” “functional food,” “nutraceuticals,” “health supplements,” “proprietary foods,” and also such other articles of food for which the Indian government is authorized to provide notification; except as set forth in the FSSA, read in conjunction with the relevant regulations.²³
- It prohibits misleading or deceptive advertising, engaging in unfair trade practices, or any unfair or deceptive practices for the purpose of promoting the sale or consumption of any food.²⁴
- It also prohibits the importation of any unsafe, substandard, or misbranded food.²⁵

b. Obligations of Food Business Operators

Apart from the general obligations, the FSSA specifically imposes obligations on “food business operators” (“**FBO**”). An FBO is defined as a person who operates or owns a business and is responsible for ensuring compliance with the FSSA and its rules and regulations.²⁶ A “food business” is further defined to mean any undertaking to carry out any activity related to manufacturing, processing, packaging, storing, transporting, distributing, or importing food, and includes food services, catering services, and the sale of food and/or food ingredients.²⁷

²² Section 3(q), the FSSA.

²³ Section 22, the FSSA.

²⁴ Section 24, the FSSA.

²⁵ Section 25, the FSSA.

²⁶ Section 3(o), the FSSA.

²⁷ Section 3(n), the FSSA.

The obligations of an FBO include:²⁸

- Obtaining a license to operate a food business;
- Ensuring that the labelling and presentation of food is not misleading;
- Ensuring that all articles of food satisfy all requirements of the FSSA and the underlying regulations at all stages within the businesses under the FBO's control;
- Refraining from manufacturing, storing, selling or distributing any article of food which is unsafe, misbranded, substandard, or containing extraneous matter, for which a licence is required (except in accordance with the conditions of the licence), or which is, for the time being, prohibited by the FSSAI or the government in the interests of public health;
- Refraining from employing any person suffering from an infectious or a contagious disease;
- Refraining from selling or offering for sale any article of food to any vendor, unless the FBO provides a guarantee, in writing, on the nature and quality of such article to the vendor; and
- Immediately initiating procedures for withdrawal of food if the FBO has reason(s) to believe that such food, which the FBO has processed, manufactured, or distributed, was not done so in compliance with the FSSA.

c. Liabilities of manufacturers/packers

A manufacturer/packer is liable for an article of food if it is not manufactured/packed in accordance with the provisions of the FSSA.²⁹

d. Liabilities of wholesalers/distributors

A wholesaler/distributor can be held liable for any item:³⁰

- Supplied after the date of expiry;
- Stored/supplied in breach of the manufacturer's safety instructions;
- Unfit for human consumption or misbranded;
- Unattributable to the manufacturer who sent the article;
- Stored or handled in breach of the provisions of the FSSA and its regulations; or
- Received by the wholesaler/distributor with knowledge of it being unsafe.

e. Liabilities of sellers

A seller can be liable for any item:³¹

- Sold after the date of expiry;
- Handled or kept in unhygienic conditions;
- Misbranded;
- Unattributable to the manufacturer or distributor from whom it was received; or
- Received by the seller with knowledge of it being unsafe.

Non-compliance with the various obligations under the FSSA can result in penalties (for civil and administrative violations) and prosecution (criminal proceedings resulting in a fine and/or imprisonment) for the violator. The nature and quantum of the punishment varies according to type of violation. Further, in certain cases, the violator also may be ordered by the adjudicating officer appointed by the state government,

²⁸ Sections 23, 26, 28, and 31, the FSSA.

²⁹ Section 27(1), the FSSA.

³⁰ Section 27(2), the FSSA.

³¹ Section 27(3), the FSSA.

or the relevant court, as the case may be, to pay compensation to a customer who is injured or has died as a result of such violation (if any).³²

(2) Indian Penal Code, 1860 (“IPC”)

The IPC is India’s main penal code. It criminalizes the adulteration of food or drink intended for sale,³³ and also the sale of noxious food or drink,³⁴ with punishment of imprisonment for up to 6 months, or a fine of up to INR 1000, or both.

(3) Insecticides Act, 1968 (“IA”)

The IA regulates the importation, manufacture, sale, transportation, distribution, and use of insecticides for the purpose of preventing a human health risk. It confers power on the government to make rules on the storage of insecticides during transportation or otherwise, along with articles of food.³⁵

Under this power, the government promulgated the Insecticide Rules, 1971, which set forth the following:

- Insecticides cannot be transported or stored in such a way as to come into direct contact with foodstuffs or animal feed.³⁶
- Foodstuffs or animal feed contaminated with insecticides as a result of contact with damaged packages containing insecticides during transportation or storage cannot be released to consignees, unless they have been examined for possible contamination by competent authorities, as the government may declare by notification.³⁷

(4) Consumer Protection Act, 2019 (“CPA”)

The definition of “goods” under Section 2(21) of the CPA also includes food, and, therefore, all the duties of a seller and the rights available to a seller and consumer in connection with goods generally also are applicable to food items. The CPA was enacted in 2019, repealing the erstwhile Consumer Protection Act, 1986,³⁸ to provide for better protection of the interests of consumers, and to establish regulatory bodies for timely and effective administration and settlement of consumer disputes.

It provides for the establishment of the Central Consumer Protection Authority (“**CPCA**”), which was established to regulate matters relating to the rights of customers.³⁹ The CPCA has the power⁴⁰ to make inquiries on, or to investigate, violations of consumer rights; file complaints with, or intervene in, proceedings before the relevant Consumer Disputes Redressal Commission;⁴¹ recommend remedial measures for the implementation of safeguards for the protection of consumers, including international best practices; undertake research on, and spread awareness of, consumer rights; issue safety notices for the purpose of

³² Section 65, the FSSA.

³³ Section 272, the IPC.

³⁴ Section 273, the IPC.

³⁵ Section 36(za), the IA.

³⁶ Rule 35(2), the Insecticides Rules, 1971.

³⁷ Rule 35(3), the Insecticides Rules, 1971.

³⁸ Section 107, the CPA.

³⁹ Section 10, the CPA.

⁴⁰ Section 18, the CPA.

⁴¹ Consumer Disputes Redressal Commissions are established at the national, state, and district levels to adjudicate on consumer complaints. (Sections 28, 42, and 53, the CPA).

alerting consumers against unsafe goods; and to advise government departments on measures relating to the promotion of consumer safety. The CPCA also has the power to order a recall of goods.⁴²

(5) Constitution of India, 1950

Apart from the statutory laws above, Indian courts also have granted the “right to food” the status of a fundamental right under Article 21 of the Constitution.⁴³ Accordingly, any person can seek a remedy before a constitutional court in India (being the Supreme Court of India and any of the High Courts) by filing a writ petition,⁴⁴ if their right to food is breached in contravention of the laws of any governmental body. The right also has been read into various directive principles of state policy under Part IV of the Constitution, which are not enforceable rights, but directives for the government.

3. Regulation of food additives

“Food additives” are dealt with primarily under the FSSA.

Under the FSSA, “food additives” are defined as:

“any substance not normally consumed as a food by itself or used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its by-products becoming a component of or otherwise affecting the characteristics of such food but does not include “contaminants” or substances added to food for maintaining or improving nutritional qualities.”⁴⁵

The FSSA provides that no article of food can contain any food additive, unless it is included in accordance with the provisions of the FSSA and its regulations.⁴⁶ It confers power on the FSSAI to make regulations on the scope of food additives that can be used,⁴⁷ under which the FSSAI promulgated the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 for the purpose of prescribing permissible quantities of food additives in different types of products.

4. Regulation of insecticides

The IA, read in conjunction with the Insecticides Rules, 1971 made thereunder, regulates the importation, registration, manufacture, sale, transportation, distribution, and use of insecticides (pesticides) with a view to preventing a risk to human and animal health, as well as all related matters, throughout India. “Insecticides” is defined with reference to a list of items in the Schedule to the IA, for which the government may make a declaration by notification from time to time.⁴⁸

⁴² Section 20, the CPA.

⁴³ *People’s Union of Civil Liberties v. Union of India (UOI) and Anr AIR 1982 SC 1473.*

⁴⁴ Articles 32 and 226, the Constitution.

⁴⁵ Section 3(k), the FSSA.

⁴⁶ Section 19, the FSSA.

⁴⁷ Section 92, the FSSA.

⁴⁸ Section 3(e), the IA.

5. Regulation of novel food

Under Indian law, “novel food” is dealt with under the FSSA. “Proprietary and novel food,” as a phrase, has been defined to mean “*an article of food for which standards have not been specified but is not unsafe. Provided that such food does not contain any of the foods and ingredients prohibited under this Act and the regulations made thereunder.*”⁴⁹

The FSSA prohibits the manufacture, distribution, sale, or importation of any novel food in a manner other than as prescribed under the FSSA.⁵⁰ Under Regulation 13 of the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purposes, Functional Food, and Novel Food) Regulations, 2016, “novel food” is defined as any food that:

- “(a) may not have a history of human consumption; or*
- (b) may have any ingredient used in it which or the source from which it is derived, may not have a history of human consumption; or*
- (c) a food or ingredient obtained by new technology with innovative engineering process, where the process may give rise to significant change in the composition or structure or size of the food or food ingredients which may alter the nutritional value, metabolism or level of undesirable substances.”*


The regulation also provides that:

- Novel food cannot be manufactured or imported for a commercial purpose without prior approval from the FSSAI obtained by filing an application along with all relevant documents and details as specified by the FSSAI; and
- The labelling of novel food must be:
 - (a) made in accordance with specific labelling requirements;
 - (b) specific to a claim relating to the novel product; or
 - (c) made in accordance with the category specified by the FSSAI in the relevant regulations.

The Food Safety and Standards (Approval for Non-Specific Food and Food Ingredients) Regulations, 2017 also makes rules relating to novel food.

In order to respond to the business needs of our clients, we publish newsletters on a variety of timely topics. Back numbers can be found [here](#). If you would like to subscribe to the N&A Newsletter, please fill out [the N&A Newsletter subscription form](#).

This newsletter is the product of its authors and does not reflect the views or opinion of Nishimura & Asahi. In addition, this newsletter is not intended to create an attorney-client relationship or to be legal advice and should not be considered to be a substitute for legal advice. Individual legal and factual circumstances should be taken into consideration in consultation with professional counsel prior to taking any action related to the subject matter of this newsletter.

Public Relations Section, Nishimura & Asahi [E-mail](#) 

⁴⁹ Section 22, the FSSA.

⁵⁰ Section 22, the FSSA.