
LEGAL LADLES: SERVING UP INDIA'S KEY FOOD SAFETY STANDARDS**I. INTRODUCTION**

- 1.1. With a rise in population and an increase in income levels, the demand for food products is on a surge. In addition to ensuring adequate food supply, it is also essential that people have access to nutritious and safe food. Further, India is one of the world's leading producers of several food products including rice, wheat, dairy products, buffalo meat, pulses, jute and fruits.¹ Accordingly, the need to regulate the Indian food industry to ensure safety of food products is urgent and inevitable.
- 1.2. The Food Safety and Standards Act, 2006 ("**the Act**") was enacted after consolidating multiple laws relating to food safety with an objective to streamline the culture of safe food and ensure that it is fit for human consumption in the country. The Act governs a wide array of activities in relation to food products and ingredients including manufacturing, importing, processing, packaging, wholesale, distribution and selling. The Act brought under its ambit multiple rules and regulations which set out the nuances to govern the various food products and their safety.
- 1.3. Established pursuant to the Act, the Food Safety and Standards Authority of India ("**FSSAI**"), is the apex regulatory body that is responsible for setting the standards for food products. The FSSAI, further ensures that food businesses comply with the obligations and conditions as applicable to them under the provisions of the Act. Under the Act, necessary penalties may be imposed for manufacturing, storing, distributing, selling and/or importing of sub-standard, misbranded, unsafe, unhygienic and adulterated food, engaging in misleading advertisement and providing false information.
- 1.4. In this article, we attempt to analyse the applicability of, registration / licensing requirements, and compliances under the Act and the rules and regulations made thereunder, along with highlighting other notable considerations for companies engaged in the food business.

II. APPLICABILITY AND REGISTRATION REQUIREMENTS UNDER THE ACT

- 2.1. **Applicability:** The Act is applicable on all entities or persons who carry out a 'food business' which means "*any undertaking, whether for profit or otherwise and whether public or private, carrying out any of the activities related to any stage of manufacturing, processing, packaging, storage, transportation, and distribution of food, importing, and includes food services, catering services, selling of food or food ingredients*".²

'Food' under the Act is defined as "*any substance, whether processed, partially processed or unprocessed, which is intended for human consumption and includes primary food³, genetically modified or engineered food or food containing such ingredients, infant food, packaged drinking water, alcoholic drink, chewing gum, and any substance, including water used into the food during its manufacture,*

¹ Please refer to: <https://www.ibef.org/industry/agriculture-india> ; <https://www.fao.org/india/fao-in-india/india-at-a-glance/en/#:~:text=India%20is%20the%20world's%20largest,poultry%2C%20livestock%20and%20plantation%20crops.>

² Section 3(1)(n) of the Act.

³ Section 3(1)(zk) of the Act defines 'primary food' as an article of food, being a produce of agriculture or horticulture or animal husbandry and dairying or aquaculture in its natural form, resulting from the growing, raising, cultivation, picking, harvesting, collection or catching in the hands of a person other than a farmer or fisherman.

preparation or treatment but does not include any animal feed, live animals unless they are prepared or processed for placing on the market for human consumption, plants prior to harvesting, drugs and medicinal products, cosmetics, narcotic or psychotropic substances”.⁴

Accordingly, the applicability of the Act has been extended over a wide category of food products intended for human consumption.

- 2.2. **Registration / License:** The relevant factors to determine the requirement to obtain a registration / license by a ‘food business operator’⁵ (“FBO”) are set out in the table below:

Particulars	Nature of license/registration		
	Registration	State License	Central License
Licensing / Registering Authority (“Licensing Authority”)	Designated officer / food safety officer or any official of local body as notified by the state food safety commissioner.	Designated officer appointed by the state food safety commissioner.	Designated officer appointed by the chief executive officer of the FSSAI.
Activities for which registration / license is required	A registration as a ‘petty FBO’ is required to be obtained by a ‘petty food manufacturer’. ⁶	An FBO who is engaged in a food business other than: (i) the business for which it is mandatory to obtain a central license; or (ii) in case the FBO is covered under the category of a ‘petty FBO’. ⁷	An FBO engaged <i>inter alia</i> in dairy unit, vegetable oil processing unit, food processing units above a prescribed threshold, 100% export-oriented units, importers, food catering entities established under central agencies or any FBO operating in 2 or more states. ⁸
Other criteria to obtain registration /	Depending on the nature of activities, the requirement to obtain a registration, state license or central license may depend upon certain		

⁴ Section 3(1)(j) of the Act.

⁵ Section 3(1)(o) defines a ‘food business operator’ as a person who carries on food business and who is responsible for undertaking compliances under the Act.

⁶ Regulation 1.2(4) of the Licensing Regulations defines a petty FBO as: A ‘petty food manufacturer’ includes a petty retailer, hawker, itinerant vendor, temporary stall holder, small scale or cottage food business industry or any food business whose annual turnover does not exceed INR 12 lakhs or production capacity does not exceed 100 kg/ltr per day or procurement or handling and collection of milk is up to 500 litres of milk per day or slaughtering capacity is 2 large animals or 10 small animals or 50 poultry birds per day or less.

⁷ Regulation 2.1.2(4) of the Licensing Regulations.

⁸ Regulation 2.1.2(3) of the Licensing Regulations.

<i>license</i>	<p>criteria, including the following⁹:</p> <ul style="list-style-type: none"> (i) annual turnover; (ii) production / processing / storage capacity of the unit; (iii) number of vehicles utilised with respect to a transporter; or (iv) star rating in relation to a hotel. <p>The aforesaid criteria will not be applicable on the FBOs engaged in activities for which the requirement to obtain a central license is mandatory (for instance, an importer or 100% export-oriented units).</p>
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Accordingly, nearly every type of food-related business is covered under the ambit of the Act and the FSSAI, and is required to obtain a registration/license. Further, penalties may be imposed on an FBO who carries out a food business without obtaining/renewing necessary registration or license. Recently, FSSAI has issued notices to several canteens and food joints operating in schools, colleges and universities without obtaining the required registration/license.¹⁰

2.3. **Key considerations for obtaining registration/ license:** Set out below are the key considerations with respect to obtaining a license / registration under the Act:

- (i) *License as a relabeller:* An FBO utilising a third-party manufacturer or processor to manufacture or package the food products, is required to obtain a license as a 'relabeller'.¹¹ Accordingly, an entity manufacturing its products through contract manufacturing is required to obtain a license as a 'relabeller'. Notably, entities who are engaged in manufacturing, but outsource the packaging of their products, will be required to obtain a license as a 'manufacturer' as well as a 'relabeller'.¹²
- (ii) *Registration/License by direct sellers:* Since direct sellers are engaged in selling food products directly to end consumers, they are categorised as a 'retailer' under the Act. Accordingly, every direct seller engaged by a direct selling entity is required to ensure compliance with the Act and obtain registration/license as a 'retailer'.¹³
- (iii) *License under e-commerce category:* FBOs which are providing online platforms for sale and purchase of the food products are required to obtain a license under the 'e-commerce' category.¹⁴ To clarify, an online platform which only lists FBOs and does not engage in any activity for sale and purchase of food products are not required to obtain an e-commerce license. However, such online platform should only list FBOs with valid

⁹ An illustrative list of activities, along with the applicable criteria and thresholds to obtain the type of license can be accessed at: <https://foscos.fssai.gov.in/assets/docs/KindofBusinessEligibility.pdf>.

¹⁰ Please refer to: <https://www.newindianexpress.com/cities/vijayawada/2023/Mar/18/no-licence-most-canteens-come-under-fssai-scanner-2557206.html>.

¹¹ Please refer to: frequently asked question no 71 at <https://foscos.fssai.gov.in/faq-license-registration>.

¹² Please refer to: frequently asked question no 3 at <https://foscos.fssai.gov.in/faqs-license-registration?faqType=LR>.

¹³ Order number 15(6)2018/FLRS/RCD/FSSAI dated July 8, 2019 and September 19, 2019.

¹⁴ Please refer to: frequently asked question no 78 at <https://foscos.fssai.gov.in/faq-license-registration>.

license/registration.¹⁵ Accordingly, food aggregators like Zomato and Swiggy can only list FBOs, including home chefs, cloud kitchens or roadside kiosks, only if the FBOs have obtained registration/license under the Act.¹⁶ Further, in case an FBO engaged solely in an e-commerce activity is operating from two or more states, it is only required to obtain a central license for the head office and no separate licenses for the premises located in all of the states are required.¹⁷ This is in contrast to FBOs engaged in activities other than e-commerce, where the requirement to obtain separate licenses for premises located in other states persists, even in case a central license for the head office/registered office has been obtained.

- (iv) *Premise-based license*: Depending upon the fulfilment of the relevant criteria as highlighted above, a separate license or registration must be obtained for each unit/premises from the relevant Licensing Authority, despite the FBO having procured a central license for the head office/registered office.¹⁸ Further, no FBO is allowed to procure multiple licenses/registration for a single premise and all kinds of food business activities that are being conducted at the same premise can be applied for in a single FSSAI license/ registration.
- (v) *Eligibility to obtain higher category of license*: If an FBO fulfils all other requirements such as conditions and compliances associated with the category of license, it is allowed to file an application to obtain a higher category of license, as compared to the kind of license for which it meets the relevant threshold. Further, in case an FBO undertakes more than one business activity from a single premise, the category of the license will be determined taking into account the activity for which a higher category of license is required to be obtained based on the fulfilment of relevant criteria.¹⁹

III. KEY COMPLIANCES UNDER THE ACT

3.1. Given the increasing importance and priority to ensure the availability of safe and nutritious food, the FSSAI has developed a robust regulatory framework governing FBOs engaged in dealing with different kinds of food products. Some of the key regulations and compliances required thereunder are set out below:

- (i) *Specific food related compliances*: The FSSAI has formulated regulations setting out standards with respect to specific categories of food products. The Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 (“**Health Supplements Regulations**”) provides for specific labelling requirements, standards for nutritional or health claims, list and usage level of ingredients which health supplements, nutraceuticals, food for special dietary use etc. should contain. The standards with respect to classification and labelling requirements for alcoholic beverages including brandy, gin, rum, wine, whisky and beer are envisaged under the Food Safety and Standards (Alcoholic Beverages) Regulations, 2018. Further, specific regulatory frameworks for ayurveda

¹⁵ Please refer to: frequently asked question no 79 at <https://foscos.fssai.gov.in/faq-license-registration>.

¹⁶ Please refer to: <https://www.financialexpress.com/life/lifestyle-a-licence-to-feed-home-chefs-cloud-kitchens-kiosks-are-under-the-lens-for-being-legit-and-following-norms-of-food-industry-2479691/>.

¹⁷ Please refer to: frequently asked question no 78 at <https://foscos.fssai.gov.in/faq-license-registration>.

¹⁸ Please refer to: frequently asked question no 1 at <https://foscos.fssai.gov.in/faq-license-registration>.

¹⁹ Please refer to: frequently asked question no 118 at <https://foscos.fssai.gov.in/faq-license-registration>.

products,²⁰ vegan foods,²¹ infant foods²² and organic foods²³ have also been formulated.

- (ii) *Import-related compliances:* To streamline the process of clearance of imported food products, the Food Safety and Standards (Import) Regulations, 2017 ("**Import Regulation**") was enacted. As per the Import Regulations, the importers of food products must adhere to labelling and packaging requirements (as highlighted below) and ensure that imported food items are stored correctly and meet conditionalities of shelf life. Upon arrival at ports of entry, imported food consignments undergo inspection by the authorised officer to ensure compliance with Indian food safety standards. Importers must promptly rectify any labelling discrepancies, if and to the extent rectifiable, within a specified timeframe. The authorised officer has the authority to reject consignments that do not comply with labelling and packaging requirements.
- (iii) *Labelling and packaging related compliances:* With a view to provide relevant and accurate details of packaged food products to consumers, the FSSAI has enacted the Food Safety and Standards (Labelling and Display) Regulations, 2020 ("**Labelling Regulations**"). As per the Labelling Regulations, every pre-packaged food product should contain details such as the product's name, ingredients, nutritional content, net quantity, manufacturing date, best before/use by date, and the manufacturer's or importer's name and address. Necessary logos to identify vegetarian and non-vegetarian food products and a logo of FSSAI along with license number should be displayed. Recently, the FSSAI has principally approved to display the nutritional information with respect to contents of salt, sugar and saturated fat on the labels of the food products.²⁴ However, an amendment giving effect to such change has not been notified yet. Such change would enable the consumers to comprehend the nutritional value and make an informed decision prior to purchase.

Additionally, an FBO should also comply with the Food Safety and Standards (Packaging) Regulations, 2018 which set out requirements with respect to packaging materials including requirement of packaging paper to be clean and hygienic, container to not be re-used and newspaper to not be used for storing or wrapping.

Further, as highlighted above, the Import Regulations, the Food Safety and Standards (Organic Foods) Regulations, 2017, Health Supplements Regulations and other regulations framed under the Act provides for certain specific labelling or packaging requirements for food products including samples of imported food products to contain information such as code number, quantity of the sample and name of the food product imported; organic food products to clearly display organic status of the product along with FSSAI's organic logo; and health supplements to display a label stating 'Health Supplement' and a warning stating that it is 'Not For Medicinal Use'.

- (iv) *Advertising related compliances:* The FSSAI has formulated the Food Safety and Standards (Advertising and Claims) Regulations, 2018 to regulate advertising of food products in India. According to the aforesaid regulations, the claims made by FBOs should be truthful,

²⁰ The Food Safety and Standards (Ayurveda Aahara) Regulations, 2022.

²¹ The Food Safety and Standards (Vegan Foods) Regulations, 2022.

²² The Food Safety and Standards (Foods for Infant Nutrition) Regulations, 2020.

²³ The Food Safety and Standards (Organic Food) Regulation, 2017.

²⁴ Please refer to: <https://legal.economictimes.indiatimes.com/news/law-policy/fssai-proposal-to-display-nutritional-information-requires-regular-audits-and-compliance-says-legal-experts/111662514>

and not mislead the consumers regarding the features and quality of the food product. Further, the claims made by FBOs regarding food products, should not reduce the importance of a healthy lifestyle or balanced diet and every nutritional or health related claim should be backed by scientific evidence. Additionally, FBOs, or a marketer of any food product, is required to seek a prior approval from the FSSAI for making any claim related to reduction of disease risk.

Recent studies show that majority of protein supplements (including powders and shakes) which are popular among consumers are mislabelled and/or advertise inaccurate nutritional information.²⁵ Further, FSSAI through a directive, has asked FBOs to remove misleading claims with respect to '100% fruit juices' in the labels or advertisements for reconstituted fruit juices.²⁶

3.2. Further, set out below are certain additional compliances which an FBO is required to undertake:

- (i) *BIS or ISI certification*: The FSSAI has prescribed mandatory certification from Bureau of Indian Standards or Indian Standards Institution, for certain food products such as infant milk food, infant formula, milk cereal based weaning food, processed cereal based weaning food, follow up formula, packaged drinking water, and packaged mineral water.²⁷
- (ii) *Returns and records*: Every importer or manufacturer is required to file an annual return to the concerned food safety commissioner.²⁸ Further, every FBO is also required to maintain food distribution records which include the names and addresses of suppliers and customers, nature of food, date of purchase etc.²⁹ The records are required to be maintained under the Food Safety and Standards (Food Recall Procedure) Regulations, 2017 which was enacted to ensure removal of food under recall from all stages of food chain.
- (iii) *Nomination of person-in charge of establishment*: An FBO is required to nominate a person-in-charge of the establishment from which it operates, and such person shall be responsible for any contravention by such establishment.³⁰ Such person is required to be authorised by the board of directors of the FBO through a resolution.

IV. ADDITIONAL PERSPECTIVES INVOLVING OTHER LEGISLATIONS

4.1. Foreign investment

In India, amongst other extant foreign exchange regulations, foreign investment is regulated through the Foreign Exchange Management (Non-debt Instruments) Rules, 2019 ("**NDI Rules**"), and the Consolidated Foreign Direct Investment Policy, 2020 ("**FDI Policy**"). Pursuant to the NDI Rules and FDI Policy, foreign direct investment in entities engaged in

²⁵ Please refer to: <https://theprint.in/health/70-of-36-popular-protein-supplements-sold-in-india-mislabeled-14-contain-toxins-says-new-study/2035264/>.

²⁶ Please refer to: <https://pib.gov.in/PressReleasePage.aspx?PRID=2022681>.

²⁷ Regulation 4 of the Food Safety and Standards (Packaging) Regulations, 2018.

²⁸ Regulation 2.1.3 of the Licensing Regulations.

²⁹ Regulation 6(1) of the Food Safety and Standards (Food Recall Procedure) Regulations, 2017.

³⁰ Rule 2.5.1 of the Food Safety and Standards Rules, 2011.

'manufacturing', wholesale trading and single brand retail trading, is permitted up to 100% under the automatic route (subject to sector specific conditionalities), and for entities engaged in multi brand retail trading ("MBRT"), it is only permitted up to 51% under the approval route.

With respect to entities that are engaged in manufacturing, the NDI Rules and FDI Policy state that *a manufacturer is permitted to sell its products manufactured in India through wholesale and/or retail trading (including through e-commerce) without governmental approval*.³¹ Accordingly, it follows that if any Indian entity is engaged in manufacturing (in India) along with MBRT of food products, foreign investment is allowed up to 100% under the automatic route.

However, an ambiguity arises due to the presence of a non-obstante provision under the 'manufacturing' section³² which states that notwithstanding the provisions under the FDI Policy/NDI Rules on the 'trading' sector, 100% foreign investment under the *approval route* is permitted for trading, including through e-commerce, with respect to food products manufactured and/or produced in India.

The above language may appear as a restriction on the trading of food products, however, given the background and context of the FDI Policy/NDI Rules, it can be interpreted that this insertion was not intended as a restriction but more to bring about a relaxation for foreign direct investment in entities not engaged in manufacturing but only engaged in MBRT of food products manufactured by other third parties in India which is permitted up to 100% under the approval route as opposed to the ceiling of 51% for MBRT of other products.

4.2. *Nutraceuticals - 'Food' or 'Drug'?*

The Indian nutraceutical industry is growing at a rapid rate attracting investments not only domestically but also from non-resident entities. As highlighted above, nutraceuticals are considered as 'food' and governed by the Health Supplements Regulations. However, as per recent media reports, the Government has constituted a panel to examine the possibility of bringing nutraceuticals under the ambit of the Drugs and Cosmetics Act, 1940 ("**D&C Act**").³³

Due to this move of the Government, entities engaged in manufacturing, importing, selling, distributing or storing of nutraceuticals may be required to comply with the provisions of the D&C Act. While the extent of compliance would need to be deliberated and finalised, the conditions could relate to adherence to additional quality standards and sale of certain nutraceuticals being carried out under the supervision of a competent person/registered pharmacist. Such conditionalities may have a significant impact on the operations of entities related to nutraceuticals and affect over-the-counter availability of certain nutraceuticals. Additionally, it would be interesting to see if there will be an impact on foreign investment in entities engaged in the business of nutraceuticals, due to the sectoral caps and conditionalities in the pharmaceutical sector.

V. CONCLUSION

India's food safety laws provide for a robust regulatory framework encompassing standards

³¹ Paragraph 5.2.5.1 of the FDI Policy read with Serial Number 5.1 of the table mentioned in Schedule I of the NDI Rules.

³² Paragraph 5.2.5.2 of the FDI Policy read with Serial Number 5.1 of the table mentioned in Schedule I of the NDI Rules.

³³ Please refer to: <https://ficci.in/public/storage/sector/Report/22526/giVzIShom2TMBEYaEkixvJieKK7p5rK8N1YtAcnf.pdf>

for various categories of food products and necessary penalties for any non-compliance. Its effectiveness hinges on consistent monitoring, stringent enforcement, and public awareness. Recently, the FSSAI ordered testing of spices and reportedly cancelled manufacturing licenses of numerous spice makers in India after it was alleged that certain spices manufactured by premiere spice makers in India contain contaminants.³⁴ Also, the FSSAI is planning to implement stringent regulations with respect to protein supplements after a study revealed that various brands feature dubious health claims and inaccurate nutritional information.³⁵ Further, it remains to be seen what approach the Government will adopt with respect to 'nutraceuticals', which will consequently impact its commerce and compliances associated with it. Accordingly, to avoid any penalties or revocation of license, it is imperative for entities engaged in the food business to understand and adopt the regulatory regime under the Act and stay abreast with evolving regulations.

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³⁴ Please refer to: <https://economictimes.indiatimes.com/industry/cons-products/food/after-mdh-and-everest-controversy-centre-orders-all-state-governments-to-test-spices-to-ensure-their-quality/articleshow/109771273.cms?from=mdr>; <https://timesofindia.indiatimes.com/life-style/food-news/fssai-cancels-manufacturing-licences-of-111-spice-producers-across-india/articleshow/111400965.cms>.

³⁵ Please refer to: <https://www.hindustantimes.com/business/fssai-cracks-down-on-protein-supplements-over-health-risks-and-misleading-claims-101719745511091.html>.