

FSSAI LICENSING FOR FOOD BUSINESSES

*Navigating Regulatory Requirements under the Food Safety and Standards
(Licensing and Registration of Food Businesses) Regulation, 2011*



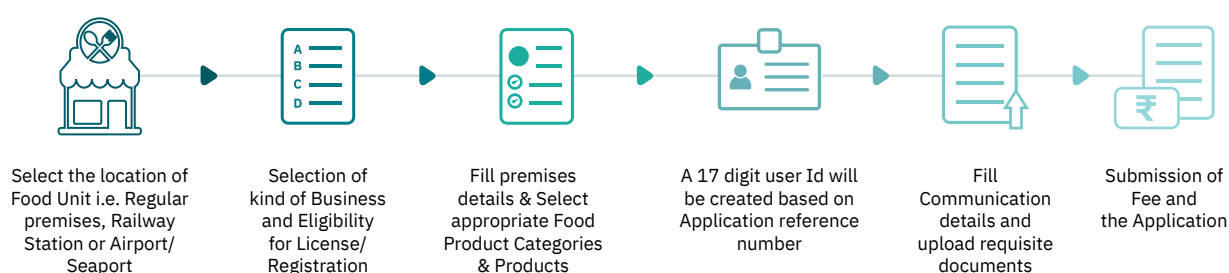


In India, a food business¹ operator seeking to manufacture, produce, import, distribute, or sell food products, including smart protein products and their ingredients, must first obtain a license with the Food Safety and Standards Authority of India (FSSAI).

The FSSAI License is a location and premises-based permit. Each Food Business Operator (FBO) facility is issued a separate license (except for transporters, where one license will be issued for all vehicles of a single transporter or business). Suppose the FBO has premises or units located in more than one state. In that case, the FBO must declare one location as the head office and obtain a central license for it and a central or state license for other places per the eligibility criteria.

An FBO's premises shall have only one FSSAI license on which any Kind of Business (KoB)² can be endorsed. To apply for a facility permit, an applicant must begin by identifying the type of food products and the nature of businesses that will be carried out in that facility.

License/ Registration Application Flow



A 17 digit Reference Number is the User Id generated for future login

To file application for Registration Certificate, Users may download **Food Safety Connect app** from Google play store.

¹ As per Section 3 (n) of the Food Safety and Standards Act, 2006 ("FSS Act"), "Food business" means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of manufacture, processing, packaging, storage, transportation, distribution of food, import and includes food services, catering services, sale of food or food ingredients.

² Please refer to the definition and categories of all Kind of Businesses (KoBs) regulated by FSSAI along with the eligibility criteria here: <https://foscos.fssai.gov.in/assets/docs/KindofBusinessEligibilityLatest.pdf>

The following five KoB groups have been specified:

1. Manufacturer: Manufacturing or processing dairy products, vegetable oil, meat products, novel food products, and all food processing units, including repackers or relabellers.
2. Trade or Retail: Conducting food business activities such as storing, wholesaling, retailing, distributing, transporting, food vending agencies, supplying, marketing, e-commerce, etc.
3. Food Service: Businesses involved in food activities related to preparing and serving fresh food and drinks.
4. Central Government Agencies: If conducting food business activities, i.e., food canteen, catering services, storing, wholesaling, retailing, or distributing food products at central government premises.
5. Head Office: If carrying out food business activities in multiple states with the same company or organisation name.

The eligibility criteria for a Central License or State License:



Central License

- 1) All food processing units with an installed capacity of more than 2 MT per day except grains, cereals, and pulse milling units
- 2) 100% export-oriented units
- 3) All importers importing food items, including ingredients and additives for commercial use
- 4) All food business operators manufacturing, processing, or importing any proprietary food for which FSSAI has given NOC
- 5) Registered or head office of FBOs operating in two or more states
- 6) Food catering services in establishments and units under central government agencies, such as railways, airports, seaports, and defence
- 7) Hotels with 5-star and above accreditation
- 8) E-commerce



State License

1) All FBOs other than those eligible for registration or central license

For the full list of Conditions of License, please visit: <https://www.fssai.gov.in/cms/licensecondition.php>

A. Application for a new FSSAI State or Central License

PARTICULARS

Licensing of a food business and its validity

Prescribed form: Form B (Schedule 2)

Payment of fees or penalty: The applicable fee varies as per the nature of the business and categories of food products:

1. INR 7,500, in case of central license or
2. Between INR 2,000 and 5,000 (as specified in the Regulations for each food product) in case of a state license.

Corresponding documents: The required documents are divided into two categories: documents for non-manufacturing and manufacturing businesses.³ Following are the additional documents that must be submitted in addition to specific documents:

- (a) Photo ID and address of proof of proprietor or partner or director or authorised signatory - issued by the government;
- (b) List of directors or partners or proprietor or executive members of society or trust with full address and contact details with the nomination of the authorised signatory;
- (c) Proof of possession of premises (sale deed or rent agreement or electricity bill, etc);
- (d) Partnership deed or self-declaration of proprietorship or Memorandum and Articles of Association towards the constitution of the firm or copy of a certificate under Cooperatives Act in case of cooperatives;
- (e) Nomination of the person in Form IX under the Food Safety and Standard Rules, 2011 (not required in case of a proprietor).

³Revised list of KoB- wise documents required to be submitted along with the application for FSSAI license - <https://foscos.fssai.gov.in/assets/docs/DocumentListMarch.pdf>.

REMARKS

- FBOs shall apply for licenses under the Regulations online through the Food Safety Compliance System (FoSCoS)⁴ portal.
- FBOs must ensure compliance with all license conditions (Annexure 3) and general requirements on hygienic and sanitary practices (Part II of Schedule 4).
- The licensing authority (LA) decides on the license within 60 days of the FBO submitting a complete application.
- If additional information is required or the application is incomplete, the applicant must provide the necessary information or complete the application within 30 days of the notice received from the LA.
- Failure to furnish the required information within the stipulated time will result in the rejection of the license application. Before denying the grant of a license, the applicant is allowed to be heard, and the reasons for the refusal are recorded in writing.
- Failure to respond to the queries from the licensing authority will result in auto-rejection of the application. FBOs can self-activate their auto-rejected applications on FoSCoS.⁵
- If a notice is issued to comply with the prescribed sanitary conditions, the applicant must carry out the required actions within 30 days and inform the licensing authority.
- If a license is not issued within 60 days from the date of the completed application or if the applicant has not received any notice of inadequacy or inspection report indicating defects, the applicant may commence the food business.
- Food businesses are prohibited from manufacturing, importing, selling, stocking, or exhibiting for distribution or sale any food article subjected to irradiation treatment without a license from the Department of Atomic Energy the Atomic Energy (Control of Irradiation of Food) Regulations, 1996.

⁴Food Safety Compliance System (FoSCoS) - <https://foscoss.fssai.gov.in>.

⁵The provision for self re-activation, that is without any intervention from the authority, of auto-rejected application shall be provided only once for up to 60 days of auto-rejection, for any filed application for new license or modification of license/registration, as the case may be. Within 30 days of auto-rejection of application, FBO is allowed to self-reactivate the application without any fee. During the period of 31st to 60th day of auto rejection of the application, FBO will require paying a fees of Rs. 500 + GST (As applicable). However, it is mandatory to provide a valid reason for such delay. - <https://www.fssai.gov.in/upload/advisories/2023/12/656ebc7a6980c20231204125427557.pdf>

- For ease of doing business and to enable instant issuance of licenses/registrations, FSSAI has developed a system for Tatkal application⁶. FBOs can now apply for a Tatkal license/registration for importers, merchant-exporters, wholesalers, distributors, retailers, transporters, and storage without an atmospheric controller.
- The license issued is valid for only (1) year.⁷

B. Renewal of FSSAI State or Central License

PARTICULARS

Prescribed form: Form B (Schedule 2)

Payment of fees or penalty: In case of delay in renewal of a license issued by the central licensing authority or the state licensing authority:

(a) Three times the existing license fee in the period– if renewal is within 90 days from the original expiry date; or (b) Additional two times of the existing license fee (i.e. total five times)–if renewal is between 91st day and 180th day from the original expiry date.⁸ No renewal is allowed after the 180th day from the original expiry date.

Corresponding documents:

- (a) Food Safety and Management System (FSMS) certificate or plan;
- (b) Updated nominee details in Form IX under the Food Safety and Standard Rules, 2011, in case of change in the nominee.

REMARKS

- FBO shall apply for the renewal under the Regulations online through the FoSCoS portal.
- The renewal of a license is instant and without the scrutiny of the licensing authority.

⁶Ease of doing business - Launch of provision for Instant (Tatkal) issuance of license/registration in certain categories of food businesses

- https://www.fssai.gov.in/upload/advisories/2024/07/668531ea91cb7Ease%20of%20doing%20Business-%20Launch%20of%20provision%20for%20instant_Tatkal_issuance%20of%20lic%20and%20reg.pdf

⁷Ease of doing business: Instant renewal of license/registration -

<https://fssai.gov.in/upload/advisories/2023/01/63bfa4c0d8679FSSAI%20Order%20dated%2011-01-2023.pdf>

⁸Implementation of policy to enable renewing the FSSAI License/Registration after the expiry date -

https://fssai.gov.in/upload/advisories/2021/10/617bd59fbcaedOrder_License_Expiry_date_29_10_2021.pdf

- A renewal application must be made no later than 30 days before the expiry date indicated in the license.
- The renewal shall be valid for only one year.
- Failure to apply for renewal within the specified period results in the license expiring and the business must apply for a fresh license.
- Renewal is not allowed in case of suspension or cancellation of license.

C. Modification, expansion or change in FSSAI License

PARTICULARS

Payment of fees or penalty:

- INR 1,000 plus the differential fee, equal to the difference in annual license fee, in case of upgradation.
- No fee is levied for non-form C modification, i.e., modification of supporting information and documents.

Corresponding documents for modification of license:

- Supporting document for the purpose modification as provided on the FoSCoS portal to be printed on the letterhead;
- Any document that is required by the licensing authority to ensure the safety of food.

REMARKS

- FBO may apply online through the FoSCoS portal to modify a license issued under the Regulations.
- FBO must apply to the licensing authority if the license certificate (Form C) information changes.
- Subject to the fulfilment of certain conditions as specified, the license shall be instantly modified.⁹

⁹https://fssai.gov.in/upload/advisories/2022/12/63ad6fef02453Order_High_Risk_Food_29_12_2022_compressed.pdf.

D. Additional Compliances

1. Revocation of License

PARTICULARS

Suspension or cancellation

REMARKS

- Suspension of license may occur if the FBO fails to comply with conditions or rectify the defects provided in improvement notices.
- FBO must immediately stop all food business activities if the license is suspended.
- If the licensing authority is satisfied with the remedial action, as directed in the improvement notice, it may revoke the suspension with or without conducting an inspection.
- If FBO fails to rectify the defects provided in the improvement notice, the licensing authority may further cancel the suspended license.
- FBO has the right to be heard before the suspension or cancellation.
- No compensation or refund is provided for a suspended or cancelled license.
- FBO can make a fresh application for a license three months after the date of cancellation.

2. Submission of annual return

PARTICULARS

Submission of return to licensing authority

Prescribed form: Form D-1

Payment of fees or penalty: The penalty of INR 100 per day is subject to a maximum penalty not exceeding five times the annual license fee in case of delay in filing beyond 31st May of each year.¹⁰ The penalty shall be submitted online by the FBOs on the FoSCoS portal.

¹⁰ Ease of doing business: Capping of penalties due to delay in submission of Annual Returns - https://www.fssai.gov.in/upload/advisories/2022/11/636c99269f006Order_Annual_Return_10_11_2022.pdf.

REMARKS

- A separate annual return for each license (Form D-1) must be submitted to the licensing authority online only through the FoSCoS portal for the previous financial year by 31 May of each year.

3. Business-to-business trade

PARTICULARS

Guarantee for articles of food sold to vendors (i.e., business-to-business trade)

Prescribed form: Form E

REFERENCE CASE

ABC Private Limited is a plant-based nuggets and patties startup that wants to set up a registered office in Delhi and a manufacturing unit in Haryana. [Their products are Proprietary Foods as per Regulation 2.12 with the closest category of 6.8.8 Textured Soy Protein (Soy Bari, Soy Chunks, or Soy Granules)].^{11,12} While they manufacture the nuggets at their new facility in Haryana, they will source the patties from XYZ Private Limited, which will manufacture patties with their branding. They will sell the products to consumers via e-commerce platforms and their partner distributor networks.*

What FSSAI license must they apply for, and for which premises?

ABC Private Limited (ABC) plans to operate its food business from two units in different states. Both premises will require an FSSAI Central License for the respective Kind of Business.

¹¹ Assumed for the purpose of this case. A product may not be compliant or can fall in an entirely different category because of slight variation in its formulation, therefore, it is important to identify the correct product standard and category as per the Food Safety and Standards (Food Products Standards and Food Additives) Regulation, 2011, based on the formulation, format, recommended usage (daily suggested serving of their product and target audience).

¹² View all FSSAI standardised products -

[\[https://foscos.fssai.gov.in/standard-product\]](https://foscos.fssai.gov.in/standard-product)

¹³ Assumed for the purpose of this case. A product may not be compliant or can fall in an entirely different category because of slight variation in its formulation, therefore, it is important to identify the correct product standard and category as per the Food Safety and Standards (Food Products Standards and Food Additives) Regulation, 2011, based on the formulation, format, recommended usage (daily suggested serving of their product and target audience).

ABC will operate a manufacturing unit for plant-based nuggets (proprietary food¹³) on Haryana premises.

Step 1: Go to the Apply for New License/Registration on FoSCoS portal.

Step 2: Select the 'General' location of operation and select the state as Haryana.

Step 3: Open the 'Manufacturer' Kind of Business tab and select the Proprietary Food category underneath the same.

Step 4: Press 'Proceed' and view eligibility.

View Eligibility

After assessment of kind of Business(s) selected and inputs provided, you are eligible for:

S.No	Kind of Business	License Category
1	Manufacturer - Proprietary Food - Section 22	Central License

You are eligible for **Central License** , Click here to proceed

For the premises in Delhi, ABC will engage in a Manufacturer (Relabeller¹⁴) kind of business for proprietary food, e-commerce, and head office.

Step 1: Go to the Apply for New License/Registration option on the FoSCoS portal.

Step 2: Select the 'General' location of operation and select the state as Delhi.

Step 3: Open the 'Manufacturer' Kind of Business tab and select the Proprietary Food category underneath the same.

Step 4: Open the 'Trader/Retailer' Kind of Business tab and select the e-Commerce kind of business.

Step 5: Open the 'Head Office' kind of business tab and select the Head Office/Registered Office option.

Step 6: Press 'Proceed' and view eligibility.

View Eligibility

After assessment of kind of Business(s) selected and inputs provided, you are eligible for:

S.No	Kind of Business	License Category
1	Manufacturer - Proprietary Food - Section 22	Central License
2	Head Office - Head Office/Registered Office	
3	Trade/Retail - e-Commerce	

You are eligible for **Central License** , Click here to proceed

¹⁴ "Relabeller" means a food business operator who gets his/her product(s) manufactured/packed from a third-party manufacturer or processor.

Therefore, ABC must apply for separate FSSAI central licenses for its Haryana and Delhi premises.

Important Links

- Food Safety Compliance System (FoSCoS) Portal - <https://foscoss.fssai.gov.in/>
- The Food Safety and Standards (Food Products Standards and Food Additives) Regulation, 2011 - <https://www.fssai.gov.in/cms/compendium-fss-fps-fa.php>
- View all FSSAI standardised products - <https://foscoss.fssai.gov.in/standard-product>
- Documents Required - <https://foscoss.fssai.gov.in/home-document>
- Eligibility Criteria & Fee Structure - <https://foscoss.fssai.gov.in/assets/docs/KindofBusinessEligibilityLatest.pdf>
- Frequently Asked Questions (FAQs) on FSSAI License and Registration - <https://foscoss.fssai.gov.in/faqs-license-registration?faqType=LR>
- Frequently Asked Questions (FAQs) on Compliance - <https://foscoss.fssai.gov.in/faqs-license-registration?faqType=C>
- Food Safety Inspection Checklist - <https://www.fssai.gov.in/cms/inspection-matrices.php>
- Condition of License - <https://www.fssai.gov.in/cms/licensecondition.php>

Important:

The reference sheet was last updated on September 15, 2024. This reference sheet, case and other published content are general notes prepared by Spice Route Legal and GFI India. They should not be construed as advice or opinion on any matter. If you have any queries or would like to raise any concerns, please contact us at india@gfi.org.

ABOUT GFI INDIA:



Since our establishment in 2017, GFI India has served as the central thought leader and convening body in plant-based, cultivated, and fermentation-based meat, eggs, and dairy, collectively known as the alternative protein or smart protein sector. The regulatory team at GFI India is led by [Astha Gaur](#) and [Ojasvi Uppal](#), who aim to build regulatory pathways between smart protein manufacturers and government bodies, convene the Regulatory Advisory Council, and provide regulatory advisory and resources for stakeholders in the smart protein sector.

ABOUT SPICE ROUTE LEGAL (SRL):



[Spice Route Legal's](#) leading healthcare, life sciences, and pharmaceuticals practice is ranked #1 by global directories, including Legal 500. [Swarna Jain](#), who is a Senior Associate and member of this practice, hyperspecialises in food and nutraceuticals, leads our engagement with GFI India and advises a diverse array of clients in the food and beverages industry on commercial agreements, distributor disputes, labelling, food testing, fundraising, and more.