**LEGAL COMPLIANCES TO START FOOD INDUSTRY**

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**Abstract:** Ensuring food safety is vital for the advancement and economic prosperity of a nation. India has made considerable strides in guaranteeing food security for its people and has achieved a commendable level of self-sufficiency in agriculture over the years. The food industry is subject to various legal compliances to ensure the safety, quality, and transparency of food products. These legal requirements encompass a wide range of regulations and standards that food businesses must adhere to quality and food safety standards. Key areas of legal compliance in the food industry include: Food safety regulations, licensing and registration, quality standards, import and export regulations. Starting a food business requires obtaining various licenses and permits to comply with legal and regulatory requirements. One of the license is FSSAI license, serves as a regulatory tool that ensures food safety, hygiene and quality standards are upheld by all food businesses across India. India is currently emerging as a significant hub for organic food products. The FSSAI has made it mandatory for businesses dealing with organic food to obtain a license. Food certifications play a crucial role in assuring consumers about the safety, quality, and sustainability of food products. These certifications assure consumers that the food has been produced, processed, and labelled in accordance with rigorous standards. Food certifications cover a wide range of aspects, including AGMARK, BIS, ISO, HACCP, GMP, halal and kosher certification. Each certification addresses specific attributes of food products, catering to diverse consumer preferences and dietary needs. This chapter discusses various legal compliances regarding food business.

**Key words**: Food safety, FSSAI license, Organic food, Certifications

**Introduction**

Ensuring food safety is imperative for the progress and economic growth of a country. Over time, India has achieved significant progress to safeguard and guarantee food security for its population and has attained substantial self-reliance in agriculture (Shelly and Kaur, 2015). As a result, the policy the emphasis has currently transitioned from merely achieving self-sufficiency to emphasizing the generation of higher and stable income for the farming population. The food processing industry in India is rightfully considered the sunrise sector of the economy due to its immense potential for substantial growth, employment opportunities and income generation. Over the past five years until 2019-20, the Food Processing Industries (FPI) Sector has demonstrated an impressive average Annual Growth Rate of approximately 11.18 % and is the 5 th industry in terms of production, consumption, exports and potential growth (www.pib.gov.in).

As the global population continues to increase, ensuring a safe, nutritious, and abundant food supply for everyone has emerged as a significant challenge. To address this challenge, all stakeholders, including the food industry, governments, and consumers, must implement effective risk management strategies founded on sound science and impartial information. Additionally, with the globalization of the food supply chain, it is crucial to harmonize policies and standards worldwide, fostering a shared understanding of food safety among authorities in different countries ([www.fao.org](http://www.fao.org)).

**1. Food licences**

Establishing and maintaining a robust food safety system requires a country to enact and enforce appropriate laws and regulations. This global concern, particularly pronounced in India, stems from two main sources: either a failure to adhere to established protocols or deliberate attempts to deceive. To ensure the safety and quality of food products, food businesses must diligently comply with stringent regulations and standards. This entails acquiring essential licenses and certifications, upholding impeccable hygiene and sanitation practices, and implementing effective food safety management systems.

Any food business operation to function in India should adhere to certain product specific standards, safety and hygienic parameters. In India, Food Business Operators (FBOs) are required to acquire multiple licenses or registrations in order to operate their food businesses (www.fssaiindia.in). The current scenario of licenses and certifications in the food business varies depending on the country and region. Licenses and certifications are crucial in the food industry to ensure: legal compliance, promote food safety, build consumer trust and loyalty, enhance business reputation and provide a competitive advantage (www.fssai.gov.in).

Food standards play a crucial role in instilling confidence among consumers regarding the safety, quality, and authenticity of the food they consume. These standards create a shared understanding among consumers, producers, and governments about various aspects of food, facilitating smooth trade operations. When countries adopt consistent food standards, trade becomes more efficient, reducing costs, and ensuring that food is safe and meets consumers' expectations worldwide. On the other hand, differing food standards between governments can lead to higher trade expenses and pose challenges in ensuring food safety and meeting consumers' needs ([www.wto.org](http://www.wto.org)).

**1.1. Terms**

**1.1.1. License**: An official authorization or permission granted by a government or regulatory authority that allows individuals or businesses to engage in specific food-related activities ([www.fssai.gov.in](http://www.fssai.gov.in)).

**1.1.2. Certificate:** A document issued by a certifying body or organization that verifies that a specific product, process or system meets certain standards or requirements ([www.iso.org](http://www.iso.org)).

A food business encompasses enterprises engaged in producing, distributing, selling, or providing food products and includes a diverse range of establishments such as restaurants, cafes, bakeries, food trucks, grocery stores, food manufacturers, and catering companies. The initial step before launching a food business is to determine the specific type of venture within the food sector. Once equipped with the necessary resources and a well-thought-out execution plan, it is essential to identify and obtain the required legal licenses or No Objection Certificates (NOCs) to avoid any legal complexities. Entrepreneurs have various registration options available, including partnership, proprietorship, limited liability partnership, one-person company, and private limited company, which can be explored In alignment with the specified requirements ([www.fssai.gov.in](http://www.fssai.gov.in)).

**1.2 FSSAI license**

The Food Safety and Standards Authority of India (FSSAI) is the governing body responsible for ensuring food regulatory compliance in India. It was established under the Food Safety and Standards Act, 2006, and became fully operational with the notification of Food Safety and Standards Rules, 2011, along with six regulations, which became operative on 5th August 2011.The enforcement of the Food Safety and Standards Act (FSS Act) falls under the responsibility of the FSSAI through its regional offices and the State Food Safety Authorities. These entities are tasked with monitoring and verifying that Food Business Operators (FBOs) comply with the relevant requirements of the law at every stage of the food business. (Mehdi *et al*., 2019).………….

The Food Safety and Standards Authority of India (FSSAI) consolidates various food-related laws under the Food Safety and Standards Act (FSSA). It takes charge of regulating the entire process, from manufacturing and processing to distribution, storage and import of food products. FSSAI establishes comprehensive standards for food articles, ensuring the proper use of additives, toxins, antibiotics, pesticides, contaminants, and more.

Furthermore, FSSAI issues licenses and registrations to food business operators, allowing them to conduct their operations. It also lays down packaging and labelling requirements for food products. The authority restricts and prohibits the sale of specific products that may pose risks to consumers. Additionally, FSSAI actively prevents misleading advertisements and unfair trade practices in the promotion of food products.

Promoting consumer awareness is another important aspect of FSSAI's role. Ensuring the availability of safe and wholesome food for human consumption remains a paramount objective. All these efforts contribute to fostering a reliable and transparent food safety system in India, while also addressing matters connected or incidental to the food industry (Goswami and Mulherkar, 2012).

**1.2.1 Objectives of FSSAI**

* To create scientifically based food standards
* To guarantee food safety when applying for a food license
* Assists with food safety and the regulation of food production, distribution, storage, sales, and imports (www.fssai.gov.in).

**1.2.2 Benefits of FSSAI act**

* The FSSAI serves as the central hub for all matters pertaining to Food Safety and Standards, Regulations, and Enforcement.
* A strong level of consumer trust in the quality and safety of food.
* he Licensing Authority issues a singular license for one or more food items and various establishments. ([www.fssai.gov.in](http://www.fssai.gov.in)).

In the past, the food safety regulations in India were managed under eight different acts and orders, each overseen by various ministries and departments related to food. However, there was a need for a single reference point that could consolidate all matters pertaining to food safety and standards, regulations, and enforcement (Sushila, 2020). In 2006, the Food Safety and Standards Act (FSSA) was introduced, effectively replacing eight laws that were in operation prior to its enforcement. The FSSA served as a comprehensive replacement for those earlier laws. (Jairath and Purohit, 2013)

(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

(i) Solvent Extracted Oil, De-oil Meal, and Edible Flour (Control)

(g) Milk and Milk Products Order, 1992

(h) Any other order under Essential Commodities Act, 1955 relating to food

The FSSAI serves as a comprehensive umbrella organization, consolidating diverse rules, legislation, and guidelines related to food safety. Its primary responsibility lies in safeguarding and promoting public health through the regulation and oversight of food safety. The headquarters of FSSAI is situated in New Delhi, and it further operates six regional offices strategically located in Delhi, Guwahati, Mumbai, Kolkata, Cochin, and Chennai (www.fssai.gov.in).

**1.2.4 FSSAI License/ Registration**

Every food business operator (FBO) in India must obtain either a license or registration under FSSAI, based on their annual turnover, production capacity, or storage capacity. This requirement applies to all FBOs engaging in food business activities within the country. The type of license or registration will depend on the specific criteria set by FSSAI for each category of food business. Under FSS Act, 2006. Ther are three types of registration/licenses:

1. Basic food registration- annual turnover is between ₹0-12 lakhs

2. State food license- annual turnover is between ₹12-20 crores

3. Central food license- annual turnover is more than ₹20 crores

There are different forms in FSSAI license to apply. For basic food registration: Form A and for state and central license: Form B. It is mandatory to obtain a license from the FSSAI to run a food business in India. The FSSAI provides Food Business Operators (FBOs) who adhere to the regulations and rules outlined in the FSS Act with a 14-digit license number. This 14-digit registration number provides data about the producer’s permit or enrolment and the assembling state. An application form is submitted to the licensing authority, accompanied by registration fees, which can now also be conveniently paid online. Upon successful registration, the business is issued a unique FSSAI number, which must be prominently displayed on all food packages produced or processed by the business. For food businesses with an FSSAI license, the initial number in the sequence will be "1," while for those with FSSAI basic registration, it will be "2." (www.fssai.gov.in).

Benefits of FSSAI license for food industry and consumers:

* Increases consumer awareness
* FSSAI gives a legal identity
* Food packages contains all required details
* FSSAI logo is mandatory on food packages
* Businesses gets extended all over
* A goodwill is created within the people

FSSAI has made consistent efforts to facilitate ease of doing business by implementing various measures. These include the adoption of cloud-based and cutting-edge technology in the form of the Food Safety Compliance System (FoSCoS), which streamlines the process of issuing registrations and licenses. The system incorporates user-friendly interfaces to guide applicants and minimize common filing errors. Moreover, FSSAI has categorized the mandatory documents required based on different types of businesses and integrated an online pan-India payment gateway for convenience. The inspection process has been made mandatory through the FoSCoS/FoSCoRIS App, ensuring transparency and accountability.

To aid enforcement agencies, customized reports are available, and third-party audit reports are accessible on the FoSCoS platform. Additionally, FSSAI has introduced an online submission option for annual returns, simplified the reinstatement process for applications, and upgraded the food consumer grievance system to version 2.0. To standardize procedures across the country, FSSAI has implemented a common format for licenses and registrations. Furthermore, the authority has reduced the number of steps involved in processing licenses, all contributing to enhancing the ease of doing food business in India ([www.fssai.gov.in](http://www.fssai.gov.in)). Follow the link https://foscos.fssai.gov.in/ for applying basic registration and license.

**1.2.5 Documents Required for FSSAI registration**

1. Authorized person address proof
2. Passport size photo
3. Business name and address
4. FSSAI declaration form
5. Nature of business details

**1.2.6 Documents Required for FSSAI license**

1. Passport-size photo
2. Certificate of the business constitution, such as a partnership deed, certificate of incorporation, shop and establishment license, or other business registration certificate.
3. Plan for a food safety management system
4. Address proof of business premises (rental agreement, a letter of authorization from the owner of the rented premises, utility bills)
5. List of food products manufactured or processed
6. Any Identity Proof documents like Aadhaar Card, Ration Card, Voter ID Card, PAN Card, or Driving License

**1.2.7 Renewal of FSSAI license:**

1. The FSSAI grants registration/licensing for a duration ranging from 1 year as a minimum to 5 years as a maximum.
2. Applicants are allowed to apply for FSSAI renewal up to 180 days prior to the expiration date.
3. In the case renewal of a license is not filed till 30 days before the expiry date, a late fee of ₹100 per day is to be paid by FBO, along with the renewal fee.
4. In the case of FBOs filling for FSSAI renewal from the 1st to 90th-day after the day of expiry, then they shall be charged 3 times the original annual fee respectively and 5 times if they appear after the 90th day from the day of expiry.
5. No renewal shall be allowed after 180 days from the original date of expiry
6. Renewal fee same as licensing fee, We can check in FSSAI license status in <https://foscos.fssai.gov.in/>
7. Renewal of the FSSAI license is obligatory before the current validity period concludes; otherwise, the option of applying for a new license is available.
8. FSSAI news update on food businesses can now be fined Rs. 5 lakh and 6 months jail for not having food license (www.fssai.gov.in).

**1.3 Food testing laboratories**

Food testing and analysis play a crucial role in ensuring food safety. As part of compliance requirements, food business operators are mandated to conduct periodic testing. FSSAI acknowledges the significance of accurate and reliable testing and, therefore, notifies NABL accredited food laboratories under Section 43 of the Food Safety and Standards Act, 2006.

Additionally, FSSAI also recognizes foreign laboratories to expedite the clearance process of food consignments at ports. The notified laboratories by FSSAI are further approved as National Reference Laboratories (NRLs) and ancillary facilities of NRLs (ANRLs) for specific purposes, bolstering the robustness of the food safety system ([www.fssai.gov.in](http://www.fssai.gov.in)).

Laboratory testing under FSSAI provides services in all areas of food testing, including-

* Food adulterant testing
* Chemical Contaminant testing
* Microbial Testing
* Drug Residue Testing

**1.3.1 Types of food laboratories under FSSAI:**

1. Primary
2. Referral
3. National reference laboratories

**1.3.1.1 Primary**

The Food Authority informs accredited food laboratories and research institutions, recognized by the National Accreditation Board for Testing and Calibration Laboratories or any other relevant accreditation agency, to perform sample analysis by food analysts.

**1.3.1.2. Referral**

The Food Authority acknowledges the existence of 20 referral food laboratories for conducting analyses of appeal samples.

**1.2.1.3. National reference**

The FSSAI has designated National Reference Laboratories (NRLs) with the responsibility of establishing nationwide standards for routine procedures, validating these standard procedures and testing methods, developing new methodologies, and ensuring proficiency in testing, especially concerning high-risk food categories. Both primary food laboratories and referral food laboratories are eligible for recognition as NRLs. Currently, there are 12 NRLs and 2 ANRLs in operation ([www.fssai.gov.in](http://www.fssai.gov.in)).

**1.4** **FSSAI License for exporting of food product**

India has gained global recognition for its food product exports to various countries. The policies of the Indian government are consistently supportive of promoting exports from the country, and this trend has been witnessing significant growth year by year. Given that food products directly impact the well-being of consumers, nations worldwide have instituted stringent measures to allow only safe and high-quality products from India into their markets. To prevent the export of substandard or unsafe food products from India, adherence to guidelines from the Food Safety and Standards Authority of India (FSSAI) is mandatory for food product exports. Exporters of food products are also obliged to obtain an FSSAI license, just like any other Food Business Operator (FBO) operating within India. ([www.fssai.gov.in](http://www.fssai.gov.in)).

**1.4.1 Documents for manufacturing exporters**

Along with the documents required for central license following documents are required:

* Import Export Code (IEC) document issued by DGFT
* Declaration that products meant for export only shall not be exposed for sale and consumption in domestic market. Further, the products (meant for export only) meet the standards
* Ministry of Commerce Certificate for 100% EOU (if availing the Scheme) ([www.fssai.gov.in](http://www.fssai.gov.in))

**1.5 FSSAI Licenses for importing of food product**

In 2017, FSSAI finally notified its long-pending import regulations, effectively resolving challenges that importers had encountered while importing food items. This move significantly reduced the information gap between exporters and importers. Now, food imports have been streamlined through a single window interface, the ICEGATE portal, which has implemented a risk-based clearance system. This simplification has enhanced the efficiency and effectiveness of food import processes, benefitting both importers and exporters alike. The Food Safety and Standards Authority of India (FSSAI) controls the import of food products into India. The following licenses and registration would be required for importing food products into India.

* Opting for a Private Limited Company or LLP is discretionary, but advisable as it enhances business transferability and restricts personal liability.
* [GST Registration](https://www.indiafilings.com/gst-registration) (Required for selling goods or products in India)
* An Importer Exporter Code from DGFT is essential for the import or export of goods.
* Product Approval from FSSAI is necessary when the intended imported product is not standardized, meaning it doesn't comply with the food standards outlined in the FSS Act and its corresponding regulations. ([www.fssai.gov.in](http://www.fssai.gov.in)).

**1.6 Licenses required for Organic Food Business**

"Organic food" denotes food items that are grown and processed in strict accordance with established standards for organic food production. India is currently gaining prominence as a significant center for organic food products. In line with this, the FSSAI has instituted a requirement for businesses engaged in the organic food sector to acquire a license. Once the license is obtained, the products must prominently display an India Organic Certificate on all their offerings. Furthermore, any organic food presented for sale or promotion must adhere to the pertinent provisions of one of the following systems:

1. National Programme for Organic Production (NPOP) implemented by Ministry of Agriculture
2. Participatory Guarantee System for India (PGS-India) Enforced by the Ministry of Commerce and Industry.

Organic food that is directly marketed to end consumers by small original producers or producer organizations, as determined by the Food Authority, will be exempted from the regulations of the respective systems. Nevertheless, it is essential for all organic food products to strictly adhere to the packaging and labeling guidelines specified in the Food Safety and Standards (Packaging and Labeling) Regulations of 2011. Additionally, these products must meet the labeling requirements specified under the relevant systems. To ensure the authenticity and compliance with safety standards, consumers are advised to check for the FSSAI organic logo (Jaivik Bharat) and the FSSAI Logo License number on the packaging of organic products.



**Fig:1 Jaivik Bharath logo**

The responsibility of certifying Organic Food lies with the Accredited Certification Bodies under the National Program for Organic Production (NPOP) and the Local Group under the Participatory Guarantee System for India (PGS-India). Under the NPOP system, a single-ingredient product that meets all the specified standards can be labelled as 'Organic'. For multi-ingredient products, if a minimum of 95% of the ingredients are of certified origin, they can be labelled as 'Certified Organic'. Under the PGS-India system, a single-ingredient product that fulfils all requirements may be labelled as 'PGS-Organic'. For multi-ingredient products, if at least 95% of the ingredients are organic, they may be labelled as 'PGS-Organic'.





**Fig:2 Logo of NPOP and PGS organic**

In organic food, the permissible limits for insecticide residues shall be 5% of the maximum limits prescribed or the Level of Quantification (LoQ), whichever is higher, as stated in the Food Safety and Standards (Contaminants, Toxins, and Residues) Regulations, 2011, for specified foods. Additionally, organic food products must conform to the established maximum thresholds for contaminants, such as metal contaminants, naturally present toxins, aflatoxins, and more. These specifications are outlined in the Food Safety and Standards (Contaminants, Toxins, and Residues) Regulations of 2011 for diverse food items (www.fssai.gov.in).

**2. Food Certification**

The provision by an independent body of written assurance (a certificate) that the product, service or system in question meets specific requirements ([www.iso.org](http://www.iso.org)). Food safety certification is a third-party verification that products, processes or systems in the food supply chain meet accepted food safety standards. Food safety certification is based on the results of tests, inspections and audits and gives confidence to the consumer. Accreditation is the formal process by which an authoritative body or organization grants recognition and certification to an entity. Educational institution, program, healthcare facility, laboratory or certification body, indicating that it meets specific standards, criteria and requirements

**2.1 Food Certifications in India**

1. AGMARK
2. BIS
3. ISO
4. HACCP
5. GMP
6. Halal Certification
7. Kosher Certification

**2.1.1 AGMARK**

AGMARK is a certification mark employed in India to verify the quality of agricultural and processed food items. This certification is issued by the Directorate of Marketing and Inspection, a government entity operating under the Ministry of Agriculture and Farmers Welfare as per the (Grading and Marking) Act of 1937. These criteria distinguish between various quality levels, with 2-3 grades assigned to each commodity. The certification procedure encompasses product testing and analysis; if the product adheres to the stipulated benchmarks, it receives the AGMARK certification insignia. The primary aim is to furnish consumers with high-quality, untainted goods. The grading system is applicable for both domestic consumption and export purposes. To date, grade standards have been established for 231 agricultural commodities (www.dmi.gov.in).

**2.1.2 AGMARK product list**

* Pulses
* Whole spices
* Vegetable oils
* Wheat products
* Milk products
* Honey
* Rice
* Tapioca sago
* Seedless tamarind
* Besan (gram flour)

Certification under AGMARK is obligatory for Blended Edible Vegetable Oils and Fat Spread, as mandated by the provisions in the FSS Act and regulations of 2006. The AGMARK certification is issued by the Government of India This mark incorporates: -

* Agricultural and horticultural items
* Food and beverages that are either wholly produced or a combination of partial production and partial manufacturing.

**2.1.3 Procedure for AGMARK Registration**

* [https://dmi.gov.in](https://dmi.gov.in/) or visit the nearest office of the (DMI) in order to get the required application form.
* Form - A outlines the application for obtaining a Certificate of Authorization for the Grading and Marking of commodities intended for the domestic market.
* The AGMARK registration fees, for instance are ₹500 for fruits and vegetables and ₹10,000 for processed goods and dairy products.
* The renewal of the Certificate of Authorization can be accomplished through Form A-4 for a fee of Rs. 5000.

**2.1.4 Eligibility for grading and certifying a notified commodity under Agmark**

* The individual should possess the essential infrastructure for processing the commodity.
* The individual should either have access to an approved grading laboratory or possess their own accredited laboratory.

**2.1.5 Documents required**

1. Application form
2. Test reports
3. Certificate of origin
4. Proof of ownership
5. Labeling and packaging details
6. Fee payment

**2.1.6 Process of certification for AGMARK**

1. The approved Chemist tests the raw material and the processed commodity before getting it packed in a suitable packing material/container.
2. The field officers of DMI keep regular check on the commodity graded and certified under AGMARK by drawing check samples from packers’ premises and market.
3. These check samples are analyzed in Regional AGMARK Laboratories and action deemed fit is taken if the graded commodity is found not conforming to the prescribed standards. verification process is complete which takes about 30-40 days (approx.) (www.dmi.gov.in).

**2.1.2 BIS**

BIS certification is issued by the Bureau of Indian Standards (BIS) within India. This certification from BIS serves as a third-party endorsement, assuring customers of a product's quality, dependability, and safety. The Bureau of Indian Standards (BIS) was established under the Bureau of Indian Standards Act, 2016, which came into force on 12 October 2017. BIS administers product certification programs that entail granting licenses to manufacturers spanning a wide range of industries, from agriculture to electronics. While obtaining BIS certification for products is typically voluntary, the Government of India has mandated it for specific products due to public health considerations. According to government directives, 380 products are required to obtain BIS certification (www.bis.gov.in).

**2.1.2.1 Objectives of BIS**

* Harmonious development of activities of standardization, marking and quality certification
* Providing new thrust to standardization and quality control
* Evolving the national strategy for according recognition to standards and integrating them with growth and development of industrial production and exports

**2.1.2.2 Activities of BIS**

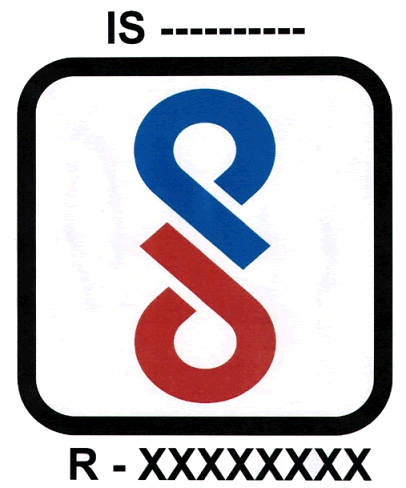
* Standards Formulation
* Certification
* Product
* Hallmarking of Gold Jewellery
* Quality Management System
* Environmental Management Systems
* Occupational Health and Safety Management System
* Hazard Analysis and Critical Control Points
* Imported Products\ FMCS
* Laboratory Management
* International Activities
* Training Services
* Others
* Information Services
* Consumer Affairs & Standards Promotion
* Sale of Standards

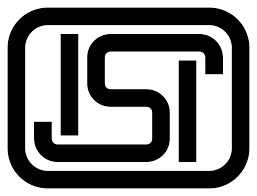
**2.1.2.3 Products with BIS certification**

* Electronic and IT Products
* ISI mark

Food-related products, glass & glassware, cylinders and regulators, building materials, primary batteries, rubber, oil pressure stoves, wire & cables, medical equipment, shoes & leather products, cement, automotive, capacitors, aluminum, chemicals and fertilizers, wheel rim & valves, household, electrical goods, steel products, electric motors and transformers

* Gold jewellery, silver jewellery (www.bis.gov.in)

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 **Fig.3. ISI logo on electronic products, food and gold**

**2.1.2.4 Types of BIS Registration Schemes**

1. ISI Mark Scheme Registration for Domestic Manufacturers
2. Registration Under Simplified Procedure for Domestic Manufacturers
3. ECO Mark Scheme Registration
4. Foreign Manufacturers Certification Scheme (FMCS)
5. BIS Compulsory Registration Scheme (CRS)

**2.1.2.5 Documents Required for BIS Certification**

* Name and address proof of office and factory
* MSME certificate, if applicable
* Manufacturing process flow
* Manufacturing machinery list
* Outsourcing of manufacturing operation, if applicable
* Testing equipment list
* Valid calibration certificate of testing equipment

The Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations impose restrictions on the production, storage, and sale of specific food items. These regulations mandate that certain food products must bear the Bureau of Indian Standards (BIS) certification emblem, in addition to the FSSAI registration or license number, before they can be manufactured or marketed. The BIS operates under the jurisdiction of the Ministry of Consumer Affairs, Food, and Public Distribution.

BIS certification grants permission to use the ISI (Indian Standards Institution) symbol, signifying adherence to established standards and quality criteria, both nationally and internationally, for over five and a half decades. International applicants can also obtain BIS certification to apply the ISI symbol to their products through the Foreign Manufacturers Certification Scheme (FMCS). Acknowledged by the FSSAI, the BIS also functions as a Food Safety Auditing Agency, in accordance with the Food Safety and Standards (Food Safety Auditing) Regulations of 2018. This recognition extends to the following areas:

**1. Food Processing.**

* Dairy
* Other Sectors\*\* (including Packaged Drinking Water, Nuts, Spices, Bakery, Edible Oil, Fruit and Vegetable processing, ready to eat/cook, *etc*)

**2. Food storage/ warehouse/ cold storage.**

The BIS registration in India holds its validity for a duration of two years, commencing from the date of issuance. Once this two-year period elapses, the applicant must initiate the renewal process by submitting Form XII.

According to its regulations, the FSSAI has stipulated that Food Business Operators (FBOs) involved in the manufacturing, marketing, warehousing, or presentation of the specified food products are required to hold the BIS certification emblem.:

* Milk cereal-based weaning food **(IS 1656)**
* Infant formula **(IS 14433)**
* Follow up formula **(IS 15757)**
* Processed cereal-based weaning food **(IS 11536)**
* Packaged mineral water **(IS 13428)**
* Packaged drinking water **(IS 14543)**
* Milk powder **(IS 1165)**
* Skimmed milk powder **(IS 13334)**
* Partly skimmed milk powder **(IS 14542)**
* Condensed milk sweetened **(IS 12176)**
* Condensed milk, partly skimmed and skimmed condensed milk **(IS 1166)**

**2.1.2.6 BIS Certificates for importer**

An importer would require to obtain two types of BIS certificates depending on the product type,

1. Compulsory Registration Scheme (CRS)

2. Foreign Manufacturers Certification Scheme (FMCS)

**2.1.2.6.1. Compulsory Registration Scheme (CRS)**

No importer is authorized to sell or distribute products in the Indian market, if it does not conform to the BIS standards. An imported product needs to conform to the established BIS established standards. Products under CRS are keyboards, electronic games, smart card reader, passport reader, micro oven, tablets, note book, digital camera, LED lights, laptop and phones.…

**2.1.2.6.2.**[**Foreign Manufacturers Certification Scheme**](https://www.jrcompliance.com/fmcs-bis-certification)**(FMCS)**

Since the year 2000, the BIS has been administering the Foreign Manufacturer Certification Scheme (FMCS) aimed at authorizing foreign manufacturers to verify their compliance with Indian standards. The FMCS covers a range of products, including food, batteries, aluminum foil, medical equipment, cattle feed, oil pressure stoves, kitchen appliances, electric motors, electric transformers, and cables (www.bis.gov.in).

**2.1.3 ISO**

The global population is currently experiencing rapid growth, leading to an increased demand for food products that frequently cross international borders. Addressing this challenge in a safe and sustainable manner relies significantly on the pivotal role played by International Standards. These standards provide invaluable guidance and best practices in food production techniques and testing, effectively promoting safety, quality, and efficiency throughout the entire food industry. All stakeholders involved in the food supply chain, including farmers, manufacturers, and retailers, can derive substantial benefits from adhering to the recommendations and best practices outlined in ISO standards. These standards cover a diverse array of aspects, ranging from food harvesting to product packaging. Furthermore, internationally recognized standards facilitate food producers in meeting their legal and regulatory obligations.……..

ISO standards address consumer-centric issues such as food safety, nutritional labeling, hygiene, food additives, and more. Regulators can rely on best-practice test methods and standardized terminology, which undergo continuous review and improvement, providing a technical basis for shaping regulations and policies. Ultimately, International Standards play a crucial role in ensuring the well-being of consumers and the efficiency and effectiveness of the global food industry.

ISO stands as an autonomous, non-governmental entity that boasts a roster of 21,500 International Standards, with an impressive addition of 100 fresh standards on a monthly basis. Among the broad spectrum of ISO standards tailored to cater to various segments of the food industry, ISO 9001, ISO 14001, and ISO 22000 stand as the widely used. Among these, the ISO 22000 certification emerges as the paramount and indispensable standard for the food industry. ISO standards find their genesis in the collaborative efforts of expert collectives, convened within technical committees (TCs). These TCs consist of representatives drawn from diverse sectors, including industry, non-governmental organizations, governments, and other stakeholders who are nominated by ISO's members ([www.iso.org](http://www.iso.org)).

**2.1.3.1 ISO standards in food sector**

* Food products
* Food safety management
* Microbiology
* Fisheries and aquaculture
* Essential oils
* Starch and its by-products

**2.1.3.1.1 Food products (ISO/TC 34)**

* ISO 20633, Infant formula and adult nutritional’s – Determination of vitamin E and vitamin A by normal phase high performance liquid chromatography.
* ISO 21415 for the determination of gluten content in wheat.
* ISO 6322 for the safe and hygienic storage of cereals and pulses.

**2.1.3.1.2 Food safety management (ISO/TC 34/SC 17)**

* ISO 22000, Food safety management systems – Requirements for any organization in the food chain, developed by ISO/TC 34/SC 17, Management systems for food safety
* ISO 7304 provides guidelines for cooking pasta to perfection
* ISO 3103 defines what makes a good cup of tea
* ISO 3959 outlines the best conditions for ripening green bananas

**2.1.3.1.3 Microbiology (ISO/TC 34)**

* ISO 16140, Microbiology of the food chain – Method validation
* ISO 6579-1, Microbiology of the food chain – Horizontal method for the detection, enumeration and serotyping of *Salmonella* – Part 1: Detection of *Salmonella* *spp*.
* ISO 10272-1, Microbiology of the food and animal feeding stuffs – Horizontal method for detection and enumeration of *Campylobacter* *spp*. – Part 1: Detection method1)
* ISO 11290-1, Microbiology of food and animal feeding stuffs – Horizontal method for the detection and enumeration of *Listeria monocytogenes* – Part 1: Detection method1)
* ISO 16654, Microbiology of food and animal feeding stuffs – Horizontal method for the detection of *Escherichia coli* O157
* ISO 19020, Microbiology of the food chain – Horizontal method for the immune enzymatic detection of *staphylococcal enterotoxins* in foodstuffs

**2.1.3.1.4 Fisheries and aquaculture (ISO/TC 234)**

* ISO 12875, traceability of finfish products – Specification on the information to be recorded in captured finfish distribution chains
* ISO 12878, Environmental monitoring of the impacts from marine finfish farms on soft bottom

**2.1.3.1.5 Essential oils (ISO/TC 54)**

More than 130 standards for essential oils are used in food products, perfumes, cosmetics, phytotherapy and aromatherapy

**2.1.3.1.6 Starch (including derivatives and by-products) (ISO/TC 93)**

Starch holds significant importance in the food manufacturing industry, finding application in a broad spectrum of food items such as processed foods, bakery products, desserts, and beverages. There are a total of 26 standards specifically dedicated to starch and its derivatives, encompassing aspects like terminology, analytical methods, sampling techniques and examination procedures.

**2.1.3.2 Different ISO standards**

**2.1.3.2.1** [**ISO 9001 Standard**](https://www.siscertifications.com/iso-14001-certification/)

ISO 9001 serves as the global benchmark for establishing Quality Management Systems (QMS) within an organization. This standard, which falls under the broader QMS umbrella that includes ISO 9001, AS9100, Six Sigma, and CMMI, ensures that the quality of your products or services aligns with customer expectations. This alignment is immensely advantageous for fostering your company's expansion. ISO 9001 is versatile and applicable to organizations of any size, irrespective of their industry or sector of operation.

**2.1.3.2.2 ISO** [**14001**](https://www.siscertifications.com/iso-14001-certification/) **Standard**

The globally acknowledged ISO 14001 standard assists in enhancing your environmental engagement by offering a structured approach to establish Environmental Management Systems (EMS). This standard also aids in the effective management of resources and the reduction of waste, promoting environmentally-friendly practices in operations.

**2.1.3.2.3 ISO 45001 Standard**

ISO 45001 is the global standard that provides a framework for implementing the Occupational Health and Safety Management System (OHSMS) in your organization. This ensures that your staff and your guests are safe from any occupation-related injuries

**2.1.3.2.4 ISO 22000 Standard**

The International Organization for Standardization (ISO) publishes the ISO 22000 standard, which assists organizations involved in the food supply chain in establishing and implementing a Food Safety Management System within their operations. ISO 22000 integrates the quality management aspects of ISO 9001 and the safety management principles of HACCP to ensure the quality and safety of food at all stages of production and distribution. This standard also supports food chain businesses in identifying food-related risks and devising corrective measures to prevent potential hazards.

Certification in ISO 22000 is applicable to Food & Beverage companies, as spoiled food can lead to contagious diseases and pose significant risks to public health. The World Health Organization (WHO) introduced the international ISO 22000 standard to ensure food safety across the entire food chain, extending from production to the final consumer or point of sale in the agri-food sector. This standard empowers companies to guarantee the delivery of safe products and services, and it can be applied to organizations of any size participating in the food chain.The ISO 22000 Certification of Food Safety Management Systems can be obtained by organizations involved in the primary production of food, food producers, retailers, catering companies and companies working in the field of food safety (cleaning and disinfection, transportation, storage and distribution, etc.).

The functions of iso are following under:

1. The ISO 22000 family includes standards specific to catering, food manufacturing, farming, packaging, and animal foodstuffs and feed production.
2. ISO does not perform certification
3. Certification is performed by external certification bodies
4. When choosing a certification body, Check if the certification body uses the relevant [CASCO standard](http://www.iso.org/committee/54998/x/catalogue/p/1/u/0/w/0/d/0)
5. The ISO's Committee on Conformity Assessment (CASCO) has developed several standards pertaining to the certification process. These standards are utilized by certification bodies.

**2.1.3.2 Certification Process for ISO**

1. Selecting the type of ISO certification

The first step at achieving the certification is by making yourself aware about the standards that are suitable for your management system. Some of the common standards are given below:

* ISO 9001 for Quality Management System
* ISO 14001 for Environmental Management System
* ISO 27001 for Information security Management system
* ISO  22000 for Food Safety Management system
* ISO 37001 for Anti Bribery Management System
* ISO 45001 for Occupational Health and Safety Management System
* ISO 50001 for Energy Management System

2. Choose an ISO Certification Body

3. Getting started with the process ([www.iso.org](http://www.iso.org))

**2.1.4 HACCP**

HACCP, which stands for Hazard Analysis and Critical Control Points, is a comprehensive management system designed to ensure food safety by meticulously scrutinizing and managing biological, chemical, and physical hazards at each stage of the food production process. It covers everything from sourcing and acquiring raw materials to the handling, manufacturing, distribution, and eventual consumption of the end product. HACCP employs precise techniques to identify potential risks and establishes critical control points along with specific limits to regulate these risks. Before implementation, rigorous validation, verification, and continuous monitoring of control measures are carried out. HACCP stands as an efficient and effective tool, serving the interests of both the food industry and health authorities in preventing foodborne diseases and upholding stringent standards of food safety (www.fda.gov).

In this context, a hazard is defined as a biological, chemical, or physical element in food or a condition of food that has the potential to cause adverse health effects. A tailored HACCP system should be developed for each food production line and adapted to suit the specific products and processes involved (source: Codex Alimentarius, 1997).

**2.1.4.1 Need of HACCP**

* Reduce the incidence of food borne disease
* Ensure a safe food supply for the population
* Facilitate trade in food products

National Centre for HACCP Certification (NCHC) is a quality organization of Government of Kerala providing professional and cost-effective assessment, audit and certification of Hazard Analysis Critical Control Point (HACCP) System for food industry and other food-related vendors.

**5.4.2 HACCP Principles**

* Conduct a hazard analysis
* Determine the critical control points (CCPs)
* Establish critical limits
* Establish monitoring procedures
* Establish corrective actions
* Establish verification procedures
* Establish record-keeping and documentation procedures

All companies involved in the food supply chain, from producers to retailers, can use HACCP. Businesses include, but are not limited to: Meat and meat products, spices and condiments, grain and cereals, hotels and restaurants, fruits and vegetables, dairy products, bakery and confectionery, fish and fishery products, nuts and walnuts products.

**5.4.4 Logic sequence for application of HACCP**

* Assemble the HACCP team
* Describe product
* Identify intended use
* Construct flow diagram
* On-site confirmation of flow diagram
* List all potential hazards
* Determine Critical Control Points
* Establish critical limits for each CCP
* Establish a monitoring system for each CCP
* Establish corrective actions
* Establish verification procedures
* Establish documentation and record keeping ([www.fao.org](http://www.fao.org))

**2.1.5 GMP**

GMP (Good Manufacturing Practice) is a certification scheme designed to assist food product manufacturers and related industries in obtaining accreditation from their clients. This certification serves as an indicator that the products are produced in a hygienic manner and adhere to the best practices in manufacturing.

Within the WHO-GMP certification scheme, the Joint Commissioner, acting with authority from the Commissioner of Food & Drug Administration, holds the responsibility for the endorsement and issuance of certificates. The GMP certification encompasses a diverse array of critical matters, encompassing documentation, meticulous record-keeping, personnel qualifications, hygiene and sanitation, equipment validation, handling of complaints, and process validation. These elements collectively guarantee that manufacturing processes adhere to elevated benchmarks of quality and safety. ([www.fda.gov](http://www.fda.gov)).

**2.1.5.1 Five main components of GMP**

1. Primary Materials and Products
2. Premises
3. People
4. Procedures
5. Processes

**2.1.6 Halal Certificate**

Halal certification is a process which ensures the features and quality of the products according to the rules established by the Islamic Council that allow the use of the mark Halal. It is mainly applied to meat products and other food products such as milk, canned food and additives. Muslims commonly use two terms to describe every subject as Halal or Haram. Halal is a Arabic word ((حلال‎‎" (Halal”) which means "permissible", lawful with respect to which no restriction exists, and the doing and consuming of which the Law-giver, Allah has allowed and Haram is the opposite of halal not permissible. These terms are commonly used in relation to food products, meat products, cosmetics, personal care products, pharmaceuticals, food ingredients, and food contact materials ([www.halalcertificate.in](http://www.halalcertificate.in)). In many Islamic countries, Halal certification is given by the government (Middle East, Saudi Arabia, Southeast Asian countries like Indonesia, Malaysia etc.). Indonesia and Malaysia are among such countries where food product import without MUI Halal or JAKIM Halal is not allowed.

Halal certificate issued by the Muslim authority of the exporting country in which it is certified that a certain agri-food or pharmaceutical product fulfills the requirements demanded by the Islamic Law for its consumption by the Muslim population. As the monitoring body for halal meat and meat products, APEDA shall have the mechanism to ensure that the certification and export of halal products has followed the I-CAS requirements of the Quality Council of India (QCI) ([www.qcin.org](http://www.qcin.org/)). Halal products are derived from animals and/or poultry that have been prepared according to Islamic law under the following statement, “In the name of God – God is the Greatest/Bismillahi Allahu Akbar” ([www.hmscommittee.com](http://www.hmscommittee.com)).

**2.1.6.1 Halal certified companies in India**

* French retailer Carrefour, which operates Wholesale Cash and Carry (WC &C)
* Nirma Salt
* Haldiram Namkeens and Sweets
* Goldwinner oil, Bikanerwala Foods Pvt Ltd
* Bacfo Pharmaceuticals
* Ambuja Group
* Daawat Basmati Rice
* Hindustan Unilever Limited
* Kwality Foods
* Amul Fed Dairy
* Dabur India Ltd
* Desai Foods
* Milky Mist Dairy Food
* Mother dairy
* Nestle India
* ITC Ltd
* Britannia Industries
* Tiffany Foods
* Om industries
* Everest Food products

**2.1.6.2 Guidelines of Halal**

* Allah’s (God’s) name must be pronounced during slaughter
* The instrument must be very sharp to ensure humane slaughter
* The animal must be slit at the throat
* Eating blood is not halal
* The animal must be hung upside down and allowed to bleed dry and must not be unconscious

**2.1.7 Kosher certificate**

KOSHER Certification is Jewish religious certification. Primarily product certification for food product. KOSHER Certification for food product is mainly pertaining to consumption practice followed by Jewish community of Israel. Term Kosher implies proper and acceptable, referring to a religious dietary practice of Jewish biblical law developed over 3,000 years ago as interpreted by rabbinic authorities. The word "Kasher" or "Kosher" comes from the Hebrew word "Kasher" or "Kosher," which indicates "purity and fit for human consumption”. Processed goods, on the other hand, are declared Kosher provided the manufacturing process has been supervised to ensure that no prohibited substances or mixes are present.

Some of the main kosher dietary guidelines ban certain food pairings — particularly the pairing of meat and dairy. There are three main kosher food categories:

* **Meat (fleishig):** Mammals or fowl, as well as products derived from them, including bones and [broth](https://www.healthline.com/nutrition/stock-vs-broth)
* **Dairy (milchig):** Milk, cheese, [butter](https://www.healthline.com/nutrition/7-reasons-why-butter-is-good-for-you), and yogurt
* **Pareve:** Any food that is not meat or dairy, including fish, eggs, and plant-based foods

Kosher certification is a mandatory requirement for food products exported to Europe, the USA, and other Asian countries with Jewish populations. Numerous Kosher certification agencies, both domestic and international, operate to furnish Kosher certificates. These agencies evaluate the compliance of facilities with Kosher certification standards and conduct audits, with auditors commonly referred to as Rabbis. All these Kosher certification bodies are affiliated with and sanctioned by the Rabbinical authorities in Israel. The process of certifying any production as kosher involves the scrutiny and oversight of two primary components: kosher ingredients and kosher equipment. Any equipment that has been employed in the production of non-kosher items or has come into contact with non-kosher substances must undergo thorough cleaning and a process known as "kosherization" before it can be used in kosher production. Kosherization might involve several methods such as boiling, sanitization, or treatment with specific agents. Additionally, the transportation of bulk liquid kosher ingredients necessitates adherence to kosher transportation protocols..

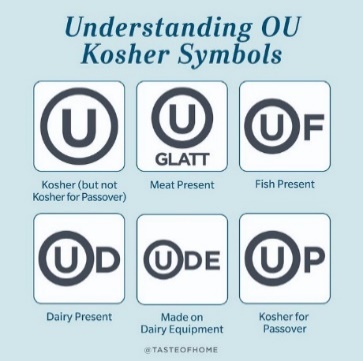
**2.1.7.1 Kosher rules**

* Land animals must eat grass
* Seafood must have fins and scales.
* Eating shellfish is not allowed
* It is forbidden to eat birds of prey. Only clean birds, meaning birds that do not eat other animals, can be eaten. Poultry is allowed
* Meat and dairy cannot be eaten together, as it says in the Torah: do not boil a kid in its mother’s milk (Exodus 23:19).

So, Jews who follow these dietary rules cannot eat cheeseburgers for example. Often this rule is extended further, so that people wait up to 6 hours after eating meat before they eat dairy.

**2.1.7.2 Kosher-Certification Agencies**

* More than 1,400 kosher-certification agencies operate globally, some on an international scale and others on a regional or local level
* All reputable kosher certifiers utilize a set of widely-held, [orthodox](https://en.wikipedia.org/wiki/Orthodox_Judaism) kosher standards
* The separation of meat and dairy are a key principle in kosher law
* Any reliable *hechsher* (Hebrew for “approval”, but commonly refers to the trademarked kosher *symbol*of the agency certifying a product) must specify which kosher category a product fall under



**Fig.4 Different kosher symbols**

**2.1.7.3 Requirements for kosher certification**

* Details of Company
* Details of Product
* List of all types of raw material used
* Request for product approval
* Details of Production plant detail
* Details of Process of production ([www.koshercertification.in](http://www.koshercertification.in))

**3. An example of dairy industry (Heritage food limited)**

Heritage Foods Limited (commonly known as Heritage Foods) is one of the largest [private sector](https://en.wikipedia.org/wiki/Private_sector) [dairy](https://en.wikipedia.org/wiki/Dairy) enterprises in Southern [India](https://en.wikipedia.org/wiki/India). Founded by Nara Chandrababu Naidu. The annual turnover of Heritage Foods stood at ₹26,429 million in the financial year 2021-22. Heritage’s milk products have market presence in Andhra Pradesh, Karnataka, Kerala, Tamil Nadu, Maharashtra, Delhi, Rajasthan and Punjab. It has retail stores across Bengaluru, Chennai, Hyderabad and Visakhapatnam. Integrated Agri operations are in Chittoor and Medak Districts and these are backbone to retail operations. The Heritage dairy plant, Gokul at Kasipentla in Chittoor District, Andhra Pradesh is certified and approved for export of ghee and butter manufactured in this plant by the Exports Inspection Agency, India. Products are exported to Europe, the Gulf and several countries in Asia. Company has taken FSSAI Central License, GST registration, trade license, import-export license, dairy plant license, HACCP, ISO 22000:2018, ISO 9001:2015, Halal certificate, *etc*. ([www.heritagefoods.in](http://www.heritagefoods.in)).

**Major exports are:**

* Heritage Pure Ghee in Bulk and Consumer Packs
* Heritage Butter in Bulk and Consumer Packs
* Heritage SMP (Skimmed Milk Powder) in Bulk & Consumer Packs

**Conclusion:**

Starting a food business requires compliance to the regulatory licenses and certifications to ensure a safe and high-quality food product to consumers. By acquiring these licenses and certifications, food businesses demonstrate their commitment to maintain high standards of quality, safety and professionalism. These credentials not only satisfy legal obligations but also give confidence in customers, showing them that their health and well-being are a top priority.

**References:**

Sushila, 2020, Legal Framework Regulating Food Safety: A Critical Appraisal. *Int J Consum Law Pract*, 8(1): 78-93

Goswami, L. and Mulherkar, C., 2012, India: Indian Food Safety Laws–Implications for Foreign Operators Importing Food Into India. *European Food and Feed Law Review*, 7(3): 154-156.

Shelly, M. and Kaur, K., 2015. Impacts of food processing industry on economic growth, FDI and exports of India. *Pacific Business Review International*, *7*(12): 63-72.

Mehdi, A., Tomar, P., Chaudhry, D. and Joshi, P., 2019, Streamlining Food Safety Compliance Ecosystem in India.

Jairath MS and Purohit P, 2013. Food safety regulatory compliance in India: A challenge to enhance agribusinesses. *Indian J Agric Econ*, 68(3): 431-48

www.fssai.gov.in (accessed on 22/04/2023)

www.iso.org (accessed on 01/05/2023)

www.dmi.gov.in (accessed on 02/05/2023)

www.bis.gov.in (accessed on 10/05/2023)

www.heritagefoods.in (accessed on 27/05/2023)

www.fda.gov (accessed on 10/05/2023)

www.koshercertification.in (accessed on 02/05/2023)

[www.pib.gov.in](http://www.pib.gov.in) (accessed on 01/05/2023)

[www.hmscommittee.com](http://www.hmscommittee.com) (accessed on 20/04/2023)

[www.fao.org](http://www.fao.org) (accessed on 01/05/2023)

www.fssaiindia.in (accessed on 22/04/2023)

[www.wto.org](http://www.wto.org) (accessed on 22/04/2023)

[www.halalcertificate.in](http://www.halalcertificate.in) (accessed on 20/04/2023)

[www.qcin.org](http://www.qcin.org) (accessed on 20/04/2023)