Title: Navigating the Food-Pharma Divide: A Critical Study of FSSAI, Market Regulations, and Health Law Compliance in India

AI Disclosure Statement

The author used AI-assisted tools during the preparation of this manuscript, consistent with the Journal's guidelines on permissible use. Claude was used to organise research notes and summarise background material, including statutory provisions, regulatory materials, and case law gathered through the author's own research, while Grammarly was used for grammar, language clarity, and sentence-level proofing. Neither tool was used to generate legal analysis, arguments, case law interpretation, research conclusions, or policy recommendations, or to draft any substantive section of the manuscript. All legal reasoning, analysis, and conclusions presented are the author's own original work.

Abstract

The rapid growth of processed foods, health supplements, and packaged goods in India has made food safety law far more complex than traditional adulteration control. Under the Food Safety and Standards Act (FSSA), 2006, the Food Safety and Standards Authority of India (FSSAI) constantly struggles to define clear legal boundaries between everyday food products, nutraceuticals, and actual medicines governed by the Drugs and Cosmetics Act, 1940. This paper examines the legal and regulatory framework governing India's food sector, with a specific focus on jurisdictional overlaps between FSSAI and the Central Drugs Standard Control Organisation (CDSCO). It evaluates statutory conflicts and the principle of overriding effect under Section 89 of the FSSA, 2006, as interpreted by the Supreme Court in Manik Hiru Jhangiani v. State of Madhya Pradesh (2023). Furthermore, the study analyses the practical enforcement of the FSS (Labelling and Display) Regulations, 2020, examining recent crackdowns on deceptive packaging, misleading health claims, and judicial pushes toward mandatory Front-of-Pack Warning Labels (FOPL). Finally, it investigates the operational and economic challenges faced by Food Business Operators (FBOs) navigating licensing under the Food Safety Compliance System (FoSCoS) portal. By analysing core statutory provisions and evolving judicial trends, this article highlights structural gaps in India's food safety ecosystem and proposes practical legal reforms to balance public health protection with commercial growth.

Keywords: FSSAI, Food Safety and Standards Act 2006, Health Supplements, Nutraceuticals, FoSCoS, Front-of-Pack Labelling.

I. Introduction: The Evolution of Food Jurisprudence in India

The Indian dietary landscape has undergone a radical transformation over the past two decades, transitioning from traditional, whole-food consumption to a heavy reliance on ultra-processed commodities, fortified staples, and functional health supplements. This shift has fundamentally altered the mandate of food safety laws, which traditionally focused on the mere prevention of adulteration. The enactment of the Food Safety and Standards Act (FSSA), 2006,[1] marked a watershed moment in Indian regulatory jurisprudence. By repealing the archaic Prevention of Food Adulteration Act, 1954,[2] and consolidating eight disparate sectoral laws under a single statutory umbrella, the legislature sought to establish a science-based regulatory framework.[3] The Food Safety and Standards Authority of India (FSSAI) was thus born,[4] tasked with laying down standards for food articles and regulating their manufacture, storage, distribution, sale, and import to ensure the availability of safe and wholesome food for human consumption.

However, as the market for wellness products expands, the regulatory architecture faces an unprecedented challenge. The boundaries separating everyday food, dietary supplements, nutraceuticals, and pharmaceutical drugs have become increasingly porous. Manufacturers frequently exploit this statutory ambiguity, leading to jurisdictional friction between the FSSAI and the Central Drugs Standard Control Organisation (CDSCO). This article critically examines the legal complexities inherent in this food-pharma divide. It analyses the statutory overlaps governing health supplements, the economic realities of corporate compliance under the Food Safety Compliance System (FoSCoS) portal, and the evolving judicial scrutiny over deceptive marketing and nutritional labelling. Ultimately, the paper seeks to highlight the structural lacunae in the current framework and proposes legislative harmonisation to safeguard public health without stifling market innovation.

II. The Jurisdictional Friction: Food, Nutraceutical, or Drug?

A. Statutory Overlaps under FSSA, 2006 and the Drugs & Cosmetics Act, 1940

The most contentious legal battleground in contemporary Indian food law revolves around the statutory classification of borderline products. The core conflict stems from the parallel

[1] The Food Safety and Standards Act, 2006, No. 34, Acts of Parliament, 2006 (India).
[2] The Prevention of Food Adulteration Act, 1954, No. 37, Acts of Parliament, 1954 (India) [Repealed].
[3] The Food Safety and Standards Act, 2006, § 97, No. 34, Acts of Parliament, 2006 (India) (repealing the Fruit Products Order, 1955; Prevention of Food Adulteration Act, 1954; Meat Food Products Order, 1973; Vegetable Oil Products (Control) Order, 1947; Edible Oils Packaging (Regulation) Order, 1998; Solvent Extracted Oil, De-oiled Meal and Edible Flour (Control) Order, 1967; and Milk and Milk Products Order, 1992)
[4] *Id.*, § 4.

operation and overlapping definitions of two distinct legislative frameworks: the Food Safety and Standards Act, 2006, and the Drugs and Cosmetics Act, 1940. Section 3 (1)(j) of the FSSA defines "food" in expansive terms as any substance, whether processed, partially processed, or unprocessed, intended for human consumption.[5] Crucially, Section 22 of the FSSA explicitly brings under the regulatory fold specific specialized categories: "genetically modified articles of food, food for special dietary uses, functional foods, nutraceuticals, health supplements, novel foods and such other articles of food."[6]

Conversely, Section 3(b) of the Drugs and Cosmetics Act, 1940, defines a "drug" to include all medicines intended for internal or external use of human beings or animals, and all substances intended to be used for or in the diagnosis, treatment, mitigation, or prevention of any disease or disorder in human beings.[7] The interpretative dilemma arises when a product, such as a concentrated vitamin capsule, an herbal extract gummy, or a fortified protein powder straddles both definitions. If a product is classified as a food supplement, it falls under the jurisdiction of the FSSAI, where regulatory compliance is predominantly self-declaratory and governed by standard food safety parameters. If, however, the same product is classified as a drug, it triggers the stringent regime of the CDSCO, requiring exhaustive clinical trials, manufacturing licenses under Schedule M of the Drugs and Cosmetics Rules, and price controls under the Drugs (Prices Control) Order.[8]

To mitigate this ambiguity, the FSSAI promulgated 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.[9] These regulations established crucial legal boundaries:

1. **Therapeutic Claim Restrictions:** Health supplements and nutraceuticals must not claim to cure, treat, or mitigate any specific disease, illness, or medical condition. Any explicit or implicit claim of a curative nature legally strips the product of its "food" status and reclassifies it as a drug.

[5] The Food Safety and Standards Act, 2006, § 3(1)(j), No. 34, Acts of Parliament, 2006 (India).
[6] *Id.*, § 22.
[7] The Drugs and Cosmetics Act, 1940, § 3(b), No. 23, Acts of Parliament, 1940 (India).
[8] The Drugs and Cosmetics Rules, 1945, Schedule M (Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products).
[9] Food Safety and Standards Authority of India, Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016, Gaz. of India, Extraordinary, Pt. III, Sec. 4 (Dec. 23, 2016).

2. **Recommended Dietary Allowance (RDA) Thresholds:** The nutrient content (vitamins, minerals, and amino acids) present in health supplements must not exceed the Recommended Dietary Allowance (RDA) limits formulated by the Indian Council of Medical Research (ICMR) and National Institute of Nutrition (NIN).[10] Where a product's formulation exceeds 100% of the daily RDA threshold, or where it contains ingredients possessing therapeutic properties, it automatically falls into the domain of pharmaceutical regulation.

Despite these regulatory benchmarks, statutory arbitrage remains widespread among Food Business Operators (FBOs). Corporate entities frequently structure their labelling and promotional claims to remain marginally below therapeutic thresholds. By framing disease prevention as general "immunity boosting" or "vitality enhancement," brands enjoy the low compliance burden of food registration while effectively marketing their products as medical remedies to consumers. This regulatory grey area poses dual risks: consumers are exposed to under-regulated products possessing potent biological activity, while legitimate pharmaceutical companies face market distortion from loosely regulated health supplement manufacturers.

B. The Doctrine of Overriding Effect: Section 89 of FSSA

The coexistence of multiple statutes regulating consumable substances inevitably leads to jurisdictional clashes between state authorities prosecuting companies under parallel laws. This conflict was decisively addressed by the judiciary through the interpretation of Section 89 of the FSSA, 2006. Section 89 contains an explicit *non-obstante* clause, declaring that the provisions of the FSSA shall have an overriding effect, notwithstanding anything inconsistent contained in any other law for the time being in force or any instrument having effect by virtue of any law other than this Act.[11]

The full judicial scope of Section 89 was evaluated by the Supreme Court of India in the landmark decision of *Manik Hiru Jhangiani v. State of Madhya Pradesh (2023)*.[12] In this case, proceedings were initiated against corporate officers under both the older provisions of the Prevention of Food Adulteration Act, 1954, and general provisions of the Indian Penal Code, 1860, following allegations of misbranding and sub-standard food distribution. The key legal question before the apex court was whether an FBO could be subjected to concurrent

[10] Indian Council of Medical Research & National Institute of Nutrition, Nutrient Requirements and Recommended Dietary Allowances for Indians: A Report of the Expert Group (ICMR-NIN 2020).
[11] The Food Safety and Standards Act, 2006, § 89, No. 34, Acts of Parliament, 2006 (India).
[12] *Manik Hiru Jhangiani v. State of Madhya Pradesh*, (2023) 15 SCC 694 (India), https://indiankanoon.org/doc/52425433/

prosecution under parallel penal provisions when the alleged act fell squarely within the regulatory ambit of the FSSA.

The Supreme Court carefully analysed the legislative intent behind consolidating food safety laws into a single code. Delivering the judgment, the Court held that the enactment of the FSSA was intended to occupy the entire field of food safety jurisprudence in India. By virtue of Section 89, the provisions of the FSSA override any inconsistent statutory provisions contained in other enactments concerning food standards and offenses. The Court clarified that where a specific statutory code provides a complete mechanism for investigation, adjudication, and penalization of an offense. This ruling firmly cemented the doctrine of single-window statutory jurisdiction under FSSAI, preventing double jeopardy and establishing that technical violations of food standards must be resolved strictly within the statutory framework of the FSSA, 2006.

III. Labelling Dynamics, Deceptive Marketing, and Consumer Protection

A. Statutory Framework under the FSS (Labelling and Display) Regulations, 2020

Packaging and labelling constitute the primary medium of communication between a Food Business Operator and the end consumer. Under Section 23 of the FSSA, no person is permitted to manufacture, distribute, sell, or import any packaged food article that is not labelled in accordance with regulations made under the Act.[13] To modernize labelling requirements in line with international Codex Alimentarius standards, FSSAI notified the Food Safety and Standards (Labelling and Display) Regulations, 2020, replacing the older 2011 labelling rules.[14]

The 2020 Regulations introduced comprehensive, mandatory display mandates for all packaged food products sold within the Indian territory:

1. **Mandatory Nutritional Disclosures:** Labels must explicitly state energy value (kcal), alongside total fat, saturated fat, trans fat, added sugars, sodium, and protein per 100 grams or 100 millilitres of the product, as well as per-serve contribution to Recommended Dietary Allowance (RDA) percentages.
2. **Allergen Information:** Explicit declarations are mandatory if a food article contains known allergens, including gluten, crustaceans, eggs, fish, peanuts, soybeans, milk, or tree nuts.
3. **Symbolic Identifiers:** The regulations updated the mandatory green filled-circle within a green square for vegetarian food, and introduced a brown filled-triangle within a

[13] The Food Safety and Standards Act, 2006, § 23, No. 34, Acts of Parliament, 2006 (India).
[14] Food Safety and Standards Authority of India, Food Safety and Standards (Labelling and Display) Regulations, 2020, Gaz. of India, Extraordinary, Pt. III, Sec. 4 (Dec. 14, 2020).

brown square for non-vegetarian food, ensuring immediate visual identification for Indian consumers.

4. **Date Markings:** The traditional "Best Before" indication was reinforced with a mandatory "Use By" or "Expiry Date" declaration, placing strict legal liability on retailers and distributors who display expired products for sale.

B. Deceptive Marketing Practices and Misleading Claims

Despite detailed labelling requirements, commercial marketing strategies routinely exploit consumer gaps in scientific literacy. Driven by the financial margins of the "health and wellness" market, corporate entities often engage in sophisticated, deceptive claims. Section 24 of the FSSA strictly prohibits misleading claims and deceptive advertising, stipulating that no person shall make any representation, whether orally, in writing, or by visual representation, that falsely implies a product possesses quality, quantity, grade, or efficacy that it does not actually hold.[15]

To operationalize Section 24, FSSAI enacted the Food Safety and Standards (Advertising and Claims) Regulations, 2018.[16] Under these rules, absolute terminology, such as "100% pure," "natural," "fresh," "authentic," or "real" is strictly regulated. For example:

- A brand cannot market reconstituted fruit juice concentrates as "100% Fresh Juice."
- Products using synthetic additives or chemical preservatives are legally barred from using the term "Natural" on front-of-pack displays.
- Claims asserting "immunity building" or "health enhancement" require prior scientific substantiation through verified clinical data approved by FSSAI panel committees.

In recent years, FSSAI has issued sweeping administrative directives against major commercial brands. Notable crackdowns include forcing multi-national beverage brands to drop terms like "health drink" from proprietary cereal-malt products, as well as directing dairy and beverage processing companies to re-label reconstituted dairy drinks that misrepresent their fresh milk content.

C. Front-of-Pack Labelling (FOPL) and Constitutional Jurisprudence

While back-of-pack numerical tables fulfil basic legal compliance, empirical research demonstrates that the majority of Indian consumers do not read or interpret complex quantitative nutritional tables located at the back of packages. Consequently, the legal focus has shifted toward **Front-of-Pack Labelling (FOPL)**, a system requiring direct, high-visibility

[15] The Food Safety and Standards Act, 2006, § 24, No. 34, Acts of Parliament, 2006 (India).
[16] Food Safety and Standards Authority of India, Food Safety and Standards (Advertising and Claims) Regulations, 2018, Gaz. of India, Extraordinary, Pt. III, Sec. 4 (Nov. 19, 2018).

warning symbols or interpretative ratings on the front display panel of foods high in fat, sugar, and salt (HFSS).

The regulatory journey toward FOPL in India has been characterized by intense corporate lobbying and institutional delays. FSSAI initially proposed the Indian Nutrition Rating (INR) system, modelled on a 5-star rating mechanism. However, public health advocates and medical associations strongly criticized star-rating models, arguing that they allow food manufacturers to "offset" high sugar or sodium content by artificially fortifying products with synthetic fibre or vitamins, thereby securing an unmerited 3 or 4-star rating. Consumer advocacy groups have consistently demanded mandatory **Front-of-Pack Warning Labels (FOPWL)**, such as black hexagonal warning seals explicitly stating "HIGH IN SUGAR" or "HIGH IN SODIUM" similar to models implemented in Latin American jurisdictions like Chile and Mexico.

This institutional impasse reached the judiciary in the Public Interest Litigation (PIL) case of *3S and Our Health Society v. Union of India.*[17] The petitioners approached the Supreme Court under Article 32 of the Constitution of India, arguing that FSSAI's prolonged failure to mandate explicit Front-of-Pack Warning Labels violated the fundamental right to life and health guaranteed under Article 21.[18] The petitioners contended that in a nation facing an unprecedented surge in non-communicable lifestyle diseases, such as type-2 diabetes, hypertension, and cardiovascular disorders, the right to informed dietary choice is an integral component of the right to health. The Supreme Court's active judicial monitoring in this matter has exerted immense pressure on FSSAI, establishing a critical constitutional doctrine: food labelling standards are not merely commercial regulations; they directly intersect with the State's constitutional obligation to raise the level of nutrition and public health under Article 47 of the Directive Principles of State Policy.[19]

IV. The Economics of Corporate Compliance: Establishing a Food Enterprise

A. The FoSCoS Legal Architecture and Licensing Dynamics

The enforcement of statutory standards must be evaluated alongside the economic mechanics of running a commercial business. To streamline regulatory interactions for Food Business Operators (FBOs), FSSAI phased out its legacy Food Licensing and Registration System

[17] *3S and Our Health Society v. Union of India*, W.P.(C) No. 437/2024 (India) (disposed of Apr. 9, 2025), https://indiankanoon.org/doc/160707635/

[18] INDIA CONST. art. 21.

[19] INDIA CONST. art. 47.

(FLRS) and launched the **Food Safety Compliance System (FoSCoS)** portal.[20] Designed as an integrated, digital, single-window compliance platform, FoSCoS maps regulatory requirements directly to standardized food product categories.

Under Section 31 of the FSSA, no person is permitted to commence or carry on any food business without obtaining an FSSAI license or registration.[21] The statutory licensing framework is divided into three distinct legal tiers based on operational scale and financial turnover. While FoSCoS has successfully digitized the submission of applications, annual returns (such as Form D1 for manufacturers), and modification requests, the substantive economic burden of compliance remains high, particularly for Micro, Small, and Medium Enterprises (MSMEs).

B. Statutory Liabilities under Section 26 and Product Approval Hurdles

Section 26 of the FSSA establishes an onerous regime of strict liability for Food Business Operators.[22] It mandates that every manufacturer, packer, wholesaler, distributor, and seller is personally responsible for ensuring that the food product satisfies all statutory requirements at every stage of production, processing, and distribution. If an FBO introduces a functional food or proprietary ingredient that does not conform to standardized categories in the FSSA schedules, it must undergo the rigorous **Product Approval Procedure** under the Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2017.[23] For large corporate entities and multinational corporations (MNCs), funding clinical safety dossier testing, heavy metal residue screening, and shelf-life stability analysis represents a routine operational expense. For domestic start-ups and small-scale processors, however, the financial costs of securing non-specified product approvals can be economically prohibitive, delaying commercial market launch by months or years.

C. Procedural Safeguards and the Principles of Natural Justice

Because the regulatory powers granted to Food Safety Officers (FSOs) under **Section 38 of the FSSA,** including powers of search, seizure, sample collection, and business closure are expansive, the law requires strict adherence to procedural fairness.[24] Arbitrary exercise of executive authority can cause severe commercial harm to an enterprise.

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[20] Food Safety and Standards Authority of India, Guidance Document on Food Safety Compliance System (FoSCoS), Operational Order F. No. 15(31)2020/FoSCoS/RCD/FSSAI (Issued May 28, 2020).
[21] The Food Safety and Standards Act, 2006, § 31, No. 34, Acts of Parliament, 2006 (India).
[22] *Id.*, § 26.
[23] Food Safety and Standards Authority of India, Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2017, Gaz. of India, Extraordinary, Pt. III, Sec. 4 (Sept. 11, 2017).
[24] The Food Safety and Standards Act, 2006, § 38, No. 34, Acts of Parliament, 2006 (India).

The landmark precedent governing executive overreach in food regulation is the decision of the Bombay High Court in *Nestle India Limited v. Food Safety and Standards Authority of India (2015).*[25] This dispute arose out of the nationwide ban imposed by FSSAI on Maggi noodles following allegations that product samples contained lead levels exceeding statutory limits and undeclared monosodium glutamate (MSG). FSSAI issued an executive order directing the immediate withdrawal and destruction of all product variants across the country.

Nestle India challenged the order before the High Court, asserting that FSSAI had violated the fundamental principles of natural justice (*audi alteram partem*) by issuing an order of such severe economic consequence without issuing a proper show-cause notice or granting the company an opportunity to present independent laboratory test findings. Furthermore, the petitioner argued that the accredited laboratories utilized by the regulatory authority were not legally recognized under Section 43 of the FSSA at the time the sample testing occurred.[26]

The Bombay High Court set aside the ban order, ruling that while the FSSAI possesses broad statutory powers to protect public health, such executive powers must be exercised within the boundaries of constitutional fairness and administrative law. The Court reaffirmed three critical legal principles:

1. **Right to a Fair Hearing:** Even in cases involving public health emergencies, administrative authorities must provide FBOs a fair opportunity to show cause unless an immediate, demonstrable public threat is proven.
2. **Statutory Laboratory Accreditation:** Sample analysis must be conducted strictly in laboratories officially accredited by the **National Accreditation Board for Testing and Calibration Laboratories (NABL)** and notified under **Section 43 of the Act**; non-compliant testing renders administrative sanctions legally unsustainable.
3. **Proportionality of Administrative Action:** Executive bans must be proportionate to the empirical risk established, preventing arbitrary corporate destruction under the guise of regulatory discretion.

V. Penalties, Adjudication, and Enforcement Mechanisms

To ensure enforcement, the FSSA provides a dual system of civil adjudication and criminal prosecution, distinguishing minor technical violations from severe health hazards.

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[25] *Nestle India Ltd. v. Food Safety & Standards Auth. of India*, 2015 SCC OnLine Bom 4713 (India), https://indiankanoon.org/doc/66718388/

[26] The Food Safety and Standards Act, 2006, § 43, No. 34, Acts of Parliament, 2006 (India).

1. **Civil Adjudication (Pecuniary Penalties):** Offences that do not cause direct bodily injury, such as selling sub-standard food (Section 51), misbranded food (Section 52), or operating without a valid license (Section 63) are adjudicated by an Adjudicating Officer (AO), typically an officer of Additional District Magistrate (ADM) rank.[27] The AO has the power to levy monetary fines up to ₹10 Lakhs, providing an efficient civil mechanism that avoids clogging traditional criminal courts.
2. **Criminal Prosecution (Imprisonment): Section 59 of the FSSA** governs the manufacturing, storage, sale, or import of **unsafe food**.[28] If consumption of an unsafe food item results in illness, severe injury, or death, the matter is referred to a Special Court presided over by a Judicial Magistrate. Penalties range from rigorous imprisonment of six months to life imprisonment, accompanied by mandatory compensation to victims or their legal heirs under **Section 65**.[29]

This bifurcated structure ensures that technical errors (such as minor labelling oversights) are resolved through administrative fines, while deliberate endangerment of public safety is met with strict criminal liability.

VI. Policy Recommendations and Conclusion

India's food safety regulatory architecture is at a critical juncture. While the FSSA, 2006, successfully unified fragmented laws, the rapid growth of functional foods and wellness formulations has created distinct statutory gaps.

To clarify the food-pharma divide and build a more effective regulatory system, several key reforms should be pursued:

1. **Joint FSSAI-CDSCO Standing Committee:** Parliament should amend Section 22 of the FSSA to establish an institutional inter-agency committee with statutory authority to issue binding classifications for borderline nutraceutical and wellness formulations.
2. **Mandatory Front-of-Pack Warning Labels (FOPWL):** Regulators should replace voluntary star-rating proposals with mandatory, interpretative warning seals for products exceeding limits for added sugar, saturated fats, and sodium, giving effect to the right to health under Article 21.

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[27] *Id.*, §§ 50–58, 68.
[28] *Id.*, § 59.
[29] *Id.*, § 65.

3. **Decentralized Testing Support for MSMEs:** To ease compliance under FoSCoS, the Central Government should expand state-level accredited testing infrastructure and provide subsidized screening facilities for small food business operators.
4. **Liability Standards for Digital Marketplaces:** Section 24 of the FSSA should be updated to establish clear intermediary liabilities for e-commerce and quick-commerce platforms distributing misbranded food products or hosting unverified health claims.

An effective food regulatory framework must balance rigorous public health protections and nutritional transparency with a predictable, fair operating environment for commercial enterprises.