International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 32, Issue 1, January 2026 **ijppr.humanjournals.com** ISSN: 2349-7203

Regulatory Practices and Compliance Challenges of Nutraceuticals in India

Bharti, Shivali Rahi*, Sudhir Kaushik, Ashutosh Upadhayay

School of Pharmaceutical Sciences, MVN University, Palwal, Haryana- 121105 India.

Received: 20 November 2025 Revised: 29 November 2025 Accepted: 21 December 2025

ABSTRACT

The nutraceutical industry in India is expanding rapidly due to increased health awareness, lifestyle changes, and a growing burden of chronic diseases. Nutraceuticals are regulated by the Food Safety and Standards Authority of India (FSSAI) under the Food Safety and Standards Act, 2006, and the Food Safety and Standards (Health Supplements, Nutraceuticals, FSMP, FSDU, Functional and Novel Food) Regulations, 2016 (revised in 2022). This review outlines the current regulatory framework, covering product classification, permitted ingredients, labelling, health claims, manufacturing practices, and post-market surveillance, along with recent updates such as revised ingredient schedules, digital licensing, and enhanced enforcement. Despite a robust framework, compliance challenges persist, including misclassification, misleading claims, labelling violations, use of non-permitted ingredients, adulteration, and GMP non-compliance. A case example of illegal protein supplement manufacturing highlights enforcement gaps. Strengthening regulatory enforcement, Nutri vigilance, risk-based inspections, and industry accountability is essential to ensure consumer safety and support sustainable sector growth in India.

Keywords: Nutraceuticals; Regulatory framework; FSSAI; Compliance challenges; Labelling and claims; Food safety.

1. INTRODUCTION

Economic growth has enhanced living standards by improving income, consumption patterns, and lifestyle choices. However, this progress has also introduced a significant challenge in the form of lifestyle-related diseases. One of the earliest areas affected by these lifestyle shifts has been dietary habits(1) The relationship between food and its role in preventing and managing various health conditions is well established.(2) This perspective emphasizes that our dietary choices can profoundly influence health outcomes. The concept of using food therapeutically dates back millennia, with traditional practices employing herbs, plants, and natural foods to treat ailments and promote recovery. Even today, nutrition is widely recognised as a key determinant of physiological function and overall well-being.(3) With global populations ageing and chronic illnesses becoming more prevalent, there is a growing demand for health-promoting food products. Traditional systems such as Ayurveda and Chinese medicine have long advocated the use of food as both a preventive and therapeutic approach to disease management.(4)

Nutraceuticals are bioactive, nutrient-rich compounds that bridge the gap between diet and medicine, providing health benefits beyond basic nutrition. (5) In India, the nutraceuticals market reached USD 8.78 billion in 2024 and is expected to grow at a compound annual growth rate (CAGR) of 13.10%, reaching USD 23.51 billion by 2032. Key drivers of this growth include an ageing population, rising incidence of lifestyle diseases such as diabetes and cardiovascular disorders, higher disposable incomes, and the proliferation of e-commerce platforms that improve consumer access.(6) Modern nutraceuticals have moved from traditional use to a scientifically validated field, with product efficacy and safety supported by research, technological advancements, and evidence-based studies.(7,8) Dietary patterns have a profound effect on quality of life, emphasising the critical role of nutrition in maintaining health. Consequently, awareness of the link between food intake and long-term health outcomes has increased, particularly in the context of rising chronic disease prevalence.(9) Unlike conventional pharmaceuticals, which aim to treat or manage specific medical conditions, nutraceuticals are primarily focused on disease prevention and the enhancement of overall wellness. This preventive approach aligns with the global trend toward holistic and personalised healthcare, which prioritises addressing underlying causes rather than merely treating symptoms.(10,11)

Nutraceuticals exist at the intersection of public health and commercial markets. When effectively regulated, they can contribute to nutrition security, mitigate micronutrient deficiencies, and complement the management of lifestyle-related diseases. Poor regulatory oversight, however, can lead to misleading claims, contamination, and confusion between therapeutic claims (which are restricted to drugs) and allowable nutritional or structure/function claims. Clear regulation and rigorous enforcement are therefore critical for consumer safety and industry credibility.(12)

International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 32, Issue 1, January 2026 ijppr.humanjournals.com ISSN: 2349-7203

Several developments make a timely regulatory review necessary as:

- FSSAI's operational directions and compendium updates since 2016 continue to refine regulatory coverage (including directions operationalising categories and lists).

- Government policy initiatives (including the introduction of PLI incentives for nutraceuticals) and trade facilitation (HSN code efforts and industry panels) are reshaping the landscape.(13)

- Enforcement campaigns and consumer complaint tools have increased scrutiny of claims, labelling, and product compliance. Together, these changes mean regulators and industry must adapt compliance strategies quickly. (14)

1.1 Global and Indian Nutraceutical Market Overview

The nutraceutical industry has witnessed significant global growth in recent years, driven by increasing consumer awareness of preventive healthcare, dietary supplementation, and lifestyle-related disorders. This expansion reflects a growing shift toward nutrition-based health management across both developed and emerging economies.

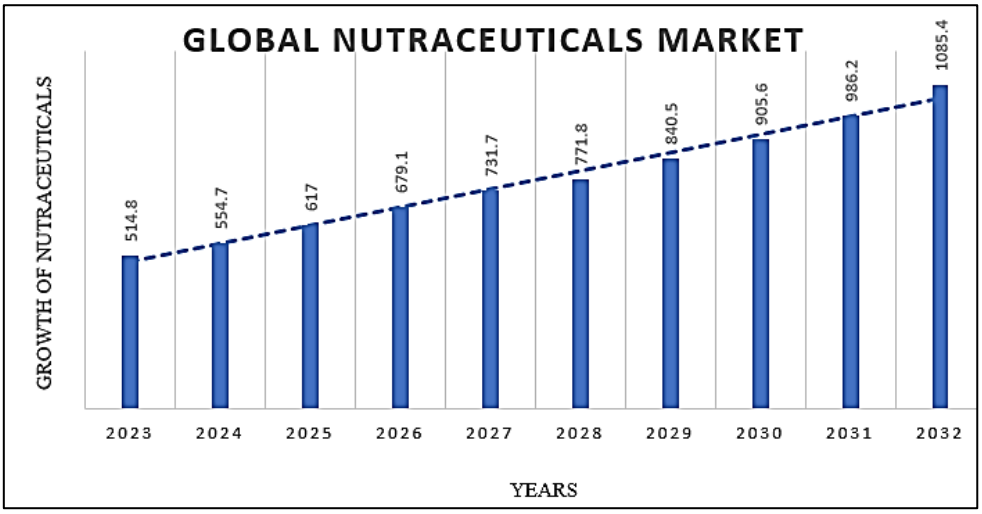

Figure 1. Global Nutraceuticals Market Size, 2022-2032 USD Billion(15)

The global nutraceutical market size and projected growth trends are illustrated in **Figure 1**, which demonstrates a steady increase in market value over the forecast period, indicating sustained consumer demand and continued industry expansion. This growth is primarily driven by rising health consciousness, increasing prevalence of chronic diseases, and growing interest in functional foods and dietary supplements. (15)

Similarly, the Indian nutraceutical sector has experienced substantial growth, driven by increasing disposable incomes, urbanization, and a rising burden of lifestyle-related disorders. (16) The growth pattern of the Indian nutraceutical market is presented in **Figure 2**, highlighting a strong shift toward preventive healthcare in response to increasing rates of diabetes, obesity, cardiovascular diseases, and immune-related conditions**.** (17) Product segments such as functional beverages, digestive health supplements, and weight-management formulations are witnessing the fastest expansion, supported by evolving urban lifestyles and demand for convenient nutrition solutions. The rapid growth of e-commerce and direct-to-consumer (D2C) platforms has further accelerated market penetration, enabling broader consumer access through digital health platforms and subscription-based models. (15) Government institutions, including the Ministry of Food Processing Industries (MoFPI), have also emphasized the sector's long-term growth potential through increased R&D investment, quality enhancement initiatives, and consumer awareness programs. (18)

International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 32, Issue 1, January 2026 ijppr.humanjournals.com ISSN: 2349-7203

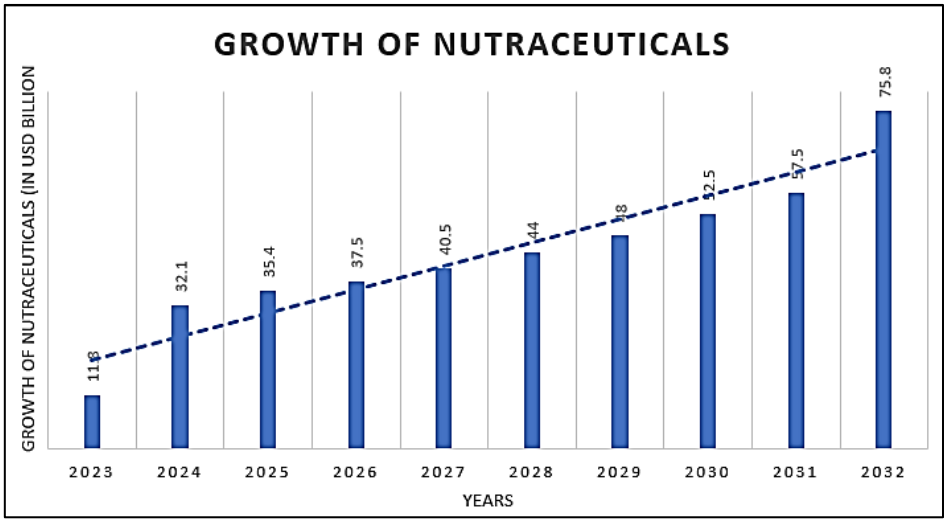

Figure 2. Market growth of nutraceuticals in India(17)

In view of the rapid expansion of the nutraceutical sector and the evolving regulatory landscape in India, this review aims to critically examine the current regulatory framework governing nutraceuticals, identify key compliance challenges, and analyse recent enforcement cases to identify regulatory gaps. The study seeks to provide insights that can support stronger regulatory oversight, improved compliance, and enhanced consumer protection in the Indian nutraceutical market.

2. Regulatory framework governing Nutraceuticals in India

In India, the regulation of nutraceuticals is primarily administered by the Food Safety and Standards Authority of India (FSSAI) under the Food Safety and Standards (FSS) Act, 2006. (19) This act serves as the legal foundation for regulating all types of food products, including those making nutritional, health, or as well as prebiotic and probiotic foods.

a) Nutraceuticals Regulations, 2016: The first major regulation specific to nutraceuticals was 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. These rules provided clear definitions and classifications for nutraceuticals and related categories. They also outlined permissible ingredients, allowable limits, labelling requirements, claims, and manufacturing standards.

b) **Revised Nutraceutical Regulations, 2022**: In March 2022, FSSAI updated the regulatory framework through its directive on functional claims. These include nutraceuticals, health supplements, functional foods, foods for special medical purposes, foods for specific dietary uses (Std/SP-05/T(Nutraceutical-2022)), resulting in the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, and Prebiotic and Probiotic Food) Regulations, 2022. This revision clarified definitions and product classifications and updated ingredient schedules to reduce ambiguity. The updated framework provided greater clarity on which products qualify as nutraceuticals and the specific regulatory categories under which they fall.

2.1 Labelling Requirements for Nutraceuticals in India

Labelling is a critical and often challenging component of nutraceutical products, as it directly influences consumer awareness, transparency, and product safety. In India, nutraceutical labels must comply with the Food Safety and Standards (Labelling and Display) Regulations, in addition to the specific provisions outlined under the Nutraceutical Regulations. (20)

Each nutraceutical product is required to display essential information, including the product name, complete list of ingredients, nutritional information per serving, recommended usage, serving size, allergen declarations, precautionary statements, and storage conditions. Clear and accurate labelling enables consumers to make informed choices and reduces the risk of misuse or overconsumption. (21) Mandatory display of the FSSAI logo and valid licence number is required on all nutraceutical labels, as stipulated under the Food Safety and Standards Act, 2006. The licence number facilitates traceability of the manufacturer or marketer, while the logo serves as an assurance of regulatory compliance. Absence, misrepresentation, or incorrect display of these elements is considered misbranding and may attract regulatory action.(22)

2.2 Regulations of Claims

Health-related claims on nutraceutical products in India are strictly regulated by the Food Safety and Standards Authority of India (FSSAI) to prevent misleading information and protect consumers. Unlike pharmaceutical products, nutraceuticals are not permitted to claim treatment or cure of diseases.

FSSAI permits the following categories of claims:

- **Health Claims:** Claims that describe a relationship between a nutrient or substance and a health benefit, permitted only when scientifically substantiated and approved under FSSAI regulations.

- **Nutrient Content Claims:** Statements that indicate the level of a nutrient present in a product, such as "high protein" or "low fat," in accordance with prescribed limits.

- **Structure/Function Claims:** Claims that describe the role of a nutrient or ingredient in supporting normal physiological functions (e.g., "supports immunity" or "helps muscle maintenance"), provided they do not imply disease prevention or treatment. (23)

Evaluation of claims is undertaken through established regulatory mechanisms, including scientific scrutiny by the Committee on Claims and Food Labelling (CCFL). (24) In addition, advertising and promotional materials are monitored by the Advertising Standards Council of India (ASCI) to ensure compliance with ethical advertising standards.

2.3 Safety Monitoring and Post-Market Surveillance

Sampling and Testing: FSSAI and state food authorities conduct random sampling from the market (retail or production) to test for labelling compliance, purity (heavy metals, contaminants), potency, and misbranded products.(25)

Adverse Event Reporting / Consumer Complaints: FBOs (Food Business Operators) are expected to maintain records and respond to consumer complaints or observed adverse reactions; documents should be available for inspection. Claims based on adverse events need to be evaluated scientifically.(26)

Enforcement Actions: Non-compliance can result in product recalls, license suspension or cancellation, penalties, or prosecution under the FSS Act. FSSAI has also instituted enforcement drives to monitor compliance specifically for nutraceuticals and health supplements.(27)

A consolidated overview of the regulatory framework governing nutraceuticals in India, as defined under various Food Safety and Standards Authority of India (FSSAI) regulations, is provided in Table 1 which outlines ten major regulatory domains that every nutraceutical manufacturer, importer, and marketer must comply with.

Table 1. Regulatory framework governing nutraceuticals in India

Section / Requirement	Regulatory Requirement	Authority	References
Product Category Determination	Classify products such as Health Supplement, Nutraceutical, Food for Special Dietary Use (FSDU), Food for Special Medical Purpose (FSMP), Functional Food, or Novel Food as per the 2016 Regulations.	FSSAI Directions on Operationalization.	(19)
Borderline Classification & Food–Drug Interface	Clarify whether a product is regulated as a Food (FSSAI), Drug (CDSCO), or AYUSH preparation; apply classification criteria for high-potency vitamins, botanicals, probiotics, amino acids, and traditional preparations.	FSSAI Directions (2022–2024); CDSCO Drug–Food Interface Committee; Ministry of Health & Family Welfare (MoHFW).	(28)

Ingredient Compliance & Schedules	Use only ingredients permitted under Schedules I–VIII / VA, follow upper limits for vitamins, minerals, botanicals, probiotics, prebiotics, amino acids, and additives.	FSSAI Nutraceutical Schedules (Compendium of Food Category Regulations).	(29)
Labelling Requirements	Mandatory elements: product name, ingredient list, nutritional facts, serving size, recommended usage, allergy statements, warnings, storage conditions, FSSAI logo + 14-digit license.	FSSAI Nutraceutical Regulations, 2022; FSS (Labelling & Display) Regulations, 2020.	(30)
Claims & Advertising Compliance	Only permitted health, nutrient content, and structure/function claims allowed. Therapeutic and disease-cure claims are prohibited. Scientific substantiation mandatory.	FSSAI Claims Regulations; Advertising Standards Council of India (ASCI); CCFL (Committee on Claims & Food Labelling).	(31)
Manufacturing Practices	Must follow GMP, hygiene requirements, and Food Safety Management Systems (FSMS) under Schedule 4 and licensing conditions.	FSSAI Licensing & Registration Regulations; State Food Safety Authorities.	(32)
Digital Compliance Systems (FoSCoS, Food Safety Connect & e-Labs)	Mandatory use of FoSCoS (Food Safety Compliance System) for licensing, renewals, inspections, returns; enable digital complaint reporting via Food Safety Connect App; integrate lab testing through e-Labs.	FSSAI (FoSCoS Operational Manual 2023); Press Information Bureau (PIB), 2022 Launch.	(33)
Testing & Quality Standards	Mandatory testing for contaminants, heavy metals, pesticides, microbiological limits, and nutrient compliance.	FSSAI Notified Laboratories; FSS Standards; FSSAI Food Testing & Referral Labs Network.	(34)
Import / Export Compliance	Import products must meet FSSAI ingredient schedules, labelling rules, customs HSN codes, and clearance procedures.	FSSAI Import Regulations; MoFPI Notifications; Press Information Bureau.	(35,36)
E-Commerce & Advertising Monitoring	Online nutraceuticals must follow same claim and label rules; marketplaces monitored for misleading claims.	FSSAI; ASCI Code; FoSCoS; Consumer Complaint Redressal System.	(14,37)
Safety Assessment & Pre-Market Approval	Safety assessment of botanicals, probiotics, prebiotics, and functional ingredients; Novel ingredients require FSSAI approval.	FSSAI 2016 Regulations; Novel Foods Framework.	(38)
Risk-Based Inspection & Surveillance	Implement risk-based inspection (RBI) model; prioritize high-risk nutraceutical categories; conduct targeted surveillance drives for mislabeling, adulteration, and misleading claims especially online.	FSSAI Risk-Based Inspection Circulars (2021–2024); FSSAI Enforcement Division.	(39)
Nutrivigilance & Post-Market Surveillance	Maintain adverse-event (AE) logs; report serious AEs; maintain recall plans; respond quickly to unsafe product complaints; follow recall protocols under 2017 guidelines.	FSSAI Food Recall Regulations (2017); FSSAI Nutraceutical Regulations (2016, 2022 Amendments).	(40)

Recall & Enforcement Compliance	Mandatory recall plan for unsafe or non-compliant products; state authorities can seize or destroy products.	FSSAI Food Recall Regulations, 2017.	(41)
Enforcement, Penalties & Recall Actions	Seize unsafe/misbranded products; suspend licenses; issue recall orders; conduct monthly enforcement actions; mandate compliance with recall procedures.	FSSAI Food Recall Regulations (2017); State Food Safety Departments; FSSAI Monthly Enforcement Reports (2022–2024).	(42)

3. Acts, schemes and government initiatives relevant to nutraceuticals in India

3.1 Primary legal instruments

- **Food Safety and Standards Act, 2006:** The principal Act establishing FSSAI and the framework for food safety regulation in India. The 2016 nutraceutical Regulations are under this Act.

- **Food Safety & Standards Regulations, 2016**: Consolidated the regulatory approach for functional foods and nutraceuticals; defines categories, labelling, schedules and permissible ingredients.

- **Food Recall Procedure Regulation, 2017**: Provides a mechanism for product recall and withdrawal for food safety reasons.(43)

3.2 Key government policy initiatives and schemes:

- **Production Linked Incentive (PLI) schemes:** The Government has introduced/extended PLI incentives to food processing and nutraceutical manufacturing to encourage domestic production and export competitiveness. Specific PLI measures for nutraceuticals (announced or discussed in government releases) provide capex and operational incentives for eligible units.(44)

- **HSN code development & export facilitation**: The Government has worked on harmonized coding for nutraceutical exports and created industry panels to improve policy outreach and trade facilitation. This helps standardize classifications for customs and trade.

- **Digital enforcement & consumer reporting**: FSSAI's Food Safety Connect / FoSCoS features allow consumers to file complaints about misleading claims and suspected unsafe products; this strengthens detection and enforcement.(14)

3.3 Complementary programs

- **Ayushman Bharat and preventive health**: Though not nutraceutical specific, national health programs that emphasise preventive care indirectly support nutraceutical adoption, and create market linkages for fortified foods and supplements in public health initiatives.(45)

- **Eat Right India (FSSAI movement/behaviour change campaign)**: FSSAI's national movement promoting safe, nutritious and sustainable food choices (launched 2018).
Why it matters: Eat Right sets consumer expectations about claims, labeling and reformulation; FSSAI uses it to drive acceptance of scientifically substantiated nutrition messaging and to reduce misleading claims.(46)

- **Ayushman Bharat Digital Mission (ABDM) & digital health platforms**: national digital health backbone for records and IDs.

Why it matters: digital health IDs and interoperability make it easier to integrate nutraceuticals in preventive health pathways, record adverse events, and, over time, link product use to outcomes data (relevant for post-market evidence).(47)

3.4 Consumer Protection Act, 2019 (and Central Consumer Protection Authority CCPA): consumer-protection law that covers misleading claims, unfair trade practices and product liability.

Why it matters: mis-leading health or "100%" claims, false advertising or unsafe products may attract action under consumer protection law in addition to FSSAI enforcement.(48)

4. Compliance challenges of Nutraceuticals in India

India's nutraceutical market is witnessing rapid expansion due to increasing health consciousness, lifestyle disorders, and a growing preference for preventive healthcare. However, this growth has been accompanied by persistent regulatory and compliance challenges. Despite the existence of an extensive regulatory framework under the Food Safety and Standards Authority of India (FSSAI), compliance failures remain widespread across the sector. These challenges not only compromise consumer safety and trust but also restrict India's ability to compete effectively in the global nutraceutical market.

a) One of the foremost challenges is the requirement for scientific substantiation of safety, quality, and efficacy. Manufacturers are expected to furnish adequate scientific evidence demonstrating that nutraceutical products are safe, therapeutically effective, and capable of delivering consistent benefits over a defined period. Establishing reproducibility of product quality through validated scientific mechanisms and reliable analytical techniques remains difficult, particularly for products containing complex or multi-ingredient formulations.(49)

b) Ingredient classification ambiguity continues to pose regulatory uncertainty. Nutraceuticals often fall into a grey zone between food, drug, and traditional medicine categories, confusing applicable regulations.(50) Although FSSAI's revised nutraceutical regulations attempted to streamline classifications such as health supplements and foods for special medical purposes, overlaps persist, especially for novel, proprietary, or high-potency ingredients. This ambiguity leads to licensing delays, inconsistent regulatory interpretations, and compliance risks for manufacturers.(51)

c) Another significant concern is the lack of standardization and testing infrastructure**.** India faces shortages of harmonized testing protocols for many nutraceutical ingredients, particularly those related to health-claim substantiation. The absence of standardized scientific methods makes it difficult for manufacturers to validate claims and for regulators to objectively assess them, weakening overall regulatory enforcement.(52)

d) The high cost of compliance further exacerbates these challenges, especially for micro, small, and medium enterprises (MSMEs). Regulatory requirements such as extensive safety dossiers, application fees, repeated scientific reviews, and certification obligations for both active ingredients and excipients increase financial burdens. In the past, stringent historical usage data requirements significantly raised entry barriers for innovation, disproportionately affecting smaller players.(53,54)

e) Misleading claims and mislabeling remain widespread despite regulatory oversight. Enforcement actions have revealed numerous cases of false or unsubstantiated claims, particularly in protein supplements, where products were found to contain substantially lower protein levels than declared. Such practices mislead consumers, pose health risks, and undermine confidence in regulatory compliance mechanisms. In recent years, thousands of substandard nutraceutical and dietary supplement samples have resulted in criminal cases filed by FSSAI, highlighting the scale of non-compliance in the sector.(55)

f) Quality control failures, adulteration, and contamination represent another critical compliance challenge. Instances of substandard products, undeclared additives, heavy metal contamination, and adulteration, especially in protein and herbal formulations, have been repeatedly reported. These issues directly threaten public health and significantly erode consumer trust in nutraceutical products.(28)

g) The sector also faces jurisdictional overlaps and regulatory friction among FSSAI, CDSCO, and the Ministry of AYUSH. Disputes over whether a product should be regulated as food, a drug, or a traditional formulation lead to enforcement inconsistencies, shifting policy interpretations, and uncertainty for manufacturers. Such overlaps complicate compliance planning and discourage long-term investment.(28)

h) Finally, weak post-market surveillance and recall mechanisms limit the effectiveness of regulatory oversight. Adverse-event reporting for nutraceuticals remains fragmented and underutilised, with limited awareness among consumers and healthcare professionals. Delays in identifying safety signals and initiating recalls allow potentially harmful products to remain in circulation longer than is acceptable. Although enforcement drives have been conducted, the lack of robust digital reporting systems and mandatory adverse-event documentation continues to hinder effective post-market control.(57)

5. Case studies findings

To contextualise the regulatory and quality control challenges discussed in our paper, two illustrative case studies are presented. These cases were selected to represent distinct but complementary dimensions of regulatory failure within India's protein supplement and nutraceutical market. The first case examines illegal, factory-level manufacturing and distribution of adulterated protein supplements operating entirely outside the licensing and regulatory framework. The second case draws on independent

analytical evidence from the Citizens' Protein Project, which evaluated the accuracy of label claims and the presence of contaminants in widely marketed protein supplements. Together, these case studies provide real-world evidence of systemic weaknesses in licensing enforcement, post-market surveillance, and supply-chain oversight. They are not intended to estimate prevalence or causality but to demonstrate how regulatory gaps translate into tangible public health risks and market distortions.

Taken together, the two case studies reveal a continuum of regulatory non-compliance in the protein supplement sector, ranging from overtly illegal manufacturing to substandard practices within formally marketed products. The Noida factory case highlights failures in upstream regulatory controls, including inadequate surveillance of manufacturing units, weak intelligence on illicit production networks, and insufficient oversight of e-commerce supply chains. The absence of licensing, quality testing, and traceability in this case represents a complete breakdown of preventive regulatory mechanisms.(58) (59) (60)

In contrast, the Citizen's Protein Project illustrates deficiencies in downstream regulatory controls, particularly post-market surveillance and enforcement of labelling standards. The high prevalence of protein mislabelling and the detection of contaminants suggest gaps in routine product testing, inconsistent compliance monitoring, and limited deterrence for violations. The coexistence of under-reported protein content, potential adulteration practices such as protein or amino spiking, and contamination with toxins or heavy metals underscores the inadequacy of current quality assurance mechanisms. (61) (62) (63) (64) (65)

Collectively, these cases demonstrate that regulatory challenges in the protein supplement market are not confined to isolated actors or informal sectors but reflect broader structural weaknesses across the regulatory lifecycle from manufacturing authorisation and supply-chain monitoring to product testing and consumer protection. The findings reinforce the need for integrated regulatory strategies that combine stronger licensing enforcement, systematic post-market testing, and enhanced accountability across both physical and digital marketplaces.

The case studies analysed in this review demonstrate that regulatory non-compliance in the nutraceutical sector occurs across multiple stages of the regulatory lifecycle. Table 2 summarizes the key observations and corresponding regulatory failures identified in each case.

Table 2. Linkage Between Case Studies and Regulatory Gaps in India

Case Study	Key Observation	Identified Regulatory Failure
Illegal protein supplement manufacturing unit (Noida)	Unlicensed production, adulteration, and absence of quality testing	Licensing failures, FoSCoS surveillance gaps, weak supply-chain monitoring
Citizen's Protein Project	Protein mislabelling, presence of toxins and contaminants	Inadequate post-market surveillance, weak Nutri vigilance systems, and insufficient deterrence

These findings indicate that regulatory failures are not limited to informal or illegal actors but extend to formally marketed products, reflecting systemic weaknesses in licensing enforcement, routine sampling, digital surveillance, and adverse-event monitoring. Strengthening risk-based inspections, improving FoSCoS integration, and institutionalising nutrivigilance mechanisms are therefore essential to address these gaps.

6. Result and Discussion

This review examined regulatory provisions, enforcement actions, and reported case examples related to nutraceuticals in India. The findings show that although a comprehensive regulatory framework exists under the Food Safety and Standards Act, 2006, and the Nutraceutical Regulations, 2016 (revised in 2022), regulatory compliance across the sector remains inconsistent. Recent initiatives, including revised ingredient schedules and digital licensing systems, have improved procedural clarity; however, uniform enforcement continues to be a challenge. Persistent difficulties were observed in product classification at the interface of foods, drugs, and traditional medicine systems. Overlapping responsibilities among FSSAI, CDSCO, and the Ministry of AYUSH contribute to misclassification, licensing delays, and variable regulatory interpretation, particularly for products containing botanicals, probiotics, and high-dose nutrients. Non-compliance related to labelling and health claims emerged as a major concern. Despite the presence of Advertising and Claims Regulations, CCFL review processes, and ASCI oversight, misleading claims and improper labelling remain common, especially in protein-based supplements. In addition, quality-related issues such as adulteration and contamination highlight weaknesses in post-market surveillance, limited product sampling, and underdeveloped nutrivigilance systems. Case study analysis indicates that regulatory failures occur at multiple stages of the product lifecycle, emphasizing the

need for stronger risk-based inspections, enhanced digital monitoring through FoSCoS, and greater industry accountability to ensure consumer safety and sustainable sector growth.

7. Conclusion

This review demonstrates that India's nutraceutical sector, despite its rapid growth and market potential, continues to face significant regulatory and compliance challenges. While the Food Safety and Standards Authority of India has established a robust framework through the FSS Act, 2006 and the 2016 and 2022 nutraceutical regulations, enforcement remains inconsistent and regulatory ambiguities persist, particularly at the interface of food, drugs, and traditional medicine. Key compliance issues include improper product classification, misleading or exaggerated health claims, labelling deficiencies, use of non-permitted ingredients, adulteration, and inconsistent adherence to Good Manufacturing Practices. Case studies, including illegal protein supplement production and mislabelled commercial products, highlight gaps in market surveillance, quality testing, traceability, and post-market monitoring, emphasizing the real risks posed to consumer health. To strengthen the sector, there is an urgent need for clearer regulatory definitions, harmonized enforcement across jurisdictions, mandatory scientific substantiation of claims, enhanced nutrivigilance systems, improved digital compliance platforms, and stricter penalties for violations. Additionally, public awareness campaigns and industry education programs can empower consumers and manufacturers alike to adhere to best practices. Addressing these challenges comprehensively will ensure product safety, restore consumer confidence, promote accountability, and support the sustainable growth and global competitiveness of India's nutraceutical industry.

8. Acknowledgement

We would like to express our profound gratitude to MVN University, Palwal, for the resources and environment that supported the completion of this work.

9. Bibliography

1. Lakhanpal G, Gupta N, Bandral JD, Sood M, Bhat A, Singh J. Nutraceuticals classification and their health benefits: A review. The Pharma Innovation Journal. 2022(11(10)):1927–33.
2. Yapijakis C. Hippocrates of Kos, the Father of Clinical Medicine, and Asclepiades of Bithynia, the Father of Molecular Medicine. In Vivo. 2009 July 1;23(4):507–514.
3. Jacquier EF, van de Wouw M, Nekrasov E, Contractor N, Kassis A, Marcu D. Local and Systemic Effects of Bioactive Food Ingredients: Is There a Role for Functional Foods to Prime the Gut for Resilience? Foods. 2024 Jan;13(5):739.
4. Manikiran SS, Prasanthi Nori L. Nutraceuticals: Regulatory process across the world. Current Trends in Pharmacy and Pharmaceutical Chemistry. 2025 July 19;4(4):137–143.
5. Lam Alekhya, Lukalapu P, Kusuma Latha L, Chegudi C, Vemireddy Madhav. Nutraceuticals: Regulatory Landscape, Clinical Evidence, Challenges, Nutrivigilance in India. RJST. 2024 Sept 2;2024(12(3)):245–254.
6. DataMIntelligence [Internet]. 2025 [cited 2025 Dec 25]. India Nutraceuticals Market Growth Rate, Industry Insights and Forecast 2025-2032. Available from: https://www.datamintelligence.com/research-report/india-nutraceuticals-market
7. Santini A, Cammarata SM, Capone G, Ianaro A, Tenore GC, Pani L, et al. Nutraceuticals: opening the debate for a regulatory framework. Br J Clin Pharmacol. 2018 Apr;84(4):659–672.
8. Regulatory Challenges in Nutraceutical Compliance [Internet]. [cited 2025 Oct 5]. Available from: https://elicit.com/notebook/b7f43ebc-7f87-4753-a765-882b72589054#186b8ee1988f729f74b3973a4c79dfef
9. Sakhare P, Jadhao K, Biyani K. Classification of Nutraceuticals: From Traditional Roots to Modern Innovations. International Journal of Pharmaceutical Sciences [Internet]. 2025 Oct 5 [cited 2025 Sept 16];03(05). Available from: https://www.ijpsjournal.com/article/Classification+of+Nutraceuticals%3A+From+Traditional+Roots+to+Modern+Innovations
10. Food Safety and Standards Authority of India (FSSAI). Direction relating to nutraceuticals. [Internet]. [cited 2025 Sept 20]. Available from: https://www.fssai.gov.in/upload/advisories/2022/03/6243ef28079ceDirection_Nutra_30_03_2022
11. Nutraceuticals: Bridging the Gap Between Nutrition and Pharmaceuticals [Internet]. Open MedScience. 2024 [cited 2025 Sept 16]. Available from: https://openmedscience.com/nutraceuticals-bridging-the-gap-between-nutrition-and-pharmaceuticals/
12. Enforcement drive- nutraceuticals [Internet]. [cited 2025 Dec 25]. Available from: https://www.fssai.gov.in/upload/advisories/2023/03/64074f3f75dacenforcement%20drive-%20nutraceuticals.
13. Press Information Bureau, Government of India. India's Nutraceutical Industry Poised for Global Growth with Supportive Initiatives [Internet]. [cited 2025 Nov 22]. Available from: https://www.pib.gov.in/www.pib.gov.in/Pressreleaseshare.aspx?PRID=2071412
14. Food Safety and Standards Authority of India (FSSAI) Press Release_Misleading Claims [Internet]. [cited 2025 Dec 25]. Available from: https://fssai.gov.in/upload/uploadfiles/files/Press%20Release_Misleading%20Claims.
15. IMARC Group. India Dietary Supplements Market to Grow at 12.82% During 2025-2033 [Internet]. [cited 2025 Nov 22]. Available from: https://www.imarcgroup.com/india-dietary-supplements-market-report

16. ASD Report. India Nutraceuticals Market - 2025-2032 [Internet]. [cited 2025 Nov 22]. Available from: https://www.asdreports.com/market-research-report-674856/india-nutraceuticals-market
17. Grand View Research. India Nutraceuticals Market Size | Industry Report, 2033 [Internet]. [cited 2025 Nov 22]. Available from: https://www.grandviewresearch.com/industry-analysis/india-nutraceuticals-market-report
18. Ministry of Food Processing Industries (MoFPI), Government of India. Nutraceutical sector profile – revised after comments from ED [Internet]. [cited 2025 Nov 20]. Available from: https://mofpi.gov.in/sites/default/files/KnowledgeCentre/Sector%20Profile/Nutraceutical_sector%20profile_%20revised_after_comments_from_ED.
19. FSSAI [Internet]. [cited 2025 Sept 16]. Available from: https://fssai.gov.in/cms/food-safety-and-standards-regulations.php
20. Franchetti J. Best Practices for Nutraceutical Product Labeling and Advertising Compliance [Internet]. JAF Consulting, Inc. 2024 [cited 2025 Sept 16]. Available from: https://jafconsulting.com/best-practices-for-nutraceutical-product-labeling-and-advertising-compliance/
21. Aggarwal S; Kumar P. Regulatory guidelines for nutraceuticals in India: an overview. In: Nutraceuticals [Internet]. Academic Press; 2021 [cited 2026 Jan 2]. p. 1273–80. Available from: https://www.sciencedirect.com/science/chapter/edited-volume/abs/pii/B9780128210383000744
22. Trust Your Supplement (corp.). Understanding FSSAI and Your Dietary Supplements: A Comprehensive Guide – Trust Your Supplements – Verified for Quality, Trusted for Health. [Internet]. [cited 2025 Sept 16]. Available from: https://www.trustyoursupplements.in/knowledge-base/safety-quality/understanding-fssai-and-your-dietary-supplements-a-comprehensive-guide/
23. Domínguez Díaz L, Fernández-Ruiz V, Cámara M. An international regulatory review of food health-related claims in functional food products labeling. Journal of Functional Foods. 2020 May 1;68:103896.
24. Committee | CODEXALIMENTARIUS FAO-WHO [Internet]. [cited 2026 Jan 2]. Available from: https://www.fao.org/fao-who-codexalimentarius/committees/committee/en/?committee=CCFL
25. Navigating the Regulations of Nutraceuticals in India • Food Safety Institute [Internet]. 2023 [cited 2025 Sept 21]. Available from: https://foodsafety.institute/emerging-trends-food-technology-safety/navigating-nutraceutical-regulations-india/
26. Mondaq (corp.). Food safety & packaging rules for health supplements, nutraceuticals, food for special dietary use, food for special medical purposes, functional food and novel food [Internet]. [cited 2025 Sept 16]. Available from: https://www.mondaq.com/india/healthcare/1266366/food-safety-packaging-rules-for-health-supplements-nutraceuticals-food-for-special-dietary-use-food-for-special-medical-purposes-functional-food-and-novel-food
27. Sharma S. Food Label Solutions-Information Centre. 2023 [cited 2025 Dec 25]. Essential Labelling Regulations for Nutraceuticals and Health Supplements to Ensure Consumer Safety – 5 Key Points. Available from: https://www.foodlabelsolutions.com/info-centre/Packaged-Foods/essential-labelling-regulations-for-nutraceuticals-and-health-supplements-to/
28. Doctorpreneur Academy (corp.). Government Panel to Review Regulatory Oversight of Nutraceuticals [Internet]. [cited 2025 Nov 22]. Available from: https://thedoctorpreneuracademy.com/government-panel-to-review-regulatory-oversight-of-nutraceuticals/
29. Direction on operationalisation of health supplements, food for special medical purpose, nutraceuticals and novel foods [Internet]. [cited 2025 Nov 22]. Available from: https://fssai.gov.in/upload/advisories/2018/02/5a93d8341b937Direction_Operationalisation_HS_SMP_NF_Nutra_24_11_2016.
30. Food Safety and Standard Authority of india (FSSAI). FAQs on nutraceutical regulations [Internet]. 2020 [cited 2025 Dec 14]. Available from: https://fssai.gov.in/upload/uploadfiles/files/FAQs_Nutraceutical_Regulations_06_10_2020.
31. Advertising Standards Council of India (ASCI). ASCI. [cited 2025 Dec 14]. Code & Complaint Outcomes | Ad Self-Regulation Cases. Available from: https://www.ascionline.in/codes-cases/
32. Food Safety and Standards Authority of India (FSSAI). Hygiene requirements. [Internet]. [cited 2025 Dec 25]. Available from: https://fssai.gov.in/cms/hygiene-requirements.php
33. Food Safety and Standards Authority of India (FSSAI). Food Safety Connect. [Internet]. [cited 2025 Dec 25]. Available from: https://www.fssai.gov.in/cms/food-safety-connect.php
34. Food Safety and Standards Authority of India (FSSAI). Food laboratories. [Internet]. [cited 2025 Dec 25]. Available from: https://fssai.gov.in/cms/food-laboratories.php
35. Food Safety and Standards Authority of India (FSSAI). Food safety standards for import. [Internet]. [cited 2025 Dec 25]. Available from: https://fssai.gov.in/upload/knowledge_hub/690575b34beafdd91fFood%20Import.
36. Press Information Bureau (PIB), Government of India. PIB. [cited 2025 Dec 25]. Ban on food products. Available from: https://www.pib.gov.in/www.pib.gov.in/Pressreleaseshare.aspx?PRID=2198694
37. Food Safety and Standard Authority of India (FSSAI). Compendium Advertising Claims Regulations_04_03_2021 [Internet]. [cited 2025 Dec 25]. Available from: https://fssai.gov.in/upload/uploadfiles/files/Compendium_Advertising_Claims_Regulations_04_03_2021.
38. Food Safety and Standards Authority of India (FSSAI). FoSCoS. [cited 2025 Dec 14]. FoSCoS – Food Safety Compliance System. Available from: https://foscos.fssai.gov.in/

39. FSSAI [Internet]. [cited 2025 Dec 14]. Available from: https://fssai.gov.in/index.php?page=inspections.php
40. S.S. Rana & Co. Understanding the Food Recall Procedure Regulations, 2017 [Internet]. [cited 2025 Dec 25]. Available from: https://ssrana.in/articles/food-recall-procedure-regulations-2017/
41. Food Safety and Standard Authority of India (FSSAI). Guidelines Food Recall [Internet]. [cited 2025 Nov 22]. Available from: https://foscos.fssai.gov.in/assets/docs/Sample_Food_Recall_Plan_and_Guidelines.
42. India L. Penalties under FSSAI for food businesses in India: Complete Guide [Internet]. [cited 2025 Dec 25]. Available from: https://www.lawfinity.in/%3Clink%20rel=%22canonical%22%20href=%22https:/www.lawfinity.in/blogs/what-are-penalty-under-fssai-for-food-businesses%22%20/%3E
43. FSSAI [Internet]. [cited 2025 Nov 22]. Available from: https://fssai.gov.in/cms/food-safety-and-standards-rules--2011.php
44. Ministry of Food Processing Industries (MoFPI), Government of India. Production Linked Incentive Scheme for Food Processing Industry (PLISFPI) [Internet]. [cited 2025 Nov 22]. Available from: https://www.mofpi.gov.in/en/PLISFPI/central-sector-scheme-production-linked-incentive-scheme-food-processing-industry-plisfpi
45. BW Healthcare World. Government Policies Fuelling The Rise Of India's Nutraceutical Industry - BW Healthcare World [Internet]. [cited 2025 Nov 22]. Available from: https://www.bwhealthcareworld.com/article/government-policies-fuelling-the-rise-of-indias-nutraceutical-industry-558208
46. Food Safety and Standards Authority of India (FSSAI). Press release: Eat Right Movement. [Internet]. [cited 2025 Nov 22]. Available from: https://www.fssai.gov.in/upload/advisories/2018/07/5b45b13175628Press_Release_Eat_Right_Movement_10_07_2018.
47. Ministry of Health and Family Welfare (MoHFW), Government of India. Ayushman Bharat Digital Mission marks a Transformative Three-Year Journey towards enabling Digital Health [Internet]. [cited 2025 Nov 22]. Available from: https://www.mohfw.gov.in/?q=en%2Fpressrelease-87
48. National Consumer Disputes Redressal Commission (NCDRC). Consumer Protection Act, 2019. [Internet]. 2019 [cited 2025 Nov 22]. Available from: https://ncdrc.nic.in/bare_acts/CPA2019.
49. Komala MG, Ong SG, Qadri MU, Elshafie LM, Pollock CA, Saad S. Investigating the Regulatory Process, Safety, Efficacy and Product Transparency for Nutraceuticals in the USA, Europe and Australia. Foods. 2023 Jan;12(2):427.
50. Yow A. NutraIngredients.com. 2025 [cited 2025 Nov 20]. India launches a series of food safety measures, but experts warn gaps remain. Available from: https://www.nutraingredients.com/Article/2025/02/19/india-launches-a-series-of-food-safety-measures-but-experts-warn-gaps-remain/
51. Mondaq. Launching A New Nutritional Product In India: A Legal And Regulatory Perspective Under FSSAI [Internet]. [cited 2025 Nov 20]. Available from: https://www.mondaq.com/india/food-and-drugs-law/1700482/launching-a-new-nutritional-product-in-india-a-legal-and-regulatory-perspective-under-fssai
52. Food Safety Institute (corp.). Navigating the Regulations of Nutraceuticals in India [Internet]. 2023 [cited 2025 Nov 20]. Available from: https://foodsafety.institute/emerging-trends-food-technology-safety/navigating-nutraceutical-regulations-india/
53. Agro & Food Processing. Agro & Food Processing. 2025 [cited 2025 Nov 20]. India Strengthens Food Safety Regulations, But Industry Calls for Greater Reforms. Available from: https://agronfoodprocessing.com/india-strengthens-food-safety-regulations-but-industry-calls-for-greater-reforms/
54. Food & Beverage News (NuFFOODS Spectrum). NuFFOODS Spectrum. 2013 [cited 2025 Nov 20]. FSSAI – hurdles to harmonisation. Available from: https://nuffoodsspectrum.in/2013/08/24/fssai-hurdles-to-harmonisation.html
55. ETHealthworld.com. Health News | Latest Healthcare Sector & Healthcare Industry news, Information and Updates [Internet]. [cited 2025 Nov 20]. Available from: https://health.economictimes.indiatimes.com/news/policy/
56. Hindustan Times. FSSAI cracks down on protein supplements over health risks and misleading claims [Internet]. [cited 2025 Nov 20]. Available from: https://www.hindustantimes.com/business/fssai-cracks-down-on-protein-supplements-over-health-risks-and-misleading-claims-101719745511091.html
57. FNB News - FSSAI seeks special drive to check quality of nutraceuticals sold in market | FNB News [Internet]. [cited 2025 Nov 22]. Available from: https://www.fnbnews.com/Top-News/fssai-seeks-special-drive-to-check-quality-of-nutraceuticals-sold-in-market-71807
58. Adulterated protein supplement factory busted after Delhi man files complaint, 3 held. The Times of India [Internet]. 2024 Dec 10 [cited 2025 Dec 4]; Available from: https://timesofindia.indiatimes.com/city/noida/fake-protein-supplement-factory-busted-in-noida-3-arrested-after-health-complaints/articleshow/116180084.cms
59. Noida Police Bust Fake Food Supplement Factory, Three Arrested [Internet]. [cited 2025 Dec 4]. Available from: https://thevocalnews.com/noida/noida-police-bust-fake-food-supplement-factory-three/cid15857949.htm
60. Noida protein powder adulteration case: How to identify fake protein powder. The Times of India [Internet]. 2024 Dec 15 [cited 2025 Dec 4]; Available from: https://timesofindia.indiatimes.com/life-style/food-news/noida-protein-powder-adulteration-case-how-to-identify-fake-protein-powder/articleshow/116256381.cms
61. Business Standard. Unsafe gains: 14% of Indian protein powders have toxins, 70% mislabelled. 2025 July 17 [cited 2025 Dec 4]; Available from: https://www.business-standard.com/health/protein-powders-india-safety-toxins-mislabelling-herbal-extract-125071700878_1.html

62. Nutralangredients. Protein products tested in India don't meet label claims [Internet]. [cited 2025 Dec 4]. Available from: https://www.nutraingredients.com/Article/2024/04/29/Protein-products-tested-in-India-don-t-meet-label-claims/
63. The Times of India. Protein Supplements: Protein Products Flexing Shaky Claims. [cited 2025 Dec 4]; Available from: https://timesofindia.indiatimes.com/city/delhi/protein-products-flexing-shaky-claims/articleshow/109326631.cms
64. Philips CA, Theruvath AH, Ravindran R, Chopra P. Citizens protein project: A self-funded, transparent, and concerning report on analysis of popular protein supplements sold in the Indian market. Medicine. 2024 Apr 5;103(14):e37724.
65. Dutta SS. Nearly 70% of 36 protein supplements sold in India mislabelled or contain toxins, says new study [Internet]. ThePrint. 2024 [cited 2025 Dec 5]. Available from: https://theprint.in/health/70-of-36-popular-protein-supplements-sold-in-india-mislabeled-14-contain-toxins-says-new-study/2035264/

	**Author Name – Shivali Rahi** **Author Affiliation:** Department of Regulatory Affairs **Author Address/Institute Address:** School of Pharmaceutical Sciences, MVN University, Palwal, Haryana- 121105 India.
	**Author Name– Bharti** **Author Affiliation:** Department of Regulatory Affairs **Author Address/Institute Address:** School of Pharmaceutical Sciences, MVN University, Palwal, Haryana- 121105 India.
	**Author Name– Sudhir Kaushik** **Author Affiliation:** Department of Pharmaceutical Chemistry **Author Address/Institute Address:** School of Pharmaceutical Sciences, MVN University, Palwal, Haryana- 121105 India.
	**Author Name– Ashutosh Upadhayay** **Author Affiliation:** Department of Pharmacology **Author Address/Institute Address:** School of Pharmaceutical Sciences, MVN University, Palwal, Haryana- 121105 India.

How to cite this article:
Shivali Rahi et al. Ijppr.Human, 2026; Vol. 32 (1): 81-92.
Conflict of Interest Statement: All authors have nothing else to disclose.