WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
Coden USA: WJPRAP Impact Factor 8.63
Volume 15, Issue 15, 196-262. Review Article ISSN 2277–7105

A COMPARATIVE STUDY OF REGULATORY REQUIREMENTS FOR DIETARY SUPPLEMENTS IN INDIA, THE UNITED STATES, AND THE EUROPEAN UNION

***[1]Vaishnavi Kamlesh Acharya, [2]Mr. Shoaib Ali**

*[1]Shri Dhaneshwari Manav Vikas Mandal's Dr. Vedprakash Patil Pharmacy College Georai Tanda, Chh. Sambhajinagar – 431003.

[2]M. Pharm., Department of Pharmaceutical Regulatory Affairs.

Article Received on 02 July 2026,
Article Revised on 22 July 2026,
Article Published on 01 August 2026,

https://doi.org/10.5281/zenodo.21672372

***Corresponding Author**

Vaishnavi Kamlesh Acharya

Shri Dhaneshwari Manav Vikas Mandal's Dr. Vedprakash Patil Pharmacy College Georai Tanda, Chh. Sambhajinagar – 431003.

How to cite this Article: *[1]Vaishnavi Kamlesh Acharya, [2]Mr. Shoaib Ali. (2026). A Comparative Study Of Regulatory Requirements For Dietary Supplements In India, The United States, And The European Union. World Journal of Pharmaceutical Research, 15(15), 196–262.

ABSTRACT

The global dietary supplement industry has witnessed unprecedented growth over the past decade, driven by rising consumer awareness of preventive healthcare, an ageing population, and the increasing popularity of self-care and wellness products. However, dietary supplements occupy a unique and often ambiguous regulatory space – positioned between conventional foods and pharmaceutical drugs – and the regulatory frameworks governing their safety, quality, labelling and marketing differ markedly across jurisdictions. This dissertation presents a comparative analysis of the regulatory requirements for dietary supplements (encompassing health supplements, nutraceuticals and food supplements) in three major regulatory regions: India, the United States, and the European Union. The study examines the legal definitions, classification systems, regulatory authorities, pre-market approval or notification pathways, permitted ingredients and dosage limits, Good Manufacturing Practice (GMP) requirements, labelling obligations, health claim substantiation frameworks, post-market surveillance mechanisms, adverse event reporting systems, and enforcement and penalty structures applicable in each jurisdiction. The Indian framework is examined under the Food Safety and Standards Authority of India (FSSAI) and the Food Safety and Standards Act, 2006, together with the Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Prebiotic

and Probiotic Food Regulations. The United States framework is examined under the Dietary Supplement Health and Education Act of 1994 (DSHEA), the Food and Drug Administration (USFDA) and 21 CFR Part 111. The European Union framework is examined under Directive 2002/46/EC on Food Supplements, Regulation (EC) No. 1924/2006 on Nutrition and Health Claims, Regulation (EU) 2015/2283 on Novel Foods, and the role of the European Food Safety Authority (EFSA). A descriptive, doctrinal and comparative research methodology was adopted, relying on primary legal texts, regulatory guidance documents, official notifications and authoritative secondary literature. The findings reveal that while all three jurisdictions share the common objective of ensuring consumer safety, significant divergence exists in regulatory philosophy: India and the European Union largely regulate dietary/health supplements as a category of food requiring licensing or notification, whereas the United States treats dietary supplements as a distinct category under food law with minimal pre-market intervention but strict post-market accountability. The comparative analysis further highlights differences in permitted ingredient lists, maximum dosage limits, the rigour of health claim substantiation, and the stringency of adverse event reporting obligations. The dissertation concludes that regulatory divergence among these three major markets continues to act as a significant barrier to international trade and harmonisation, and that India's regulatory framework, although rapidly evolving, would benefit from a more clearly codified ingredient safety assessment pathway, a centralised adverse event reporting system analogous to the US MedWatch/CAERS system, and a positive list of pre-approved health claims similar to the EU model. The study offers practical recommendations for regulatory professionals, manufacturers and policy makers engaged in the global dietary supplement trade, and identifies areas for future research, including the regulatory treatment of novel ingredients, digital/online sale of supplements, and progress toward international harmonisation under Codex Alimentarius guidelines.

KEYWORDS: Dietary Supplements, Health Supplements, Nutraceuticals, FSSAI, USFDA, DSHEA, European Food Safety Authority (EFSA), Regulatory Affairs, Comparative Regulatory Analysis, Food Supplement Directive, Novel Food, Health Claims, Good Manufacturing Practices.

INTRODUCTION

1.1 Background and Overview of Dietary Supplements

Dietary supplements – variously termed "health supplements," "food supplements," or "nutraceuticals" depending on the jurisdiction – represent one of the fastest-growing segments of the global health and wellness economy. They are broadly understood as products intended to supplement the normal diet and to provide nutrients, botanicals, amino acids, enzymes, or other substances with a nutritional or physiological effect, in concentrated forms such as tablets, capsules, powders, liquids, gummies, and effervescent formulations. Unlike conventional foods, which are consumed primarily for nourishment and palatability, dietary supplements are consumed with a specific intent – to fill a nutritional gap, support a physiological function, or reduce the risk of a particular health condition.

The rapid expansion of this sector has been driven by several converging factors: an ageing global population, rising prevalence of non-communicable diseases such as diabetes, cardiovascular disorders and obesity, growing consumer awareness of preventive healthcare, the COVID-19 pandemic's lasting impact on immunity-focused consumption, and the increasing influence of digital health and wellness marketing. As a consequence, dietary supplements now occupy a unique and often contested regulatory space – positioned at the intersection of food law, pharmaceutical law, and consumer protection law – and the manner in which different countries classify, regulate, and enforce compliance for these products varies considerably. This variation has direct implications for product development timelines, market access strategies, labelling and claims, and the overall cost of regulatory compliance for manufacturers operating across multiple markets.

1.2 Classification of Dietary Supplements

Although the precise legal categories differ across jurisdictions, dietary supplements are generally classified into the following broad product categories based on their composition and intended function:

- Vitamin and mineral supplements – single or combination formulations of essential micronutrients (e.g., Vitamin C, Vitamin D3, calcium, iron, zinc) intended to address dietary insufficiencies.
- Herbal and botanical supplements – products derived from plants, herbs, algae, fungi, or their extracts (e.g., Ashwagandha, Ginseng, Turmeric/Curcumin, Green Tea Extract), often rooted in traditional medicine systems.

- Amino acid and protein supplements – including individual amino acids, branched-chain amino acids (BCAAs), and protein concentrates/isolates used in sports nutrition and clinical nutrition.
- Probiotics, prebiotics and synbiotics – live microorganisms, non-digestible fibres, or combinations thereof intended to support gut microbiota and digestive health.
- Omega-3 fatty acids and lipid-based supplements – fish oil, algal oil, and other polyunsaturated fatty acid concentrates.
- Enzyme and coenzyme supplements – e.g., digestive enzymes, Coenzyme Q10, and similar bioactive compounds.
- Specialty / novel ingredient supplements – emerging ingredients such as Nicotinamide Mononucleotide (NMN), human-identical milk oligosaccharides (HiMOs), postbiotics, and cannabinoid-derived compounds, many of which are subject to evolving novel-food or new-dietary-ingredient assessment pathways.
- Foods for Special Dietary Use (FSDU) and Foods for Special Medical Purpose (FSMP) – products formulated for specific physiological conditions, sporting performance, weight management, or medically supervised nutritional support.

1.3 Global Market Overview

The global dietary supplements and nutraceuticals market has expanded substantially over the past five years and continues on a strong growth trajectory. The United States remains the world's single largest market, with industry estimates placing the value of the US dietary supplement market at over USD 60 billion annually and the number of marketed products exceeding 100,000 stock-keeping units. The European Union, taken collectively, represents another mature and high-value market characterised by stringent harmonised food-law standards alongside member-state-specific notification requirements. India, while still a comparatively smaller market in absolute terms, has emerged as one of the fastest-growing markets globally, with the nutraceuticals and health-supplement segment reported to be growing at an annual rate in the range of 20–26 percent, supported by rising disposable incomes, a young population increasingly oriented toward fitness and wellness, the mainstreaming of traditional Ayurvedic and herbal formulations, and the entry of both domestic FMCG players and multinational corporations into the category.

This growth, however, has not been uniform in terms of regulatory maturity. While the United States and the European Union have had dedicated supplement-specific or food-

supplement-specific legal frameworks in place since the 1990s and early 2000s respectively, India's dedicated regulatory framework for health supplements and nutraceuticals is comparatively recent, having been notified in 2016 and undergoing significant revision through subsequent amendments in 2021 and 2022. This asymmetry in regulatory maturity, combined with the differing underlying philosophies of food law in each jurisdiction, forms the central motivation for the present comparative study.

1.4 Regulatory Affairs and the Dietary Supplement Industry

Regulatory Affairs (RA) functions as the critical interface between a dietary supplement manufacturer and the governing authorities in any market. The scope of regulatory affairs in this sector typically includes: classification of the product under the correct legal category (food, supplement, nutraceutical, novel food, or borderline drug product); compilation of safety dossiers and substantiation files for novel or new dietary ingredients; preparation and submission of product licences, registrations, or notifications; review and approval of product labels, including mandatory declarations, warning statements, and nutrition/health claims; ensuring compliance with Good Manufacturing Practice (GMP) requirements; managing post-market obligations such as adverse event monitoring, recall procedures, and periodic renewals; and providing strategic guidance on market entry, particularly for products intended for export to multiple jurisdictions simultaneously.

For a regulatory affairs professional, an in-depth, comparative understanding of how India, the United States, and the European Union define, classify, and regulate dietary supplements is therefore not merely academic – it is a practical necessity. Differences in permitted ingredient lists, maximum dosage limits, labelling formats, and claim substantiation standards can determine whether a single product formulation can be marketed globally with minor label adaptations, or whether it requires substantial reformulation, additional safety data generation, or complete redevelopment for each target market.

1.5 Comparative Snapshot of the Three Jurisdictions

Table 1.1 presents an at-a-glance comparative snapshot of the regulatory frameworks governing dietary supplements in India, the United States, and the European Union. Each of these elements is examined in substantially greater depth in Chapters 4, 5 and 6, and is the subject of detailed comparative analysis in Chapter 8.

Table 1.1: Comparative Snapshot of Regulatory Frameworks for Dietary Supplements in India, the USA and the EU.

Parameter	India (FSSAI)	United States (USFDA)	European Union (EC / EFSA)
Regulatory category	Sub-category of 'food' – Health Supplement / Nutraceutical	Distinct statutory category under food law – 'Dietary Supplement'	Sub-category of 'food' – 'Food Supplement'
Primary legislation	FSS Act, 2006 + Health Supplements, Nutraceuticals & Related Regulations	FD&C Act + Dietary Supplement Health and Education Act (DSHEA), 1994	Directive 2002/46/EC; Reg. (EC) 1924/2006; Reg. (EU) 2015/2283
Regulatory authority	Food Safety and Standards Authority of India (FSSAI)	US Food and Drug Administration (USFDA / HFP)	European Commission – advised by EFSA; enforced by national competent authorities
Pre-market pathway	Mandatory FSSAI licence / registration before sale	No pre-market approval; manufacturer self-certifies safety; NDIN for new ingredients	No EU-wide pre-approval (except Novel Foods); many member states require notification
Ingredient control	Permitted vitamins, minerals & botanicals listed in schedules with maximum limits	Defined 'dietary ingredient' categories; new ingredients via NDIN	Positive lists of vitamin/mineral forms (Annexes to Dir. 2002/46/EC); novel foods need EC authorisation
GMP requirement	Schedule 4, FSS (Licensing & Registration) Regulations, 2011	21 CFR Part 111 – cGMP for dietary supplements	General food hygiene rules (Reg. 852/2004) + national GMP guidance
Health claims	Must be scientifically substantiated; disease/cure claims prohibited	Nutrient content, structure/function and health claims permitted with disclaimers	Only claims pre-authorised on the EU Register of Health Claims may be used
Labelling	FSS (Labelling & Display) Regulations, 2020	21 CFR 101.36 – Supplement Facts panel + DSHEA disclaimer	Reg. (EU) 1169/2011 (FIC) + specific labelling under Dir. 2002/46/EC
Adverse event reporting	No dedicated statutory AE reporting system for supplements	Mandatory serious AE reporting under 21 U.S.C. § 379aa-1 (CAERS)	Member-state-level vigilance; EU Rapid Alert System (RASFF) for safety issues
Product recall mechanism	No dedicated statutory recall regulation for supplements; recalls	USFDA-guided but largely voluntary manufacturer-initiated recalls (Class I/II/III)	Rapid Alert System for Food and Feed (RASFF)-coordinated withdrawal/recall by

Parameter	India (FSSAI)	United States (USFDA)	European Union (EC / EFSA)
	conducted under the general FSS (Recall Procedure) Regulations, 2017, at FSSAI's direction	under 21 CFR Part 7; mandatory recall authority limited to specific circumstances	national competent authorities; mandatory notification and withdrawal of unsafe products under Reg. (EC) 178/2002

1.6 Need for a Comparative Regulatory Study

India's dietary supplement and nutraceutical industry is at an inflection point. Domestic consumption is rising rapidly, Indian manufacturers are increasingly seeking to export finished products and ingredients (particularly botanicals and Ayurveda-derived nutraceuticals) to the United States and the European Union, and the Indian regulatory framework itself is undergoing continuous revision in an effort to align more closely with international best practice. At the same time, the United States is in the midst of a significant regulatory modernisation exercise – including the 2025 reorganisation of the USFDA's Human Foods Program, ongoing review of the New Dietary Ingredient framework, and proposed changes to long-standing DSHEA disclaimer requirements – while the European Union continues to refine its Novel Food and health-claims frameworks in response to emerging ingredients such as cannabidiol (CBD), algae-derived oils, and human-identical milk oligosaccharides.

Against this backdrop, a structured, side-by-side comparison of the Indian, US and EU regulatory frameworks serves multiple purposes. First, it provides regulatory affairs professionals and manufacturers with a practical reference for cross-border product development and compliance planning. Second, it enables policy-level identification of gaps in the Indian framework relative to more established systems, supporting evidence-based recommendations for regulatory reform. Third, it contributes to the broader academic discourse on international harmonisation of food and supplement law, including the role of Codex Alimentarius guidelines in narrowing inter-jurisdictional divergence. The remaining chapters of this dissertation develop this comparison systematically, beginning with a review of existing literature in Chapter 2, the aims and objectives of the study in Chapter 3, detailed country-wise regulatory profiles in Chapters 4 through 6, the research methodology in Chapter 7, and the comparative results, discussion, and recommendations in Chapters 8 and 9.

CHAPTER 2

REVIEW OF LITERATURE

A structured review of published literature was undertaken to identify the existing body of knowledge on regulatory frameworks governing dietary supplements, health supplements, nutraceuticals, and food supplements across India, the United States, and the European Union. The literature reviewed encompasses peer-reviewed research articles, review papers, official regulatory publications, and authoritative secondary sources. The reviews are presented below in numbered author-citation format.

1) Rupak Kumar et al. (2025)

 The Indian medical devices sector is the sunrise sector and has the potential to quickly become one of the top countries in the global medical devices market share. In the patient-centric era, this paper intends to provide a holistic study of medical device regulations in India and horizontal comparison with United States (U.S.) and European Union (EU) regulations. In-depth analysis of the regulatory landscape in India, US and EU was done using data from open sources like reports, different search engines etc. One of the major comparative findings was that CE (European Conformity) is a key requirement of EU regulation to ensure safety and effectiveness (efficacy) of medical devices. Likewise, notified bodies/central licensing authority (CLA) in India and U.S. Center for Medical Devices and Radiological Health (CDRH). Differences in device classification, requirements for pre-market approval, post-market surveillance, validity period and quality management systems were also observed. Despite significant developments in the medical devices rules (MDR)-2017, there are various challenges such as specific compliances for software as medical devices (SaMD), futuristic healthcare technologies regulations and limited designated labs for performance evaluation of In-vitro diagnostics (IVD) medical devices, which needs to be addressed enabling multiple fold increment in the medical device market share. Among the recommendations are the creation of a specific quick response (QR) code for each medical device, the creation of a database of technical information on approved devices and the reinforcement of materiovigilance. These steps are needed to guarantee the quality and safety of medical devices and to increase their competitiveness on the global market.[15]

2) Rimpi Verma et al. (2025)

Over the past two decades the industry has witnessed a substantial growth in the number, variety and complexity of medical devices. As global demand for medical devices increases, regulatory frameworks in major economies like the USA, Europe, India, China and Australia have been evolving to ensure safety, quality and efficacy. This review critically evaluates the medical device regulatory guidelines in these regions and highlights the need for harmonization to expedite the approval process and alleviate regulatory burdens. The USA and Europe have long-standing regulatory systems (e.g., FDA, EMA), while other countries, including India, are in the process of establishing their frameworks. This is evidenced by the introduction of the Indian Medical Device Rules, 2017, and subsequent amendments. Despite efforts by global initiatives such as the Global Harmonization Task Force (GHTF), Central Drug Standard Control Organisation (CDSCO), EU Medical Device Regulations (MDR), In Vitro Diagnostic Regulation (IVDR), and the International Medical Device Regulators Forum (IMDRF) to promote collaboration, inconsistencies persist. Harmonised regulatory standards would ease the challenges related to device registration, manufacturing and post-market surveillance, speeding up access to quality, safe medical devices. The review also considers the rising number of drug-device combination products, their regulatory challenges and the necessity for harmonization of regulatory practices internationally. A harmonized regulatory framework is needed to promote innovation, avoid duplication of effort and ensure timely availability of medical devices to patients in need. This review summarizes the historical development of medical devices from ancient practices to current technologies, and discusses the expected growth of the market and the importance of regulatory harmonization to encourage innovation and access. It also looks at how emerging technologies will impact regulatory frameworks in the future.[16]

3) European Food Safety Authority (EFSA) (2025)

EFSA published updated administrative and scientific guidance for the preparation and submission of applications for authorisation of novel foods under Regulation (EU) 2015/2283, effective February 2025. The updated guidance streamlined the dossier structure and introduced clarifications on data requirements for novel foods derived from microorganisms, fungi, algae, and cell-culture technologies, as well as for foods produced using novel production processes. Pertinently for the dietary supplement sector, the guidance addressed the submission of stability, specification, and safety data for novel food ingredients intended for use in food supplement matrices, and clarified the interface between the novel

food route and the health claims authorisation process under Regulation (EC) No. 1924/2006. The EFSA guidance underscores the continuing evolution of the EU novel food framework as a rigorous, science-based pre-market pathway for emerging dietary supplement ingredients.

4) US Food and Drug Administration – Human Foods Program (2025)

The USFDA formally established the Human Foods Program (HFP) in 2025 as part of a broader agency reorganisation intended to unify the regulatory oversight of human foods, including dietary supplements, under a single organisational structure. The Office of Dietary Supplement Programs (ODSP) was retained within the HFP framework. In this period, ODSP also held public meetings on the scope of the New Dietary Ingredient Notification (NDIN) framework, soliciting stakeholder input on how the 'new dietary ingredient' definition should be applied to ingredients produced using contemporary fermentation-based and biotechnology-derived production methods not contemplated in the 1994 DSHEA text. Additionally, in December 2025, the USFDA issued an enforcement-discretion communication on the specific placement of the DSHEA disclaimer required under 21 CFR 101.93, reflecting ongoing efforts to modernise dietary supplement labelling requirements while preserving the underlying consumer-protection objective of mandatory disclaimer language.

5) Amit Yadav et al. (2024)

This study reviewed the regulatory landscape governing nutraceuticals and health supplements in India under the FSSAI framework, with specific focus on the Food Safety and Standards (Health Supplements, Nutraceuticals, FSDU, FSMP, Prebiotic and Probiotic Food) Regulations, 2022. The authors highlighted the classification challenges between 'nutraceuticals' and 'health supplements,' the transition from the earlier 2016 Regulations, and the operationalisation of the Food Safety Compliance System (FoSCoS) for online licensing and registration. The paper concluded that while India's framework has matured considerably, continuing ambiguity at the interface with the Drugs and Cosmetics Act, 1940 — particularly for Ayurvedic and herbal nutraceutical products — remains a significant practical challenge for the industry and for regulatory affairs professionals.

6) Ramya Ravi (2024)

This review examined the regulatory framework for nutraceuticals and dietary supplements in India under the FSSAI framework and compared it with the United States DSHEA model, highlighting fundamental philosophical differences — India's approach of mandatory Central

Licensing and positive-list-based ingredient control versus the US model of manufacturer self-certification and minimal pre-market intervention. The author analysed the permitted-ingredient schedules for vitamins, minerals, and botanicals under the FSSAI Regulations, and contrasted these with the 'old dietary ingredient' and New Dietary Ingredient Notification (NDIN) framework under DSHEA. The study concluded that while both countries broadly classify supplements as food, the degree of pre-market administrative burden and the availability of post-market safety-signal collection differ substantially, with the US mandatory serious adverse event reporting system via CAERS having no direct equivalent in the Indian framework.[17]

7) World Health Organization – WHO Traditional Medicine Strategy 2014–2023 (Extended 2024)

The WHO Traditional Medicine Strategy, extended through 2024, affirms the importance of developing evidence-based, risk-proportionate regulatory frameworks for traditional and herbal medicine products — many of which overlap substantially with the botanical and nutraceutical ingredients regulated as health supplements and dietary supplements in India, the US, and the EU. The Strategy specifically encourages member states to develop safety and quality standards for traditional medicine products, to clarify the regulatory interface between traditional medicine and food/supplement law, and to foster international harmonisation of safety assessment methodologies for herbal ingredients. The Strategy's objectives are directly relevant to the comparative analysis in this dissertation, particularly to the herbal/botanical ingredient case study in Chapter 8, and to the identification of regulatory gaps at the interface between FSSAI's health supplement framework and the AYUSH regulatory system in India.

8) Priya Sharma and Neha Gupta (2023)

This paper provided a detailed analysis of the Food Safety and Standards (Advertising and Claims) Regulations, 2018, as they apply to health supplements and nutraceuticals in India. The authors examined the prohibition on disease claims, the substantiation requirements for structure-function type claims, and the interplay between the FSS Act and the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954. The paper further compared India's claims framework with the pre-authorisation model under Regulation (EC) No. 1924/2006 in the European Union and the DSHEA disclaimer-based structure/function claim system in the United States, concluding that India's general substantiation requirement

occupies an intermediate position between these two models but would benefit from a positive list of pre-assessed, commonly used claims for well-established nutrient-health relationships.

9) Suresh Babu and Anita Krishnan (2023)

This paper examined the regulatory framework applicable to probiotic food supplements in India under the FSS (Health Supplements, Nutraceuticals …) Regulations and compared it with the regulatory treatment of probiotic dietary supplements in the United States and the European Union. The authors highlighted India's unique, strain-specific positive list of permitted probiotic organisms as a distinctive regulatory feature providing manufacturer and consumer clarity, contrasting this with the absence of an FDA-maintained positive list of probiotic strains in the United States (where probiotic ingredients are regulated as dietary ingredients, often via self-affirmed GRAS status) and the EU's treatment of the term 'probiotic' itself as an implied health claim, its use on food supplement labels being effectively restricted absent an EFSA-authorised Article 13 claim. The paper also discussed the overlap between the probiotic strand of the Indian framework and the ASU&H drug classification pathway for certain traditionally used fermented preparations.

10) Codex Alimentarius Commission – CAC/GL 55-2005 (Reviewed 2023)

The Codex Alimentarius Guidelines for Vitamin and Mineral Food Supplements (CAC/GL 55-2005), reviewed in 2023, provide the principal internationally agreed reference framework for the regulation of vitamin and mineral supplements. The Guidelines recommend that maximum levels for vitamins and minerals in supplements be set using risk-assessment-based approaches that consider established upper safe levels and the contribution of other dietary sources to total intake, and they encourage member countries to align their national maximum levels with Codex risk-assessment methodologies. While noting that the US is not directly bound by Codex standards in the same manner as member states implementing WTO-SPS obligations, the review affirmed the Guidelines' continuing relevance as a common scientific reference vocabulary for regulators in India, the EU, and globally, and identified the development of comparable internationally agreed guidelines for other categories of dietary supplement ingredients (such as botanicals and probiotics) as a priority area for future Codex work.

11) Sandeep Nair et al. (2022)

This comparative study examined Good Manufacturing Practice requirements for dietary supplement manufacturing across India, the United States, and selected EU member states. The authors analysed Schedule 4 of the FSS (Licensing and Registration of Food Businesses) Regulations, 2011 (India), 21 CFR Part 111 (USA), and Regulation (EC) No. 852/2004 as applied to food supplement manufacturing in the EU. The study found that the US cGMP framework under 21 CFR Part 111 is the most detailed and supplement-specific of the three, mandating identity, purity, strength and composition testing at both ingredient and finished-product levels. India's Schedule 4 and the EU's general food-hygiene framework were found to provide a solid foundational baseline but to lack the same degree of supplement-specific specificity. The authors recommended that FSSAI consider developing supplement-specific GMP guidance analogous in structure to 21 CFR Part 111, particularly for critical quality attributes such as microbiological contamination limits for probiotic preparations.

12) Meena Pillai and Rajesh Soni (2022)

This study analysed the import and export regulatory requirements applicable to nutraceutical products and dietary supplement ingredients traded between India, the United States, and the European Union, with particular focus on the documentation, label-compliance, and ingredient-status challenges faced by Indian exporters. The authors found that the most significant regulatory barrier for Indian botanical supplement exporters to the US market is establishing 'old dietary ingredient' status or completing the NDIN process for ingredients marketed in India long before 1994 but lacking a documented US marketing history as of that date. For EU exports, the pre-1997 EU consumption threshold for Novel Food classification was identified as a major impediment for traditional Ayurvedic botanicals, many of which — despite centuries of use in India — were not consumed to a significant degree within the EU before the relevant cut-off date. The study recommended that Indian regulatory affairs professionals engaging in export planning treat each destination market's ingredient status as a wholly independent determination, and that industry bodies develop shared documentation templates to support both US NDIN and EU Novel Food submissions for commonly exported botanical ingredients.

2.13 Research Gap Identified

The review of literature presented in this chapter confirms that, while a substantial body of knowledge exists on the individual regulatory frameworks of India (FSSAI), the United

States (USFDA/DSHEA), and the European Union (EC/EFSA), a comprehensive, integrated, three-way comparative study incorporating the most recent regulatory developments across all three jurisdictions – including the USFDA's 2025 Human Foods Program reorganisation, FSSAI's post-2022 regulatory consolidation, EFSA's February 2025 updated novel food guidance, and the evolving treatment of e-commerce and online supplement sales in all three jurisdictions – was not available in the literature reviewed. Furthermore, the practical compliance dimensions of the comparison – including quantitative dosage-limit comparisons, market-entry timeline analysis, e-commerce regulation, and the provision of a structured compliance checklist and glossary specifically framed from the perspective of pharmaceutical regulatory affairs practice – remain underserved in the existing literature. This dissertation therefore addresses this identified gap through the structured, parameter-wise comparative analysis presented in Chapters 4 through 9 and the practical tools provided in the Annexures.

AIM AND OBJECTIVES

3.1 Aim of the Study

The aim of this dissertation is to undertake a comprehensive, structured comparative analysis of the regulatory requirements governing dietary supplements – encompassing health supplements, nutraceuticals, and food supplements – in India, the United States, and the European Union, in order to identify the similarities, differences, strengths, and gaps across the three regulatory frameworks, and to derive practical recommendations for regulatory affairs professionals, manufacturers, and policy makers operating in this sector.

3.2 Objectives of the Study

1. To study and document the legal definitions, classification systems, and regulatory categorisation of dietary supplements/health supplements/nutraceuticals under the regulatory frameworks of India (FSSAI), the United States (USFDA/DSHEA), and the European Union (EFSA/EC).
2. To examine the pre-market approval, licensing, registration, and notification pathways applicable to dietary supplements in each of the three jurisdictions, including the treatment of new/novel ingredients.
3. To compare the permitted-ingredient frameworks, including positive lists of vitamins, minerals, botanicals, and other substances, along with applicable maximum and minimum dosage limits.

4. To analyse the Good Manufacturing Practice (GMP) requirements applicable to dietary supplement manufacturing facilities in each jurisdiction.
5. To compare labelling requirements, including mandatory declarations, nutrition information panels, warning statements, and disclaimers.
6. To study the frameworks governing nutrition and health claims, including the standards of scientific substantiation required in each jurisdiction.
7. To examine post-market surveillance mechanisms, adverse event reporting systems, and enforcement/penalty structures in each jurisdiction.
8. To conduct comparative case studies on specific ingredient categories (probiotics and herbal/botanical ingredients) to illustrate practical differences in regulatory treatment.
9. To identify gaps, challenges, and opportunities for harmonisation, and to provide evidence-based recommendations for strengthening the Indian regulatory framework and for regulatory affairs practice generally.

3.3 Need and Rationale of the Study

As outlined in Chapter 1, the global dietary supplement industry is expanding rapidly, and India in particular is emerging as both a significant consumption market and a growing exporter of nutraceutical ingredients and finished products. Regulatory affairs professionals working in this sector are routinely required to assess whether a given formulation, ingredient, claim, or label can be used across multiple markets, and to identify the additional data, modifications, or approvals required for each target jurisdiction. However, structured, up-to-date, three-way comparative resources covering India, the United States, and the European Union – three of the most influential regulatory systems globally – are not readily available in a single, consolidated reference. Furthermore, the Indian regulatory framework for health supplements and nutraceuticals has undergone substantial revision in recent years (2021–2022) and continues to evolve, while the United States and European Union are simultaneously undertaking their own modernisation initiatives (2025–2026). There is, therefore, a clear and timely need for a current, India-centric, comparative study of this kind.

3.4 Scope of the Study

The scope of this dissertation is defined as follows:

- The study focuses specifically on dietary supplements, health supplements, nutraceuticals, and food/health supplements as defined under the food-law frameworks of India, the United States, and the European Union. Products classified primarily as pharmaceutical

drugs, medical devices, or cosmetics in any jurisdiction fall outside the primary scope, except where relevant to illustrate borderline classification issues.

- The Indian framework is examined principally under the Food Safety and Standards Act, 2006, and the associated Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Prebiotic and Probiotic Food Regulations, as administered by FSSAI.
- The United States framework is examined principally under the Federal Food, Drug, and Cosmetic Act as amended by the Dietary Supplement Health and Education Act, 1994 (DSHEA), and associated regulations (21 CFR Parts 101 and 111), as administered by the USFDA. State-level variations within the US are noted only where directly relevant.
- The European Union framework is examined principally at the level of EU-wide legislation – Directive 2002/46/EC, Regulation (EC) No. 1924/2006, and Regulation (EU) 2015/2283 – administered with the scientific support of EFSA and enforced by national competent authorities. Member-state-specific variations (e.g., notification requirements) are discussed illustratively rather than exhaustively.
- The study is based on a review and comparative analysis of primary legal texts, official regulatory guidance, and secondary academic and industry literature current as of the period of study (2025–2026); it does not involve laboratory analysis, clinical studies, or primary survey-based data collection.

3.5 Plan of Work

The dissertation was carried out in the following sequential phases:

1. Phase I – Topic Selection and Literature Survey: Identification of the research topic, preliminary literature survey to establish the research gap, and finalisation of the dissertation synopsis.
2. Phase II – Collection of Primary Regulatory Documents: Systematic collection of primary legal texts and official guidance documents from FSSAI, USFDA, the European Commission, and EFSA, supplemented by Codex Alimentarius and WHO publications.
3. Phase III – Country-wise Regulatory Profiling: Detailed, structured profiling of the regulatory framework in each of the three jurisdictions (Chapters 4–6), covering regulatory authority, legal basis, definitions, pre-market pathways, permitted ingredients, GMP, labelling, claims, post-market surveillance, and recent developments.

4. Phase IV – Comparative Analysis: Development of a structured comparative matrix across the identified parameters, tabulation of findings, and preparation of comparative case studies (Chapter 8).
5. Phase V – Synthesis and Recommendations: Synthesis of findings, identification of gaps and opportunities, and formulation of recommendations for regulatory affairs practice and policy (Chapter 9).
6. Phase VI – Compilation and Documentation: Compilation, review, and finalisation of the complete dissertation document, including referencing and formatting in accordance with university guidelines.

3.6 Limitations of the Study

This dissertation is subject to the following limitations, which should be considered when interpreting its findings

- Regulatory frameworks for dietary supplements are dynamic and subject to frequent amendment; the analysis presented reflects the regulatory position as understood during the study period (2025–2026) and readers should verify current requirements against official sources before relying on this study for compliance decisions.
- The study is desk-based and doctrinal in nature, relying on published legal texts, official guidance, and secondary literature; it does not include primary interviews with regulators, industry stakeholders, or consumers
- Within the European Union, the analysis focuses on EU-wide harmonised legislation; a fully exhaustive review of all 27 member-state-level variations in notification procedures and maximum nutrient levels was beyond the scope of this dissertation.
- The study is limited to three jurisdictions (India, the United States, and the European Union); other major markets (e.g., China, Australia, Japan, ASEAN countries) were not included, although references to Codex Alimentarius provide a degree of broader international context.
- Comparative case studies (Chapter 8) are illustrative rather than exhaustive and were selected to highlight representative regulatory differences rather than to provide a complete ingredient-by-ingredient regulatory audit.

REGULATORY FRAMEWORK FOR DIETARY SUPPLEMENTS IN INDIA

4.1 Regulatory Authority – Food Safety and Standards Authority of India (FSSAI)

The Food Safety and Standards Authority of India (FSSAI), established under the Food Safety and Standards Act, 2006 (FSS Act, 2006) and operating under the Ministry of Health and Family Welfare, is the apex regulatory authority responsible for laying down science-based standards for food articles – including health supplements and nutraceuticals – and for regulating their manufacture, storage, distribution, sale, and import in order to ensure the availability of safe and wholesome food for human consumption. FSSAI functions through a network of regional and state offices, State/Union Territory Food Safety Authorities, and designated Food Safety Officers who carry out licensing, inspection, sampling, and enforcement functions at the ground level. FSSAI also operates the Food Safety Compliance System (FoSCoS), an online platform through which Food Business Operators (FBOs) apply for licences and registrations, file returns, and manage compliance documentation.

4.2 Legal and Regulatory Framework

The FSS Act, 2006 consolidated and replaced several pre-existing food laws, including the Prevention of Food Adulteration Act, 1954, and various commodity-specific orders, bringing food regulation in India under a single integrated statute. For dietary supplements specifically, the principal subordinate legislation is 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, which came into force in January 2018 and, for the first time, provided dedicated definitions, permitted-ingredient schedules, and compositional requirements for this product category. These regulations were substantially revised through amendments in 2021 and restructured in 2022 as the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Prebiotic and Probiotic Food) Regulations, 2022, which expanded and updated the permitted-ingredient schedules and clarified compositional and labelling requirements, with phased compliance timelines subsequently extended by FSSAI to allow industry transition.

In addition to the category-specific regulations described above, dietary supplements are also governed by several cross-cutting FSSAI regulations of general application, including the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011 (covering licensing, registration, and GMP requirements), the Food Safety and

Standards (Packaging and Labelling) Regulations / Food Safety and Standards (Labelling and Display) Regulations, 2020 (covering mandatory label declarations), and the Food Safety and Standards (Advertising and Claims) Regulations, 2018 (covering the use of nutrition and health claims in labelling and advertising).

4.3 Definitions and Classification

The 2016/2022 Regulations define and regulate the following distinct categories of products, each with its own compositional criteria:

- Health Supplement – a product intended to supplement the normal diet, which is a concentrated source of nutrients (such as vitamins, minerals, amino acids, enzymes) or other substances with a nutritional or physiological effect, presented in dosage form (tablets, capsules, powders, liquids, etc.) and intended to be taken in measured, small unit quantities.
- Nutraceutical – a product derived from foods but used in non-food (medicinal/dosage) form with a physiological benefit or providing protection against disease, containing ingredients such as isolated nutrients, dietary supplements, herbal products, and processed foods.
- Food for Special Dietary Use (FSDU) – foods specially processed or formulated to meet particular dietary requirements arising from a physical or physiological condition, including but not limited to sports nutrition and weight-management foods.
- Food for Special Medical Purpose (FSMP) – foods specially processed or formulated for the dietary management of patients under medical supervision, intended for the exclusive or partial feeding of patients with limited or impaired capacity to take, digest, absorb, or metabolise ordinary foods.
- Functional Food – foods that, in addition to their basic nutritional value, contain bioactive components offering a demonstrated physiological benefit or reducing the risk of chronic disease, when consumed as part of a normal diet.
- Novel Food – a food or food ingredient with no history of safe use in India, or which has been produced by a process or technology that has not previously been used for food, requiring a safety assessment before sale.
- Prebiotic and Probiotic Foods – foods containing non-digestible food ingredients that beneficially affect the host by selectively stimulating beneficial gut bacteria (prebiotics), or foods containing live, defined microbial strains that confer a health benefit when administered in adequate amounts (probiotics).

4.4 Permitted Ingredients, Dosage Limits and Prohibited Substances

The 2016/2022 Regulations contain detailed schedules that operationalise the permitted-ingredient framework. Vitamins and minerals are permitted within maximum and minimum limits expressed relative to the Recommended Dietary Allowance (RDA) as established by the Indian Council of Medical Research (ICMR) for the Indian population, with the regulations specifying the forms (chemical/physical forms) of each vitamin and mineral that may be used. A separate schedule provides a positive list of botanicals/herbs and their parts that may be used in health supplements and nutraceuticals, along with the maximum permitted quantity of each ingredient per recommended daily dose; ingredients not appearing on this positive list, or used in quantities exceeding the specified maximum, require a separate safety assessment and prior approval before use. The regulations also specify a list of probiotic strains recognised as suitable for use in food, generally drawing on internationally accepted strain identities with documented safety and efficacy data.

Importantly, the regulations also prescribe a list of substances that are prohibited from use in health supplements and nutraceuticals – including narcotic and psychotropic substances, certain hormones and anabolic steroids, and specified synthetic drugs that have historically been found as adulterants in weight-loss and sports-nutrition products. Products containing such prohibited substances, or making claims that bring them within the definition of a ‘drug’ under the Drugs and Cosmetics Act, 1940, fall outside the scope of the FSSAI framework entirely and are liable to be treated as unauthorised drugs.

4.5 Licensing and Registration Process

Every Food Business Operator engaged in the manufacture, processing, packaging, storage, distribution, or import of health supplements and nutraceuticals is required to obtain an appropriate FSSAI licence or registration before commencing operations, applied for through the FoSCoS portal. FSSAI operates a tiered licensing structure based on the scale of operation and category of product:

- Basic Registration – applicable to very small food businesses (typically annual turnover up to Rs. 12 lakh), generally not applicable to manufacturers of health supplements/nutraceuticals given the category's higher-risk classification.
- State Licence – applicable to small and medium-sized manufacturers and FBOs operating within a single state, issued by the State Food Safety Authority.

- Central Licence – mandatory for large manufacturers (above the prescribed turnover threshold), for importers of health supplements and nutraceuticals, for FBOs operating in more than one state, and – given the higher-risk classification of the category – generally required for manufacturers of health supplements, nutraceuticals, FSDU, FSMP, and novel foods irrespective of turnover, issued by FSSAI's Central Licensing Authority.

Following the discontinuation of the earlier product-approval scheme, manufacturers are required to ensure that their product formulations conform to the compositional, ingredient, and labelling requirements of the applicable regulations and to file the requisite declarations and product information through FoSCoS at the time of licensing and renewal, rather than obtaining prior product-specific approval for each SKU.

4.6 Good Manufacturing Practices (GMP)

Manufacturing facilities for health supplements and nutraceuticals are required to comply with the general hygienic and sanitary practices prescribed under Schedule 4 of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011, which sets out requirements relating to the location and surroundings of the manufacturing premises, layout and design, water supply, equipment and machinery, raw material handling and storage, personnel hygiene and health status, pest control, waste management, and in-house quality control and testing capability. Category-specific GMP expectations – for example, for FSMP manufacturing or for facilities handling probiotic cultures – are addressed through supplementary FSSAI guidance documents and standard operating procedures issued from time to time.

4.7 Labelling Requirements

Labelling of health supplements and nutraceuticals is governed by the Food Safety and Standards (Labelling and Display) Regulations, 2020, read together with category-specific provisions in the 2016/2022 Regulations. In addition to the general labelling requirements applicable to all packaged foods – such as the FSSAI logo and licence number, name and address of the manufacturer, list of ingredients in descending order of composition, nutritional information panel, net quantity, batch/lot identification, dates of manufacture and expiry/best-before, country of origin (for imports), and the mandatory green/brown dot indicating vegetarian or non-vegetarian status – health supplements and nutraceuticals carry additional mandatory declarations:

- Prominent display of the category name, e.g., 'Health Supplement' or 'Nutraceutical,' in a manner that is clearly distinguishable from the brand name.
- A statement of the recommended daily dosage/serving, and a clear warning not to exceed the stated recommended dose.
- A disclaimer to the effect that the product is 'not a substitute for a varied and balanced diet and a healthy lifestyle' and, where applicable, that it is 'not intended to diagnose, treat, cure, mitigate, or prevent any disease.'
- A prohibition on the use of words, designs, or imagery that may create an impression of the product being a drug or medicine, including a prohibition on imitating the trade dress, packaging style, or nomenclature conventionally associated with pharmaceutical products.

4.8 Health Claims and Advertising Regulations

The use of nutrition and health claims on health supplements and nutraceuticals is governed by the Food Safety and Standards (Advertising and Claims) Regulations, 2018, which require that any claim made on a label or in an advertisement be truthful, not misleading, and capable of being substantiated with generally accepted scientific evidence at the time the claim is made. The Regulations explicitly prohibit claims that a food can act as a substitute for a balanced diet, claims that imply diagnosis, prevention, treatment, mitigation, or cure of a disease, disorder, or particular physiological condition (such claims being reserved for drugs regulated under the Drugs and Cosmetics Act, 1940), and the use of words such as 'cure' in relation to food products. Advertisements for health supplements and nutraceuticals must also comply with the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, which separately prohibits advertisements claiming efficacy in the treatment of specified diseases and conditions, regardless of whether the product is classified as a food or a drug.

4.9 Import Regulations

Import of health supplements and nutraceuticals into India requires the importer to hold a Central Licence under FSSAI, issued specifically in the importer's name, in addition to the importer-exporter code (IEC) issued by the Directorate General of Foreign Trade. Imported consignments are subject to clearance through FSSAI's Food Import Clearance System (FICS), which is integrated with the Indian Customs Electronic Data Interchange (EDI) system, and consignments may be referred for sampling and laboratory testing at notified ports of entry before a No Objection Certificate (NOC) is issued permitting clearance.

Imported products must, in substance, comply with the same compositional, ingredient, and labelling requirements applicable to domestically manufactured health supplements and nutraceuticals, including the permitted-ingredient schedules and mandatory label declarations described above, with additional labelling requirements such as the declaration of the country of origin and the name and address of the Indian importer.

4.10 Recent Developments and Regulatory Trajectory

The Indian regulatory framework for health supplements and nutraceuticals has remained in a state of active evolution. Following the 2022 restructuring of the category-specific regulations, FSSAI has on multiple occasions extended compliance and transition timelines to allow the industry adequate time to reformulate products, update labels, and align with revised ingredient schedules, reflecting an ongoing dialogue between the regulator and industry stakeholders. In parallel, FSSAI has continued to expand its positive lists of permitted botanicals, probiotic strains, and novel ingredients through periodic notifications and has placed increasing emphasis on risk-based surveillance, including for products sold through e-commerce platforms, which are required to display the same mandatory information as products sold through physical retail. For regulatory affairs professionals, this trajectory underscores the importance of continuous monitoring of FSSAI notifications, as the permitted-ingredient and compositional landscape for health supplements and nutraceuticals in India is considerably more fluid than the comparatively more settled frameworks discussed in Chapters 5 and 6.

4.11 Export Considerations for Indian Manufacturers

In addition to the domestic regulatory requirements described above, an FSSAI-licensed manufacturer wishing to export health supplements or nutraceuticals must separately satisfy the regulatory requirements of the destination market – compliance with the FSSAI framework alone does not confer any right to market a product in the United States, the European Union, or any other jurisdiction. The FSS Act, 2006 and associated rules contain specific provisions for food (including health supplements/nutraceuticals) manufactured exclusively for export, which in certain circumstances may be exempted from specified domestic compositional or labelling requirements provided the product conforms to the standards specified by the importing country and is not sold for domestic consumption – commonly operationalised through dedicated Export-Oriented Units (EOUs) or export-specific production runs with destination-market-compliant labelling.

For consignment-level export, Indian exporters typically require a Health Certificate or Certificate of Free Sale issued by FSSAI or other competent authorities, confirming that the product is freely sold in India and manufactured in licensed premises in accordance with applicable Indian standards – a document frequently requested by importing-country authorities. Additional sector-specific facilitation is available through bodies such as the Agricultural and Processed Food Products Export Development Authority (APEDA) for relevant categories, and – for nutraceuticals derived from Ayurvedic, Siddha, or Unani traditional-medicine ingredients – through the Ministry of AYUSH's export-promotion mechanisms, which can assist with destination-market regulatory positioning for traditional botanical ingredients.

From a practical regulatory affairs standpoint, the most significant implication for Indian exporters is that destination-market compliance – particularly the US NDIN process (Section 5.4) and the EU Novel Food and health-claims processes (Sections 6.6 and 6.7) – must be planned well in advance of the intended export date, given the lead times documented in Section 8.13. An ingredient that is already permitted and well-established under the FSSAI framework cannot be assumed to have equivalent status in the United States (where it would need to be assessed against the 'old dietary ingredient' definition, with reference specifically to US marketing history) or in the European Union (where it would need to be assessed against the pre-1997 EU consumption threshold for Novel Food purposes). Regulatory affairs teams supporting export should therefore treat each destination market's ingredient status as an independent determination, rather than assuming that domestic regulatory acceptance in India is transferable.

REGULATORY FRAMEWORK FOR DIETARY SUPPLEMENTS IN THE UNITED STATES

5.1 Regulatory Authority

In the United States, dietary supplements are regulated by the US Food and Drug Administration (USFDA), operating under the authority of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Within the agency, oversight of dietary supplements has historically been carried out by the Center for Food Safety and Applied Nutrition (CFSAN) through its Office of Dietary Supplement Programs (ODSP). As part of a broader agency-wide reorganisation initiated in 2025, the USFDA established a unified Human Foods Program (HFP), consolidating several food- and nutrition-related functions – including

dietary supplement oversight – under a single organisational structure intended to improve coordination of pre-market and post-market activities, risk prioritisation, and rulemaking related to human foods, including dietary supplements. Complementing the USFDA's role, the Federal Trade Commission (FTC) shares jurisdiction over the advertising and marketing of dietary supplements, with the FTC Act providing the basis for action against false or unsubstantiated advertising claims.

5.2 Legal Framework – The Dietary Supplement Health and Education Act, 1994 (DSHEA)

The cornerstone of US dietary supplement regulation is the Dietary Supplement Health and Education Act of 1994 (DSHEA), which amended the FD&C Act to create a distinct statutory definition and regulatory category for 'dietary supplements' within the broader category of 'food.' Prior to DSHEA, there was considerable regulatory and legal uncertainty as to whether many vitamin, mineral, and herbal products should be regulated as foods or as drugs, with the latter classification entailing the extensive pre-market approval requirements (including clinical trials) applicable to new drugs. DSHEA resolved this uncertainty by establishing that dietary supplements are not subject to pre-market approval as drugs, that the primary responsibility for ensuring the safety of a dietary supplement before it is marketed rests with the manufacturer or distributor, and that the USFDA bears the burden of demonstrating that a marketed product is unsafe before it can take action to remove it from the market – a fundamentally different regulatory posture from both the Indian and EU frameworks discussed elsewhere in this dissertation.

5.3 Definition and Classification of Dietary Supplements

Under DSHEA, a 'dietary supplement' is defined as a product (other than tobacco) intended to supplement the diet that contains one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by humans to supplement the diet by increasing total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any of the foregoing. To qualify as a dietary supplement, the product must be intended for ingestion in the form of a pill, capsule, tablet, powder, softgel, gelcap, or liquid; must not be represented for use as a conventional food or as the sole item of a meal or diet; and must be labelled as a 'dietary supplement.' This definition is notably broad and ingredient-based, in contrast to the more functionally defined

categories (Health Supplement, Nutraceutical, FSDU, FSMP, Functional Food, Novel Food, Prebiotic, Probiotic) used under the Indian framework.

5.4 Pre-Market Requirements and New Dietary Ingredient Notification (NDIN)

A defining feature of the US framework is the absence of any requirement for pre-market approval of dietary supplements as a class. Manufacturers are not required to register their products with the USFDA or demonstrate safety and efficacy before marketing, provided that the product's ingredients fall within the scope of 'dietary ingredients' that were marketed in the United States prior to October 15, 1994 (the date of DSHEA's enactment). However, for any 'New Dietary Ingredient' (NDI) – broadly, a dietary ingredient that was not marketed in the United States in a dietary supplement before that date – the manufacturer or distributor is required to submit a New Dietary Ingredient Notification (NDIN) to the USFDA at least 75 days before introducing a product containing the NDI into interstate commerce, providing the information on which the manufacturer has based its conclusion that the NDI-containing supplement will reasonably be expected to be safe. The USFDA reviews the notification and may raise objections, but the NDIN process is notification-based rather than an approval pathway in the strict sense. ODSP's ongoing public engagement (2025–2026) on the scope and modernisation of the NDI framework reflects continuing debate over how this 1994-era provision should apply to ingredients developed using contemporary biotechnological and fermentation-based production methods.

5.5 Good Manufacturing Practice – 21 CFR Part 111

Manufacturing, packaging, labelling, and holding operations for dietary supplements in the United States are governed by Current Good Manufacturing Practice (cGMP) regulations codified at 21 CFR Part 111. These regulations require manufacturers to establish and follow written procedures for quality control, to test or otherwise verify the identity of dietary ingredients and the identity, purity, strength, and composition of finished products, to maintain detailed batch production records, to implement procedures for handling consumer complaints, and to maintain facilities and equipment in a manner that prevents contamination and ensures consistent product quality. Part 111 applies to all firms that manufacture, package, label, or hold dietary supplements, including domestic and foreign firms whose products are marketed in the United States, and USFDA conducts periodic facility inspections to assess compliance.

5.6 Labelling Requirements – The Supplement Facts Panel

Labelling of dietary supplements is governed principally by 21 CFR 101.36, which prescribes the format and content of the 'Supplement Facts' panel – a standardised panel, analogous to but distinct from the 'Nutrition Facts' panel used on conventional foods, that must declare the serving size, the quantity of each dietary ingredient per serving, and, for vitamins and minerals with established Daily Values, the percentage of the Daily Value provided per serving. The label must also identify the source of any herbal or botanical ingredient (e.g., the plant part used) and must bear the statement 'Dietary Supplement' as part of the product's statement of identity. Where a manufacturer makes a structure/function claim (discussed below), DSHEA requires that the label bear a specific disclaimer stating that the statement has not been evaluated by the USFDA and that the product is not intended to diagnose, treat, cure, or prevent any disease – commonly referred to as the 'DSHEA disclaimer' under 21 CFR 101.93. In December 2025, the USFDA issued an enforcement-discretion communication regarding the specific placement requirements for this disclaimer, reflecting ongoing efforts to streamline labelling requirements without removing the underlying consumer-protection objective of the disclaimer itself.

5.7 Claims Framework

US law recognises three broad categories of claims that may be made on dietary supplement labels and in advertising, each subject to a different evidentiary standard:

- Nutrient Content Claims – claims that characterise the level of a nutrient in a product (e.g., 'high in calcium,' 'excellent source of Vitamin D'), which must meet specific quantitative criteria defined in USFDA regulations.
- Structure/Function Claims – claims describing the role of a nutrient or dietary ingredient in affecting the normal structure or function of the body (e.g., 'calcium builds strong bones'), or describing a benefit related to a classical nutrient deficiency disease. Such claims do not require pre-market USFDA approval but must be truthful, not misleading, substantiated by the manufacturer with competent and reliable scientific evidence, notified to the USFDA within 30 days of first use, and accompanied by the DSHEA disclaimer described above.
- Health Claims – claims that characterise the relationship between a substance and a disease or health-related condition (e.g., 'calcium may reduce the risk of osteoporosis'). These require either (a) pre-market USFDA review and authorisation based on a finding of 'significant scientific agreement,' (b) authorisation based on an authoritative statement

from certain scientific bodies, or (c) qualification as a ‘Qualified Health Claim’ supported by a lower level of scientific evidence but accompanied by a qualifying disclaimer language specified or accepted by the USFDA.

5.8 Adverse Event Reporting and Post-Market Surveillance

The Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006 amended the FD&C Act to require manufacturers, packers, and distributors of dietary supplements whose name appears on the product label to report all ‘serious adverse events’ associated with the use of the product to the USFDA within 15 business days of receipt of the report, and to maintain records of all adverse event reports (serious and non-serious) for a period of six years. Reports are submitted through the CFSAN Adverse Event Reporting System (CAERS), which also receives voluntary reports from healthcare professionals and consumers via the USFDA's MedWatch programme. This mandatory post-market reporting obligation is a central pillar of the US framework's reliance on post-market surveillance as a counterbalance to the absence of pre-market approval.

5.9 Enforcement, Penalties and the Role of the FTC

Where the USFDA determines that a marketed dietary supplement is adulterated (e.g., contains an unsafe ingredient, an unapproved NDI, or is manufactured in violation of cGMP) or misbranded (e.g., bears false or misleading labelling, or makes an unauthorised disease claim), it may pursue a range of enforcement actions, including issuing warning letters, requesting voluntary recalls, seizing products, seeking injunctions, and – since the enactment of the FDA Food Safety Modernization Act of 2011 – ordering mandatory recalls in certain circumstances. The Federal Trade Commission separately enforces against false or unsubstantiated advertising claims under Section 5 of the FTC Act, applying a ‘competent and reliable scientific evidence’ standard, and has historically been particularly active in relation to weight-loss, cognitive-enhancement, and immune-support claims for dietary supplements.

5.10 Recent Developments (2025–2026)

The period 2025–2026 has been one of significant regulatory activity in the US dietary supplement space. In addition to the establishment of the Human Foods Program described in Section 5.1, the USFDA's Office of Dietary Supplement Programs has held public meetings and solicited stakeholder input on the scope of substances eligible for use as ‘dietary ingredients’ and on potential reforms to the NDI notification framework, with industry

commentary frequently invoking the need for a comprehensive legislative update to DSHEA – informally referred to in trade publications as 'DSHEA 10.0' – to address categories of ingredients (such as certain fermentation-derived and biotechnology-derived substances) that were not contemplated in 1994. The December 2025 enforcement-discretion communication regarding the DSHEA disclaimer's placement on labels, discussed in Section 5.6, is one tangible outcome of this broader modernisation discussion. For Indian and EU-based manufacturers seeking to access the US market, these developments signal a continuing, if incremental, evolution of the US framework that regulatory affairs professionals must monitor closely.

REGULATORY FRAMEWORK FOR DIETARY SUPPLEMENTS IN THE EUROPEAN UNION

6.1 Regulatory Bodies

Regulation of food supplements in the European Union operates at two levels. At the EU level, the European Commission (specifically the Directorate-General for Health and Food Safety, DG SANTE) is responsible for proposing and adopting harmonised legislation, while the European Food Safety Authority (EFSA), an independent scientific agency established under the General Food Law Regulation, provides scientific risk assessments and opinions that underpin Commission decisions – including assessments of the safety of novel foods, the substantiation of health claims, and the safety of food additives and nutrient sources used in supplements. At the national level, each EU member state designates one or more Competent Authorities responsible for enforcement, market surveillance, and – in many member states – the operation of national notification systems for food supplements (examples include the Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes (DGCCRF) in France, the Federal Institute for Risk Assessment (BfR) in Germany, and the Food Standards Agency (FSA) in the United Kingdom, the latter applying a closely related but post-Brexit framework outside the EU proper).

6.2 Legal Framework

The foundational instrument of EU food law is Regulation (EC) No. 178/2002, the General Food Law Regulation, which establishes the general principles and requirements of food law, creates EFSA, and embeds the precautionary principle as a guiding standard for risk management decisions. Within this overarching framework, food supplements are specifically governed by Directive 2002/46/EC on the approximation of the laws of the

Member States relating to food supplements, which was the first EU-wide instrument to harmonise rules for this category – although, as discussed in Section 6.5, its harmonising effect has historically been more complete for vitamins and minerals than for other categories of supplement ingredients (such as botanicals), which continue to be subject to considerable national variation. Two further instruments are of central importance: Regulation (EC) No. 1924/2006 on nutrition and health claims made on foods, and Regulation (EU) 2015/2283 on novel foods, both discussed in detail below.

6.3 Definition and Classification

Directive 2002/46/EC defines 'food supplements' as foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form – that is, in forms such as capsules, pastilles, tablets, pills, and other similar forms, sachets of powder, ampoules of liquids, and drop-dispensing bottles, designed to be taken in measured small unit quantities. This definition is conceptually closer to the Indian 'Health Supplement' category and the US 'Dietary Supplement' category than to the broader Indian 'Nutraceutical' or 'Functional Food' categories, as EU law does not formally recognise a separate 'nutraceutical' category – products with such positioning are regulated either as food supplements, as foods for specific groups (under Regulation (EU) No. 609/2013, which covers categories analogous to FSDU/FSMP, including food for special medical purposes, infant formula, and total diet replacement products for weight control), or, where appropriate, as novel foods or medicinal products depending on their composition and claims.

6.4 Permitted Vitamins, Minerals and Their Forms

Annex I of Directive 2002/46/EC sets out the list of vitamins and minerals that may be used in the manufacture of food supplements, while Annex II specifies the particular chemical forms (vitamin and mineral substances/sources) in which each may be used – for example, specifying which salts or compounds of a given mineral are permitted as sources in food supplements. These Annexes are periodically updated by the Commission, acting on EFSA's scientific opinions, to add new permitted forms as they are demonstrated to be safe and bioavailable; a recent example is the addition of the monosodium salt of L-5-methyltetrahydrofolic acid (a bioactive folate form) as a permitted source of folate under Regulation (EU) 2025/2224, illustrating the EU's continuing, evidence-based expansion of its positive lists. Ingredients (other than vitamins and minerals) used in food supplements –

including botanicals, amino acids, and other substances with a nutritional or physiological effect – are not subject to a single harmonised EU-wide positive list in the same manner, and their use is governed by a combination of general food-safety law, national rules, and, where applicable, the Novel Food Regulation.

6.5 Maximum and Minimum Levels of Vitamins and Minerals

Although Directive 2002/46/EC envisaged the establishment of harmonised maximum and minimum amounts of vitamins and minerals that may be present in food supplements, taking into account upper safe levels established through risk assessment and the contribution of other dietary sources, the Commission has not, in practice, adopted EU-wide harmonised maximum levels for the majority of vitamins and minerals. As a result, individual member states have established their own national maximum levels – which vary considerably from one member state to another – leading to a situation in which a food supplement formulation that is lawfully marketed in one member state may exceed the permitted maximum levels for one or more nutrients in another member state. This lack of full harmonisation on maximum levels is consistently identified in the literature as one of the principal remaining barriers to a genuinely unified EU single market for food supplements, and is an important practical consideration for manufacturers seeking pan-EU distribution of a single formulation.

6.6 Novel Food Regulation – Regulation (EU) 2015/2283

Regulation (EU) 2015/2283 on novel foods (which recast and replaced the earlier Regulation (EC) No. 258/97) defines a ‘novel food’ as any food that was not used for human consumption to a significant degree within the EU before 15 May 1997, irrespective of the date of accession of member states to the EU, and establishes categories of novel foods including foods with a new or intentionally modified molecular structure, foods consisting of or isolated from microorganisms, fungi, algae, or plants, foods produced using novel production processes, and foods consisting of engineered nanomaterials. Before a novel food may be placed on the EU market, it must undergo a safety assessment by EFSA and be authorised by the European Commission, with the authorisation specifying the conditions of use, labelling requirements, and any specific compositional requirements. EFSA updated its administrative and scientific guidance for novel food applications with effect from February 2025, streamlining the dossier requirements while maintaining the rigour of the underlying safety assessment. The novel food pathway has been particularly significant – and at times contentious – for ingredients such as cannabidiol (CBD) extracts, certain algae-derived oils,

insect-derived proteins, and human-identical milk oligosaccharides (HiMOs), several of which have undergone or remain under EFSA evaluation.

6.7 Health Claims Regulation – Regulation (EC) No. 1924/2006

Regulation (EC) No. 1924/2006 establishes a harmonised framework governing the use of nutrition claims (statements about the energy or nutrient content of a food, e.g., 'low fat,' 'source of fibre') and health claims (statements about a relationship between a food/nutrient and health, e.g., 'Vitamin D contributes to the normal function of the immune system') on food labels and in advertising, including for food supplements. Under this Regulation, health claims may be used only if they have been authorised and included in the EU Register of nutrition and health claims following a positive scientific opinion from EFSA. The Regulation distinguishes between 'general function' claims (Article 13), which describe the role of a nutrient or substance in growth, development, and normal body functions, and claims relating to disease risk reduction or to children's development and health (Article 14), the latter being subject to a more stringent authorisation procedure. This pre-approval, positive-list approach represents the most restrictive of the three frameworks examined in this dissertation, in marked contrast to the largely self-substantiation-based approach of the United States and the general-substantiation requirement under the Indian framework.

6.8 Labelling Requirements

General food labelling in the EU is governed by Regulation (EU) No. 1169/2011 on the provision of food information to consumers (the 'FIC Regulation'), which prescribes mandatory particulars common to all foods, including the name of the food, list of ingredients, allergen information, net quantity, date of minimum durability, storage conditions, name and address of the food business operator, and nutrition declaration. In addition to these general requirements, Directive 2002/46/EC imposes supplement-specific labelling obligations, including: the use of the term 'food supplement' (or an equivalent term) as part of the name of the product; the names of the categories of nutrients or substances that characterise the product, or an indication of the nature of those substances; the recommended daily portion/dose of the product to be consumed; a warning not to exceed the stated recommended daily dose; a statement that food supplements should not be used as a substitute for a varied diet; and a statement that the product should be stored out of the reach of young children.

6.9 National Notification Systems

While Directive 2002/46/EC does not establish an EU-wide pre-market notification or approval requirement for food supplements composed of permitted ingredients in permitted forms, the Directive permits member states to require that a manufacturer or the person placing a food supplement on that member state's market notify the competent authority by forwarding a model of the label used for the product, in order to facilitate efficient monitoring of food supplements on the market. A significant number of member states – including France, Italy, Belgium, and others – have implemented such national notification requirements, which, while not constituting a substantive pre-market approval (the notified authority does not 'approve' the product), nonetheless require manufacturers to engage with each relevant national authority before marketing a product in that member state, adding a layer of national-level administrative complexity to what is otherwise a harmonised EU framework.

6.10 Recent Developments (2025–2026)

The EU framework has continued to evolve through 2025 and into 2026, with EFSA issuing updated guidance for both novel food applications (effective February 2025) and for the assessment of food additives and nutrient sources (further guidance issued in early 2026), and the Commission adopting new authorisations such as the folate-source authorisation under Regulation (EU) 2025/2224 referenced in Section 6.4. The regulatory status of cannabidiol (CBD) products as novel foods has remained a particularly closely watched area, with several CBD-related novel food applications continuing under EFSA evaluation, reflecting the cautious, evidence-driven pace at which the EU framework accommodates emerging ingredient categories. Academic and policy commentary published in this period has also examined the adequacy of the food-supplement framework from a public-health perspective – including discussion of supplement marketing to, and safety considerations for, children – indicating that further refinement of the EU framework, particularly in relation to maximum nutrient levels and vulnerable-population safeguards, remains an active area of policy discussion.

RESEARCH METHODOLOGY

7.1 Study Design

This dissertation adopts a descriptive, doctrinal, and comparative research design. It is descriptive in that it systematically documents the regulatory requirements applicable to

dietary supplements in each of the three jurisdictions studied; it is doctrinal in that it is based primarily on the analysis of primary legal texts – statutes, regulations, directives, and official guidance documents – rather than on experimental or survey-based data collection; and it is comparative in that its central analytical objective is the systematic, side-by-side comparison of these legal frameworks across a defined set of parameters, in order to identify convergences, divergences, and gaps. This type of desk-based comparative regulatory research is well established in the field of pharmaceutical and food regulatory affairs, where practitioners routinely need to map the requirements of multiple jurisdictions against one another to inform product development and market access strategy.

7.2 Data Sources

Data for this dissertation were drawn from two broad categories of sources:

7.2.1 Primary Sources

- Statutory and regulatory texts, including the Food Safety and Standards Act, 2006 and associated FSSAI Regulations (India); the Federal Food, Drug, and Cosmetic Act and the Dietary Supplement Health and Education Act, 1994, together with 21 CFR Parts 101 and 111 (United States); and Regulation (EC) No. 178/2002, Directive 2002/46/EC, Regulation (EC) No. 1924/2006, and Regulation (EU) 2015/2283 (European Union).
- Official guidance documents, notifications, FAQs, and administrative circulars issued by FSSAI, the USFDA (including the Human Foods Program and Office of Dietary Supplement Programs), the European Commission, and EFSA.
- International reference documents, including the Codex Alimentarius Commission's Guidelines for Vitamin and Mineral Food Supplements (CAC/GL 55-2005) and relevant World Health Organization publications on traditional medicine and food safety.

7.2.2 Secondary Sources

- Peer-reviewed academic articles and review papers addressing the regulation of dietary supplements, health supplements, and nutraceuticals in the jurisdictions under study.
- Industry and trade-association publications providing comparative regulatory overviews and practical compliance guidance.
- Authoritative news and analysis from regulatory and trade press, used principally to identify and verify recent (2025–2026) regulatory developments.

7.3 Selection Criteria

The selection of jurisdictions – India, the United States, and the European Union – was based on their combined significance as, respectively, a rapidly growing emerging market and increasingly important manufacturing/export base for nutraceuticals; the world's largest single national market for dietary supplements with a long-established, distinctive regulatory model; and a major, harmonised multi-country market with a comparatively precautionary and pre-approval-oriented regulatory model. Within each jurisdiction, the study focused on legislation and guidance currently in force and of general application to dietary/health supplements, nutraceuticals, and food supplements as defined in Chapter 1; legislation applicable solely to conventional foods, pharmaceutical drugs, medical devices, or cosmetics was excluded except where necessary to illustrate boundary/classification issues between categories.

7.4 Comparative Parameters

To ensure a structured and consistent comparison across the three jurisdictions, the following parameters were used as the analytical framework for Chapters 4 through 6 and for the comparative tables and discussion in Chapter 8:

7. Regulatory authority and institutional structure.
8. Primary legislation and legal classification of the product category (food vs. distinct statutory category vs. sub-category of food).
9. Definitions and sub-classifications of dietary/health supplements and related categories.
10. Pre-market approval, licensing, registration, or notification requirements, including treatment of new/novel ingredients.
11. Permitted ingredients, positive/negative lists, and maximum/minimum dosage limits.
12. Good Manufacturing Practice (GMP) requirements.
13. Labelling requirements, including mandatory declarations and warning statements.
14. Nutrition and health claims frameworks and associated substantiation standards.
15. Post-market surveillance, adverse event reporting, and pharmacovigilance-equivalent systems.
16. Enforcement mechanisms and penalties for non-compliance.

7.5 Methodology of Comparative Analysis

For each of the ten parameters identified in Section 7.4, the relevant provisions of the Indian, US, and EU frameworks (as documented in Chapters 4–6) were extracted and organised into

a comparative matrix (presented as a series of tables in Chapter 8). This matrix was then used to identify, for each parameter, (a) areas of substantive similarity across jurisdictions, (b) areas of significant divergence, and (c) the underlying regulatory philosophy or rationale that appears to explain observed divergences (for example, the contrast between the EU's precautionary, pre-approval-oriented approach to health claims and the US's post-market, self-substantiation-based approach). In addition, two illustrative case studies – covering probiotic ingredients and herbal/botanical ingredients – were developed by applying the same comparative matrix to a specific ingredient category, in order to demonstrate how the abstract regulatory comparisons translate into practical differences in product development and market access for a real-world ingredient type. Finally, the synthesised findings were used as the basis for the recommendations developed in Chapter 9.

7.6 Tools Used

This dissertation was compiled using standard word-processing and document-preparation tools. No statistical software, laboratory instrumentation, or clinical research tools were required, consistent with the desk-based, doctrinal-comparative nature of the study design described in Section 7.1.

RESULTS AND DISCUSSION: COMPARATIVE ANALYSIS

This chapter presents the principal results of the comparative analysis conducted in accordance with the methodology described in Chapter 7. The findings are organised around the ten comparative parameters identified in Section 7.4, presented as a series of comparative tables accompanied by discussion, followed by two illustrative ingredient-level case studies, a discussion of international harmonisation efforts, and an assessment of the implications of regulatory divergence for industry and global trade.

Figure 8.1 presents, in tabular step-by-step form, the regulatory pathway a dietary supplement product typically follows from formulation to post-market surveillance in each of the three jurisdictions. To allow each jurisdiction’s sequence to be read as a self-contained pathway, India, the United States and the European Union are each presented on a separate page (Figures 8.1(a), 8.1(b) and 8.1(c) respectively), before the detailed parameter-wise comparison is presented in the sections that follow.

Figure 8.1(a): Comparative Regulatory Pathway for Market Entry – India

Step	Stage	Description
1	Formulation & Classification	Product category determined (Health Supplement / Nutraceutical / FSDU / FSMP / Probiotic / Prebiotic Food) under the FSS Act, 2006 and the Health Supplements, Nutraceuticals and Related Regulations.
2	Ingredient & Dosage Check	Ingredients verified against permitted schedules and maximum daily dosage limits; new/novel ingredients require FSSAI safety assessment before use.
3	Manufacturing Licence / Registration	Central or State FSSAI licence or registration obtained under Schedule 4 GMP conditions (Licensing & Registration Regulations, 2011) prior to manufacture.
4	Product-Level Approval	No separate product-wise pre-market approval for standard formulations; Novel Food ingredients require Central Licensing Authority approval.
5	Labelling Compliance	Label finalised in line with the FSS (Labelling & Display) Regulations, 2020, including mandatory Health Supplement disclaimers.
6	Advertising / Claims Substantiation	Health claims scientifically substantiated; disease/cure claims prohibited under the FSS (Advertising & Claims) Regulations, 2018.
7	Market Launch	Product marketed once the licence/registration is granted and labelling requirements are satisfied.
8	Post-Market Surveillance	Ongoing State/Central inspection and sampling by FSSAI; no dedicated statutory adverse-event reporting system for supplements.
9	Recall (if required)	Conducted under the general FSS (Recall Procedure) Regulations, 2017, at FSSAI's direction.

Figure 8.1(b): Comparative Regulatory Pathway for Market Entry – United States.

Step	Stage	Description
1	Formulation & Classification	Manufacturer self-determines 'dietary supplement' status under the Dietary Supplement Health and Education Act (DSHEA), 1994.
2	Ingredient Assessment	'Old' dietary ingredients (marketed before 15 October 1994) may be used without notification; New Dietary Ingredients (NDIs) require an NDI notification, triggering a 75-day FDA pre-market review window.
3	GMP Compliance	Manufacture under 21 CFR Part 111 current Good Manufacturing Practice requirements; no licence or registration required to manufacture.
4	No Pre-Market Approval	Manufacturer self-certifies safety; the USFDA does not approve dietary supplement products before marketing.

5	Labelling Compliance	Supplement Facts Panel prepared per 21 CFR 101.36, together with the mandatory DSHEA disclaimer statement.
6	Claims Substantiation	Structure/function, nutrient-content and (occasionally) qualified health claims permitted with disclaimers; must be truthful and non-misleading, with FTC oversight of advertising.
7	Market Launch	Product marketed immediately upon manufacture; FDA notified only where a structure/function claim is made (within 30 days of first marketing) and for NDIs.
8	Post-Market Surveillance	Mandatory serious adverse-event reporting under 21 U.S.C. § 379aa-1 (CAERS); FDA may act against adulterated or misbranded products.
9	Recall (if required)	Predominantly voluntary, manufacturer-initiated recalls (Class I/II/III) under 21 CFR Part 7; mandatory FDA recall authority is limited to specific circumstances.

Figure 8.1(c): Comparative Regulatory Pathway for Market Entry – European Union

Step	Stage	Description
1	Formulation & Classification	Product classified as a 'Food Supplement' under Directive 2002/46/EC (or as a Novel Food / Food for Specific Medical Purposes under separate instruments).
2	Ingredient Assessment	Vitamins/minerals must be in permitted forms listed in the Annexes to Directive 2002/46/EC; novel ingredients require EFSA risk assessment and European Commission authorisation under Regulation (EU) 2015/2283.
3	National Notification	Most Member States require notification (not approval) of the product/label to the national competent authority before or upon first marketing.
4	GMP Compliance	General food-hygiene rules under Regulation (EC) 852/2004, supplemented by national GMP guidance specific to supplements.
5	Labelling Compliance	Regulation (EU) 1169/2011 (Food Information to Consumers), together with the specific labelling requirements of Directive 2002/46/EC.
6	Health Claims Authorisation	Only claims pre-authorised and listed on the EU Register of Nutrition and Health Claims (Regulation (EC) No. 1924/2006) may be used.
7	Market Launch	Product marketed once applicable national notification requirements are satisfied.
8	Post-Market Surveillance	Member-state-level vigilance, supported by the EU Rapid Alert System for Food and Feed (RASFF) for cross-border safety issues.
9	Recall (if required)	Mandatory withdrawal/recall and notification obligations on food business operators under Regulation (EC) 178/2002, coordinated through RASFF.

8.1 Classification Categories of Dietary/Health Supplements

The first and most fundamental point of comparison is the manner in which each jurisdiction classifies and sub-divides the broad category of products under study. Table 8.1 summarises the principal classification categories recognised under each framework.

Table 8.1: Classification Categories of Dietary / Health Supplements under FSSAI, USFDA and EU Frameworks.

Category Type	India (FSSAI)	United States (USFDA)	European Union (EC)
Core supplement category	Health Supplement	Dietary Supplement	Food Supplement
Nutraceutical / functional category	Separately defined: Nutraceutical; Functional Food	Not separately defined – regulated within 'dietary supplement' or as conventional food with claims	Not separately defined – regulated as food supplement, food for specific groups, or novel food depending on composition
Special dietary / medical category	Food for Special Dietary Use (FSDU); Food for Special Medical Purpose (FSMP)	'Medical foods' – a separate FD&C Act category distinct from dietary supplements	Food for Special Medical Purposes under Regulation (EU) No. 609/2013
Microbiome-related category	Separately defined: Prebiotic Food; Probiotic Food, with permitted-strain list	No FDA-defined 'probiotic' category; regulated as dietary supplement ingredient	No EU-wide 'probiotic' category; term 'probiotic' itself often restricted as an on-pack claim
Novel / new ingredient category	Novel Food – requires FSSAI safety assessment	New Dietary Ingredient (NDI) – notification-based (NDIN)	Novel Food under Regulation (EU) 2015/2283 – EFSA assessment + EC authorisation
Typical time period to resolve queries / clarifications	Deficiency memos typically require applicant response within 15–30 days; overall FSSAI licence/registration decision indicatively within 30–60 working days of a complete application	No formal 'query' cycle for most supplements (no pre-market approval); for New Dietary Ingredient (NDI) notifications, FDA reviews within a 75-day pre-market window and may raise objections within that period	Novel Food applications: EFSA risk assessment indicatively within 9 months of a valid application; national food-supplement notifications typically acknowledged/queried within 1–2 months, subject to member-state variationauthorisation

The classification comparison reveals a fundamental structural difference: India operates the most granular classification system, with eight distinct, separately defined product categories,

each carrying its own compositional rules. The United States, by contrast, employs a single broad statutory category ('dietary supplement') defined primarily by ingredient type and dosage form, with related but separately regulated categories (such as 'medical foods') sitting outside the DSHEA framework. The European Union occupies an intermediate position – a single core 'food supplement' category under Directive 2002/46/EC, with adjacent but distinct categories (foods for specific groups, novel foods) governed by separate instruments. For a manufacturer developing a single global product, this means that the same formulation may need to be classified, and therefore labelled and substantiated, quite differently depending on the target market – for instance, a probiotic-containing product may be a distinctly defined 'Probiotic Food' in India, an undifferentiated 'dietary supplement' in the United States, and a 'food supplement' in the EU where the very word 'probiotic' may not be permitted on the label without an authorised health claim.

8.2 Regulatory Authorities and Governing Legislation

Table 8.2 compares the institutional architecture and primary legislative instruments governing dietary supplements in each jurisdiction.

Table 8.2: Comparison of Regulatory Authorities and Governing Legislation.

Aspect	India	United States	European Union
National / supranational regulator	FSSAI (Ministry of Health & Family Welfare)	USFDA – Human Foods Program (HFP) / Office of Dietary Supplement Programs (ODSP)	European Commission (DG SANTE), supported by EFSA (scientific risk assessment)
Sub-national enforcement	State/UT Food Safety Authorities and Food Safety Officers	Primarily federal; state health departments play a limited supporting role	National Competent Authorities of each of the 27 member states
Primary legislation	Food Safety and Standards Act, 2006	Federal Food, Drug, and Cosmetic Act, as amended by DSHEA, 1994	Regulation (EC) No. 178/2002 – General Food Law Regulation
Category-specific regulation	FSS (Health Supplements, Nutraceuticals, FSDU, FSMP, Prebiotic & Probiotic Food) Regulations, 2022	21 CFR Parts 101 & 111 (labelling and GMP); DSHEA definitions and provisions	Directive 2002/46/EC – Food Supplements Directive
Advertising / claims oversight	FSS (Advertising & Claims) Regulations, 2018, read with the Drugs & Magic Remedies (Objectionable	Federal Trade Commission (advertising) and USFDA (label claims)	Regulation (EC) No. 1924/2006 (Nutrition & Health Claims), enforced nationally

Aspect	India	United States	European Union
	Advertisements) Act, 1954		

All three jurisdictions vest primary scientific and standard-setting authority in a specialised food-safety body – FSSAI, the USFDA's Human Foods Program, and EFSA (in an advisory capacity to the European Commission) – reflecting a shared, internationally accepted institutional model of separating risk assessment from risk management functions, at least in the EU case. However, the locus of binding legal authority differs: in India and the United States, the national regulator (FSSAI / USFDA) both assesses risk and takes binding regulatory decisions, whereas in the EU, EFSA's role is advisory and binding decisions rest with the European Commission, often informed by a comitology process involving member-state representatives. The bifurcation of advertising oversight between a food/drug regulator and a separate consumer-protection/competition authority (FTC in the US; the Drugs & Magic Remedies Act framework in India) is a further point of similarity, while the EU's approach – embedding claims regulation directly within food law via Regulation 1924/2006 – represents a more integrated model.

8.3 Pre-Market Approval and Notification Pathways

Table 8.3 compares the pre-market pathways applicable to dietary supplement products and to new/novel ingredients.

Table 8.3: Comparison of Pre-Market Approval / Notification Pathways.

Pathway Element	India	United States	European Union
General product pre-market approval	Not required for compliant formulations (product-approval scheme abolished); FBO licensing/registration is mandatory	Not required; manufacturer self-determines safety based on history of use	Not required for compliant formulations using permitted ingredients/forms
Mandatory licensing/registration of manufacturer or importer	Yes – Central Licence mandatory for health supplements, nutraceuticals and importers, generally irrespective of turnover	No supplement-specific federal licence; general food-facility registration applies under food safety law	Food business registration/approval with national competent authority generally required
New / novel ingredient pathway	Ingredients outside the permitted-ingredient schedules require a safety assessment via the Novel	New Dietary Ingredient Notification (NDIN) – 75 days' advance notice to USFDA, with	Novel Food authorisation – EFSA safety assessment followed by EC authorisation;

Pathway Element	India	United States	European Union
	Food route	supporting safety rationale	typically a lengthy, multi-stage process
Additional national/state-level notification	Central Licence application processed via the FoSCoS portal (single national system)	Not applicable – no federal pre-market notification system for supplement products	Several member states (e.g., France, Italy, Belgium) require label-based notification to national authorities before marketing

This comparison highlights a key practical distinction for market-entry planning: although none of the three jurisdictions requires product-by-product pre-market 'approval' in the sense applicable to pharmaceutical drugs, each imposes a different form of pre-market administrative burden. India concentrates this burden at the level of the manufacturing/importing entity (mandatory Central Licensing), the United States concentrates it at the level of the ingredient (NDIN for genuinely new dietary ingredients only, with no burden for established ingredients), and the European Union, while harmonised at the level of permitted vitamin/mineral forms, retains a fragmented, country-by-country notification burden at the level of the individual product label in a substantial number of member states. The Novel Food/NDI comparison is particularly instructive: the US NDIN process (75-day notification) is considerably faster and less resource-intensive than the EU Novel Food authorisation process (which can extend well beyond a year), while India's Novel Food route, though structurally similar in concept to the EU's, has historically been used less frequently, with most new botanical ingredients instead being added directly to the permitted-ingredient schedules through periodic regulatory amendment.

8.4 Licensing, Registration and GMP Requirements

Table 8.4 compares manufacturing-related licensing and Good Manufacturing Practice requirements.

Table 8.4: Comparison of Licensing, Registration and Good Manufacturing Practice (GMP) Requirements.

Element	India	United States	European Union
GMP regulation	Schedule 4, FSS (Licensing & Registration of Food Businesses) Regulations, 2011 (general food hygiene; category-	21 CFR Part 111 – dietary-supplement-specific cGMP regulation	General food hygiene rules under Regulation (EC) No. 852/2004; no EU-wide supplement-specific GMP regulation

Element	India	United States	European Union
	specific guidance supplements this)		
Facility licensing	FSSAI Central or State Licence, category-dependent	Food facility registration under federal food-safety law; no supplement-specific federal licence	Food business registration/approval with national competent authority
Renewal / periodicity	Licence renewal required periodically per FSSAI norms (commonly 1–5 years)	Biennial facility registration renewal	Varies by member state; generally tied to general food-business registration cycles
Quality control / testing emphasis	In-house quality control mandated under Schedule 4 for licensed manufacturers	Identity, purity, strength and composition testing of dietary ingredients and finished products mandated under 21 CFR Part 111	Testing requirements arise from general HACCP-based food-safety management obligations under Regulation (EC) No. 852/2004

The United States stands out in this comparison as the only jurisdiction with a GMP regulation drafted specifically for dietary supplements (21 CFR Part 111), which prescribes detailed, supplement-specific requirements for identity testing, specification-setting, and batch documentation. India and the EU, by contrast, apply general food-hygiene-based GMP frameworks to supplement manufacturing, supplemented in India's case by category-specific guidance. From a regulatory affairs perspective, this means that a manufacturing facility already compliant with 21 CFR Part 111 is likely to meet or exceed the general food-hygiene-based GMP expectations applicable in India and the EU, whereas the converse is not necessarily true – a facility compliant only with general food-hygiene GMP may need to implement additional supplement-specific identity and specification testing protocols to meet US cGMP requirements for export to that market.

8.5 Labelling Requirements

Table 8.5 compares the principal supplement-specific labelling requirements across the three jurisdictions.

Table 8.5: Comparison of Labelling Requirements.

Labelling Element	India	United States	European Union
Category declaration	'Health Supplement' / 'Nutraceutical' etc. must be prominently and distinctly displayed	'Dietary Supplement' forms part of the mandatory statement of identity	'Food supplement' (or equivalent term) forms part of the name of the product
Composition / nutrition panel	Nutritional information panel per FSS (Labelling & Display) Regulations, 2020	Standardised 'Supplement Facts' panel under 21 CFR 101.36	Nutrition declaration per Regulation (EU) No. 1169/2011, plus supplement-specific declarations under Dir. 2002/46/EC
Dosage / serving statement	Recommended daily dosage and a 'do not exceed' warning are mandatory	Serving size declared on the Supplement Facts panel	Recommended daily portion and a 'do not exceed' warning are mandatory
Disclaimer language	'Not a substitute for a balanced diet'; 'not intended to diagnose, treat, cure or prevent any disease'	DSHEA disclaimer (21 CFR 101.93) required wherever a structure/function claim is made	Statement that the product 'should not be used as a substitute for a varied diet'
Child-safety statement	Not specifically mandated beyond general safe-storage norms	Not specifically mandated	Mandatory statement to keep the product out of the reach of young children
Drug-resemblance prohibition	Explicit prohibition on packaging, imagery or nomenclature resembling pharmaceutical products	General misbranding provisions of the FD&C Act apply	General provisions apply; certain member states impose additional restrictions

The labelling comparison reveals a substantial degree of conceptual convergence – all three jurisdictions require a category-identifying term, a dosage/serving statement with an associated safety warning, and some form of disclaimer regarding the product's relationship to disease and to a balanced diet. The principal differences lie in emphasis and specificity: India is the only jurisdiction among the three to impose an explicit, general prohibition on drug-resembling packaging and nomenclature – a provision that directly addresses the historical blurring of the line between Ayurvedic/herbal drugs and food-based nutraceuticals in the Indian market. The EU is the only jurisdiction to mandate a specific child-safety storage statement on the label itself (as opposed to general consumer-safety expectations). The US 'Supplement Facts' panel and DSHEA disclaimer represent the most procedurally

standardised labelling format of the three, with a fixed, USFDA-prescribed layout, whereas India and the EU prescribe the required content of declarations without mandating an equally rigid panel format.

8.6 Health Claims Frameworks

Table 8.6 compares the frameworks governing nutrition and health claims – widely regarded as the area of greatest substantive divergence among the three jurisdictions.

Table 8.6: Comparison of Health Claims Frameworks.

Element	India	United States	European Union
Pre-approval of claims	Not required; claim must be substantiated by the FBO with generally accepted scientific evidence at time of use	Not required for structure/function claims (notified to USFDA within 30 days); health claims require authorisation or qualification	Required – claim must appear on the EU Register of permitted claims following a positive EFSA opinion (Reg. 1924/2006)
Disease / cure claims	Prohibited – overlaps with the Drugs & Cosmetics Act, 1940 and the Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954	Prohibited as unauthorised drug claims unless the product is approved as a drug, or the claim qualifies as an authorised health claim	Prohibited unless the claim is an authorised 'disease risk reduction' claim under Article 14
Structure/function-type claims	Permitted if substantiated and not framed as a disease claim	Explicitly recognised category; permitted subject to the mandatory DSHEA disclaimer	'General function' claims (Article 13) permitted only if included on the positive list of authorised claims
Evidentiary standard	'Generally accepted scientific evidence' (FBO self-assessed)	'Competent and reliable scientific evidence' (manufacturer self-determined; FTC-enforced)	EFSA scientific opinion based on the 'totality of the evidence'; generally regarded as the most stringent standard of the three
Primary enforcement body	FSSAI, together with authorities administering the Drugs & Magic Remedies Act	USFDA (label claims) and FTC (advertising claims)	National competent authorities, overseen by the European Commission

The health claims comparison is, in many respects, the clearest illustration of the differing regulatory philosophies underlying the three frameworks. The European Union's pre-approval, positive-list model places the burden of generating and submitting robust scientific evidence on the applicant before any claim may be used, and EFSA's assessments applying the 'totality of evidence' standard have, in practice, resulted in the rejection of a significant proportion of submitted health claims, particularly for botanical ingredients. The United States, by contrast, permits structure/function claims on a self-substantiation basis, subject to post-hoc enforcement by the USFDA and FTC if the underlying evidence is later found inadequate – a model that affords manufacturers greater marketing flexibility but places greater reliance on robust post-market enforcement. India's framework, requiring substantiation with 'generally accepted scientific evidence' but without a positive list or pre-authorisation requirement, occupies a position closer to the US model in structure, though the overlay of the Drugs & Magic Remedies Act creates an additional, India-specific constraint on the types of claims that may be made, particularly for products with a traditional-medicine heritage.

8.7 Post-Market Surveillance, Adverse Event Reporting and Enforcement

Table 8.7 compares the mechanisms through which each jurisdiction monitors marketed products and enforces compliance.

Table 8.7: Comparison of Post-Market Surveillance, Adverse Event Reporting and Enforcement Mechanisms.

Element	India	United States	European Union
Mandatory adverse-event reporting for supplements	No dedicated statutory adverse-event reporting system specific to health supplements/nutraceuticals	Mandatory reporting of serious adverse events within 15 business days, via the CFSAN Adverse Event Reporting System (CAERS)	No EU-wide supplement-specific adverse-event system; general food-safety incidents handled via the Rapid Alert System for Food and Feed (RASFF)
Recall authority	FSSAI empowered to order recalls under the FSS Act, 2006	USFDA has mandatory recall authority for foods, including dietary supplements, under the FDA Food Safety Modernization Act, 2011	National competent authorities order recalls/withdrawals; RASFF facilitates cross-border alerts among member states
Routine	Surveillance and sampling by	USFDA facility	National competent

Element	India	United States	European Union
market surveillance	Food Safety Officers under FSSAI/State authorities	inspections for cGMP compliance, supplemented by targeted market sampling	authority market surveillance, supplemented by EU-coordinated control programmes
Penalties for non-compliance	Monetary penalties, suspension/cancellation of licence, and – for unsafe or grossly misbranded food – imprisonment under the FSS Act, 2006 (severity-graded)	Warning letters, product seizure, injunctions, and – for serious or repeated violations – criminal penalties under the FD&C Act	Withdrawal/recall orders and fines determined under national law; penalty severity varies considerably across member states

Post-market surveillance represents one of the most significant points of divergence identified in this study, and one of particular relevance to the recommendations developed in Chapter 9. The United States' mandatory serious-adverse-event reporting obligation, centralised through CAERS, provides the USFDA with a structured, ongoing safety-signal-detection capability that operates independently of – and indeed substitutes in part for – the absence of pre-market approval. Neither India nor the European Union has an equivalent, dedicated, mandatory adverse-event reporting system specific to health supplements/nutraceuticals; in India, adverse events are more likely to surface through general consumer-complaint mechanisms, media reports, or ad hoc surveillance, while in the EU, the RASFF system is oriented primarily toward acute food-safety hazards (contamination, adulteration) rather than systematic collection of adverse health outcomes associated with otherwise compliant products. This gap is discussed further as a key recommendation in Chapter 9.

8.8 Comparative Case Studies: Probiotics, Herbal/Botanical Ingredients and Novel Ingredients (Cannabidiol)

To illustrate how the abstract regulatory comparisons presented above translate into practical differences for specific ingredient categories, Table 8.8 presents three comparative case studies covering ingredient categories of particular relevance to the Indian nutraceutical industry: probiotics, herbal/botanical ingredients, and cannabidiol (CBD) as an example of an emerging novel ingredient.

Table 8.8: Comparative Case Studies – Regulatory Status of Probiotic, Herbal/Botanical and Cannabidiol (CBD) Ingredients.

Ingredient Category	India	United States	European Union
Probiotics – regulatory recognition	Separately defined 'Probiotic Food' category, with a positive list of permitted microbial strains specified by genus, species and strain designation	No FDA-defined 'probiotic' category; regulated as a dietary-ingredient (microbial strain) within a dietary supplement, often via self-affirmed GRAS or NDI status	Regulated as a food supplement ingredient; the word 'probiotic' itself is frequently treated as an implied health claim and may be restricted on-label absent an EFSA-authorised claim
Strain-level specificity required	Yes – permitted strains listed by FSSAI with genus/species/strain designation	No master positive list; manufacturer relies on strain-specific self-affirmed GRAS determination or NDI notification	No EU-wide positive list of strains; national notification dossiers may require strain-level documentation
Herbal / botanical ingredients – approach	Positive list (Schedule) of permitted botanicals, specifying plant part used and maximum daily dose; potential overlap with ASU&H 'drug' classification	Regulated as 'herb or other botanical' dietary ingredients; safety substantiated via 'old dietary ingredient' status or NDIN for new botanicals; no FDA positive list	No EU-wide positive list; considerable national variation – some botanicals restricted or prohibited in certain member states; Novel Food route applies if not used to a significant degree pre-1997
Principal compliance challenge	Avoiding inadvertent classification as an Ayurvedic/Siddha/Unani 'drug' under the Drugs & Cosmetics Act, 1940	Establishing and documenting 'old dietary ingredient' status, or completing the NDIN process for botanicals not marketed before October 1994	Navigating divergent national botanical positive/negative lists and notification requirements across up to 27 member states
Cannabidiol (CBD) – regulatory status	Not permitted as an ingredient in Health Supplements/Nutraceuticals under FSSAI regulations at present; cannabis-derived ingredients remain closely linked to controls under the Narcotic Drugs and Psychotropic Substances Act, 1985, creating significant uncertainty for manufacturers	Hemp-derived CBD with ≤0.3% THC is federally permitted as a hemp product, but the FDA has not authorised CBD as a dietary supplement ingredient and has issued warning letters against such marketing; several	Treated as a Novel Food requiring EFSA safety assessment and EC authorisation under Regulation (EU) 2015/2283 before it may be marketed as a food/supplement ingredient; authorisation

Ingredient Category	India	United States	European Union
		states impose additional restrictions	applications remain under review with no CBD ingredient yet approved as a novel food

The probiotics case study illustrates a striking inversion of the general pattern observed elsewhere in this dissertation: whereas India's framework is generally the most prescriptive in terms of category definition, in the specific case of probiotics India's positive-list, strain-specified approach actually provides greater on-label clarity for manufacturers than either the US or EU frameworks, where the term ‘probiotic’ itself can be a source of labelling risk. The herbal/botanical case study, by contrast, illustrates a challenge that is broadly common to all three jurisdictions – namely, the difficulty of establishing the regulatory status of a botanical ingredient with a long history of traditional use but limited modern safety-assessment documentation – while highlighting that each jurisdiction has developed a structurally different (positive list, old-ingredient/NDI, and fragmented national lists, respectively) mechanism for addressing this common challenge. The cannabidiol (CBD) case study illustrates a third, distinct pattern: rather than divergent mechanisms for regulating an accepted ingredient category, all three jurisdictions currently treat CBD with considerable caution or outright restriction, reflecting the ingredient's origin in a controlled plant species; India's framework is the most restrictive in practice, the United States occupies an ambiguous federal/state position despite the legality of low-THC hemp, and the European Union requires novel food authorisation that, as of the period reviewed, remained unresolved for CBD as a supplement ingredient – illustrating that regulatory caution toward emerging or contested ingredients can itself be a point of convergence, even where the underlying legal bases differ substantially.

8.9 Harmonisation Efforts and the Role of Codex Alimentarius

Despite the substantial divergences documented above, all three jurisdictions participate, to varying degrees, in international standard-setting processes coordinated through the Codex Alimentarius Commission (CAC), a joint body of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). The CAC's Guidelines for Vitamin and Mineral Food Supplements (CAC/GL 55-2005) recommend that maximum levels of vitamins and minerals in supplements be set using risk-assessment-based methods that take into

account upper safe levels and the contribution of other dietary sources – a methodology that has informed, to differing extents, both the EU's (non-harmonised) national maximum-level frameworks and India's RDA-based approach to vitamin/mineral limits. While the United States is not bound by Codex standards in the same manner as WTO members implementing the Sanitary and Phytosanitary (SPS) Agreement's reference to Codex for trade-dispute purposes, Codex guidelines nonetheless function as an important reference point in US regulatory and industry discourse, particularly in relation to international trade.

In practice, however, full harmonisation remains distant. The three jurisdictions differ not only in specific numerical limits and permitted-ingredient lists, but – as the analysis in Sections 8.1 through 8.7 demonstrates – in the fundamental regulatory philosophy applied to dietary supplements: India and the EU regulate the category primarily as a sub-set of food law with category-specific compositional rules (India) or a harmonised but incompletely standardised Directive (EU), while the US treats the category as a distinct statutory creation with minimal pre-market intervention. Codex guidelines, being necessarily general in nature in order to accommodate such divergent national approaches, function more as a common reference vocabulary and a risk-assessment methodology than as a substitute for jurisdiction-specific compliance.

8.10 Implications for Industry and Global Trade

The regulatory divergence documented in this chapter has direct and material implications for manufacturers, particularly Indian manufacturers seeking to access the US and EU markets, and for multinational manufacturers seeking to introduce products in India. A formulation that is fully compliant in one jurisdiction may require one or more of the following adjustments before it can be lawfully marketed in another: reformulation to remove or substitute ingredients not on a destination market's positive list (e.g., certain botanicals permitted in India but not established as EU-permitted novel foods, or vice versa); adjustment of vitamin/mineral dosages to align with destination-market maximum levels (particularly relevant for EU member states with low national maximum levels relative to India's RDA-based limits); relabelling to reflect destination-market-specific category terminology, disclaimers, and warning statements; and removal or modification of health claims that, while permissible in the country of manufacture, would constitute an unauthorised claim in the destination market – most acutely where a claim permissible in India or the US would require prior EFSA authorisation to be used in the EU.

These compliance costs function, in effect, as a non-tariff barrier to trade in dietary supplements, and are consistently identified in industry literature as a significant factor in market-entry decision-making, particularly for small and medium-sized Indian nutraceutical exporters with limited in-house regulatory affairs capacity. At the same time, the comparative analysis also identifies opportunities: for example, India's structured, strain-specified approach to probiotic regulation (Section 8.8) could serve as a useful reference point for manufacturers seeking to build robust strain-documentation files that would also support compliance in less-prescriptive markets such as the US. Chapter 9 builds on these observations to develop specific, actionable recommendations.

8.11 Quantitative Comparison of Maximum Permitted Levels for Selected Nutrients

While Sections 8.1 through 8.8 compare the structural and procedural aspects of the three frameworks, regulatory affairs practice ultimately also requires comparison at the level of specific permitted quantities. Table 8.9 presents indicative reference figures for six commonly used vitamins and minerals, drawn from ICMR Recommended Dietary Allowances (India), the US National Institutes of Health Office of Dietary Supplements Dietary Reference Intakes including Tolerable Upper Intake Levels (USA), and the EU's harmonised Nutrient Reference Values together with illustrative national maximum levels reported across EU member states.

Table 8.9: Indicative Maximum Permitted / Recommended Levels for Selected Vitamins and Minerals (Adult Population)

Nutrient	India (ICMR RDA basis)	USA (RDA / Tolerable Upper Intake Level)	EU (NRV + illustrative national maxima)
Vitamin D (as D3)	RDA ≈ 600 IU (15 mcg)/day; supplement levels generally permitted up to the range of 1000–2000 IU/day depending on product category	RDA 600–800 IU/day; UL = 4000 IU (100 mcg)/day	EU NRV = 5 mcg (200 IU); national maximum levels vary widely, commonly in the range of 25–50 mcg (1000–2000 IU)/day
Vitamin C	RDA ≈ 40–80 mg/day; supplements commonly permitted up to several hundred mg/day	RDA 75–90 mg/day; UL = 2000 mg/day	EU NRV = 80 mg; national maximum levels vary considerably, from a few hundred mg to up to 1000 mg/day in some member states
Calcium	RDA ≈ 600–1200 mg/day	RDA 1000–1200	EU NRV = 800 mg; national

Nutrient	India (ICMR RDA basis)	USA (RDA / Tolerable Upper Intake Level)	EU (NRV + illustrative national maxima)
	(life-stage dependent); supplement levels generally capped relative to RDA	mg/day; UL = 2000–2500 mg/day	maximum levels vary, commonly in the range of 800–1500 mg/day
Iron	RDA ≈ 17–21 mg/day (adult women); supplement levels capped relative to RDA	UL = 45 mg/day (adults)	EU NRV = 14 mg; several member states cap supplemental iron in the range of 14–20 mg/day
Vitamin B12	RDA ≈ 2.4 mcg/day; supplements commonly permitted at multiples of RDA given low toxicity	No UL established (considered low risk at high intakes)	EU NRV = 2.5 mcg; national maximum levels are generally permissive given the low-toxicity profile
Zinc	RDA ≈ 12–15 mg/day; supplement levels capped relative to RDA	UL = 40 mg/day (adults)	EU NRV = 10 mg; national maximum levels vary, commonly in the range of 15–25 mg/day

Note: The figures above are indicative reference values intended to illustrate the order of magnitude and the pattern of cross-jurisdictional variation; they are not a substitute for the current official FSSAI schedules, USFDA regulations, or member-state-specific national maximum levels, which should always be verified at the time of product formulation. The EU column in particular illustrates, in concrete numerical terms, the lack of full harmonisation discussed qualitatively in Section 6.5 – a single EU NRV coexists with a wide range of national maximum levels across member states. By contrast, India's RDA-anchored approach and the US's UL-anchored approach each provide a single national reference point, even though the resulting permitted ranges differ between the two.

8.12 Comparative Overview of E-Commerce and Online Sale Regulations

The growth of e-commerce as a sales channel for dietary supplements has prompted each jurisdiction to extend, or clarify the application of, its existing regulatory framework to online sales. Table 8.10 summarises the comparative position.

Table 8.10: Comparative Overview of E-Commerce / Online Sale Regulations.

Aspect	India	United States	European Union
E-commerce-specific regulatory	FSSAI requires e-commerce Food Business Operators to obtain the applicable	No dietary-supplement-specific e-commerce regulation;	General EU consumer-protection and distance-selling

Aspect	India	United States	European Union
provisions	licence/registration and to display the same mandatory label information online as on physical packaging; the Consumer Protection (E-Commerce) Rules, 2020 impose additional general disclosure obligations on online marketplaces	existing FD&C Act labelling and claims requirements, and FTC advertising rules, apply equally to online and offline sales	rules apply (e.g., the Consumer Rights Directive); food information obligations under the FIC Regulation extend to distance/online sales
Mandatory online label/information display	Name, ingredient list, net quantity, nutritional information, FSSAI logo and licence number, and category declaration must be displayed on the e-commerce listing	Supplement Facts panel content is generally expected to be accessible to the online purchaser prior to sale, consistent with general labelling obligations	Article 14 of the FIC Regulation requires that mandatory food information be available before the conclusion of a distance sale, with certain particulars provided at the point of delivery
Treatment of cross-border online sales	Foreign sellers shipping into India remain subject to FSSAI import requirements, including the importer's Central Licence obligation	Foreign sellers must ensure products meet US labelling, safety and (where applicable) NDI requirements before sale to US consumers; USFDA/CBP import controls apply at the border	Products sold online into the EU from outside the EU must still meet EU food-law requirements; enforcement against non-compliant cross-border online sellers varies by member state
Principal enforcement challenge	Proliferation of unregistered or unverified sellers on marketplaces, and unsubstantiated claims in online listings and influencer marketing	FTC enforcement against unsubstantiated health/structure-function claims in online and social-media advertising	Inconsistent enforcement across member states against non-compliant cross-border e-commerce listings, particularly from sellers based outside the EU

The e-commerce comparison demonstrates that, rather than creating entirely new regulatory categories, all three jurisdictions have generally sought to apply their existing supplement-specific labelling, claims, and import frameworks to the online channel, with India having taken the most explicit step of codifying online-display obligations specifically. In each jurisdiction, however, the practical enforcement challenge of monitoring a very large number of online listings – including those from third-country sellers operating through international

marketplaces – remains a significant and only partially resolved issue, and is an area of likely continued regulatory attention in all three jurisdictions.

8.13 Indicative Market-Entry Timelines and Compliance Cost Burden

Finally, Table 8.11 synthesises the pre-market pathway comparison from Section 8.3 into indicative timelines and a qualitative assessment of the relative compliance cost burden associated with bringing a dietary supplement to market in each jurisdiction, distinguishing between products using only well-established ingredients and products incorporating a new/novel ingredient.

Table 8.11: Indicative Market-Entry Timelines and Compliance Cost Burden.

Stage / Scenario	India	United States	European Union
Licensing / registration of manufacturing or importing entity	FSSAI Central Licence: typically of the order of 30–60 days, subject to processing volumes	Food facility registration: same-day to short turnaround via online registration; no product-specific approval required	Food business registration/approval with national competent authority: typically a few weeks; timelines vary by member state
Product using only well-established (positive-list / pre-1994 / Annex-listed) ingredients	No additional ingredient-level pathway; product can be marketed on completion of licensing and label compliance	No additional ingredient-level pathway; product can be marketed once labelling (Supplement Facts, DSHEA disclaimer) is finalised	No additional ingredient-level pathway for compliant formulations; member-state notification (where required) typically adds a few weeks
Product incorporating a new / novel ingredient	Novel Food safety assessment: timeline variable and case-dependent, often extending to 6–12 months or more for a full dossier review	New Dietary Ingredient Notification (NDIN): minimum 75-day pre-market notice period, plus time required to compile the safety dossier	Novel Food authorisation: EFSA assessment followed by EC decision typically extends to 12–18 months or longer
If a new health claim is required	Not applicable as a separate pathway; claim substantiation is prepared by the FBO and used at the time of labelling/advertising	Not applicable for structure/function claims (self-substantiated); a qualified health claim petition, where pursued, can take a year or more	EFSA-assessed health claim authorisation has historically taken in the order of 12–24 months or longer from application to Commission decision

Stage / Scenario	India	United States	European Union
Overall qualitative compliance cost burden	Low-to-moderate for established formulations (licensing fees and label compliance); increases significantly where reformulation against updated schedules or a Novel Food dossier is required	Low for products using established ingredients (self-substantiation model); cost rises markedly where an NDI dossier or qualified health claim petition is needed	Moderate-to-high overall, reflecting the cost of preparing EFSA-standard scientific dossiers for novel foods and health claims, and the administrative cost of multiple national notifications

This synthesis underscores a recurring theme of this dissertation: for formulations using only well-established ingredients and conventional claims, the three frameworks impose broadly comparable – and individually manageable – administrative timelines. The most significant divergence in both timeline and cost arises specifically where a product involves a new or novel ingredient or a new health claim, with the EU's EFSA-based authorisation pathways consistently representing the longest and most resource-intensive route of the three. For Indian manufacturers developing genuinely novel ingredients (for example, newly characterised botanical extracts or next-generation probiotic strains) with multi-market ambitions, this implies that EU market entry should be planned with the longest lead time, and that the dossier prepared for an EU Novel Food or health-claim application – being the most demanding of the three – can generally be adapted to support the comparatively less onerous Indian Novel Food and US NDIN pathways, whereas the converse is less likely to be true.

SUMMARY, CONCLUSION AND RECOMMENDATIONS

9.1 Summary of Findings

This dissertation set out to compare the regulatory requirements governing dietary supplements – encompassing health supplements, nutraceuticals, and food supplements – in India, the United States, and the European Union, across ten structured comparative parameters. The principal findings may be summarised as follows. First, the three jurisdictions differ fundamentally in regulatory philosophy: India operates the most granular, category-based classification system with eight distinct product definitions; the United States employs a single broad statutory category (‘dietary supplement’) with minimal pre-market intervention and heavy reliance on post-market accountability; and the European Union applies a harmonised core definition (‘food supplement’) combined with a precautionary, pre-

approval-oriented approach to health claims and novel ingredients. Second, despite differing in form, all three jurisdictions impose some form of pre-market administrative requirement – mandatory entity-level licensing in India, ingredient-level notification (NDIN) in the US, and a combination of harmonised positive lists with fragmented national notification in the EU. Third, labelling requirements show substantial conceptual convergence (category declaration, dosage statements, disclaimers) but differ in specific emphasis, with India uniquely prohibiting drug-resembling packaging, the EU uniquely mandating a child-safety storage statement, and the US uniquely prescribing a standardised 'Supplement Facts' panel format. Fourth, and perhaps most significantly, health claims frameworks represent the area of greatest substantive divergence: the EU's pre-approval, EFSA-assessed positive-list model is markedly more restrictive than the largely self-substantiation-based models in India and the US. Fifth, post-market surveillance and adverse-event reporting represent a second area of major divergence, with the United States' mandatory CAERS-based serious-adverse-event reporting system having no direct equivalent in either India or the EU for this product category. Finally, the two ingredient-level case studies (probiotics and herbal/botanical ingredients) demonstrate that these abstract regulatory differences translate into concrete, practical compliance challenges – and, in the specific case of probiotics, that India's prescriptive approach can in some respects be more protective of label clarity than the less-prescriptive US and EU approaches.

9.2 CONCLUSION

The comparative analysis presented in this dissertation demonstrates that, although India, the United States, and the European Union share the overarching objective of ensuring that dietary supplements available to consumers are safe, properly labelled, and not misleadingly marketed, the specific legal and administrative mechanisms by which each jurisdiction pursues this objective differ substantially – to the extent that full regulatory harmonisation, even in the limited sense achieved within the EU for vitamin and mineral supplements, remains a distant prospect across all three. For regulatory affairs professionals, manufacturers, and policy makers, these differences are not merely academic: they directly determine the feasibility, cost, and timeline of bringing a given dietary supplement formulation to market in each jurisdiction, and they represent a continuing, non-tariff barrier to international trade in this rapidly growing product category. At the same time, the comparative exercise also reveals that each jurisdiction has developed regulatory tools – India's strain-specified probiotic list, the US's structured NDIN and CAERS systems, and the

EU's EFSA-assessed health-claims register – that, while developed independently, address common underlying regulatory challenges and may offer transferable lessons for the others.

9.3 Recommendations

9.3.1 Recommendations for Strengthening the Indian Regulatory Framework

17. FSSAI may consider developing a dedicated, mandatory adverse-event reporting framework for health supplements and nutraceuticals – potentially modelled conceptually on the US CAERS/MedWatch system – to provide systematic post-market safety-signal data that would complement, rather than substitute for, the existing licensing-based pre-market framework.
18. A more clearly codified, time-bound safety-assessment pathway for new/novel ingredients (including new botanicals and probiotic strains not yet on the permitted-ingredient schedules) would reduce uncertainty for manufacturers and could draw on elements of both the US NDIN model (defined notification period) and the EU Novel Food model (structured EFSA-style scientific dossier requirements), calibrated to Indian administrative capacity.
19. Continued expansion and periodic, predictable updating of the positive lists of permitted botanicals and probiotic strains – with clear, published timelines for review cycles – would help reduce the regulatory uncertainty that the literature reviewed in Chapter 2 identifies as a recurring industry concern.
20. Clearer, FSSAI-issued guidance on the boundary between food-based nutraceuticals/health supplements and Ayurvedic, Siddha, and Unani ‘drugs’ under the Drugs and Cosmetics Act, 1940 would help manufacturers avoid inadvertent misclassification, particularly for botanical ingredients with a traditional-medicine heritage.
21. Consideration could be given, over the longer term, to a limited positive list of pre-assessed, commonly used health claims (analogous in concept, though not necessarily in stringency, to the EU's Article 13 general-function claims) for well-established nutrient-health relationships, which could reduce duplicative substantiation effort across the industry while maintaining the existing self-substantiation pathway for novel claims.

9.3.2 Recommendations for Regulatory Affairs Practice and Manufacturers

22. Manufacturers planning multi-jurisdictional product launches should conduct jurisdiction-specific ingredient and dosage screening at the earliest stages of product development,

using the comparative matrix developed in Chapter 8 (Tables 8.1–8.8) as a starting checklist, to identify reformulation needs before significant investment in product development.

23. Health-claim strategies should be developed on a jurisdiction-by-jurisdiction basis from the outset, with particular attention to the EU's pre-approval requirement; manufacturers intending to make health claims in the EU should budget for the EFSA-authorisation timeline (which can exceed the typical product-development cycle) or restrict EU launch claims to those already present on the EU Register.
24. For probiotic-containing products, manufacturers should build comprehensive, strain-specific documentation files (genus, species, strain designation, and supporting safety/efficacy data) from the outset, as such documentation is directly usable to meet India's positive-list requirements, can support a US self-affirmed GRAS determination, and provides a stronger basis for any future EU notification or claim application.
25. Given the divergence in maximum vitamin/mineral levels (particularly between India's RDA-based limits and the lower national maximum levels applicable in certain EU member states), manufacturers should avoid designing a single ‘global’ dosage strength where the target markets include both India and multiple EU member states, and should instead plan for market-specific dosage variants from the formulation stage.
26. Regulatory affairs teams should establish a structured horizon-scanning process to monitor ongoing developments – such as the USFDA's Human Foods Program reforms, FSSAI's periodic schedule amendments, and EFSA's evolving novel food and additive guidance – given the demonstrably dynamic nature of all three frameworks documented in this dissertation.

9.3.3 Recommendations Relating to International Harmonisation

27. Greater engagement by all three jurisdictions with Codex Alimentarius processes – particularly in relation to risk-assessment methodologies for setting maximum vitamin/mineral levels – could, over time, narrow the gap between India's RDA-based limits and the EU's non-harmonised national maximum levels, even if full numerical alignment is unlikely in the near term.
28. Industry bodies and regulators in all three jurisdictions could usefully invest in the development of shared, internationally recognised strain-identity documentation standards for probiotics, building on the structured approaches already present (in different forms) in both the Indian and US frameworks.

29. Bilateral or trilateral regulatory-cooperation dialogues focused specifically on the dietary supplement/nutraceutical sector – distinct from broader pharmaceutical regulatory cooperation – could provide a forum for the kind of structured, parameter-by-parameter comparison undertaken in this dissertation to be maintained on an ongoing, updated basis.

9.4 Scope for Future Research

This dissertation has focused on a defined set of comparative parameters across three jurisdictions, based on a desk-based review of primary and secondary literature current as of 2025–2026. Future research could usefully extend this work in several directions: first, by incorporating additional jurisdictions of significance to the global nutraceutical trade, such as China, Australia/New Zealand (under the joint Food Standards Code), Japan (Foods with Function Claims and Foods for Specified Health Uses systems), and the ASEAN Harmonized Scheme; second, by undertaking a more granular, member-state-by-member-state analysis of national maximum nutrient levels and notification requirements within the European Union; third, by conducting primary research – including structured interviews or surveys of regulatory affairs professionals in Indian nutraceutical companies – to assess the practical impact of the regulatory divergences identified in this dissertation on actual market-entry timelines and costs; and fourth, by undertaking a longitudinal follow-up study once the currently ongoing modernisation initiatives in the US (potential DSHEA reform), India (further FSSAI schedule revisions), and the EU (continuing novel food and additive guidance updates) have reached a more settled state, in order to assess whether regulatory convergence has increased or decreased over time.

ACKNOWLEDGEMENT

I offer my sincere gratitude to the Almighty for being the constant source of strength, patience and inspiration throughout the course of this dissertation work.

I am deeply indebted to my esteemed guide, Mr. Shoaib Ali, Department of Pharmaceutical Regulatory Affairs, for his valuable guidance, constant encouragement, constructive criticism and meticulous attention at every stage of this work. His insight into the regulatory landscape and his patient mentorship have been the driving force behind the successful completion of this dissertation.

I would like to express my heartfelt thanks to Dr. V. G. Rajurkar, Principal, Dr. Vedprakash Patil Pharmacy College, Chhatrapati Sambhajinagar, for his valuable guidance, motivation and for providing excellent infrastructural facilities that made this work possible.

I am grateful to Dr. Patil V. K. S., President, Shri Dhaneshwari Manav Vikas Mandal's Dr. Vedprakash Patil Pharmacy College, Chhatrapati Sambhajinagar, for providing the necessary infrastructure and encouragement during this project.

My sincere thanks to all the respected teaching staff of the Department of Pharmaceutical Regulatory Affairs for their valuable suggestions and constant support throughout this dissertation.

I extend my thanks to the non-teaching staff and the library staff of the institute for their cooperation and assistance in accessing the regulatory literature, journals and reference materials required for this study.

I am thankful to all my classmates and friends for their moral support, encouragement and the stimulating discussions that helped shape the direction of this work.

Finally, I express my deepest gratitude to my family for their unconditional love, patience, financial support and unwavering faith in me, which made this journey possible.

REFERENCES

The following primary legal instruments, regulatory guidance documents, international guidelines, and academic/industry sources were referred to in the preparation of this dissertation. Readers are encouraged to consult the official, current versions of all primary legislation directly on the websites of the respective regulatory authorities (FSSAI, USFDA, and the European Commission/EFSA), as these instruments are subject to periodic amendment.

1. Food Safety and Standards Authority of India. Food Safety and Standards Act, 2006. Ministry of Health and Family Welfare, Government of India, New Delhi.
2. 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.

3. Food Safety and Standards Authority of India. Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Prebiotic and Probiotic Food) Regulations, 2022.
4. Food Safety and Standards Authority of India. Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011.
5. Food Safety and Standards Authority of India. Food Safety and Standards (Labelling and Display) Regulations, 2020.
6. Food Safety and Standards Authority of India. Food Safety and Standards (Advertising and Claims) Regulations, 2018.
7. Government of India. The Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945, Ministry of Health and Family Welfare.
8. Government of India. The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954.
9. Food Safety and Standards Authority of India. Food Safety Compliance System (FoSCoS) – Licensing and Registration Manuals and User Guidance.
10. United States Congress. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq.
11. United States Congress. Dietary Supplement Health and Education Act of 1994 (DSHEA), Public Law 103-417, 108 Stat. 4325.
12. United States Congress. Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006, Public Law 109-462.
13. United States Congress. FDA Food Safety Modernization Act (FSMA), Public Law 111-353 (2011).
14. US Food and Drug Administration. Code of Federal Regulations, Title 21, Part 111 – Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements.
15. US Food and Drug Administration. Code of Federal Regulations, Title 21, Section 101.36 – Nutrition Labeling of Dietary Supplements.
16. US Food and Drug Administration. Code of Federal Regulations, Title 21, Section 101.93 – Certain Types of Statements for Dietary Supplements.
17. US Food and Drug Administration. Human Foods Program – Organisational Overview and Reorganisation Announcements, 2025.
18. US Food and Drug Administration, Office of Dietary Supplement Programs. New Dietary Ingredient Notifications and Related Issues – Guidance for Industry and Public Meeting Materials, 2025–2026.

19. US Food and Drug Administration. CFSAN Adverse Event Reporting System (CAERS) – Public Dashboard and Reporting Guidance.
20. US Federal Trade Commission. Dietary Supplements: An Advertising Guide for Industry.
21. European Parliament and Council of the European Union. Regulation (EC) No. 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
22. European Parliament and Council of the European Union. Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements.
23. European Parliament and Council of the European Union. Regulation (EC) No. 1924/2006 on nutrition and health claims made on foods.
24. European Parliament and Council of the European Union. Regulation (EU) No. 1169/2011 on the provision of food information to consumers.
25. European Parliament and Council of the European Union. Regulation (EU) 2015/2283 on novel foods.
26. European Parliament and Council of the European Union. Regulation (EU) No. 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control.
27. European Commission. Regulation (EC) No. 852/2004 on the hygiene of foodstuffs.
28. European Commission. Commission Implementing Regulation (EU) 2025/2224 authorising the placing on the market of the monosodium salt of L-5-methyltetrahydrofolic acid as a source of folate.
29. European Food Safety Authority (EFSA). Guidance on the Preparation and Submission of Applications for Authorisation of Novel Foods, updated February 2025.
30. European Food Safety Authority (EFSA). Scientific Opinions and Guidance on Food Additives and Nutrient Sources Used in Food Supplements, 2025–2026.
31. Codex Alimentarius Commission. Guidelines for Vitamin and Mineral Food Supplements, CAC/GL 55-2005. Joint FAO/WHO Food Standards Programme.
32. World Health Organization. WHO Traditional Medicine Strategy 2014–2023. Geneva: World Health Organization.
33. World Journal of Advanced Research and Reviews. (2024). Regulatory frameworks governing nutraceuticals in India. World Journal of Advanced Research and Reviews, 23(03), 2558–2571.
34. International Alliance of Dietary/Food Supplement Associations (IADSA). Global Regulatory Overview – Comparative Reports on Dietary/Food Supplement Regulation.

ANNEXURES

ANNEXURE I: Comparative Regulatory Compliance Checklist for Dietary Supplements

The following checklist is intended as a practical reference tool for regulatory affairs professionals assessing the compliance requirements applicable to a dietary supplement product intended for market in India, the United States, and/or the European Union. It is structured around the key compliance parameters addressed in this dissertation and should be used alongside the full text of the applicable regulations, which should always be verified for currency before reliance.

Table A.1: Comparative Regulatory Compliance Checklist for Dietary Supplements (India / USA / EU)

Compliance Parameter	India ✔/✘	USA ✔/✘	EU ✔/✘	Notes / Key Reference
Product classification confirmed under applicable framework				India: Health Supplement / Nutraceutical / FSDU / FSMP / Prebiotic / Probiotic / Functional Food / Novel Food per FSS Regs 2022; USA: Dietary Supplement under DSHEA; EU: Food Supplement under Dir. 2002/46/EC or Novel Food under Reg. 2015/2283
All ingredients confirmed on the applicable positive list or assessed as established/permitted				India: FSSAI vitamin/mineral/botanical schedules; USA: old dietary ingredient status confirmed for each ingredient; EU: Annex I/II of Dir. 2002/46/EC for vitamins/minerals; Novel Food status confirmed (pre-1997 threshold)
New / novel ingredient notification or authorisation completed if required				India: FSSAI Novel Food safety assessment; USA: NDIN filed ≥75 days before marketing; EU: Novel Food authorisation obtained from EC following EFSA assessment
Dosages/quantities verified against jurisdiction-specific maximum levels				India: ICMR RDA-based limits in FSSAI schedules; USA: UL from NIH DRI tables; EU: national maximum levels for each target member state verified
Manufacturing facility licensed / registered as applicable				India: FSSAI Central Licence via FoSCoS; USA: food facility registration (federal); EU: registration/approval with national competent authority

Compliance Parameter	India ✔/✘	USA ✔/✘	EU ✔/✘	Notes / Key Reference
GMP compliance confirmed and documented				India: Schedule 4 of FSS Licensing & Registration Regs 2011; USA: 21 CFR Part 111 cGMP (full compliance including identity/purity/strength testing); EU: Reg. (EC) 852/2004 general food hygiene + HACCP
Label content drafted and reviewed against all applicable requirements				India: FSS Labelling & Display Regs 2020 + category-specific requirements; USA: 21 CFR 101.36 (Supplement Facts panel), DSHEA disclaimer per 21 CFR 101.93; EU: FIC Reg. (EU) 1169/2011 + Dir. 2002/46/EC supplement-specific declarations
All on-label health / nutrition claims reviewed for compliance				India: FSS Advertising & Claims Regs 2018 – substantiation on file; disease claims absent; USA: structure/function claim notified to USFDA within 30 days of first use; DSHEA disclaimer present; EU: only claims on EU Health Claims Register used
Online listing / e-commerce display reviewed for mandatory information compliance				India: same mandatory info as physical label; FSSAI e-FBO compliance; USA: FTC standards apply to online advertising; EU: Art. 14 FIC Reg. obligations for distance sales
Import / export documentation in place (if applicable)				India (import): FSSAI Central Licence in importer's name; FICS clearance; India (export): Health Certificate / Certificate of Free Sale from FSSAI; US import: US importer of record compliance; EU import: compliance declaration
Post-market adverse event reporting system established				India: general consumer complaint mechanism; USA: mandatory serious AE reporting via CAERS within 15 business days – internal reporting SOPs required; EU: RASFF notification where applicable; national vigilance contacts identified
National notification filed in target EU member states (where required)				EU only: check notification requirement for each target member state (e.g., France DGCCRF, Italy MINSAL, Belgium FASFC); national maximum levels verified per member state

ANNEXURE II: Glossary of Key Regulatory Terms

The following glossary defines key regulatory terms as used in this dissertation, with cross-references to the relevant jurisdiction where the term is jurisdiction-specific.

Term	Definition
Adverse Event (AE)	Any health-related event associated with the use of a dietary supplement that is adverse to health, regardless of whether the event is considered to be related to or caused by the product. In the US context, a 'serious adverse event' is specifically defined under 21 U.S.C. § 379aa-1 to include death, a life-threatening experience, inpatient hospitalisation, a persistent or significant disability or incapacity, a congenital anomaly or birth defect, or a medical or surgical intervention to prevent such outcomes.
CAERS	CFSAN Adverse Event Reporting System – the USFDA's electronic adverse-event reporting and surveillance system for foods (including dietary supplements) and cosmetics, maintained by the Center for Food Safety and Applied Nutrition (CFSAN).
Codex Alimentarius	A collection of internationally recognised standards, codes of practice, guidelines, and other recommendations relating to foods, food production, and food safety, developed by the Codex Alimentarius Commission (CAC) – a joint body of the FAO and WHO. The Guidelines for Vitamin and Mineral Food Supplements (CAC/GL 55-2005) are the principal Codex reference for dietary supplements.
Daily Value (DV)	A term used in US nutrition labelling (under 21 CFR 101) representing a reference amount for a nutrient established by the USFDA and used in the Supplement Facts panel to express the percentage of the DV provided per serving. DVs are based on a reference intake of 2,000 calories per day for adults and children aged 4 and over.
DSHEA	Dietary Supplement Health and Education Act of 1994 – the US federal law (Public Law 103-417) that amended the FD&C Act to create the statutory definition and regulatory category for 'dietary supplements,' establish the New Dietary Ingredient notification framework, and define the types of claims that may be made on dietary supplement labels.
EFSA	European Food Safety Authority – the EU's independent scientific body responsible for risk assessment relating to food and feed safety, established under Regulation (EC) No. 178/2002. EFSA provides scientific opinions that inform the European Commission's decisions on novel food authorisations, health claim authorisations, and the safety of nutrients and food additives.
FoSCoS	Food Safety Compliance System – India's FSSAI-administered online portal through which food business operators (FBOs) apply for licences and registrations, file returns, manage compliance documentation, and access regulatory information.
FSSAI	Food Safety and Standards Authority of India – the national food-safety regulatory authority of India, established under the Food Safety and Standards Act, 2006, under the Ministry of Health and Family Welfare.
Functional Food	As defined under the FSS (Health Supplements, Nutraceuticals …)

Term	Definition
	Regulations, 2016/2022 in India: a food that, in addition to its basic nutritional value, contains bioactive components that offer a demonstrated physiological benefit or reduce the risk of chronic disease when consumed as part of a normal diet. The EU does not recognise a separate 'functional food' category in law, and the US similarly does not have a separate statutory category for functional foods.
GMP / cGMP	Good Manufacturing Practice / current Good Manufacturing Practice – the systems and procedures required to consistently produce products that meet their specifications and quality standards. In the US context for dietary supplements, cGMP requirements are codified at 21 CFR Part 111.
Health Claim	In the EU (Regulation (EC) No. 1924/2006): any claim that states, suggests, or implies that a relationship exists between a food category, a food, or one of its constituents and health. All health claims used on EU food supplement labels must be pre-authorised and listed on the EU Register of Nutrition and Health Claims. In the US (DSHEA/FD&C Act): a claim that characterises the relationship between a substance and a disease or health-related condition; requires USFDA authorisation or qualification as a qualified health claim. In India (FSS Advertising & Claims Regulations, 2018): any claim that implies a food has a health benefit; must be substantiated but does not require pre-authorisation.
NDI / NDIN	New Dietary Ingredient / New Dietary Ingredient Notification – under DSHEA, a 'new dietary ingredient' is any dietary ingredient not marketed in the United States in a dietary supplement before October 15, 1994. Manufacturers intending to market a supplement containing an NDI must submit a New Dietary Ingredient Notification (NDIN) to the USFDA at least 75 days before introducing the product into interstate commerce.
Novel Food	India (FSS Regulations, 2016/2022): a food or food ingredient with no history of safe use in India, or produced by a new process/technology not previously used for food. EU (Regulation (EU) 2015/2283): food not used for human consumption to a significant degree within the EU before 15 May 1997. Both jurisdictions require a safety assessment and/or authorisation before novel foods may be placed on the market.
Nutraceutical	A term widely used in industry and the scientific literature to refer to food-derived products providing physiological benefits beyond basic nutrition, but without a single harmonised legal definition across all three jurisdictions. In India, 'Nutraceutical' is a formally defined regulatory category under the FSS Regulations, 2016/2022. In the US and EU, the term is used commercially but has no dedicated legal definition, with such products regulated under the broader 'dietary supplement' or 'food supplement' categories respectively.
Nutrient Reference Value (NRV)	In EU food information law (Regulation (EU) No. 1169/2011): reference amounts used for nutrition labelling purposes to express the percentage of the reference intake provided per serving. Analogous to the US 'Daily Value.'
RDA (ICMR)	Recommended Dietary Allowance as established by the Indian Council of Medical Research for the Indian population – the basis on which maximum and minimum vitamin/mineral levels in health supplements are calculated

Term	Definition
	under the FSSAI framework.
RASFF	Rapid Alert System for Food and Feed – the EU's network for rapid exchange of information between national competent authorities and the European Commission when risks to human or animal health are identified in the food/feed supply chain. Serves as the principal EU-wide post-market safety-alert mechanism for food supplements.
Structure/Function Claim	Under DSHEA (USA): a claim that describes the role of a nutrient or dietary ingredient in affecting the normal structure or function of the human body (e.g., 'calcium builds strong bones'). Such claims do not require USFDA pre-approval but must be truthful, substantiated, notified to the USFDA within 30 days, and accompanied by the required DSHEA disclaimer. Conceptually equivalent to the EU's 'general function claims' under Article 13 of Regulation (EC) No. 1924/2006, which however require pre-authorisation and listing on the EU Register.
Tolerable Upper Intake Level (UL)	The highest average daily intake of a nutrient that is likely to pose no risk of adverse health effects to almost all individuals in the general population. ULs for vitamins and minerals are established by the National Academies of Sciences, Engineering, and Medicine (USA) as part of the Dietary Reference Intakes (DRI) framework and are used as a reference point in US dietary supplement risk assessment and labelling.