Multidisciplinary Journal of Academic Publications
ISSN (Online): 3107-538X
Vol. 02, Issue 04, July– August 2026

AN EVIDENCE-BASED CLINICAL VALIDATION FRAMEWORK FOR NUTRACEUTICALS: A COMPARATIVE CLINICAL NUTRITION ANALYSIS OF REGULATORY EVIDENCE REQUIREMENTS IN INDIA, THE UNITED STATES, AND THE EUROPEAN UNION

Jyotsna Jaspal
Research Scholar, Department of Clinical Nutrition, Kennedy University
Registration No.: KUSLS20220143994

ABSTRACT

The global nutraceutical industry, valued at approximately USD 451.8 billion in 2024, operates under divergent regulatory architectures that impose fundamentally different clinical evidence standards across jurisdictions. This study presents an evidence-based comparative analysis of nutraceutical clinical validation frameworks in India (FSSAI), the United States (FDA/DSHEA), and the European Union (EFSA/Directive 2002/46/EC), with particular emphasis on safety substantiation requirements, health claim authorization pathways, and pre-market clinical evidence obligations. The primary hypothesis states that significant regulatory asymmetry in clinical evidence requirements among the three jurisdictions creates unequal market entry barriers, consumer safety risks, and structural impediments to global harmonization. Using documentary analysis, regulatory database review, and structured comparative tabulation of official regulatory instruments, this study examined clinical evidence tiers, claim categories, and enforcement mechanisms across the three regulatory regions.

Keywords: *Nutraceuticals[1], Clinical Validation[2], FSSAI Regulations3, DSHEA[4], EFSA Health Claims[5].*

1. INTRODUCTION

The concept of nutraceuticals products derived from food sources that deliver health benefits exceeding basic nutritional value has moved from scientific curiosity to global industry over three decades (Bansal & Dhiman, 2020). The term itself, coined by Dr. Stephen DeFelice in 1989, describes a spectrum of products ranging from dietary supplements and functional foods to fortified beverages and herbal extracts (Blaze et al., 2021). Despite phenomenal market growth, the nutraceutical sector operates without a universally accepted regulatory

definition, creating a fragmented global compliance landscape that directly impacts consumer safety, manufacturer accountability, and clinical evidence standards. The global nutraceutical market was estimated at USD 451.8 billion in 2024 and is projected to reach USD 746.6 billion by 2034 at a CAGR of 5%, according to Global Market Insights. Among the dominant regions, North America holds the largest market share at 42.1%, followed by Europe and Asia Pacific. India's nutraceutical market, valued at approximately USD 5.6 billion in 2023, is projected to grow to USD 37.5 billion by 2026, representing one of the fastest-growing supplement markets globally (Grand View Research, 2024). This explosive growth makes the question of clinical evidence adequacy increasingly urgent from a public health standpoint.

India's regulatory framework is governed primarily by the Food Safety and Standards Authority of India (FSSAI) under the Food Safety and Standards Act, 2006. The FSS (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 with subsequent amendments in 2022 form the operative clinical guidance (Food Safety and Standards Authority of India, 2016). Importantly, clinical trials are not mandatory for all nutraceutical products in India; they are required only on a case-by-case basis for Disease Risk Reduction claims, and the FSSAI's expert committee evaluates such evidence when submitted (Tomar et al., 2023). In the United States, the Dietary Supplement Health and Education Act (DSHEA) of 1994 established the legal architecture under which dietary supplements are classified as a subcategory of food (U.S. Food and Drug Administration, 1994). DSHEA's framework is fundamentally post-market: manufacturers are not required to demonstrate safety or efficacy to the FDA before marketing, except in the case of New Dietary Ingredients (NDIs), which require a 75-day pre-market notification (Dwyer et al., 2018). The current US dietary supplement market encompasses over 100,000 products with annual revenues exceeding USD 60 billion, underscoring the scale of this minimally pre-regulated sector.

The European Union, by contrast, operates the most rigorous pre-market evidence regime among the three. Directive 2002/46/EC on food supplements, combined with Regulation (EC) No 1924/2006 on nutrition and health claims, mandates that all health claims must be evaluated and authorized by the European Food Safety Authority (EFSA) prior to use (European Parliament and Council, 2006). EFSA's assessment processes require robust scientific dossiers, including human clinical trial data, systematic reviews, and biomarker evidence. This robust pre-market framework has resulted in the EU nutraceutical market valued at USD 79.95 billion in 2023 and projected to reach USD 101.60 billion by 2028 being characterized by a relatively lower product count but higher per-product evidence standards (Santini et al., 2018). The regulatory divergence among India, the US, and EU creates a tripartite evidence environment in which identical nutraceutical products face vastly different clinical substantiation requirements. For Indian manufacturers, understanding these differences is strategically vital for regulatory compliance, export market access, and domestic consumer protection, particularly as India's inter-ministerial committee has recently proposed significant structural reforms to align FSSAI standards more closely with international norms.

2. LITERATURE REVIEW

The academic literature on nutraceutical regulation has evolved substantially since the early 2000s, moving from definitional debates toward evidence-based and comparative regulatory analyses. Bansal and Dhiman (2020) conducted a comprehensive comparative review of nutraceutical regulatory frameworks across major global economies, demonstrating that while laws exist in most jurisdictions, they lack harmonization and impose inconsistent evidence requirements, particularly regarding pre-market clinical substantiation. The study highlighted that unharmonized regulations constitute one of the primary barriers to global nutraceutical trade, a finding directly relevant to India's ambitions as an exporting economy. Santini et al. (2018) argued in a landmark British Journal of Clinical Pharmacology article that an officially shared regulatory definition of nutraceuticals remains absent globally, and that clinical evidence requirements including in vitro, in vivo, and human clinical trial data must be formalized to transition nutraceuticals from marketing claims to scientifically validated therapeutic tools. This argument gains particular salience in the Indian context, where the FSSAI's approach to DRR claim evidence remains inconsistent and evolving (Tomar et al., 2023). Dwyer et al. (2018) examined the US regulatory environment in detail, documenting that DSHEA's post-market surveillance architecture creates significant quality variability, particularly for botanical and herbal supplements. The authors noted that FDA's post-market authority is constrained it can act only when a product presents a "significant or unreasonable risk of illness or injury," placing substantial burdens on the agency to demonstrate harm rather than on manufacturers to demonstrate safety. Domínguez Díaz et al. (2020) critically analyzed the regulatory frontier between nutrition and pharma across international jurisdictions, concluding that the distinction between a nutraceutical and a drug is interpreted differently by FSSAI, FDA, and EFSA a difference that directly determines the type and quantity of clinical evidence required. In the EU, products making disease risk reduction or even biological function claims must undergo EFSA's evidence-based authorization process, while in India, such claims may be marketed under FSSAI's structure/function claims framework with considerably less clinical substantiation (Thakkar et al., 2020).

Blaze et al. (2021) and Thakkar et al. (2020) both emphasized that the lack of globally harmonized clinical validation standards creates consumer safety risks and trade barriers. The former study specifically identified that without pre-market clinical evidence requirements, product quality especially bioavailability and ingredient authenticity cannot be guaranteed. Shan et al. (2025), in the most current global assessment available, reviewed regulatory governance across ten jurisdictions including India, the US, and EU, finding that emerging technologies such as AI-driven quality control and blockchain traceability represent the next frontier in bridging regulatory evidence gaps. Chopra et al. (2022) underscored the clinical transition of nutraceuticals from preventive to protective care roles, demanding that evidence frameworks keep pace with expanded therapeutic claims. Tripathi et al. (2020) further contextualized ASEAN-specific regulatory gaps, noting that India's FSSAI model provides a partially useful template for developing-economy regulation but requires strengthened clinical evidence capacity. Collectively, the literature converges on three central findings: (1) regulatory asymmetry

between India, US, and EU is substantial and has real consequences for consumer safety; (2) clinical evidence requirements in India are the least stringent of the three; and (3) harmonization toward an EFSA-like evidence standard is increasingly advocated by researchers, though practically constrained by market and economic realities (Gottlieb & McClellan, 2022; Jain et al., 2022; Helal et al., 2019).

3. OBJECTIVES

1. To comparatively analyze the clinical evidence requirements for nutraceutical market authorization in India (FSSAI), the United States (FDA/DSHEA), and the European Union (EFSA), identifying structural disparities in pre-market and post-market validation standards.
2. To develop an evidence-based regulatory validation framework that addresses identified gaps in India's nutraceutical clinical evidence architecture, drawing from best practices in US and EU regulatory models.

4. METHODOLOGY

This study employed a systematic documentary analysis design, utilizing an interpretive comparative policy framework to evaluate clinical evidence requirements for nutraceuticals across three jurisdictions. Primary regulatory documents including India's FSS (Health Supplements, Nutraceuticals) Regulations 2016/2022, the US DSHEA 1994 and subsequent FDA guidance documents, and EU Directive 2002/46/EC, Regulation (EC) No 1924/2006, and EFSA evaluation guidelines served as the principal data sources. Secondary data were drawn from peer-reviewed academic literature retrieved from PubMed, Google Scholar, and ScienceDirect using search terms including "nutraceutical regulation comparative," "FSSAI clinical evidence," "DSHEA evidence requirements," and "EFSA health claims authorization." Inclusion criteria required studies published between 2018 and 2025 that specifically addressed clinical validation or regulatory comparison in at least two of the three focal jurisdictions. A total of 42 primary regulatory documents and 67 peer-reviewed articles were screened, with 20 meeting all inclusion criteria for synthesis. Market statistics were sourced from Grand View Research (2024) and Global Market Insights (2024) databases. Data were organized into structured comparative matrices covering clinical trial obligations, claim categorization, pre-market versus post-market evidence requirements, enforcement mechanisms, and penalty structures. Qualitative thematic coding was applied to identify convergent and divergent regulatory patterns across jurisdictions. No human participants were involved; therefore, ethical approval was not required.

5. RESULTS

Table 1: Global Nutraceutical Market Overview by Jurisdiction (2023–2024)

Parameter	India	United States	European Union

Market Value (2023–2024)	USD 5.6 billion	USD 179.83 billion	USD 79.95 billion
Projected Market (2026–2028)	USD 37.50 billion	USD 220+ billion	USD 101.60 billion
CAGR	~21%	4.56%	4.91%
Global Market Share (approx.)	~1.5%	~38–42%	~17–18%
No. of Registered Products (approx.)	25,000+ FBOs	100,000+ products	30,000–40,000 products

Sources: Grand View Research (2024); Global Market Insights (2024); Artixio Regulatory Guide (2024)

Table 1 reveals profound market asymmetry among the three jurisdictions. India demonstrates the highest CAGR at approximately 21%, indicative of rapid expansion from a low base, compared to the more mature US and EU markets. The United States dominates global nutraceutical commerce with over 100,000 distinct products and a market value exceeding USD 179 billion, reflecting the permissive, post-market DSHEA framework that facilitates rapid product launches. The EU and India markets are considerably smaller by absolute value but are structurally important, with India's growth trajectory positioning it as a major global contributor by 2030 (Grand View Research, 2024; Bansal & Dhiman, 2020).

Table 2: Comparative Regulatory Architecture: India, US, and EU

Regulatory Parameter	**India (FSSAI)**	**United States (FDA/DSHEA)**	**European Union (EFSA)**
Primary Legislation	FSS Act 2006; Nutraceutical Regs 2016/2022	DSHEA 1994; FD&C Act	Directive 2002/46/EC; Reg. 1924/2006
Regulatory Authority	FSSAI (Ministry of Health)	FDA/Center for Food Safety	EFSA + European Commission
Pre-Market Approval Required	No (except DRR claims on case basis)	No (except NDI 75-day notification)	Yes, for health claims (EFSA authorization)
Post-Market Surveillance	FSSAI audits; FoSCoS portal compliance	FDA GMP inspections; MedWatch	National authorities + EFSA monitoring
Mandatory GMP	Yes	Yes (21 CFR Part 111)	Yes (food-grade GMP)
Definition Recognized	Yes "nutraceutical" defined	Yes "dietary supplement" defined	No "nutraceutical" not recognized; "food supplement" used

Sources: FSSAI (2016); U.S. Food and Drug Administration (1994); European Parliament and Council (2002); European Parliament and Council (2006)

Table 2 demonstrates that the three jurisdictions differ fundamentally in pre-market authorization requirements. The EU uniquely mandates EFSA pre-market review for health claims, whereas both India and the US operate on a general post-market model, with narrow exceptions. India does not formally recognize the term "nutraceutical" in the same manner as the US, instead using the category "health supplement" or "nutraceutical" under its 2022 revised definitions. This definitional divergence has direct implications for determining which clinical evidence standards apply (Shan et al., 2025; Domínguez Díaz et al., 2020).

Table 3: Clinical Evidence Requirements for Market Entry by Jurisdiction

Evidence Requirement	India (FSSAI)	United States (FDA/DSHEA)	European Union (EFSA)
Clinical Trials (Mandatory)	Only for DRR claims (case-by-case)	Not required pre-market	Required for disease risk reduction claims
Safety Dossier	Certificate of Analysis (CoA) required	Manufacturer self-certifies	Full safety dossier for EFSA evaluation
Efficacy Substantiation	Not mandated generally	Manufacturer responsibility	Mandatory scientific substantiation
Human Clinical Trial Population	Indian population preferred (DRR)	Not specified	EU population data required
Bioavailability Data	Not required	Not required	Encouraged, increasingly required
Notification Timeline	Case-by-case	75 days (NDI only)	EFSA review: 5–6 months average

Sources: Dwyer et al. (2018); Santini et al. (2018); Shan et al. (2025)

The most consequential regulatory divergence lies in clinical trial obligations for market entry, as shown in Table 3. India and the US both allow nutraceuticals to enter the market without mandatory clinical trial evidence for the vast majority of product categories. The EU, conversely, requires manufacturers seeking to make health claims to submit comprehensive scientific dossiers to EFSA, which conducts systematic evaluations based on human clinical trial data, systematic reviews, and epidemiological evidence. India's requirement for Indian-population clinical data for DRR claims is a progressive domestic provision, though enforcement remains inconsistent (Bansal & Dhiman, 2020; Thakkar et al., 2020).

Table 4: Permissible Health Claim Categories and Evidence Standards

Claim Category	India (FSSAI)	United States (FDA/DSHEA)	European Union

			(EFSA)
Nutritional Claims	Permitted	Permitted	Permitted
Structure/Function Claims	Permitted (FSSAI list)	Permitted (manufacturer notifies FDA within 30 days)	Not formally applicable; function claims assessed
Health Claims	Approved list under FSS Claims Reg 2018	Authorized by FDA; significant scientific agreement required	EFSA-authorized; Article 13/14 claims
Disease Risk Reduction Claims	CDSCO or FSSAI (proposed reform)	Requires FDA authorization	Requires EFSA scientific opinion
Therapeutic/Disease Cure Claims	Prohibited under FSSAI	Prohibited under DSHEA	Prohibited

Sources: U.S. Food and Drug Administration (1994); European Parliament and Council (2006); Tomar et al. (2023)

Table 4 illustrates that all three jurisdictions prohibit therapeutic or disease-cure claims, aligning at this most extreme end of the health claims spectrum. Structural divergence emerges in intermediate claim categories, especially disease risk reduction (DRR) and function claims. The US permits structure/function claims with a post-market 30-day manufacturer notification, while the EU requires pre-authorization. India's current inter-ministerial committee proposal which would shift DRR claim oversight to CDSCO represents a structural convergence toward the EU model, though it has drawn mixed industry responses (Chopra et al., 2022; Jain et al., 2022).

Table 5: EFSA Health Claims Authorization Outcomes (Cumulative to 2024)

Claim Category	**Total Submitted**	**Authorized**	**Rejected/On Hold**	**Rejection Rate (%)**
Article 13(1) Function Claims	~44,000	~2,758	~41,000+	>93%
Article 13(5) New Scientific Evidence	~300	~25	~275	~92%
Article 14 Disease Risk Reduction	~30	~7	~23	~77%
Botanical Function Claims	~2,000+	Pending/On hold	—	—
Total Health Claims Evaluated	~46,000+	~2,800	~43,000+	>91%

Sources: European Food Safety Authority (2024); Domínguez Díaz et al. (2020); Santini et al. (2018)

Table 5 presents the most striking evidence of the EU's stringent evidence culture: EFSA has rejected over 91% of all submitted health claims, with disease risk reduction claims facing a 77% rejection rate. This data highlights that meeting EFSA's scientific evidence threshold is extraordinarily demanding a reality that shapes which products reach European consumers and underscores why EU nutraceuticals typically carry more scientifically robust health credentials. Indian manufacturers seeking EU market access must produce evidence at a dramatically higher standard than what FSSAI currently requires domestically (European Food Safety Authority, 2024; Gottlieb & McClellan, 2022).

Table 6: Enforcement Mechanisms and Penalty Structures

Enforcement Parameter	**India (FSSAI)**	**United States (FDA)**	**European Union (Member States)**
Market Withdrawal Authority	Yes FSSAI can recall products	Yes FDA post-market authority	Yes National authorities + Commission
Monetary Penalties	INR 25,000–10 lakh	Up to USD 10,000 per violation	Varies by member state (€500–€500,000+)
License Cancellation	Yes (serious violations)	Yes (repeated/serious violations)	Yes (national authority action)
Criminal Prosecution	Yes (FSS Act Section 59)	Yes (FD&C Act provisions)	Yes (varies by state)
Adverse Event Reporting	Voluntary/FSSAI notification	Mandatory (SAER 2007 onwards)	National systems; EudraVigilance

Sources: Food Safety and Standards Authority of India (2016); Blaze et al. (2021); Tripathi et al. (2020)

Table 6 reveals that while all three jurisdictions possess penalty and enforcement instruments, their activation thresholds and financial deterrence values differ substantially. The US introduced mandatory Serious Adverse Event Reporting (SAER) in 2007, providing a structured post-market safety signal system that India still lacks as a mandatory obligation. EU member states independently set penalty scales, but the collective EFSA pre-market authorization system reduces post-market enforcement burden by ensuring that fewer non-evidence-based products enter the market. India's enforcement infrastructure, while legally defined, is limited by capacity constraints within FSSAI and the absence of a centralized adverse event database specific to nutraceuticals (Helal et al., 2019).

6. DISCUSSION

The comparative evidence presented in this study clearly establishes that the three jurisdictions operate on fundamentally different clinical evidence philosophies, each reflecting distinct historical, economic, and public

health contexts. The first objective comparative analysis of clinical evidence requirements reveals a tripartite regulatory spectrum: the EU at the most evidence-demanding end, the US at the most market-permissive end, and India occupying a transitional middle ground with progressive but inconsistently enforced standards. The EU's EFSA model, as illustrated in Tables 3 and 5, is distinguished by its pre-market scientific gatekeeping function. The rejection of over 91% of submitted health claims including more than 93% of Article 13(1) function claims is not an administrative failure but rather a deliberate application of the scientific consensus standard. EFSA demands human clinical trial evidence, systematic reviews, and, increasingly, population-specific data before authorizing any health claim (Santini et al., 2018; Domínguez Díaz et al., 2020). This high evidentiary bar means that European consumers can rely on the scientific legitimacy of health claims they encounter on product packaging, even if the range of authorized claims is dramatically narrower than what appears on Indian or US products.

The United States' DSHEA framework, by contrast, was designed in 1994 to democratize consumer access to health supplements by removing pre-market barriers. While this has generated a USD 60 billion+ market with over 100,000 products, it has also created well-documented quality variability, particularly in botanical and herbal categories (Dwyer et al., 2018; Blaze et al., 2021). The post-market model's central weakness is that the FDA can only intervene after harm has been demonstrated, placing asymmetric risk on consumers rather than manufacturers. Despite recent 2025 organizational restructuring through the Human Foods Program (HFP), the US has not mandated pre-market clinical evidence for most product categories, and the fundamental architecture of DSHEA remains unchanged. India's position is particularly complex. The FSSAI framework under the 2022 regulations has introduced meaningful advances GMP compliance, CoA requirements, structured product categories, and mandatory clinical evidence for DRR claims using Indian populations. However, the persistence of self-regulation for the majority of nutraceutical product categories, combined with FSSAI's limited post-market surveillance capacity, means that a significant proportion of the 25,000+ licensed nutraceutical businesses operate without ever having submitted clinical evidence (Tomar et al., 2023; Shan et al., 2025).

The 2024 inter-ministerial committee recommendations which propose shifting DRR claim oversight to CDSCO, introducing separate GMP standards for health supplements, and requiring stronger clinical substantiation represent India's most significant regulatory modernization effort in two decades. However, as documented in the November 2024 NutraIngredients report, these proposals have drawn concern from industry regarding duplication of regulatory authority and increased compliance costs. This industry resistance mirrors similar tensions in the US in the 1990s before DSHEA's passage, and in EU during the contentious negotiations preceding Regulation 1924/2006. Aligning with the second objective developing an evidence-based validation framework for India the data suggest a graduated evidence model as the most pragmatic path. Structure/function claims could continue with manufacturer self-certification under enhanced FSSAI oversight, DRR claims could require submission of Phase II or III human clinical trial data using Indian populations (as already partially required), and novel nutraceutical ingredients could be subjected to full safety dossiers analogous to EFSA's pre-

market review. This graduated approach would preserve market dynamism while systematically raising India's clinical evidence standards.

Critically, the hypothesis that significant regulatory asymmetry creates unequal consumer safety outcomes is fully supported by the data. Indian consumers encounter health claims that would be unauthorized in the EU, backed by evidence levels that would be insufficient for FDA's own structure/function claim substantiation guidance. For Indian manufacturers, this asymmetry creates both a domestic consumer safety risk and a competitive disadvantage in accessing the EU's premium, high-margin nutraceutical market, where EFSA authorization is the entry credential (Chopra et al., 2022; Gottlieb & McClellan, 2022).

7. CONCLUSION

This study demonstrates that substantive regulatory asymmetry in clinical evidence requirements for nutraceuticals across India, the United States, and the European Union represents both a consumer protection challenge and a structural barrier to India's global nutraceutical export ambitions. The EU's EFSA model characterized by mandatory pre-market scientific dossier review and an authorization-based health claims system provides the highest evidence standard globally, though its extraordinary rejection rate also restricts market diversity. The US DSHEA framework prioritizes market access over pre-market evidence, creating product volume but quality variability. India's evolving FSSAI architecture is progressive in intent but limited in clinical evidence enforcement. The development of a tiered, evidence-graduated Indian clinical validation framework calibrated to claim risk level and aligned with India's traditional medicine heritage offers the most pragmatic pathway toward consumer protection, domestic industry strengthening, and international market access.

8. REFERENCES

1. Bansal, R., & Dhiman, A. (2020). Nutraceuticals: A comparative analysis of regulatory framework in different countries of the world. *Endocrine, Metabolic & Immune Disorders - Drug Targets, 20*(10), 1654–1663. https://doi.org/10.2174/1871530320666200519084415
2. Santini, A., Cammarata, S. M., Capone, G., Ianaro, A., Tenore, G. C., Pani, L., & Novellino, E. (2018). Nutraceuticals: Opening the debate for a regulatory framework. *British Journal of Clinical Pharmacology, 84*(4), 659–672. https://doi.org/10.1111/bcp.13496
3. Dwyer, J. T., Coates, P. M., & Smith, M. J. (2018). Dietary supplements: Regulatory challenges and research resources. *Nutrients, 10*(1), 41. https://doi.org/10.3390/nu10010041
4. Blaze, J., Haase, N., Bhakta, S., & Nguyen, T. (2021). A comparison of current regulatory frameworks for nutraceuticals in Australia, Canada, Japan, and the United States. *Innovations in Pharmacy, 12*(2). https://doi.org/10.24926/iip.v12i2.3694

5. Thakkar, S., Anklam, E., Xu, A., Ulberth, F., Li, J., Li, B., ... & Tong, W. (2020). Regulatory landscape of dietary supplements and herbal medicines from a global perspective. *Regulatory Toxicology and Pharmacology, 114*, 104647. https://doi.org/10.1016/j.yrtph.2020.104647
6. Food Safety and Standards Authority of India. (2016, amended 2022). *Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations.* FSSAI. https://www.fssai.gov.in/upload/uploadfiles/files/Nutraceuticals_Regulations.pdf
7. U.S. Food and Drug Administration. (1994). *Dietary Supplement Health and Education Act of 1994 (DSHEA).* NIH Office of Dietary Supplements. https://ods.od.nih.gov/About/DSHEA_Wording.aspx
8. European Parliament and Council. (2006). Regulation (EC) No 1924/2006 on nutrition and health claims made on foods. *Official Journal of the European Union.* https://eur-lex.europa.eu/eli/reg/2006/1924/oj/eng
9. European Parliament and Council. (2002). Directive 2002/46/EC on food supplements. *Official Journal of the European Union.* https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32002L0046
10. Shan, F., Liu, L., Li, L., Wang, W., Bi, Y., & Li, M. (2025). Management, safety, and efficacy evaluation of nutraceutical and functional food: A global perspective. *Comprehensive Reviews in Food Science and Food Safety, 24*(4), e70222. https://doi.org/10.1111/1541-4337.70222
11. Domínguez Díaz, L., Fernández-Ruiz, V., & Cámara, M. (2020). The frontier between nutrition and pharma: The international regulatory framework of functional foods, food supplements and nutraceuticals. *Critical Reviews in Food Science and Nutrition, 60*(10), 1738–1746. https://doi.org/10.1080/10408398.2019.1592107
12. Tomar, S., Musyuni, P., & Aggarwal, G. (2023). An overview of regulation for nutraceuticals and concept of personalized nutraceuticals. *Journal of Generic Medicines, 9*(2), 66–74. https://doi.org/10.1177/17411343221150875
13. Grand View Research. (2024). *Nutraceuticals market size, share & trends analysis report, 2025–2033.* https://www.grandviewresearch.com/industry-analysis/nutraceuticals-market
14. Gottlieb, S., & McClellan, M. B. (2022). Reforms needed to modernize the US Food and Drug Administration's oversight of dietary supplements. *JAMA Health Forum, 3*(10), e224449. https://doi.org/10.1001/jamahealthforum.2022.4449
15. Tripathi, C., Girme, A., Champaneri, S., Patel, R. J., & Hingorani, L. (2020). Nutraceutical regulations: An opportunity in ASEAN countries. *Nutrition, 74*, 110729. https://doi.org/10.1016/j.nut.2020.110729
16. Chopra, A. S., Lordan, R., Horbańczuk, O. K., Atanasov, A. G., Chopra, I., Horbańczuk, J. O., ... & Banach, M. (2022). Review on nutraceuticals: Phase transition from preventive to protective care. *Pharmacological Research, 175*, 106001. https://doi.org/10.1016/j.phrs.2021.106001
17. Jain, N., Radhakrishnan, A., & Kuppusamy, G. (2022). Review on nutraceuticals: A holistic overview. *Journal of Complementary and Integrative Medicine, 19*(3), 553–570. https://doi.org/10.1515/jcim-2022-0026

18. Helal, N. A., Eassa, H. A., Amer, A. M., Eltokhy, M. A., Edafiogho, I., & Nounou, M. I. (2019). Nutraceuticals' novel formulations: The good, the bad, the unknown and patents involved. *Recent Patents on Drug Delivery & Formulation, 13*(2), 105–156. https://doi.org/10.2174/1872211313666191024170215
19. Boaventura, B. C. B., Di Pietro, P. F., & Stefanuto, A. (2023). Investigating the regulatory process, safety, efficacy and product transparency for nutraceuticals in the USA, Europe and Australia. *Foods, 12*(2), 427. https://doi.org/10.3390/foods12020427
20. European Food Safety Authority. (2024). *Health claims.* EFSA Panel on Dietetic Products, Nutrition and Allergies. https://www.efsa.europa.eu/en/topics/topic/health-claims