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Ethical landscape of nutraceuticals from a global perspective; Investigating the regulatory process, safety, efficacy and product transparency for nutraceuticals

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ABSTRACT

Nutraceuticals, including dietary supplements and functional foods, are increasingly used for health promotion and disease prevention. However, inconsistent definitions and varying regulatory frameworks across countries create challenges in ensuring product safety, efficacy, and transparency. Ethical issues such as misleading health claims, insufficient clinical validation, and regulatory loopholes further complicate consumer protection. This Systematic review examines regulatory systems in the USA, Europe, Australia, Canada, Japan, China, Brazil, Mexico, and India. Using a structured PRISMA-based methodology, peer-reviewed literature and official documents were analyzed to assess regulatory gaps and market practices. Key concerns include inadequate quality control, inconsistent categorization, and lack of post-market surveillance. Findings highlight the need for science-based standards, global harmonization, and stricter oversight. Policy recommendations include uniform classification, mandatory clinical substantiation, and improved product traceability. Addressing these gaps is crucial to safeguard public health, enhance transparency, and build trust among consumers and healthcare professionals in the growing nutraceutical sector.

KEYWORDS

Nutraceuticals; Food-based therapeutics; Regulatory frameworks; Safety; Efficacy; Product transparency; Harmonization

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Introduction

Nutraceuticals, functional foods, and dietary supplements have gained remarkable global traction over the past few decades, driven by increasing public interest in preventive healthcare and natural remedies. Nutraceuticals are broadly defined as products derived from food sources that offer additional health benefits beyond basic nutritional value, often intended to prevent or treat disease. Functional foods refer to food products that have been fortified with bioactive compounds to provide health-promoting or disease-preventing properties. Meanwhile, dietary supplements include vitamins, minerals, herbs, amino acids, enzymes, and other ingredients consumed to supplement the diet and enhance overall health [1].

The global rise in nutraceutical use raises critical questions about their safety, efficacy, and regulatory oversight, especially as these products blur the line between food and medicine. In 2024, the global nutraceutical market was projected to reach approximately US$278 billion, reflecting the escalating consumer demand across regions like the United States, Europe, India, and Australia [2]. For instance, nearly 77% of Americans report using at least one dietary supplement, and approximately 18.8% of Europeans take botanical supplements regularly [3].

Despite their widespread use and perceived safety compared to synthetic pharmaceuticals, scientific evidence supporting the efficacy and safety of many nutraceutical products remains limited. Moreover, ethical concerns have emerged, including the proliferation of misleading health claims, the lack of robust clinical trials, and regulatory loopholes that allow products with potential adverse effects, such as hepatotoxicity or carcinogenicity, to enter the market without comprehensive safety evaluations [4].

Another pressing challenge is the lack of consensus in terminology and classification, which complicates regulatory oversight. Terms such as nutraceuticals, herbal medicines, food supplements, and functional foods are often used interchangeably, despite having distinct meanings in different countries. This variability in nomenclature and legal frameworks has led to inconsistencies in product categorization, quality control, and permissible health claims. A product considered a food supplement in one country may be classified and regulated as a medicine in another [5].

Global discussions, such as those held at the 8th Global Summit on Regulatory Science (GSRS), have highlighted the urgent need for harmonized definitions and regulatory pathways. Regulatory agencies from the USA, Canada, China, Japan, the EU, and Australia have acknowledged these disparities and called for collaborative efforts to improve transparency, quality standards, and consumer safety. Figure 1 illustrates the conventional and emerging safety and quality assessment methods presented at GSRS18, emphasizing the evolving global perspective on regulatory science [6].

This review explores the current landscape of nutraceutical use, examines regulatory challenges, and considers how emerging technologies such as big data analytics and next-generation sequencing can play a transformative role in ensuring the safety, efficacy, and standardization of these products in global markets [7].

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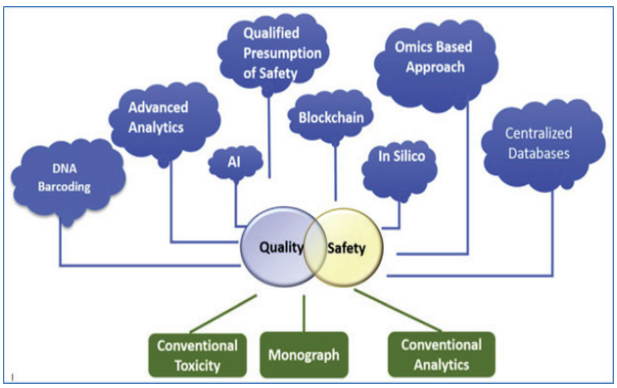

Figure 1. Conventional and emerging safety and quality assessment methods presented at GSRS18.

Methodology

A comprehensive literature review was conducted to examine global regulatory frameworks, safety issues, and classification discrepancies associated with nutraceuticals, dietary supplements, and functional foods. The methodology followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines to ensure transparency and reproducibility.

Data sources and search strategy

Electronic databases including PubMed, Scopus, ScienceDirect, and Google Scholar were searched for relevant literature published between 2013 and 2024. The last search was conducted in March 2025. Keywords and Medical Subject Headings (MeSH) used included:

- "Nutraceuticals"
- "Dietary supplements"
- "Functional foods"
- "Regulatory framework"
- "Global harmonization"
- "Safety and efficacy of herbal medicines"
- "Quality control in nutraceuticals"

Boolean operators (AND, OR) were used to refine the search. Example:(nutraceuticals OR "dietary supplements") AND (regulation OR "regulatory framework") AND (safety OR efficacy OR quality control) [8].

Inclusion and Exclusion Criteria

Inclusion criteria

- Peer-reviewed journal articles, reviews, regulatory reports, and official policy documents
- Articles published in English
- Studies discussing regulatory guidelines, safety, adverse events, or standardization of nutraceuticals

Exclusion criteria

- Non-English publications
- Conference abstracts without full text
- Studies unrelated to regulatory or safety aspects of nutraceuticals
- Duplicates

Study Selection and Data Extraction

All search results were imported into Mendeley for reference management. After removing duplicates, titles and abstracts were screened independently by two reviewers. Full-text articles were then assessed for eligibility. Any disagreements were resolved through discussion or consultation with a third reviewer [9].

Data extracted included publication year, study region, key regulatory themes, safety outcomes, and categorization approaches. The final selection included 74 articles that directly contributed to the objectives of this review [10].

Market Trends in the Nutraceutical Industry

The global nutraceutical market has shown remarkable growth over the past decade, driven by increasing consumer awareness about preventive healthcare and wellness. As of 2023, the global nutraceutical market was valued at approximately USD 455 billion and is expected to exceed USD 700 billion by 2030, growing at a compound annual growth rate (CAGR) of 8.9% [11].

Global trends

Developing nations are showing rising demand due to the influence of Western lifestyles and a growing middle-class population with disposable income. In Asia-Pacific countries, especially India and China, there is a surge in the use of herbal and functional foods due to traditional practices aligning with modern health trends [12].

U.S. market data

The U.S. continues to dominate the global nutraceutical market. According to the Council for Responsible Nutrition (CRN), nearly 77% of American adults reported using dietary supplements in 2022. The U.S. market is expected to reach USD 140 billion by 2028, supported by an aging population and a shift towards self-care and preventive medicine [13].

Europe and Australia

Europe represents a mature market, with increasing emphasis on clean-label and plant-based nutraceuticals. Countries such as Germany, Italy, and France are leading in functional food innovation. In Australia, regulatory support and consumer trust in natural products have led to strong growth, with a particular focus on gut health and mental wellness supplements [14].

Usage statistics vs. market size

While market size refers to the revenue and sales projections, usage statistics reflect consumer behavior. A global survey conducted by Mintel (2022) revealed that 64% of consumers use supplements daily or weekly, with immunity, energy, and digestive health being the top reasons for consumption [15].

COVID-19 pandemic impact

The COVID-19 pandemic significantly accelerated the adoption of nutraceuticals worldwide. Immune-boosting products such as vitamin C, D, zinc, and botanical extracts experienced exponential sales. This surge has reinforced nutraceuticals as a core component of health management strategies even in the post-pandemic era [16].

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Regulatory Process for Nutraceuticals

The regulation of nutraceuticals is complex, varying significantly across countries. Regulatory authorities are tasked with ensuring that these products are safe, effective, and truthfully labeled. Although substances such as vitamins, minerals, amino acids, and herbs are generally considered safe, the regulatory process becomes stringent for novel or bioactive ingredients [17].

Product development and formulation

- Ingredient selection: Based on safety data and intended health benefits.
- Scientific basis: Products are formulated using evidence supporting health claims.
- Regulatory compliance: Formulation must adhere to country-specific rules.

Pre-Market approval or notification

- Documentation: Includes product composition, safety data, and health benefit rationale.
- Approval vs. Notification:
  - Some countries (e.g., China, Canada) require pre-market approval.
  - Others (e.g., U.S., India) follow a notification system for dietary supplements [18].

Good Manufacturing Practices (GMP)

- Manufacturers must follow GMP standards to ensure quality and consistency.
- Third-party testing may be conducted to enhance transparency and product trust.

Labeling and health claims

- Accurate labeling: Includes ingredients, dosage, warnings, and usage instructions.
- Health claims: Must be scientifically substantiated; regulations vary by region (e.g., EFSA in Europe, FDA in the U.S.).

Safety and risk assessment

- Adverse event reporting: Required for ongoing safety surveillance.
- Risk mitigation: Manufacturers must monitor and address side effects or contraindications.

Post-market surveillance

- Involves monitoring product safety, addressing consumer complaints, and adapting to emerging scientific data [19].

Compliance with specific regulations

- Country-specific frameworks govern claims, marketing, and permissible ingredients.
- Testing and certification may be required from accredited labs in some jurisdictions [20].

Record-keeping and regulatory audits

- Companies must maintain documentation on manufacturing, testing, and distribution.
- Regulatory audits are conducted to verify ongoing compliance [21].

Challenges in global regulation

- Regulatory variations complicate international market entry.
- Scientific substantiation of health claims remains a key hurdle.
- Labeling accuracy and rapid adaptation to regulatory changes are critical.

Ethical and Safety Concerns in Nutraceutical Regulation

Despite their widespread use, nutraceuticals pose unique ethical and safety challenges. Unlike pharmaceutical products, nutraceuticals often enter the market with limited scientific validation and minimal post-marketing oversight [22].

Key ethical and safety issues

Misleading health claims

Many consumers equate “natural” with “safe,” a perception that is frequently exploited by unregulated or loosely regulated products. These claims may lack robust clinical backing and may mislead patients seeking alternatives to conventional treatments.

Lack of post-market surveillance

In several jurisdictions, once a nutraceutical product is on the market, there is minimal requirement for ongoing safety or efficacy monitoring, increasing the risk of long-term adverse effects [23].

Adulteration and undeclared substances

Some products have been found to contain undisclosed pharmaceutical ingredients, raising serious health risks and ethical violations.

Example: The FDA (2023) issued multiple warnings about "natural" supplements containing undisclosed prescription drugs like sildenafil or steroids [24].

Toxicological reports

Case studies have documented instances of hepatotoxicity, nephrotoxicity, and even carcinogenic effects due to poorly regulated herbal supplements.
Notable Case: Herbal products containing kava have been associated with liver damage, leading to their ban in some countries [25].

Regulatory agencies

Nutraceuticals are products that combine elements of both nutrition and pharmaceuticals, often taken in the form of dietary supplements. The regulations governing nutraceuticals vary by country, and in many cases, they are subject to a combination of food and drug regulations [26].

Here are some general aspects of nutraceutical regulations:

Regulation of nutraceuticals varies by country, and multiple agencies may be involved in overseeing the safety, labeling, and marketing of these products. Here is an overview of regulatory agencies in various countries that play key roles in overseeing nutraceuticals in (Table 1).

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Table 1. Neutraceutics regulatory agencies in various countries.

Country	Regulatory agencies
United States	Food and Drug Administration (FDA): The FDA is the primary regulatory authority for nutraceuticals in the U.S. It enforces regulations under the Dietary Supplement Health and Education Act (DSHEA). The Office of Dietary Supplement Programs (ODSP) within the FDA oversees dietary supplement regulations.
European Union	European Food Safety Authority (EFSA): EFSA provides scientific advice to the European Commission on health claims and assesses the safety of novel ingredients. The European Commission, together with member states, regulates food supplements under the Food Supplements Directive (FSD).
Canada	Health Canada: Health Canada is responsible for regulating nutraceuticals under the Natural Health Products Regulations. The Natural and Non-prescription Health Products Directorate (NNHPD) within Health Canada manages the approval process for natural health products.
Australia	Therapeutic Goods Administration (TGA): The TGA regulates therapeutic goods, including dietary supplements, in Australia. Complementary medicines, which include nutraceuticals, are regulated by the TGA.
Japan	Pharmaceuticals and Medical Devices Agency (PMDA): The PMDA is responsible for the regulation of pharmaceuticals and medical devices in Japan, including some nutraceuticals. The Consumer Affairs Agency (CAA) oversees labeling and advertising of food products, including dietary supplements.
India	Food Safety and Standards Authority of India (FSSAI): FSSAI is the regulatory body overseeing food safety and standards in India. It sets regulations for health supplements and nutraceuticals.
China	China National Medical Products Administration (NMPA): NMPA is responsible for the regulation of pharmaceuticals, including some nutraceuticals, in China. The China Food and Drug Administration (CFDA) was formerly responsible for food and drug regulation but was merged into the NMPA.
Brazil	National Health Surveillance Agency (ANVISA): ANVISA regulates health products, including dietary supplements, in Brazil. Nutraceuticals may be subject to specific regulations regarding registration and labeling.
South Africa	Medicines Control Council (MCC): The MCC, now part of the South African Health Products Regulatory Authority (SAHPRA), oversees the regulation of medicines, including some nutraceuticals, in South Africa.
Singapore	Health Sciences Authority (HSA): HSA regulates health products, including traditional medicines and health supplements, in Singapore.
Mexico	Federal Commission for Protection against Health Risks (COFEPRIS): COFEPRIS is responsible for regulating health products, including dietary supplements, in Mexico.
Other Countries	Regulations in other countries may vary widely. Some countries treat nutraceuticals as food products, while others may regulate them more like pharmaceuticals. It's essential for manufacturers and distributors to be aware of and comply with local regulations in each market.

It's important to note that regulatory structures and agencies may change, and new regulations may be introduced. Businesses in the nutraceutical industry should stay updated on regulatory developments in the countries where they operate or plan to market their products. Additionally, consulting with regulatory experts is advisable to ensure compliance with specific requirements in each jurisdiction [27].

Role of Emerging Technologies in Nutraceutical Regulation

The regulation of nutraceuticals is undergoing a transformative shift with the integration of cutting-edge technologies, which are beginning to address the long-standing challenges of quality assurance, traceability, and safety. Recent innovations such as next-generation sequencing (NGS), metabolomics, artificial

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intelligence (AI), and blockchain technologies are not only enhancing product authenticity but also reinforcing regulatory credibility on a global scale [28].

NGS has emerged as a powerful tool for species identification and genetic authentication of raw botanical ingredients, thus mitigating issues related to adulteration, substitution, and contamination—concerns that have historically plagued the nutraceutical industry. Simultaneously, metabolomics provides a comprehensive profiling of phytochemicals and bioactive compounds, enabling regulators to assess efficacy and toxicity based on metabolite signatures rather than relying solely on traditional chemical analyses [29].

AI-driven platforms now support risk prediction by analyzing large datasets related to pharmacodynamics, consumer health outcomes, and molecular interactions. These systems enhance regulatory vigilance by identifying patterns associated with adverse effects, guiding real-time decision-making. In parallel, blockchain technology is gaining traction as a novel regulatory tool, especially in ensuring end-to-end supply chain transparency. It allows for immutable data records of sourcing, processing, and distribution, fostering consumer trust and accountability [30].

Furthermore, global efforts such as the Global Coalition for Regulatory Science Research (GCRSR) exemplify the movement towards international collaboration in adopting such tools. These initiatives signify a paradigm shift toward data-driven, proactive regulation that could redefine how nutraceutical safety and efficacy are established worldwide [31].

Discussion

Despite the exponential growth of the nutraceutical industry worldwide, patient safety remains a critical concern due to divergent regulatory approaches, varying levels of pre-market scrutiny, and inconsistent post-market surveillance. A comparative analysis reveals that regions like the European Union, which mandate scientific substantiation of health claims through the European Food Safety Authority (EFSA), demonstrate a higher degree of consumer protection than markets such as the United States, where the FDA does not require pre-market approval for dietary supplements. This discrepancy exposes patients in loosely regulated regions to greater risks, including exposure to adulterated products, unverified health claims, and insufficient labeling [32].

In India and several developing countries, regulatory frameworks, though evolving, often lack robust mechanisms for ensuring the safety of proprietary nutraceutical products. In contrast, countries like Canada and Australia enforce mandatory licensing and evidence-based evaluation through agencies like Health Canada and the TGA, respectively. These models underscore the value of integrating mandatory clinical evidence and risk assessment protocols into nutraceutical regulation to safeguard public health [33-35].

Furthermore, emerging technologies such as AI-driven toxicity prediction, metabolomics-based profiling, and blockchain-enabled traceability systems offer promising pathways to close existing regulatory gaps. Their integration could harmonize international safety standards, minimize batch-to-batch variability, and detect adulterants before products reach consumers [36].

The imperative to harmonize global regulatory frameworks lies not only in facilitating trade but, more crucially, in ensuring equitable patient safety across all geographies. Future regulatory models must adopt a patient-centered approach—prioritizing evidence, transparency, and technology—to ensure that nutraceuticals function as safe, effective, and trusted components of preventive and therapeutic healthcare [37].

Challenges and Future Trends

Nutraceutical regulations are continually evolving, and there are ongoing discussions about harmonizing global standards. The industry is also facing challenges related to the need for more robust scientific evidence supporting health claims, ensuring product quality, and addressing issues such as contamination and mislabeling [38].

Businesses in the nutraceutical industry must stay informed about the latest regulatory developments and compliance requirements in the regions where they operate or intend to sell their products [39]. Working with regulatory experts and conducting thorough due diligence is essential to navigate the complex landscape of nutraceutical regulations (Table 2).

Table 2. Types of challenges and its future direction.

		Challenge	Future trend/Direction
1	Scientific Substantiation	Increasing demand for scientific evidence supporting health claims.	Investment in research to establish robust scientific substantiation for the health benefits of nutraceutical ingredients.
2	Regulatory Harmonization	Divergent regulatory frameworks globally	Advocacy for regulatory harmonization to facilitate international market access and ensure consistent standards.
3	Quality Assurance:	Ensuring product quality and safety.	Implementation of advanced quality control measures, adherence to Good Manufacturing Practices (GMP), and transparency in the supply chain.
4	Consumer Education:	Addressing misinformation and ensuring consumer understanding.	Increased efforts in consumer education, transparent labeling, and responsible marketing practices.

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5	Innovation and Novel Ingredients:	Identifying and incorporating novel, scientifically validated ingredients	Emphasis on research and development to discover and integrate innovative ingredients with demonstrable health benefits.
6	Global Market Access:	Navigating diverse regulatory landscapes for international market entry.	Collaboration between industry stakeholders and regulatory bodies to facilitate smoother market access globally.
7	Personalized Nutrition	Meeting the growing demand for personalized nutrition solutions.	Integration of technology and data analytics to offer personalized nutraceutical products based on individual health profiles.
8	Environmental Sustainability:	Addressing concerns about the environmental impact of sourcing and manufacturing.	Embracing sustainable sourcing practices, eco-friendly packaging, and responsible 9manufacturing processes.
9	Efficacy and Standardization:	Ensuring consistent product efficacy.	Development of standardized testing methods and quality benchmarks to ensure the effectiveness of nutraceutical products.
10	Digital Platforms and Direct-to-Consumer (DTC) Trends:	Shifting consumer preferences towards online shopping and direct-to-consumer models.	Companies adapting to digital platforms, focusing on e-commerce, and leveraging technology for consumer engagement.

The nutraceutical industry is positioned for significant growth, driven by increasing consumer awareness of health and wellness. Successfully navigating future challenges and capitalizing on emerging opportunities will require a proactive and adaptive approach from industry stakeholders (Table 3) [40].

Table 3. Emerging opportunities and direction.

		Opportunities	Direction
1	Immune Health	Growing interest in products that support immune health.	Innovation in immune-boosting ingredients and formulations.
2	Personalized Nutrition	Rising demand for personalized nutrition plans.	Customization of nutraceutical products based on individual health needs and genetic profiles.
3	Functional Foods and Beverages	Expansion of functional food and beverage categories.	Development of nutraceutical-infused foods and beverages that offer convenience and health benefits.
4	Plant-Based Nutraceuticals	Increasing popularity of plant-based diets.	Development of plant-based nutraceuticals to meet consumer preferences for sustainable and plant-derived options.
5	Digital Health Integration	Integration of digital health technologies for monitoring and enhancing health outcomes.	Collaboration with technology companies to incorporate wearables, apps, and other digital tools.
6	Anti-Aging and Beauty from Within:	Growing interest in products promoting anti-aging and beauty from within.	Development of nutraceuticals targeting skin health, hair, and overall well-being.
7	Cognitive Health	Rising awareness of cognitive health and brain-boosting supplements.	Research and development of ingredients supporting cognitive function.
8	Microbiome Health	Exploration of the gut microbiome and its impact on overall health.	Development of nutraceuticals supporting gut health and microbial balance.
9	Collaboration and Partnerships:	Collaborations between nutraceutical companies, research institutions, and technology partners.	Joint initiatives to drive innovation, research, and market expansion.
10	Sustainable Practices	Consumer preference for sustainable and eco-friendly products.	Adoption of sustainable sourcing, environmentally friendly packaging, and corporate social responsibility initiatives.

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Conclusions

Nutraceuticals are subject to varying regulations in the USA, Europe, and Australia. Gaps in regulation and challenges in technical analysis have led to an increase in public health risks associated with nutraceuticals. National authorities should play a role in monitoring and regulating the nutraceutical industry. Harmonization of international regulatory regimes is recommended to create consistent standards and improve global oversight. Establishing clear risk assessment criteria can help evaluate the safety and efficacy of nutraceutical products. Product traceability through technologies like blockchain can offer transparency and improve recall efficiency. Resource limitations and data quality issues may undermine the effectiveness of traceability systems. The nutraceutical industry faces complexity and challenges in regulatory oversight, necessitating improvements in education, manufacturing practices, and international harmonization. Despite challenges, nutraceuticals have demonstrated potential benefits that can be fully realized with the development of an effective and transparent regulatory system. The use of technology, such as blockchain, is suggested as a path for the future development of the nutraceutical industry, particularly in Australia, to enhance safety and build brand value.

Disclosure Statement

No potential conflict of interest was reported by the authors.

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