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GLOBAL PERSPECTIVES ON NUTRACEUTICAL REGULATIONS: INDIA, USA, AND EUROPEAN UNION

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ABSTRACT

Nutraceuticals, introduced by Dr.Stephen DeFelice in 1989, refer to products derived from food sources that provide health benefits beyond basic nutrition. Positioned at the crossroads of nutrition and medicine, these products have garnered attention for their potential to prevent and treat various diseases. This thesis explores the concept of nutraceuticals, their classification, and the regulatory frameworks that govern them. Nutraceuticals are broadly categorized into traditional and non-traditional types. Traditional nutraceuticals are naturally occurring substances used for centuries across different cultures for their health benefits. This category includes essential nutrients like vitamins and minerals, bioactive compounds such as phytochemicals and flavonoids, and functional foods enhanced with additional health benefits, like omega-3-rich foods that support cardiovascular health and probiotics for gut health. Non-traditional nutraceuticals, in contrast, are products modified or fortified through technological advancements, including foods enhanced with additional nutrients or recombinant nutraceuticals produced through genetic engineering. These innovations aim to address specific health needs, such as combating nutritional deficiencies in populations with limited diet diversity. This thesis underscores the increasing importance of nutraceuticals in global health and wellness. As demand for these products rises, there is a critical need for harmonized, science-based regulations that ensure consumer safety, product efficacy, and support the growth of the nutraceutical industry worldwide.

KEYWORDS: Neutraceuticals regulation, Global perceptives, European Union.

INTRODUCTION: The term "nutraceutical" was coined by Stephen DeFelice, MD, in 1989 by combining "nutrition" and "pharmaceutical". According to DeFelice, "Nutraceuticals are food or parts of food that provide health benefits and are used to prevent or treat illness"**.** Hippocrates (460-377 BC), known as the father of modern medicine, famously stated, "Let food be the medicine and medicine be the food," emphasizing the connection between diet and health.

There is often confusion surrounding terms like "nutraceuticals," "functional foods," "dietary supplements," "designer foods," "medical foods," "pharmafoods," and "phytochemicals," as they are sometimes used interchangeably. Pharmaceuticals are generally considered drugs used to treat diseases, while nutraceuticals are intended to prevent them. However, this distinction is superficial and misleading. Pharmaceuticals undergo rigorous testing and patent protection, while many nutrients may never receive such approval due to the prohibitive costs of testing substances that cannot be patented. Both pharmaceuticals and nutrients can cure and prevent diseases, but only pharmaceuticals have official government sanction. It's worth noting that many pharmaceuticals are derived from natural sources, making them as "natural" as nutrients.

Concept of nutraceuticals

In pharmaceutical development, clinical test results from animal studies are essential to verify therapeutic effects. Historically, however, no such verification methods existed for foods in disease prevention. Recently, as scientific evidence has increasingly linked food composition to lifestyle-related diseases, this issue has gained significant attention.

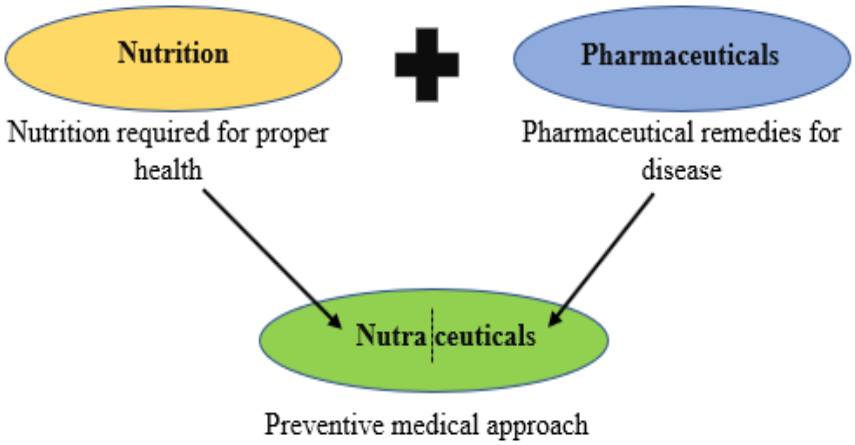

Figure 1: Concept of Nutraceutical Term.

Classification of Nutraceuticals

Nutraceuticals or functional foods can be categorized based on their origin: natural (traditional) or artificial (non-traditional).

- Traditional Nutraceuticals are derived from natural sources such as plants, animals, minerals, or microbes.
- Non-Traditional Nutraceuticals are those developed using biotechnological methods.

Fortified Nutraceuticals

These nutraceuticals are derived from agricultural breeding or have nutrients and ingredients added to them. Examples include cereals enriched with vitamins or minerals, milk fortified with cholecalciferol for treating vitamin D deficiency, and products with added folic acid. Additionally, prebiotic and probiotic-enriched milk containing Bifidobacterium Lactis HN019 is used to manage diarrhea, respiratory infections, and severe illnesses in children. Another example is orange juice fortified with calcium.

Recombinant Nutraceuticals

Foods produced through genetic recombination and engineering are referred to as recombinant nutraceuticals. These foods are genetically modified to enhance their nutritional content by introducing recombinant substances and proteins, making them healthier. Examples of recombinant nutraceuticals include iron-fortified rice, golden rice, genetically enhanced maize, golden mustard, multivitamin corn, and gold kiwifruit. In particular, a recombinant gene in gold kiwifruit increases levels of ascorbic acid, carotenoids, and lutein, thereby boosting immune function. Additionally, gold kiwifruit is recognized as a good source of fiber, potassium, and vitamins.

Global Regulatory Scenario for Nutraceuticals

In the United States, the Dietary Supplement Health and Education Act (DSHEA) of 1994 established regulations for nutraceuticals, distinguishing them from conventional foods and drugs. Under DSHEA, manufacturers must ensure product safety before marketing, while the FDA is responsible for addressing issues with unsafe products once they are on the market. The Good Manufacturing Practice (GMP) regulation introduced in 2007 mandates that companies, both domestic and international, ensure the safety and quality of nutraceuticals, with enforcement by the FDA and the Department of Health and Human Services.

Companies must comply with current GMP standards and report serious adverse events to the FDA.

Table 1: Regulatory Act(s) and issues of Asian & European countries.

Country	Regulatory act and Isuues
Japan	**FOSHU 1991:** Concentrates on health assertions related to particular products.
	FHC)2001: The product range has been broadened to encompass capsules and tablets.
	FNFC 2005 : Limited to the designated nutrients that possess nutritional function claims in FHC.
China	**SFDA 2003:** Manages and coordinates the agencies responsible for health, food, and pharmaceuticals.
	SFDA 2005: The regulations for the registration of functional foods have been officially issued.
	SCLO 2009: Oversees food products that are linked to specific functional or health-related claims regarding their consumption.
India	**FSSA 2006:** The production, distribution, or importation of innovative food products, genetically modified foods, irradiated foods, organic foods, specialized dietary foods, functional foods, nutraceuticals, and health supplements.
	FSSAI 2008: A centralized source for all issues concerning food safety and standards.
	Food Safety & Standards Rules and Regulations 2009: Greater focus on decisions that are grounded in scientific evidence and involve active participation.
	FSSAI 2010: Executed.
USA	**NLEA 1990:** The Agency regulates the nutrition labeling of the majority of food products.
	DSHEA 1994: Explain how a nutrient or dietary component contributes to the typical structure or functioning of the human body.
	FDAMA 1997: The Federal Food, Drug, and Cosmetic Act pertains to the oversight of food, pharmaceuticals, medical devices, and biological products.
	FSMA 2011: Safeguard the food supply in the United States by mitigating the risk of contamination.
European union	**FUFOSE 1996:** Develop a scientifically grounded methodology for principles in the field of functional food science.
	Regulation EC no. 258/97(1997): Relevant to Good Manufacturing Practices (GMP), as well as food products and their ingredients.
	Regulation (EC) No 1831(2003):

	Regarding the approvals of probiotics utilized as additives.
	Directive 2004/24/EC: Claims regarding its medicinal properties are derived from the historical use of various herbs.
	Regulation (EC) No 1924(2006): Sets guidelines for the labeling, presentation, and marketing of food products.
	Regulation (EC) No 353(2008): Sets forth the guidelines for health claims as outlined in Regulation (EC) No 1924/2006.
	Regulation (EU) No 383(2010): Endorse nutrition that lowers disease risk and promotes children's health.
Brazil	**ANVISA 2002:** Examine both natural and synthetic substances that exhibit proven physiological activity.
Canada	**Canadian Food and Drugs Act and regulation(1953):** Provided a definition of food.
	Food Directorate of the Health Protection Branch of Health Canada(1996): Nutraceuticals are typically marketed in medicinal formats that are not commonly linked to food products.
	Canadian Food and Drugs Act(2001): Discuss foods that offer health advantages that extend beyond fundamental nutritional value.
	NHPD 2003: Define nutraceutical
Australia & New Zealand	**FSANZ 1991:** Establishes food standards to regulate the food industry across Australia and New - Zealand.
	Australian Capital Territory(Food Regulations Act, 2002): Amendments to the Food Act are now accessible through the Parliamentary Counsel.
	Queensland (Food Act, 2006): Guarantee that the food available for sale is safe and appropriate for human consumption.
	New South Wales GovernmentFood Regulation (2010): Oversight of food safety regulations for the food industry.

MARKET GROWTH OF NUTRACEUTICALS

Pharmaceutical companies like Novartis, GlaxoSmithKline, and Cadila Healthcare have recently ventured into the dietary supplement industry. In India, FMCG suppliers and pharmaceutical firms are key players in the nutraceutical market, with vitamin and mineral supplements comprising 64% of the sector. Globally, Japan holds the second-largest share of the nutraceutical market after the USA, but China is expected to overtake Japan due to rising health awareness among its middle class.

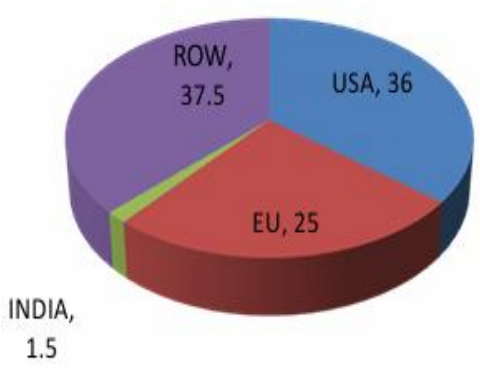

Figure 2: Global Market.

The European Union's stringent regulations and complex approval processes have limited innovation in the nutraceutical sector, leading companies to focus on expanding existing products rather than developing new ones. In 2010, the global nutraceutical market was valued at $140.1 billion, with the US holding a 36% share, the European Union 25%, and India 1.5%. The Indian market was projected to reach $2,731 million by 2016, according to the Asian Edition of Bio-spectrum.

Figure 3: Global Nutraceuticals Market (2021-2025).

Aim

The regulatory landscape for nutraceuticals, encompassing dietary supplements, functional foods, and related products, is a critical area of study, given its impact on public health, industry practices, and global trade. The aim of this section is to comprehensively explore and compare the regulatory frameworks governing nutraceuticals in three key regions: The United States, Europe, and India. Each of these regions represents a distinct approach to the regulation of nutraceuticals, influenced by historical, cultural, and economic factors. This comparative analysis seeks to highlight the similarities, differences, and unique challenges faced by each regulatory environment.

Objectives

1. Understanding Regulatory Frameworks: The first objective is to delve into the foundational aspects of how nutraceuticals are regulated in the USA, Europe, and India. This involves understanding how each region legally defines and categorizes nutraceuticals, which can include dietary supplements, functional foods, and other health-related products. The objective also covers the identification of key regulatory bodies—such as the FDA in the USA, EFSA in Europe, and FSSAI in India—and their specific roles in overseeing the nutraceutical industry. Additionally, this objective aims to outline the various legislative acts, guidelines, and standards that dictate the rules for manufacturing, labeling, marketing, and distributing these products in each region. By understanding these frameworks, the study aims to provide a comprehensive overview of the regulatory landscape in each region.

2. Comparing Regulatory Approaches: This includes evaluating the methodologies each region uses for assessing product safety, efficacy, and quality, as well as their respective compliance requirements. The comparison will highlight differences in enforcement mechanisms, such as the extent of pre-market approval processes, post-market surveillance, and penalties for non-compliance. It also involves analyzing how each region handles health claims—particularly the level of scientific evidence required to substantiate these claims—and the standards they set for product quality control. Through this comparison, the study aims to identify both the strengths and weaknesses of each regulatory approach, offering insights into potential areas for improvement, harmonization, and collaboration across these regions to enhance the global regulation of nutraceuticals.

DISCUSSION

Regulatory Aspects

Regulatory differences across countries pose significant challenges to the growth of nutraceuticals. Unlike pharmaceuticals, nutraceuticals do not undergo the same rigorous evaluation and approval processes. Generally, they are regulated as foods, provided no specific claims are made on their labels. There is no universal regulation for nutraceuticals, as each country has its own set of rules. These regulations primarily focus on safety and labelling, often placing less emphasis on the claims made by the products. The following section outlines the regulatory approaches for nutraceuticals in various countries.

Europe

In the EU, food regulations are unified under the European Food Safety Authority (EFSA), established in 2002. EFSA operates independently, offering guidance to member states, gathering data to predict risks, and conducting scientific assessments. However, it is not responsible for risk management. EFSA's primary focus is on "food supplements," which are defined as concentrated sources of nutrients such as vitamins, minerals, and proteins. The key legislation governing food supplements in the EU is Directive 2002/46/EC.

The EU has created a list of approved vitamins and minerals, and any product containing ingredients not on this list requires an application to the European Commission before it can be marketed. New products must comply with stringent European development and quality regulations, which contributes to the high reputation of European nutraceutical products. While strict rules govern product claims across Europe, these regulations can vary between different European countries. To maintain product quality, nutraceutical companies in the EU formed Food Supplements Europe (FSE).

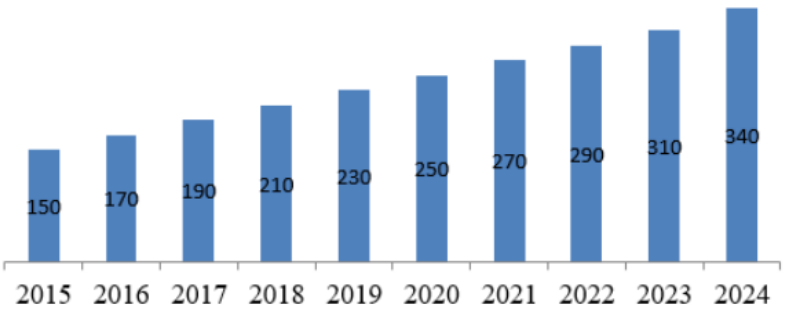

Figure 4: Expected market size of nutraceuticals from 2015-2024 (US$ Billion).

Nutraceuticals Registration in EU

All items classified as proprietary foods include the following specifications:

a) Proprietary foods that do not contain NF/FF/IF/FSN/GMF or that include extracts or concentrates derived from botanicals, herbs, or animal sources must adhere to the following guidelines:

1. Submit a license application.
2. Provide a comprehensive list of ingredients and food additives used in the product.
3. Include the IFC category number.
4. Ingredient approval is not necessary if it aligns with point 1(a).
5. Only the food additive requires approval.

6. A fee of Rs. 25,000 applies for five products that are largely similar, with variations only in flavors or colors.
7. The Product Approval and Screening Committee (PASC) will oversee the process.

b) Foods that fall under NF/FF/IF/FSN/GMF or that contain extracts or concentrates from botanicals, herbs, or animal sources.

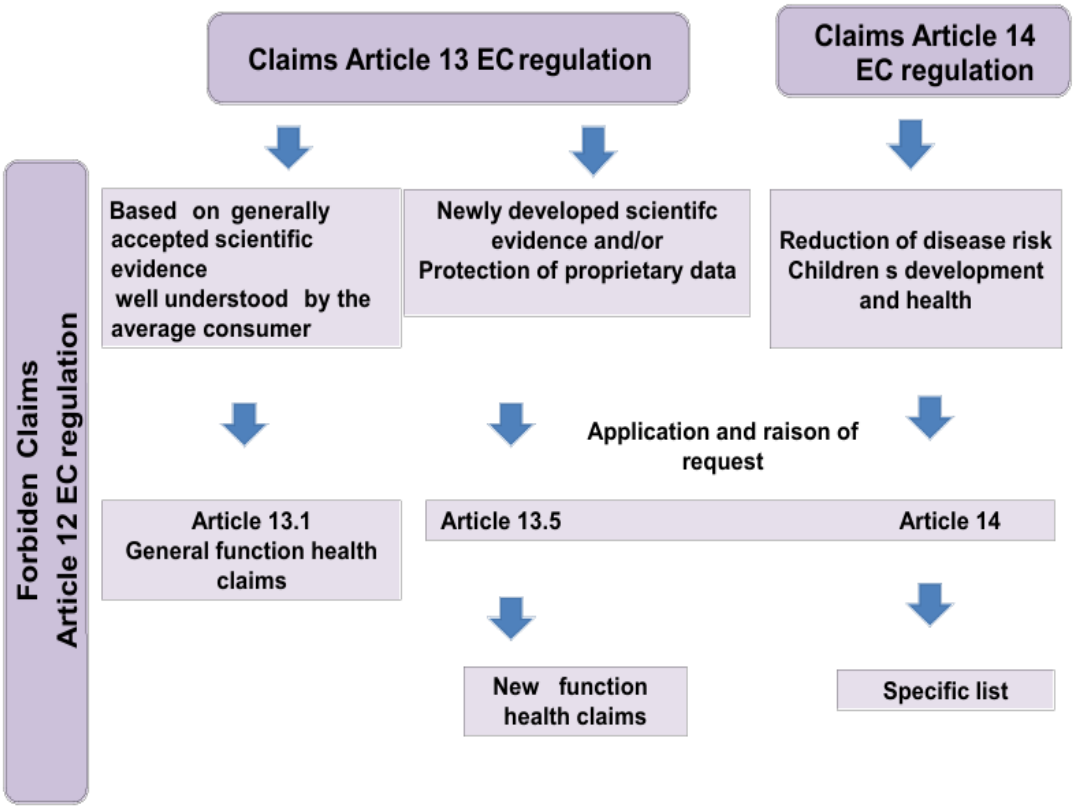

Figure 5: Health claims EC regulation.

Health claim

A health claim refers to any assertion that indicates, implies, or suggests a relationship between a specific category of food products or their components and overall health. This type of claim pertains to a state of physiological well-being in the absence of illness and focuses on prevention rather than treatment. It is consistent with the physiological effects outlined in the European Directive 2002/46/CE. Such claims must be tailored to a specific function or product and supported by scientific evidence that substantiates the claimed relationship. For instance, a health claim could state, "Omega-3 fatty acids support enhanced cardiovascular health."

Documents Required for FSSAI Food License

The documents mandated by the FSSAI for obtaining a Food License vary based on the type of registration needed either the straightforward Registration Form A or the Food License Form B, which is determined by the annual turnover. For small Food Business Operators (FBOs), only registration with the food authority is necessary.

Table 2: Classification of Licenses Based on Annual Turnover.

Registration/ License	Annual Turnover
Registration	Below 12 Lakhs FORM A
State License	12 – 20 Lakhs FORM B
Central License	Above 20 Lakhs FORM B

Documents required along with Form A

- A Passport-size photograph of Food Business Operator
- Acceptable documents for identity verification include a ration card, voter ID card, PAN card, driving license, passport, Aadhaar card, senior citizen card, and any ID issued by a government department.
- Supporting documents, if applicable, include a No Objection Certificate (NOC) from the Municipality or Panchayat, as well as a Health NOC. A state license is mandatory for Food Business Operators (FBOs) with an annual turnover ranging from 12 to 20 lakhs.

Documents required along with Form B (State License)

- Form B must be accurately filled out and signed in duplicate by either the owner or the partner of the authorized signatory.
- Manufacturing and processing facilities are required to submit a detailed blueprint of their processing units. This blueprint must include measurements in meters or square units, a breakdown of area allocation by operation, and a comprehensive list of equipment and machinery, including their quantities, installed capacities, and horsepower specifications.
- Companies are required to provide a comprehensive list of their Partners, Proprietors, and Executive Members, including full addresses and contact information.
- Documentation verifying address and a government-issued photo identification.
- For manufacturers, please provide a list of the food categories you wish to produce.

Documents required along with Form B (Central License)

- A detailed blueprint or layout plan of the processing unit must be provided, indicating dimensions in meters or square meters and specifying area allocations based on operational requirements (this is a requirement for manufacturing and processing units only).
- A comprehensive list of Directors, including their full addresses and contact information, is required (this is mandatory for companies only).
- A detailed inventory of equipment and machinery is necessary, including their quantities, installed capacities, and horsepower specifications (this is mandatory for manufacturing and processing units only).
- Government-issued photo identification and address verification for the Proprietor, Partner, Director(s), or Authorized Signatory is optional.
- A list of food categories intended for production must be submitted (this applies to manufacturers).
- A letter of authority must be submitted, including the name and address of the person appointed by the manufacturer, as well as an alternative responsible individual. This document should outline the powers assigned to them, such as aiding officials during inspections, sample collection, and overseeing packing and dispatch. This is a mandatory requirement for both manufacturing and processing entities.
- An analysis report, covering both chemical and bacteriological aspects, of the water to be utilized as a food ingredient must be sourced from a recognized public health laboratory to ensure its potability. This requirement is mandatory only for manufacturing and processing units.

Regulatory Challenges

Nutraceuticals encounter numerous regulatory hurdles globally, as they are frequently classified in a gray area between food and pharmaceutical products. Below are some of the primary regulatory challenges associated with nutraceuticals:

1. Disparity in regulatory frameworks:

Nutraceuticals face varying regulations across different nations, leading to a significant lack of harmonization in the regulatory standards. This inconsistency complicates the ability of companies to effectively manage compliance and may lead to variations in product quality and safety.

2. Safety Issues

Although numerous nutraceuticals are typically regarded as safe, there have been cases of negative reactions and, in some instances, fatalities linked to their consumption. The absence of pre-market safety assessments and ongoing monitoring complicates the ability to guarantee the safety of these products.

3. Labeling and marketing claims

Nutraceuticals frequently feature health claims on their labels and in promotional content, which can be challenging to verify. Regulatory authorities globally are intensifying their scrutiny of unsupported health claims, posing difficulties for companies in effectively promoting their products.

4. Quality control

Maintaining the quality of nutraceutical products presents challenges, primarily because many ingredients originate from natural sources, which can lead to variations in potency and purity. This variability complicates the establishment of consistent quality standards for these products.

5. Intellectual property

The process of developing and marketing nutraceuticals can be hindered by intellectual property challenges, such as patents and trademarks. This complexity often poses significant obstacles for smaller firms trying to compete against larger industry leaders.

6. Lack of clinical trials

Although certain nutraceuticals have been evaluated in clinical trials, a significant number have not been subjected to thorough scientific examination. This lack of rigorous testing can complicate the determination of their effectiveness and may impede their acceptance within the medical community.

CONCLUSION

The ongoing expansion of the nutraceutical industry presents significant opportunities for economic growth, particularly in regions emerging as key players in the global market. Countries such as India, with its rich biodiversity and traditional knowledge of medicinal plants, are well-positioned to become major suppliers of raw materials and finished nutraceutical products. This potential for growth is not only economic but also scientific, as

these regions invest in research and development to explore the health benefits of their native botanicals. The combination of traditional wisdom and modern scientific research could lead to the discovery of new nutraceuticals that offer unique health benefits, further enriching the global market.

As the market grows, so too does the need for collaboration between industry stakeholders and regulatory bodies. International harmonization of regulations, while challenging, is a goal that could significantly benefit both consumers and manufacturers. Currently, the lack of standardized regulations across different regions poses barriers to trade and complicates the process of bringing new products to market. By working towards more unified regulatory frameworks, countries can help ensure that nutraceuticals meet consistent safety and efficacy standards, thereby facilitating global trade and ensuring that consumers worldwide have access to high-quality products.

Moreover, the role of nutraceuticals in addressing global health disparities cannot be overstated. In developing countries, where malnutrition and nutrient deficiencies are prevalent, nutraceuticals could serve as a vital resource for improving public health. Fortified foods and supplements can help bridge the gap where traditional diets may lack certain essential nutrients, contributing to the overall well-being of populations. This aspect of nutraceuticals aligns with broader public health goals, such as the United Nations' Sustainable Development Goals (SDGs), which aim to ensure healthy lives and promote well-being for all.

Innovation within the nutraceutical sector is also likely to be driven by advances in biotechnology and food science. Techniques such as genetic engineering and fermentation are opening new avenues for the production of enhanced nutraceuticals. These methods allow for the development of products with higher concentrations of beneficial compounds or the inclusion of novel ingredients that were previously difficult to source or produce. Such innovations not only improve the efficacy of nutraceuticals but also expand the range of health issues they can address, from chronic diseases to cognitive decline and beyond.

In conclusion, nutraceuticals are poised to play a transformative role in the future of global health. Their ability to prevent and manage a wide array of health conditions makes them an invaluable tool in both individual and public health strategies. However, the success of the nutraceutical industry will depend on the continued development of rigorous, science-based

regulations, the education of consumers, and the fostering of innovation. By addressing these challenges, the nutraceutical sector can not only meet the growing demand for health-enhancing products but also contribute to a healthier, more sustainable future for people around the world. The path forward for nutraceuticals is one of great promise, with the potential to improve health outcomes on a global scale and to solidify their place as a cornerstone of modern wellness.

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