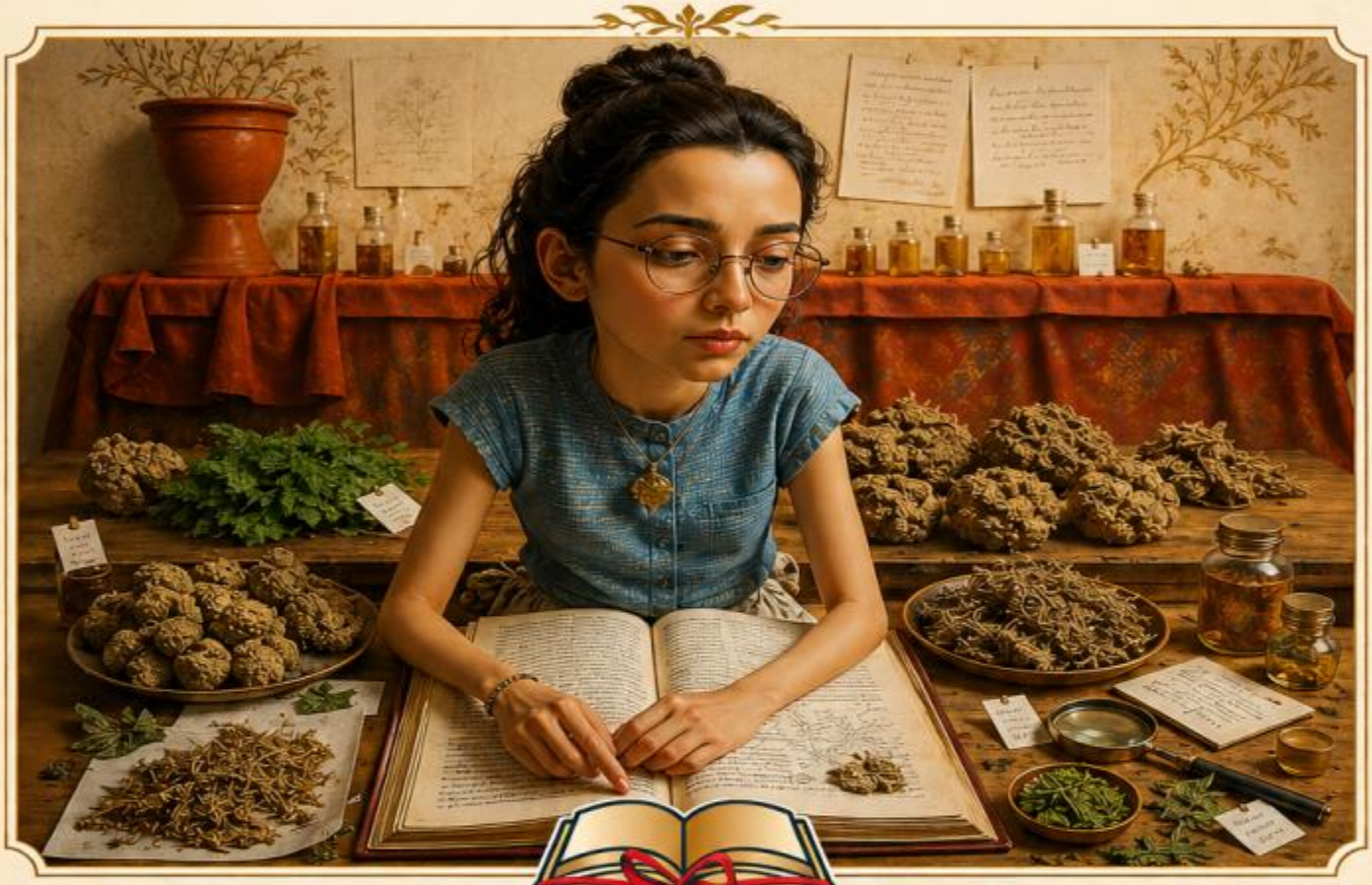
AS PER PCI – M. Pharmacy (Regulatory Affairs)

A Textbook of

REGULATORY ASPECTS OF FOOD & NUTRACEUTICALS



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FOR M. PHARMACY – REGULATORY AFFAIRS

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As Per PCI – M. Pharmacy (Regulatory Affairs) Syllabus

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Preface

The field of food regulation and nutraceutical science has undergone rapid transformation in recent years, driven by increasing consumer awareness, globalization of food supply chains, and advancements in health and nutritional sciences. The growing demand for safe, high-quality, and functionally beneficial food products has made regulatory frameworks more critical than ever before. In this context, *A Textbook of Regulatory Aspects of Food & Nutraceuticals* has been carefully designed to provide a comprehensive and structured understanding of the regulatory landscape governing food and nutraceutical products.

This textbook aims to bridge the gap between theoretical knowledge and practical regulatory requirements. It presents key concepts related to food laws, standards, safety assessment, labeling requirements, quality control, and compliance procedures. Special emphasis has been placed on nutraceuticals, functional foods, dietary supplements, and their evolving regulatory frameworks across different jurisdictions. The book also highlights the role of regulatory authorities, risk assessment strategies, and international guidelines that shape modern food governance.

The content has been systematically organized to cater to the needs of undergraduate and postgraduate students in pharmacy, food technology, nutrition, and allied health sciences. It will also serve as a valuable reference for researchers, academicians, and industry professionals involved in product development, quality assurance, and regulatory affairs. Each chapter is structured to enhance clarity, with a focus on conceptual understanding, real-world applications, and current regulatory perspectives.

Efforts have been made to present the subject matter in a clear, concise, and student-friendly manner while maintaining scientific rigor. The authors have incorporated recent developments, guidelines, and case-based insights to ensure that readers gain a practical understanding of regulatory challenges and opportunities in the food and nutraceutical sector.

We express our sincere gratitude to all contributors, colleagues, and well-wishers who have supported us in the completion of this work. We also acknowledge the role of regulatory bodies, scientific communities, and industry experts whose continuous efforts contribute to the advancement of safe and effective food systems.

We hope that this textbook will serve as a reliable resource and inspire learners to develop a deeper interest in regulatory sciences, ultimately contributing to public health and consumer safety.

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I express my deepest and most sincere gratitude to all those who have supported, guided, and encouraged me throughout the preparation and completion of this book. Their unwavering assistance and belief in my work have played a crucial role in bringing this endeavor to fruition.

I dedicate this work with profound love, respect, and heartfelt appreciation to my beloved parents, **P. Radharani** and **P. Sreenivasulu**, whose constant encouragement, invaluable blessings, and countless sacrifices have been the strongest foundation of my academic and professional journey. Their guidance and moral support have always inspired me to strive for excellence.

I extend my heartfelt thanks to my brother, **P. Bharat**, for his continuous support, motivation, and encouragement at every stage of this work. His presence has been a constant source of strength.

I am also deeply thankful to my beloved son and daughter, whose love, patience, understanding, and unwavering support have been a great source of inspiration. Their encouragement has helped me maintain balance and determination throughout this demanding process.

I would like to express my sincere appreciation to all the co-authors for their valuable contributions, cooperation, and dedication. Their collective efforts, insights, and commitment have significantly enriched the quality and completion of this book.

I also extend my gratitude to all teachers, colleagues, mentors, and well-wishers who have directly or indirectly contributed to the successful completion of this work. Their guidance and support have been invaluable.

Finally, I thank everyone who, in any way, has contributed to this endeavor, whether through guidance, encouragement, or support.

- **V. R. Teja Sruthi Pagadala**

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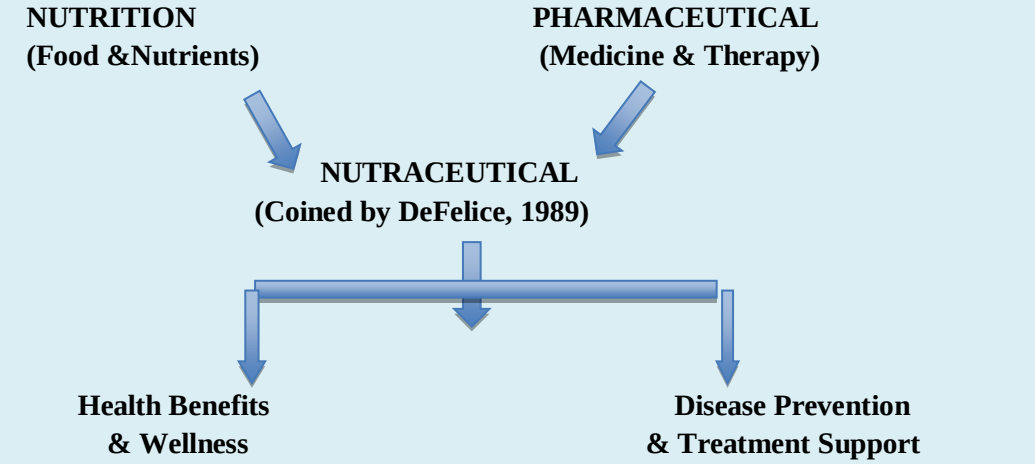
TOPIC 1: INTRODUCTION TO NUTRACEUTICALS

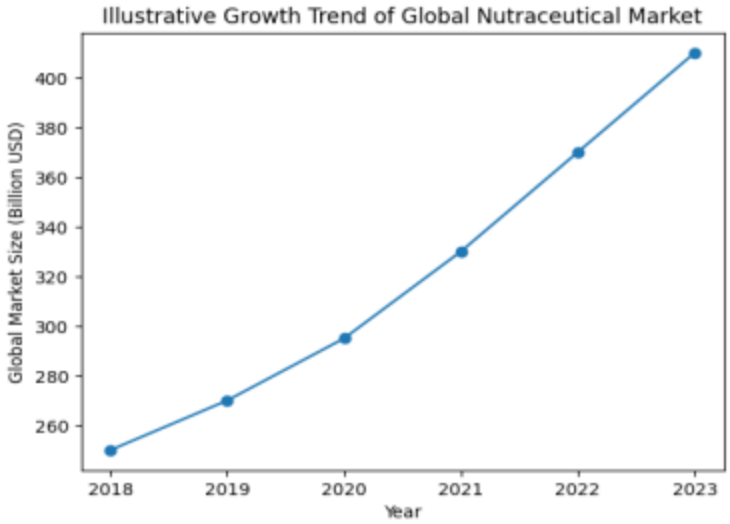
1.1 Introduction

The term **"Nutraceutical"** is derived from two words: *"Nutrition"* and *"Pharmaceutical"*. It was first introduced by **Stephen L. DeFelice in 1989**, who defined nutraceuticals as:
"Any substance that is a food or part of a food and provides medical or health benefits, including the prevention and treatment of disease."



Flowchart 1.1: Definition of Nutraceutical

Nutraceuticals represent a class of bioactive, naturally derived compounds that offer health-promoting, disease-preventing, or therapeutic benefits, extending beyond their basic nutritional functions. These products bridge the interface between traditional food and modern pharmacotherapy, thereby forming a crucial component of preventive and integrative healthcare systems.
In recent years, global interest in nutraceuticals has expanded significantly due to increasing awareness about the role of diet in health maintenance and disease prevention. Consumers are shifting toward natural, safer, and holistic health solutions, fuelling rapid market growth in the nutraceutical sector.
From a regulatory affairs perspective, nutraceuticals constitute a complex product category positioned between foods and drugs. Regulatory professionals are responsible for determining product classification, compliance requirements, permissible claims, safety evaluation, and post-market monitoring, making nutraceutical regulation a vital and evolving discipline.



Graph 1.1: Illustrative Growth Trend of Global Nutraceutical Market

1.2 Concept of Nutraceuticals

The concept of nutraceuticals is deeply rooted in the ancient philosophy of **"**Food as Medicine**"**, which emphasizes that proper nutrition can maintain physiological balance, promote well-being, and prevent disease onset. However, in modern science, nutraceuticals are recognized as standardized, evidence-based functional products formulated to deliver specific biological activities.

Figure 1.1: Concept of Nutraceuticals

Key Features of Nutraceuticals

- Derived from food sources, plants, herbs, marine organisms, or microbial fermentation.
- Provide health benefits beyond basic nutrition.
- Support physiological functions, reduce disease risk, or exhibit therapeutic properties.
- Formulated as dosage forms such as tablets, capsules, powders, gummies, drinks, etc.
- Recognized globally under various regulatory categories (e.g., dietary supplements, functional foods).

Evidence-Based and Regulatory-Compliant Products

In regulatory science, nutraceuticals must be supported by scientific evidence for safety, quality, stability, and claim substantiation. Authorities increasingly demand compliance with ingredient specifications, toxicological limits, GMP standards, and labelling regulations, emphasizing the need for regulatory oversight during formulation and commercialization.

Why Nutraceuticals Are Unique

Unlike conventional pharmaceuticals that primarily target disease symptoms, nutraceuticals aim to:

- **Enhance general well-being:** Nutraceuticals support overall physical and mental health by providing essential bioactive nutrients.
- **Regulate metabolic processes:** They help maintain normal metabolism by improving enzymatic and hormonal balance in the body.
- **Improve immunity:** Nutraceuticals strengthen the immune system and enhance the body's resistance to infections and diseases.
- **Prevent chronic diseases:** Regular consumption reduces the risk of lifestyle-related disorders such as diabetes, cardiovascular diseases, and obesity.
- **Delay aging and oxidative stress-related degeneration:** Antioxidant nutraceuticals slow cellular aging by neutralizing free radicals and reducing oxidative damage.

Therefore, they represent a preventive, holistic, and wellness-oriented approach to healthcare.

1.3 Need for Nutraceuticals

Modern lifestyle challenges such as sedentary behaviour, stress, poor diets, exposure to pollutants, and overuse of processed foods have contributed to a dramatic increase in chronic disorders like:

- **Diabetes mellitus:** A metabolic disorder characterized by chronic hyperglycaemia due to impaired insulin secretion, action, or both.
- **Obesity:** A condition marked by excessive body fat accumulation that increases the risk of metabolic and cardiovascular diseases.
- **Cardiovascular diseases:** A group of disorders affecting the heart and blood vessels, often associated with hypertension, atherosclerosis, and dyslipidaemia.
- **Arthritis and joint disorders:** Inflammatory or degenerative conditions causing joint pain, stiffness, and reduced mobility.
- **Neurodegenerative conditions:** Progressive disorders characterized by the gradual loss of neuronal structure and function, leading to cognitive and motor impairment.
- **Hormonal imbalance:** A condition in which abnormal levels of hormones disrupt normal physiological and metabolic processes.
- **Digestive disorders:** Disorders affecting the gastrointestinal tract that impair digestion, absorption, and nutrient utilization.

These conditions place a heavy burden on healthcare systems. As a result, nutraceuticals have emerged as a cost-effective, safe, and sustainable alternative or adjunct to conventional medical therapy.

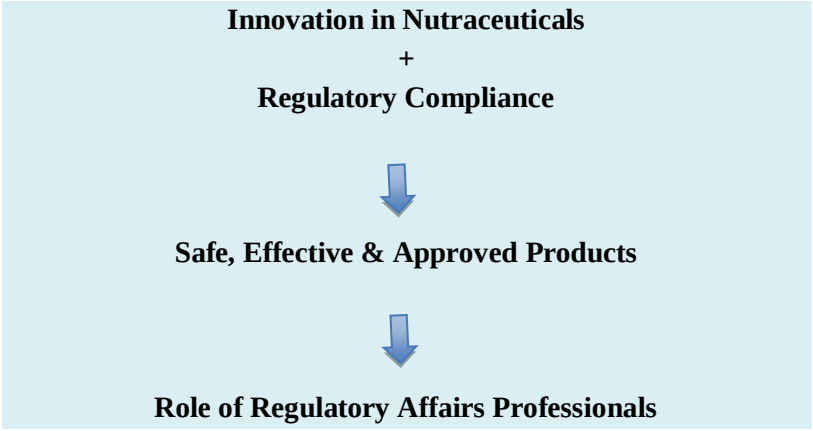
1.3.1 Key Reasons for Increasing Demand

Lifestyle Disorder	Major Cause	Role of Nutraceuticals
Diabetes Mellitus	Insulin resistance, poor diet	Blood glucose control, antioxidant support
Obesity	Excess calorie intake, inactivity	Weight management, metabolism regulation
Cardiovascular Diseases	Hypertension, dyslipidaemia	Heart protection, cholesterol control
Arthritis & Joint Disorders	Inflammation, aging	Anti-inflammatory & joint lubrication
Neurodegenerative Disorders	Oxidative stress, aging	Neuroprotection, cognitive support
Hormonal Imbalance	Stress, nutrition deficiency	Hormonal regulation
Digestive Disorders	Poor gut health	Improved digestion & nutrient absorption

Table 1.1: Disorders and Role of Nutraceuticals

1. **Preventive Healthcare Trend**
   People now prefer to prevent diseases rather than treat them after onset. Nutraceuticals help maintain normal physiological functions and reduce the risk of long-term disorders.
2. **Rising Consumer Awareness**
   Greater knowledge of nutrition, wellness, and natural medicine has increased demand for scientifically validated nutraceuticals.
3. **Limitations of Pharmaceuticals**
   Many drugs come with side effects, high cost, and long-term toxicity. Nutraceuticals offer a gentler and often safer approach.
4. **Aging Population**
   Global demographic shifts toward older age groups require solutions that support healthy aging, mobility, and cognitive function.
5. **Immunity Enhancement**
   Post-pandemic, immune-supporting nutraceuticals (vitamin C, zinc, probiotics, herbal extracts) have seen exponential growth.

From an industry and regulatory viewpoint, nutraceuticals require balanced innovation and compliance, highlighting the importance of regulatory affairs expertise.



Flowchart 1.2: Industry& Regulatory Perspective

1.4 Regulatory Perspective of Nutraceuticals

The regulation of nutraceuticals varies widely between countries due to differing definitions, safety standards, and classification systems. A regulatory overview is essential for understanding product registration, marketing authorization, and compliance.

Region	Regulatory Classification	Regulating Authority
India	Nutraceuticals, Health Supplements, Foods for Special Dietary Use	FSSAI
USA	Dietary Supplements	FDA (DSHEA 1994)
European Union	Food Supplements	EFSA
Canada	Natural Health Products	Health Canada
Japan	FOSHU (Foods for Specified Health Use)	MHLW

Table 1.2: Global Regulatory Classifications

1.4.1 Regulatory Requirements Commonly Include:

- Safety assessment of ingredients
- Permissible additives, vitamins, minerals, and herbal extracts
- Labelling guidelines (nutritional, health claims, warnings)
- Quality standards (purity, stability, microbial limits)
- Evidence to support functional or health claims
- Good Manufacturing Practices (GMP)

Governments focus heavily on ensuring that nutraceuticals are safe, standardized, properly labelled, and supported by scientific evidence. Regulatory affairs professionals ensure compliance throughout the product lifecycle—from formulation to post-market surveillance.

1.5 Common Regulatory Requirements

Common regulatory requirements refer to the minimum legal, scientific, and quality standards prescribed by regulatory authorities for the approval, manufacture, labeling, marketing, and post-marketing monitoring of nutraceutical products.

Why they are called **"common"**:

- Applicable to most countries (with minor variations)
- Mandatory for market authorization
- Focus on consumer safety and truthful claims
- Ensures standardization and regulatory compliance

Purpose of Common Regulatory Requirements:

- To prevent unsafe or adulterated products
- To control misleading health claims
- To ensure consistent product quality
- To protect public health
- To enable regulatory monitoring and enforcement

Simply, Common regulatory requirements are the essential compliance standards that nutraceuticals must meet before and after marketing to ensure safety, quality, and regulatory acceptance. i.e.,

1.5.1 Ingredient Safety and Toxicological Assessment

Regulatory authorities require all nutraceutical ingredients to be safe for human consumption based on toxicological evaluation such as acute, sub-chronic toxicity, genotoxicity, and allergenicity.

Example:

- FSSAI mandates safety assessment for novel foods like plant sterols or algae-derived omega-3 before approval.
- FDA requires new dietary ingredients (NDIs) to submit safety data at least 75 days before marketing.

1.5.2 Approved Vitamin, Mineral, and Herbal Limits

Authorities prescribe maximum permissible limits for vitamins, minerals, and herbal actives to prevent toxicity and overdose.

Example:

- Vitamin A has strict upper intake limits due to risk of hypervitaminosis.
- FSSAI Schedule I specifies maximum limits for vitamins and minerals in nutraceutical formulations.

1.5.3 Labelling and Health Claim Guidelines

Labelling rules ensure that product information is truthful, accurate, and non-misleading. Disease treatment or cure claims are generally prohibited.

Example:

- Claims like *"prevents diabetes"* are not allowed, whereas *"helps maintain healthy blood glucose levels"* may be permitted.
- FDA allows structure–function claims with a disclaimer: *"This statement has not been evaluated by the FDA."*

1.5.4 Quality and Purity Specifications

Nutraceuticals must comply with quality standards related to identity, purity, and strength, including limits on contaminants.

Example:

- Heavy metals such as lead, mercury, and arsenic must be within prescribed limits.
- Herbal extracts must meet pharmacopeial or in-house specifications for active content.

1.5.5 Stability and Microbial Limits

Stability studies ensure that the product remains safe and effective throughout its shelf life, while microbial testing ensures freedom from harmful microorganisms.

Example:

- Shelf life of 24 months assigned only after successful stability testing.
- Absence of pathogens like E. coli, Salmonella, and Staphylococcus aureus is mandatory.

1.5.6 Good Manufacturing Practices (GMP)

GMP ensures nutraceuticals are manufactured under controlled, hygienic, and standardized conditions.

Example:

- FSSAI Schedule IV prescribes GMP requirements for food and nutraceutical manufacturers.
- FDA's 21 CFR Part 111 applies to dietary supplement manufacturing.

1.5.7 Post-Marketing Surveillance and Adverse Event Reporting

Manufacturers must monitor product safety after marketing and report adverse events to authorities.

Example:

- Reporting cases of allergic reactions to herbal supplements.
- FDA MedWatch system for reporting serious adverse events associated with dietary supplements.

Regulatory Aspect	**Key Requirement**	**Purpose**	**Examples (FSSAI / FDA)**
Ingredient Safety & Toxicology	Toxicological evaluation of all ingredients	To ensure safety for human consumption	Safety assessment for novel foods (FSSAI); NDI notification 75 days prior (FDA)
Approved Vitamin & Mineral Limits	Maximum permissible limits for nutrients	To prevent toxicity and overdose	Upper limit for Vitamin A; FSSAI Schedule I limits
Labelling & Health Claims	Truthful, accurate, non-misleading labels	To protect consumers from false claims	"Helps maintain glucose levels" allowed; disease cure claims prohibited
Quality & Purity Specifications	Compliance with identity, purity, and strength standards	To ensure consistent product quality	Limits on heavy metals; standardized herbal extract content
Stability &	Shelf-life validation and	To ensure product	24-month shelf life after

Microbial Limits	microbial testing	safety throughout shelf life	stability studies; absence of pathogens
Good Manufacturing Practices (GMP)	Controlled and hygienic manufacturing conditions	To maintain quality and prevent contamination	FSSAI Schedule IV; FDA 21 CFR Part 111
Post-Marketing Surveillance	Monitoring and reporting of adverse events	To protect public health after product launch	Reporting allergic reactions; FDA MedWatch system

Table 1.3: Common Regulatory Requirements for Nutraceuticals

1.6 Role of Regulatory Affairs in Nutraceutical Lifecycle

Regulatory Affairs ensures that nutraceutical products comply with all laws and regulations throughout their lifecycle from development to market and post-marketing.

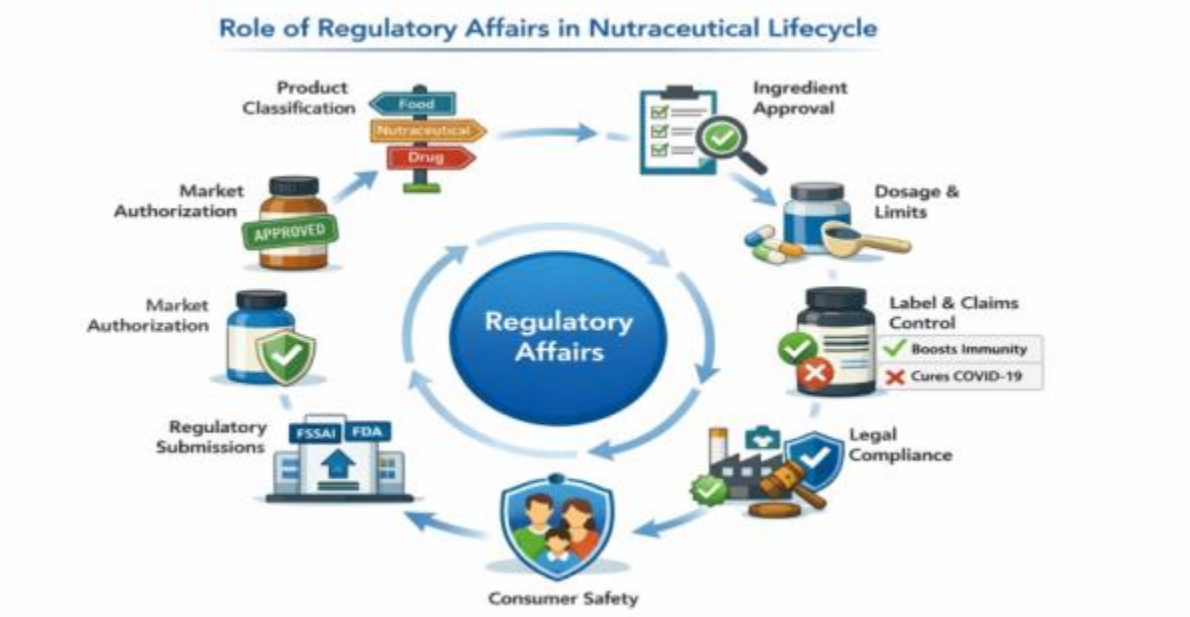


Figure 1.2: Role of Regulatory Affairs in Nutraceutical Lifecycle

1.6.1 Product Classification and Regulatory Strategy

Regulatory professionals determine correct product classification, which defines approval and compliance requirements.

Example:

- A turmeric capsule classified as a nutraceutical cannot claim anti-arthritic treatment.
- Incorrect classification may lead to product seizure or penalties.

1.6.2 Ingredient Approval and Compliance Verification

They ensure ingredients are legally permitted and used within regulatory limits.

Example:

- Verification of Ashwagandha inclusion as per FSSAI permitted botanical list.
- Checking if probiotics meet minimum viable count requirements.

1.6.3 Label Review and Claim Substantiation

Regulatory affairs ensure claims are scientifically valid and legally compliant.

Example:

- "Boosts immunity" supported by literature on vitamin C and zinc.
- Removal of unapproved claims like *"cures COVID-19"*.

1.6.4 Dossier Preparation and Submissions

Preparation of technical dossiers for regulatory review.

Example:

- Submission of product details via FOSCOS portal under FSSAI.
- NDI notification dossier submission to FDA.

1.6.5 Coordination with Quality and Manufacturing Teams

Regulatory affairs coordinates across departments to ensure compliance at all stages.

Example:

- Ensuring batch manufacturing records align with approved formulations.
- Verifying stability protocol compliance before shelf-life declaration.

1.6.6 Market Authorization and Lifecycle Management

They manage approvals, renewals, and regulatory updates.

Example:

- Updating labels when FSSAI revises vitamin limits.
- Managing product reformulation due to regulatory changes.

1.7 Global Regulatory Challenge

1.7.1 The lack of global harmonization remains a major challenge in nutraceutical regulation.

Example:

- Melatonin is a dietary supplement in the USA but regulated as a medicine in some EU countries.
- Health claims allowed in Japan (FOSHU) may be prohibited in India.
- Similarly, probiotics, herbal products, vitamins, CBD, and novel foods face varying regulatory classifications, dosage limits, and approval requirements worldwide.

This leads to increased costs, delayed product launches, and the need for market-specific modifications.

1.7.2 To Overcome These Challenges:

- Conduct early regulatory assessment for target markets
- Develop market-specific formulations and dosage levels
- Use flexible labelling and country-specific health claims
- Build a strong Regulatory Affairs team with local expertise
- Follow International Quality Standards (GMP, ISO, Codex)
- Maintain strong scientific and safety documentation
- Continuously monitor regulatory updates and changes

By combining strategic regulatory planning, scientific evidence, and global compliance practices, nutraceutical companies can successfully navigate international regulatory differences and achieve market access.

Product	USA	EU	Japan	India

Category				
Melatonin	Dietary Supplement	Medicine (some countries)	Quasi-drug	Prescription / Restricted
Probiotics	Food / Supplement	Novel Food / Health Claim restricted	FOSHU approved	Food supplement
Herbal Products	Dietary Supplement	Traditional Herbal Medicinal Product	Kampo / FOSHU	AYUSH regulated
Vitamins & Minerals	High-dose allowed	Strict dosage limits	Approved list	RDA-based limits
CBD	State-dependent	Mostly prohibited	Not approved	Narcotic-related
Novel Foods	GRAS / NDIN	EFSA approval	FOSHU	FSSAI approval

Table 1.4: Examples of Regulatory Differences Across Countries

1.8. Advantages of Nutraceuticals

Figure 1.3: Advantages of Nutraceuticals

- Safe and natural origin
- Fewer side effects compared to pharmaceuticals
- Support both prevention and treatment
- Enhance immunity and vitality
- Improve quality of life
- Cost-effective and easily accessible
- Useful for long-term consumption.

1.9 Summary and Regulatory Significance

Nutraceuticals have emerged as an essential component of modern healthcare by integrating the principles of nutrition, pharmacology, and preventive medicine. Their growing acceptance worldwide reflects a shift toward natural, safe, and holistic therapeutic approaches. The scientific evidence

supporting their role in disease prevention, metabolicregulation, healthy aging, and immune enhancement has positioned nutraceuticals as valuable adjuncts to conventional therapies.

From a regulatory affairs perspective**,** nutraceuticals demand strict adherence to quality, safety, and efficacy standards. Regulatory bodies across the globe have established frameworks for:

- Ingredient approval
- Product classification
- Labelling and permissible claims
- Good Manufacturing Practices (GMP)
- Post-marketing surveillance

A clear understanding of these regulatory requirements is crucial for ensuring consumer safety, product integrity, and market compliance. As the nutraceutical industry continues to expand, regulatory professionals must stay updated with evolving global guidelines to support safe innovation and responsible commercialization.

Aspect	Description
Concept of Nutraceuticals	Nutraceuticals combine nutrition, pharmacology, and preventive medicine to support health and reduce disease risk.
Role in Modern Healthcare	Widely accepted as natural, safe, and holistic therapeutic options complementing conventional treatments.
Health Benefits	Contribute to disease prevention, metabolic regulation, immune system enhancement, and healthy aging.
Scientific Evidence	Growing research supports their effectiveness as adjuncts to traditional medical therapies.
Regulatory Importance	Require strict regulatory oversight to ensure safety, quality, and efficacy.
Ingredient Approval	Regulatory authorities assess safety and source of ingredients before market authorization.
Product Classification	Products are categorized (dietary supplement, functional food, etc.) based on intended use and composition.
Labelling & Claims	Labels must be accurate, truthful, and compliant with permitted health and nutritional claims.
Good Manufacturing Practices (GMP)	Mandatory compliance ensures consistent product quality and contamination control.
Post-Marketing Surveillance	Ongoing monitoring for adverse effects and product performance after commercialization.
Regulatory Professional Role	Staying updated with evolving global regulations to support innovation and consumer protection.

Table 1.5:Summary and Regulatory Significance of Nutraceuticals

TOPIC 2: HISTORY OF FOOD AND NUTRACEUTICALS

2.1 Introduction

The history of food and nutraceuticals is deeply rooted in the evolution of human civilization. Since ancient times, food has been considered not only a source of nutrition but also a means of maintaining health and preventing disease. Traditional systems of medicine across the world have always emphasized the therapeutic and functional properties of food.

Period	Key Features	Examples / Contributions
Ancient Era	Food used as medicine; holistic health approach	Ayurveda (India), TCM (China), Greek medicine
India (Ayurveda)	Classification based on Rasa, Virya, Vipaka; balance of Doshas	Turmeric, amla, ashwagandha, ginger, honey
China (TCM)	Balance of Yin and Yang; functional foods	Ginseng, green tea, medicinal mushrooms
Greece & Rome	Diet as therapy	Hippocrates: "Let food be thy medicine"
Medieval Period	Herbal remedies; spice trade	Use of herbs, essential oils, minerals
18th–19th Century	Discovery of nutrients; deficiency diseases	Vitamins, minerals; scurvy, rickets
Late 20th Century	Birth of nutraceutical concept	Coining of term "Nutraceutical"
21st Century	Scientific validation; global industry	Functional foods, supplements, probiotics

Table 1.6: Historical Evolution of Food and Nutraceuticals

2.2 Ancient Perspective

In ancient civilizations, foods and herbs were used as remedies for various ailments. The concept of 'Food as Medicine' was well-established long before the advent of modern pharmaceuticals.

- **India:** The Ayurvedic system of medicine, dating back over 5000 years, categorized foods based on their taste (Rasa), energy (Virya), and post-digestive effect (Vipaka). Ayurveda emphasized a balanced diet for maintaining harmony between body, mind, and spirit. Ingredients like turmeric, amla, ashwagandha, ginger, and honey were considered both nutritional and medicine.
- **China:** Traditional Chinese Medicine (TCM) also incorporated functional foods that balance Yin and Yang energies, such as ginseng, green tea, and mushrooms.
- **Greece and Rome:** Hippocrates, the father of modern medicine, stated, "Let food be thy medicine and medicine be thy food," highlighting the therapeutic role of diet.

2.3 Medieval and Early Modern Era

During the medieval period, the medicinal use of food continued through herbal formulations and home remedies. Trade routes between Asia, the Middle East, and Europe facilitated the exchange of spices, herbs, and natural medicines. Foods rich in essential oils, antioxidants, and minerals gained importance for promoting vitality and immunity.
By the 18th and 19th centuries, with advancements in chemistry and physiology, specific nutrients like vitamins, minerals, and amino acids were discovered. This led to the recognition of 'deficiency diseases' such as scurvy (vitamin C deficiency) and rickets (vitamin D deficiency), reinforcing the scientific importance of nutrition.

Period	Key Developments	Examples / Significance
Medieval Era (5th–15th Century)	Use of food as medicine through herbal remedies and home treatments	Herbal decoctions, spice-based medicines
	Expansion of trade routes	Exchange of spices and herbs between Asia, Middle East, and Europe
	Focus on immunity and vitality	Use of foods rich in essential oils, antioxidants, and minerals
Early Modern Era (18th–19th Century)	Advances in chemistry and physiology	Scientific study of food components
	Discovery of essential nutrients	Vitamins, minerals, amino acids
	Identification of deficiency diseases	Scurvy (Vitamin C), Rickets (Vitamin D)
	Shift toward scientific nutrition	Foundation of modern nutritional science

Table 1.7: Medieval and Early Modern Contributions to Food and Nutrition

2.4 Modern Development of Nutraceutical Concept

The modern concept of nutraceuticals began in the late 20th century.

- 1989: The term “Nutraceutical” was first coined by Dr. Stephen L. DeFelice, founder of the Foundation for Innovation in Medicine (FIM), USA. He defined nutraceuticals as “any substance that is a food or part of a food and provides medical or health benefits, including the prevention and treatment of disease.”
- 1990s: Growing consumer interest in preventive healthcare and natural remedies led to the rapid expansion of the nutraceutical industry. Scientific research validated the health-promoting roles of bioactive food components such as flavonoids, omega-3 fatty acids, and probiotics.

- 21st Century: Nutraceuticals became a global trend, integrating traditional knowledge with modern science. Clinical studies began focusing on functional foods, dietary supplements, and bioavailability enhancement techniques.

Year / Era	Milestone	Significance
Ancient Times	Food as Medicine	Preventive and therapeutic nutrition
1989	Term "Nutraceutical" coined by Dr. Stephen L. DeFelice	Formal definition and recognition
1990s	Growth of nutraceutical industry	Focus on preventive healthcare
2000s onwards	Clinical and bioavailability research	Evidence-based nutraceutical products

Table 1.8: Development of the Nutraceutical Concept

2.5 Global Evolution of Food and Nutraceutical Regulations

With the increasing popularity of nutraceuticals, regulatory frameworks were developed globally to ensure safety, efficacy and quality.

- **United States:** The Dietary Supplement Health and Education Act (DSHEA) was enacted in 1994, defining and regulating dietary supplements. The U.S. FDA monitors labeling and claims related to these products.
- **European Union:** The European Food Safety Authority (EFSA) regulates functional foods and supplements under strict safety and health-claim evaluation systems.
- **Japan:** Introduced the concept of "Foods for Specified Health Uses (FOSHU)" in the early 1990s, pioneering the regulation of functional foods.
- **India:** Adopted regulations under the Food Safety and Standards Act (FSSA), 2006, administered by the Food Safety and Standards Authority of India (FSSAI). Categories include health supplements, nutraceuticals, and functional foods.

Country / Region	Regulatory Authority	Key Regulation / System
USA	FDA	DSHEA (1994)
European Union	EFSA	Health claims and safety assessment
Japan	Ministry of Health	FOSHU (Foods for Specified Health Uses)
India	FSSAI	Food Safety and Standards Act, 2006

Table 1.9: Global Regulatory Framework for Nutraceuticals

2.6 Integration of Traditional and Modern Systems

The combination of ancient traditional systems like Ayurveda, Siddha, and Unani with modern nutraceutical science has opened new pathways in preventive and therapeutic healthcare. India, with its biodiversity and traditional knowledge, has emerged as a global hub for herbal and functional food research.

The evolution of nutraceuticals reflects humanity's journey from traditional food-based healing to scientifically validated dietary therapies. From ancient civilizations to modern pharmacological advancements, the focus has always been on using food as a means to promote health and longevity. The growing recognition of nutraceuticals as a vital part of healthcare marks a new era of nutrition-based medicine.

Figure 1.4: Integrating Traditional Knowledge with Modern Science

Traditional System	Modern Application	Outcome
Ayurveda	Herbal nutraceuticals	Preventive healthcare
Siddha & Unani	Functional foods	Chronic disease management
Ethnobotany	Clinical research	Global nutraceutical innovation

Table 1.10: Integration of Traditional and Modern Systems

- The concept of food as medicine has existed since ancient times. - Ayurveda and Traditional Chinese Medicine emphasized functional foods for health and disease prevention.
- The modern term "Nutraceutical" was introduced by Dr. Stephen DeFelice in 1989. - Global regulatory frameworks like DSHEA (USA), EFSA (EU), and FSSAI (India) govern nutraceutical standards.
- Integration of traditional knowledge with modern science is shaping the future of nutraceuticals.

TOPIC-3: MEANING OF NUTRACEUTICALS

The term "Nutraceutical" is a combination of the words "Nutrition" and "Pharmaceutical." It refers to any substance that is a food or part of a food which provides medical or health benefits, including the prevention and treatment of disease. Nutraceuticals represent the intersection between nutrition (which provides nourishment for normal physiological function) and pharmacology (which deals with the therapeutic effects of bioactive compounds). These products are derived from natural sources such as plants, animals, or microbes, and are used not only for their nutritional value but also for their therapeutic potential.

3.1 Examples

- Curcumin from turmeric – antioxidant and anti-inflammatory activity.
- Lycopene from tomatoes – protective against prostate cancer.
- Omega-3 fatty acids from fish oil – beneficial for heart and brain health.
- Flavonoids from green tea – powerful antioxidants.
- Garlic extract – supports cardiovascular and immune function.

3.2 Characteristics of Nutraceuticals

- They are derived from natural food sources and contain bioactive compounds.
- They provide physiological benefits beyond basic nutrition.
- They are generally considered safe when consumed in recommended amounts.
- They can be used for health promotion, disease prevention, and adjunct therapy.
- They may improve quality of life and slow the progression of certain diseases.

3.3 Classification of Nutraceuticals

Nutraceuticals can be broadly classified into the following categories:

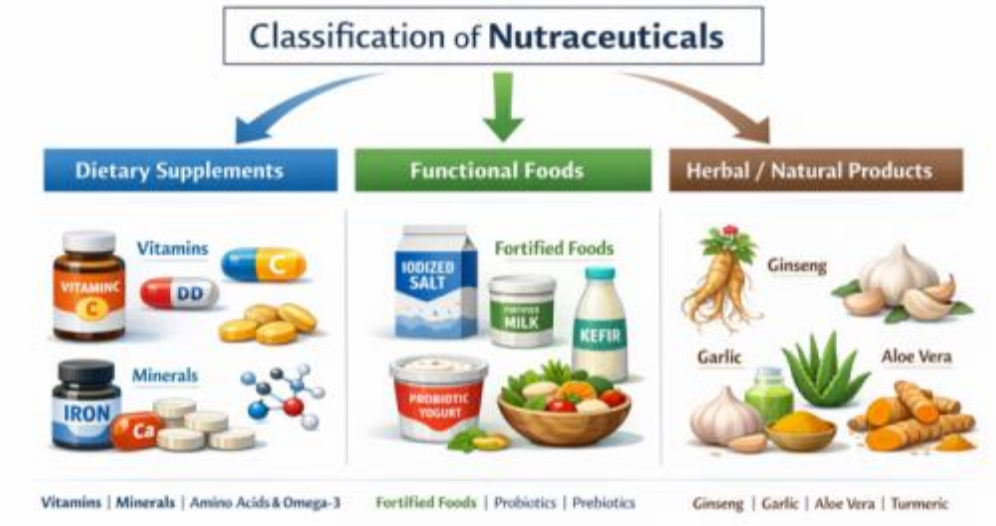


Figure 1.5: Classification of Nutraceutical

1. **Dietary Supplements**
   - Vitamins (Vitamin C, Vitamin D)
   - Minerals (Calcium, Iron, Zinc)
   - Amino acids and fatty acids
2. **Functional Foods**
   - Fortified foods (iodized salt, fortified milk)
   - Probiotic foods (yogurt, kefir)
   - Prebiotic foods (dietary fibers)
3. **Herbal/Natural Products**
   - Ginseng
   - Garlic
   - Aloe vera
   - Turmeric

3.4 Difference Between Nutraceuticals and Pharmaceuticals

Nutraceuticals	**Pharmaceuticals**
Derived from foods	Synthetic or semi-synthetic
Preventive and supportive role	Curative role
Fewer side effects	Possible adverse effects
Long-term health benefits	Short-term disease treatment

Table 1.11: Difference between Nutraceuticals & Pharmaceuticals

3.5 Importance and Applications

- Enhance immune system function

- Support cardiovascular health
- Improve digestive health
- Help manage lifestyle-related disorders
- Promote anti-aging and mental health

3.6 Regulatory Aspect (Brief)

- Nutraceuticals are regulated as foods or dietary supplements, not as drugs.
- Quality, safety, and labelling standards are monitored by regulatory authorities.
- They cannot claim to cure diseases, only to support health.

Figure 1.6: Regulation of Nutraceutical

Nutraceuticals play a vital role in modern healthcare by bridging the gap between food and medicine. With increasing awareness of preventive healthcare and natural therapies, nutraceuticals are gaining global importance as safe, effective, and accessible health-promoting agents.

Figure 1.7: The Importance of Nutraceuticals

- Nutraceuticals are bioactive compounds found in foods that have beneficial effects on health.
- They are not synthetic drugs, but natural health-promoting agents.
- They can be consumed in the form of food, capsules, tablets, powders, or beverages.
- They help in maintaining well-being, improving immunity, and reducing the risk of chronic diseases such as cardiovascular diseases, diabetes, arthritis, obesity, and cancer.

TOPIC 4: DIETARY SUPPLEMENTS

Figure 1.8: Dietary Supplements

Dietary supplements are products intended to supplement the diet and provide nutrients that may not be consumed in sufficient quantities through food alone. They include a wide range of ingredients such as vitamins, minerals, amino acids, herbs or other botanical enzymes and metabolites.

These supplements are designed to maintain or improve overall health, support normal physiological functions, and reduce the risk of chronic diseases. They are not meant to replace conventional food but to enhance the nutritional intake of individuals.

4.1 Forms of Dietary Supplements:

- Tablets
- Capsules
- Powders
- Gummies
- Liquids

Form	Description	Common Examples
Tablets	Solid compressed form	Vitamin C tablets, Calcium tablets
Capsules	Gelatin or plant-based shell	Fish oil capsules, Ashwagandha
Powders	Loose form mixed with liquids	Protein powder, ORS
Gummies	Chewable, flavored supplements	Multivitamin gummies
Liquids	Syrup or liquid form	Iron syrup, Multivitamin drops

Table 1.12: Forms of Dietary Supplements

4.2 Classification of Dietary Supplements

Dietary supplements can be classified based on their source, composition, function, and form. This classification helps in understanding their purpose and appropriate use.

1. Based on Nutrient Content
- Vitamin Supplements – Vitamin A, B-complex, C, D, E, K
- Mineral Supplements – Calcium, Iron, Zinc, Magnesium
- Multivitamin–Mineral Supplements – Combination of vitamins and minerals

2. Based on Functional Components
- Protein and Amino Acid Supplements – Whey protein, BCAAs, Glutamine
- Fatty Acid Supplements – Omega-3, Omega-6, Omega-9
- Fiber Supplements – Psyllium husk, Inulin

3. Based on Source
- Plant-Based (Herbal) Supplements – Ashwagandha, Ginseng, Turmeric
- Animal-Based Supplements – Fish oil, Cod liver oil, Collagen
- Microbial-Based Supplements – Probiotics (Lactobacillus, Bifidobacterium)

4. Based on Purpose or Health Benefit
- Bone Health Supplements – Calcium, Vitamin D
- Cardiovascular Health Supplements – Omega-3 fatty acids

- Digestive Health Supplements – Probiotics, Digestive enzymes
- Immune Support Supplements – Vitamin C, Zinc, Herbal extracts
- Sports and Energy Supplements – Protein powders, Creatine

5. Based on Dosage Form

- Solid Forms – Tablets, capsules, soft gels
- Semi-Solid Forms – Gummies, chewables
- Liquid Forms – Syrups, drops

6. Based on Regulatory Category (India – FSSAI)

- Health Supplements
- Nutraceuticals
- Food for Special Dietary Use (FSDU)
- Food for Special Medical Purpose (FSMP)

4.3 Examples

- Vitamin D and calcium supplements – for bone health.
- Omega-3 fatty acids – for cardiovascular health.
- Probiotics – to support gut microbiota.
- Ashwagandha capsules – for stress management and immunity.

4.4 Characteristics of Dietary Supplements

- Dietary supplements contain concentrated sources of nutrients or bioactive substances.
- They are intended for oral consumption in measured doses.
- They help to fill nutritional gaps caused by poor diet, lifestyle, age, or health conditions.
- They are generally used for health maintenance and prevention, not for treating diseases.
- Their effectiveness depends on proper dosage and regular use.

Feature	Description
Nutrient concentration	High levels of vitamins, minerals, or bioactives
Mode of intake	Oral consumption
Dosage	Measured and controlled
Purpose	Nutritional support and prevention
Dependency	Effectiveness depends on correct usage

Table 1.13: Characteristics of Dietary Supplements

4.5 Importance of Dietary Supplements

- Help prevent nutrient deficiencies.
- Support bone, heart, brain, and immune health.
- Useful for elderly people, pregnant women, athletes, and individuals with special nutritional needs.
- Assist in managing stress, fatigue, and lifestyle-related disorders.
- Promote overall well-being and quality of life.

Target Group	Importance
Elderly	Prevent age-related deficiencies
Pregnant women	Support fetal growth
Athletes	Improve performance and recovery
General population	Maintain overall health

Table 1.14: Importance of Dietary Supplements

4.6 Difference Between Dietary Supplements and Conventional Food

Dietary Supplements	Conventional Food
Concentrated nutrients	Provide basic nutrition
Taken in small doses	Consumed in larger quantities
Available as tablets, capsules, powders	Natural food form
Used to complement diet	Primary source of nutrients

Table 1.15: Difference between Dietary supplementary and Conventional food

4.7 Regulation in India:

In India, dietary supplements are regulated by the Food Safety and Standards Authority of India (FSSAI) under the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food, and Novel Food) Regulations, 2016. These products must comply with safety, labeling, and quality standards and must not claim to diagnose, treat, cure, or prevent any disease.

Aspect	Details
Regulatory body	FSSAI
Applicable regulation	FSS Regulations, 2016
Labelling	Dosage, warnings mandatory
Health claims	Disease-related claims prohibited
Safety monitoring	Regular compliance checks

Table 1.16: Regulatory Aspects of Dietary Supplements in India

4.8 Safety and Precautions

- Excess intake may lead to toxicity or side effects.
- Should be taken as per recommended daily allowance (RDA).
- Not suitable as a substitute for a balanced diet.

- Consultation with a healthcare professional is advised for long-term use.

4.9 Regulatory Status in India (Expanded)

- Dietary supplements in India are regulated by FSSAI.
- Manufacturers must follow approved ingredient lists.
- Products must carry proper labelling, including dosage instructions and warnings.
- Claims related to curing or treating diseases are strictly prohibited.

- Regular monitoring ensures consumer safety and product quality.

4.10 Conclusion

Dietary supplements play an important role in supporting nutritional adequacy and health promotion. When used responsibly and under proper guidance, they can effectively enhance dietary intake and contribute to preventive healthcare without replacing conventional foods.

TOPIC 5: FUNCTIONAL FOODS

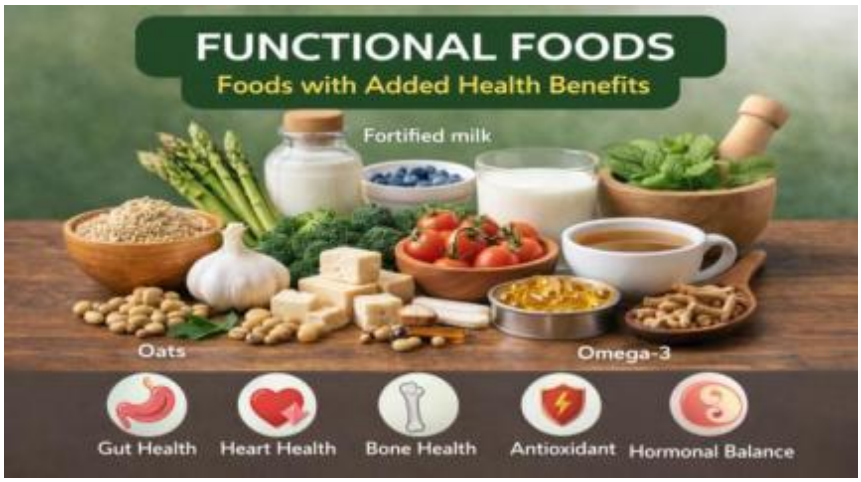


Figure 1.9: Functional Foods

Functional foods are conventional or processed foods that provide health benefits beyond basic nutrition when consumed regularly. These foods contain bioactive compounds that improve physiological functions or reduce the risk of chronic diseases.

5.1 Key Features

- Contain bioactive compounds such as polyphenols, flavonoids, phytosterols, omega-3 fatty acids, and probiotics.
- Promote overall health and wellness.

- Help in disease prevention (e.g., cardiovascular disease, diabetes, obesity).
- Consumed as part of normal diet without prescription.

5.2 Classification of Functional Foods

1. Probiotic Foods – Contain live beneficial microorganisms (e.g., yogurt, kefir).
2. Prebiotic Foods – Contain non-digestible fibers that promote growth of beneficial gut bacteria (e.g., garlic, onions, asparagus).
3. Fortified Foods – Foods enriched with vitamins, minerals, or bioactive compounds (e.g., fortified cereals, iodized salt).
4. Medical or Disease-Specific Foods – Designed to manage or reduce disease risk (e.g., low-sodium foods for hypertension).

5.3 Examples of Functional Foods

Food	Bioactive Component	Health Benefit
Yogurt with probiotics	Lactobacillus, Bifidobacterium	Improves gut health, enhances immunity
Oats	Beta-glucan	Lowers cholesterol, supports heart health
Fortified milk	Calcium, Vitamin D	Strengthens bones, prevents osteoporosis
Green tea	Catechins	Antioxidant activity, reduces cancer risk
Soy products	Isoflavones	Supports hormonal balance, reduces menopausal symptoms
Tomatoes	Lycopene	Antioxidant, reduces risk of prostate cancer

Table 1.17: Examples of Functional Foods

5.4 Characteristics of Functional Foods

- Provide additional physiological benefits beyond nutrition
- Consumed in normal dietary amounts
- Generally safe for long-term consumption
- Effectiveness depends on regular intake
- Do not replace conventional foods but enhance dietary value
-

5.5 Benefits of Functional Foods

- Enhances immune system function
- Reduces risk of chronic diseases
- Improves gut microbiota balance

- Supports cardiovascular and bone health
- Acts as a natural antioxidant

5.6 Difference Between Functional Foods and Dietary Supplements

Functional Foods	Dietary Supplements
Consumed as normal food	Taken in tablet/capsule form
Provide health benefits through diet	Provide concentrated nutrients
No measured dosage required	Require specific dosage
Regulated as foods	Regulated as health supplements

Table 18: Difference Between Functional Foods and Dietary Supplements

5.7 Regulation

- Japan: FOSHU (Foods for Specified Health Use)
- USA: Regulated as foods; claims reviewed by FDA
- India: Regulated by FSSAI under Health Supplements, Functional Foods & FSMP Regulations, 2016
-

5.8 Safety and Precautions

- Should be consumed as part of a balanced diet
- Excess intake may reduce effectiveness
- Health claims should be scientifically supported
- Special populations should follow professional advice

Functional foods play a vital role in preventive healthcare by enhancing nutrition and reducing disease risk. When included regularly in the diet, they contribute to long-term health, wellness, and improved quality of life without the need for medical intervention.

6. MEDICAL FOODS

Medical foods are specially formulated foods intended for the dietary management of specific diseases or medical conditions. They are designed to meet unique nutritional requirements that cannot be fulfilled by a normal diet alone. Unlike drugs, medical foods are not meant to diagnose, treat, or cure a disease, but they support medical nutrition therapy under the guidance of a physician.

FDA Definition: “Medical foods are foods which are formulated to be consumed or administered enterally under the supervision of a physician and which are intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements are established by medical evaluation.”

6.1 Key Features of Medical Foods

1. Physician Supervision: Must be consumed under the guidance of a healthcare professional.
2. Disease-Specific: Designed to meet nutritional needs for a particular condition, e.g., metabolic disorders, kidney disease.
3. Nutritionally Complete or Partial: Can be complete (providing total nutrition) or supplemental (providing specific nutrients).
4. Regulatory Compliance: In India, medical foods fall under the category of Foods for Special Medical Purpose (FSMP), regulated by FSSAI, 2016.
5. Distinct from Drugs: Unlike pharmaceuticals, medical foods are regulated as foods, not medicines.

6.2 Classification of Medicinal Nutraceuticals

Medicinal nutraceuticals are food-derived products that provide therapeutic and preventive health benefits**.** They are classified based onsource, chemical nature, and therapeutic function**.**

1. Classification Based on Source

a) Plant-based Nutraceuticals

- Turmeric (Curcumin), Garlic (Allicin), Ginger (Gingerol), Ashwagandha, Green tea (Catechins)

b) Animal-based Nutraceuticals

- Fish oil (Omega-3 fatty acids), Cod liver oil, Collagen, Chondroitin sulphate

c) Microbial-based Nutraceuticals

- Probiotics (Lactobacillus, Bifidobacterium), Fermented products

2. Classification Based on Chemical Nature

a) Vitamins

- Vitamin C, D, E

b) Minerals

- Calcium, Iron, Zinc

c) Fatty Acids

- Omega-3, Omega-6 fatty acids

d) Proteins & Peptides

- Bioactive peptides
- Whey proteins

e) Phytochemicals

- Polyphenols
- Flavonoids
- Carotenoids
- Alkaloids

3. Classification Based on Therapeutic Function

a) Antioxidant Nutraceuticals

- Vitamin C, Vitamin E
- Lycopene
- Polyphenols

b) Anti-inflammatory Nutraceuticals

- Curcumin
- Omega-3 fatty acids

c) Cardioprotective Nutraceuticals

- Omega-3 fatty acids
- Phytosterols

d) Immunomodulatory Nutraceuticals

- Probiotics
- Vitamin D
- Zinc

e) Antidiabetic Nutraceuticals

- Fenugreek
- Bitter gourd extract

4. Classification Based on Health Application

- Bone health nutraceuticals
- Digestive health nutraceuticals
- Neuroprotective nutraceuticals
- Anticancer nutraceuticals
- Anti-aging nutraceuticals

6.3 Examples of Medical Foods

1. Phenylalanine-free formulas – for patients with Phenylketonuria (PKU).
2. High-protein diets – for patients recovering from burns, trauma, or surgery.
3. Low-sodium or renal-specific formulas – for patients with chronic kidney disease.
4. Glucose-free diets – for patients with diabetes mellitus.
5. Elemental diets – for patients with malabsorption syndromes or inflammatory bowel disease (IBD).

6.4 Characteristics of Medicinal Nutraceuticals

Medicinal nutraceuticals possess properties of bothfood and medicineand are used forhealth promotion, disease prevention, and therapeutic support**.**

- Derived fromnatural food sourcessuch as plants, animals, or microorganisms
- Containbioactive compoundswith therapeutic properties
- Provide health benefitsbeyond basic nutrition
- Help inprevention and management of diseases
- Exhibitantioxidant, anti-inflammatory, immunomodulatory, and antimicrobialactivities
- Generallysafe for long-term usewhen taken in recommendeddoses
- Consumed orally ascapsules, tablets, powders, or functional foods
- Do not replace medicines butsupport conventional therapy
- Scientifically validated forefficacy and safety
- Regulated underfood laws (e.g., FSSAI in India)**,** not as drugs

6.5 Advantages of Medical Foods

- Help in disease management when standard diets are insufficient.
- Reduce complications and hospitalization by providing targeted nutrition.
- Improve patient quality of life and clinical outcomes.
- Complement pharmacological therapy without causing drug-food interactions.

6.6 Difference Between Dietary Supplements, Functional Foods, and Medicinal Nutraceuticals

Basis	Dietary Supplements	Functional Foods	Medicinal Nutraceuticals
Definition	Products used to supplement the diet with nutrients	Conventional foods providing health benefits beyond nutrition	Food-derived products with therapeutic and disease-preventive properties
Nature	Concentrated nutrients	Normal foods with added or natural bio-actives	Food + medicinal properties
Form	Tablets, capsules, powders, liquids	Consumed as part of normal diet	Capsules, tablets, powders, functional foods
Dosage	Taken in measured doses	No specific dosage	Specific recommended intake
Purpose	Prevent nutrient deficiencies	Improve health and reduce disease risk	Support treatment and prevention of diseases
Health Claims	No disease treatment claims allowed	Limited health claims	Therapeutic support claims (non-curative)
Examples	Vitamins, minerals, omega-3	Yogurt, oats, green tea	Curcumin, garlic extract, probiotics
Regulatory Status(India)	Regulated by FSSAI	Regulated by FSSAI	Regulated by FSSAI (nutraceutical category)
Role in Therapy	Preventive and supportive	Preventive	Preventive and adjunct therapeutic
Replacement of Food	Do not replace food	Part of daily diet	Do not replace medicines

Table 1.19: Difference Between Dietary Supplements, Functional Foods, and Medicinal Nutraceuticals

6.7 Regulatory Status

- United States: Regulated by the FDA under the Orphan Drug Act and Medical Food guidelines.
- India: Regulated by FSSAI, 2016 under FSMP rules.
- Must meet safety standards, labeling requirements, and nutritional specifications.
- Cannot claim to diagnose, treat, cure, or prevent diseases, but can indicate dietary management.

6.8Safety and Precautions of Medicinal Nutraceuticals

Medicinal nutraceuticals are generally safe when used appropriately, but certain precautions are essential to avoid adverse effects.

- Should be consumed only in recommended doses; excess intake may cause toxicity or side effects
- Not intended to replace prescribed medicines; used only as supportive therapy
- Long-term use should be done under medical or healthcare supervision
- Some nutraceuticals may cause drug–nutrient interactions (e.g., garlic, ginseng, omega-3)
- Pregnant and lactating women should take nutraceuticals only after medical advice
- Individuals with chronic diseases (diabetes, hypertension, kidney or liver disorders) must be cautious
- Allergic reactions may occur in sensitive individuals
- Quality and safety depend on standardized manufacturing and proper labelling
- Products should be purchased from approved and certified manufacturers
- Must comply with FSSAI regulations and should not claim to cure diseases

Medical foods are an important part of therapeutic nutrition, bridging the gap between regular foods and drugs. With increasing prevalence of chronic and metabolic disorders, the demand for medical foods is growing, providing opportunities for pharmaceutical, nutraceutical, and clinical nutrition industries.

They provide health benefits beyond basic nutrition by supplying bioactive compounds that help in disease prevention, health promotion, and supportive therapy. When used responsibly, following recommended doses and regulatory guidelines, medicinal nutraceuticals can enhance overall well-being and improve quality of life. However, they should not replace conventional medicines and must be consumed under proper guidance to ensure safety and effectiveness

TOPIC 7: SCOPE AND OPPORTUNITIES IN NUTRACEUTICAL MARKET

7.1 Global Market Scenario

- The global nutraceutical market is rapidly growing and is projected to exceed USD 700 - billion by 2030, driven by a shift toward health-focused lifestyles.
- Major markets include North America, Europe, and Asia-Pacific, with Asia-Pacific showing the fastest growth due to increasing health awareness, urbanization, and rising disposable incomes.

- Factors driving growth: increasing lifestyle-related diseases, aging population, growing consumer preference for preventive healthcare, and rising demand for functional foods and dietary supplements.

Key factors driving global growth include:

1. Rising prevalence of lifestyle-related disorders such as diabetes, obesity, and cardiovascular diseases
2. Increasing aging population and demand for healthy aging solutions
3. Growing consumer preference for preventive healthcare over curative treatment
4. Expanding demand for functional foods, fortified beverages, and dietary supplements
5. Advances in food technology and bioactive ingredient research

7.2 Indian Nutraceutical Market

- India is among the fastest-growing nutraceutical markets globally, valued at approximately USD 4–5 billion in 2025, with strong double-digit growth potential. Market expansion is fuelled by:
    - Rapid urbanization and changing dietary habits
    - Increased health consciousness among middle-class consumers
    - Rising incidence of diabetes, cardiovascular diseases, obesity, and micronutrient deficiencies
    - Government initiatives promoting nutrition and wellness

7.3 Key Segments of Nutraceuticals

1. **Dietary Supplements**

   Vitamins, minerals, amino acids, herbal extracts, antioxidants
2. **Functional Foods**
   Fortified cereals, dairy products, probiotics, prebiotics, functional beverages
3. **Medical Foods / FSMP (Foods for Special Medical Purposes)**
   Specialized formulations for disease-specific nutritional management
4. **Sports Nutrition Products**
   Protein powders, amino acid supplements, energy bars, recovery drinks

7.4 Opportunities in Nutraceutical Market

- **Preventive Healthcare:**
  Rising demand for products that help prevent chronic and lifestyle-related diseases
- **Aging Population:**
  Increasing need for anti-aging, bone health, cognitive health, and joint-support nutraceuticals
- **Personalized Nutrition:**
  Growing trend toward customized nutrition based on genetics, lifestyle, and health status
- **Online Retail and E-commerce:**
  Rapid expansion of direct-to-consumer sales through digital platforms
- **Research and Development:**
  Innovation in plant-based bioactives, probiotics, omega-3s, and functional ingredients
- **Sustainability and Clean Label Products:**
  Demand for natural, organic, and environmentally friendly nutraceuticals

7.5 Challenges

- Strict regulatory requirements for safety and labeling.
- Need for scientific validation and clinical studies to prove efficacy.
- Market competition and price sensitivity in emerging markets.
- Lack of Consumer Awareness in rural and semi-urban areas.
- Counterfeit and Substandard Products affecting brand trust.
- High Cost of Clinical Trials limiting innovation for small companies

The nutraceutical market offers immense opportunities for growth in both global and Indian markets. With rising health awareness, preventive healthcare trends, and increasing disposable incomes, nutraceuticals are poised to become an integral part of modern healthcare. The market encourages innovation, research, and entrepreneurship, making it an attractive sector for pharmaceutical, food, and biotech industries.

UNIT – 2nd

TOPIC 1: GLOBAL ASPECTS IN NUTRACEUTICAL REGULATION

Figure 2.1: GLOBAL ASPECTS IN NUTRACEUTICAL REGULATION

Globalization and the growing emphasis on health and wellness have led to substantial expansion of the nutraceutical and dietary supplement industry worldwide. Nutraceuticals, derived from food sources, provide health benefits beyond basic nutrition, including disease prevention and health promotion. Due to their widespread consumption and therapeutic potential, robust global regulatory frameworks are essential to ensure their safety, efficacy, and quality.

The regulation of nutraceuticals involves a complex network of international organizations and national regulatory authorities. Key global bodies include the World Health Organization (WHO), which provides guidance on nutrition and public health policy, and the Codex Alimentarius

Commission, established by WHO and FAO, which develops internationally recognized food standards, labelling guidelines, and safety limits. These standards facilitate fair trade practices and protect consumer health across borders.

Organization	Scope	Key Functions
WHO (World Health Organization)	Global	Develops nutrition guidelines, public health policies, and risk assessment frameworks
Codex Alimentarius Commission	Global	Establishes international food standards, labelling guidelines, and safety limits
NSF International	Global	Third-party certification, GMP audits, product testing
FDA (USA)	National	Regulates dietary supplements under DSHEA; oversees labelling and safety
EFSA (European Union)	Regional	Scientific assessment of safety, novel foods, and health claims
FSSAI (India)	National	Regulates nutraceuticals, health supplements, and functional foods

Table 2.1: Major Global Regulatory Bodies for Nutraceuticals

NSF International plays a crucial role in third-party certification of dietary supplements by verifying compliance with Good Manufacturing Practices (GMP), ingredient authenticity, and absence of contaminants. GMP implementation ensures consistent quality, proper documentation, hygiene control, and traceability throughout the manufacturing process.

GMP Element	Purpose
Raw material control	Ensures ingredient purity and authenticity
Standard Operating Procedures (SOPs)	Maintains consistency in production
Sanitation & hygiene	Prevents contamination
Documentation & record keeping	Enables traceability and audits
Quality control testing	Confirms safety and efficacy of products

Table 2.2: Role of Good Manufacturing Practices (GMP)

At the regional level, regulatory oversight varies significantly. In the United States, nutraceuticals are regulated as dietary supplements under the Dietary Supplement Health and Education Act (DSHEA) by the FDA. In the European Union, the European Food Safety Authority (EFSA) evaluates safety, novel food approvals, and scientific substantiation of health claims. Countries such as Japan (FOSHU), India (FSSAI), and China have distinct regulatory pathways reflecting local dietary practices and health policies.

Region/Country	Regulatory Authority	Product Classification	Key Regulatory Feature

USA	FDA	Dietary Supplements	Pre-market notification not mandatory
European Union	EFSA	Food Supplements / Novel Foods	Mandatory scientific substantiation of claims
Japan	CAA	FOSHU / FFC	Government-approved functional claims
India	FSSAI	Nutraceuticals	Specific product approval &labeling norms
China	SAMR	Health Foods	Registration and filing system

Table 2.3: Comparison of Nutraceutical Regulation in Selected Countries

The regulation of health and nutrition claims is a critical aspect of nutraceutical governance. Authorities require scientific evidence to support claims, restrict misleading advertising, and differentiate between therapeutic claims and nutritional benefits. Failure to regulate claims effectively can lead to consumer misinformation and health risks.

Type of Claim	**Description**	**Regulatory Control**
Nutritional claims	Describe nutrient content (e.g., high fibre)	Allowed with compliance
Structure/function claims	Affect normal body functions	Scientific evidence required
Health claims	Link food to disease risk reduction	Strict approval needed
Therapeutic claims	Disease treatment or cure	Generally prohibited

Table 2.4: Regulation of Health and Nutrition Claims

International regulation has become increasingly important due to the rise in global trade and e-commerce. Without harmonized standards, the risk of adulteration, contamination, mislabelling, and substandard manufacturing increases, potentially endangering public health. Post-market surveillance systems and adverse event reporting further enhance consumer protection by monitoring product safety after commercialization.

Despite progress, challenges remain in achieving global regulatory harmonization due to differences in product classification, approval processes, and enforcement capabilities. Strengthening international collaboration and regulatory convergence is essential for the sustainable growth of the nutraceutical industry.

Challenge	**Impact**
Diverse regulatory definitions	Inconsistent classification
Lack of harmonized standards	Trade barriers
Weak enforcement in some regions	Risk to consumer safety
E-commerce growth	Difficulty in regulatory monitoring
Limited post-market surveillance	Delayed identification of adverse effects

Table 2.5: Challenges in Global Harmonization of Nutraceutical Regulation

Understanding global regulatory frameworks enables students and professionals to appreciate how international standards, certifications, and policies influence the development, manufacturing, marketing, and regulation of nutraceutical products worldwide.

The need for international regulation has become crucial as the demand for safe and effective nutraceutical products rises and global trade facilitates cross-border distribution. Without standardized regulations, there is a heightened risk of product contamination, mislabeling, and substandard manufacturing practices, all of which can negatively impact consumer health.

This chapter offers a comprehensive examination of global aspects of nutraceutical regulation. It explores WHO guidelines on nutrition, Codex Alimentarius standards, the role of NSF International in certifying dietary supplements, and the implementation of Good Manufacturing Practices (GMP) to ensure consistent product quality. Understanding these global frameworks helps students appreciate how international policies and certifications influence the development, marketing, and regulation of nutraceuticals worldwide

TOPIC 2: WHO GUIDELINES ON NUTRITION

Table 2.2: Who Guidelines on Nutrition

2.1 WHO Guidelines on Nutrition

The World Health Organization (WHO) plays a pivotal role in establishing and promoting global nutrition policies aimed at improving public health, preventing malnutrition, and reducing the burden of diet-related diseases. WHO provides evidence-based guidelines,standards, and recommendations that support countries in designing, implementing, and evaluating nutrition programs across the life course.

The WHO nutrition framework encompasses:

- Development of international nutrition guidelines
- Nutrient intake recommendations
- Surveillance and monitoring systems
- Policy guidance to address both undernutrition and overnutrition

These frameworks guide national nutrition, public health, and nutraceutical policies worldwide.

2.2 Objectives of WHO Nutrition Guidelines

Challenge	Impact
Diverse regulatory definitions	Inconsistent classification
Lack of harmonized standards	Trade barriers
Weak enforcement in some regions	Risk to consumer safety
E-commerce growth	Difficulty in regulatory monitoring
Limited post-market surveillance	Delayed identification of adverse effects

Table 2.6: Objectives of WHO Nutrition Guidelines

The primary objectives of WHO nutrition guidelines are:

1. **To achieve optimal nutritional status across populations**, ensuring adequate intake of essential nutrients at all stages of life.
2. **To prevent micronutrient deficiencies**, such as:
   - Iron deficiency anaemia
   - Iodine deficiency disorders (goiter)
   - Vitamin A deficiency
   - Vitamin D deficiency and rickets
3. **To combat noncommunicable diseases (NCDs)** related to diet, including:
   - Obesity
   - Type 2 diabetes
   - Cardiovascular diseases
   - Certain diet-related cancers
4. **To ensure food safety and quality** through regulatory control, risk assessment, and food standards.
5. **To support countries in formulating evidence-based nutrition policies and interventions**, particularly in low- and middle-income countries.
6. **To reduce health inequalities and promote sustainable, healthy diets**, aligned with global development and sustainability goals.

2.3 Core Components of WHO Nutritional Policy

Component	Key Focus Areas

Balanced Diet Recommendations	Macronutrients, micronutrients, dietary diversity
Food Fortification	Iodized salt, iron-fortified flour, vitamin A enrichment
Disease Prevention Guidelines	Reduced salt, sugar, trans fats; increased fruits & vegetables
Maternal & Child Nutrition	Breastfeeding, complementary feeding, maternal nutrition
Food Labelling	Nutrition labels, front-of-pack labelling, consumer education
Monitoring & Surveillance	Global Nutrition Monitoring Framework, data systems

Table 2.7: Core Components of WHO Nutritional Policy

The WHO nutritional policy framework includes the following core components:

- **Balanced Diet and Nutrient Recommendations**
  - Guidance on energy, macronutrients, and micronutrients based on age, sex, and physiological status.
- **Food Fortification Strategies**
  - Promotion of fortification of staple foods (e.g., salt iodization, iron-fortified flour, vitamin A–fortified oils) to prevent deficiencies.
- **Dietary Guidelines for Disease Prevention**
  - Recommendations to limit salt, sugar, saturated fats, and trans fats while encouraging fruits, vegetables, whole grains, and physical activity.
- **Maternal, Infant, and Child Nutrition (MICN)**
  Policies supporting:
  - Exclusive breastfeeding for the first 6 months
  - Appropriate complementary feeding
  - Maternal nutrition before, during, and after pregnancy
- **Food Labelling and Consumer Awareness**
  Promotion of clear nutrition labelling, front-of-pack labels, and public education to support healthier food choices.
- **Global Monitoring and Data Systems**
  Surveillance systems such as:
  - Global Nutrition Monitoring Framework
  - WHO Global Health Observatory. These systems track malnutrition trends, dietary risks, and policy implementation.
- **Nutrition in Emergencies and Vulnerable Populations**
  Guidance for nutrition interventions during humanitarian crises, conflicts, and natural disasters.

2.4 WHO and Codex Alimentarius Commission

Organization	Primary Role

WHO	Public health protection, nutrition guidance, risk assessment
FAO	Food production, agriculture, food security
Codex Alimentarius Commission	Development of international food standards
National Governments	Adoption and enforcement of Codex standards

Table 2.8: WHO–Codex Alimentarius Collaboration

The Codex Alimentarius Commission is an international food standards body jointly established in 1963 by the WHO and the Food and Agriculture Organization (FAO). It develops international food standards, codes of practice, and guidelines to:

- Protect consumer health and food safety
- Ensure quality and safety of food products
- Promote fair practices in international food trade
- Provide a scientific basis for resolving food-related trade disputes

Codex standards are widely used by national governments as the foundation for food laws and regulations, and they complement WHO's nutrition and public health objectives.

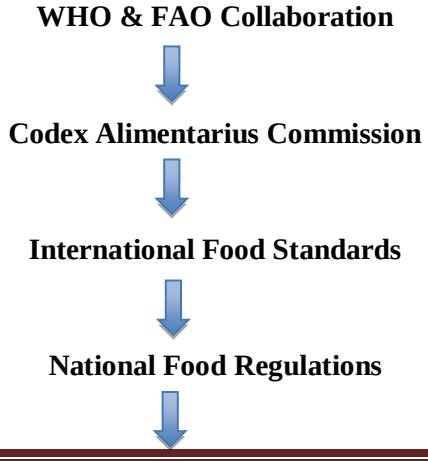
"Codex Alimentarius" is Latin for "Food Code". The Commission sets global rules for food safety, quality, labelling, and hygiene so that food is safe to eat and fairly traded across countries.

Key Functions of Codex Alimentarius Commission:

- Establishes food safety standards
- Regulates food additives, contaminants, and pesticide residues
- Sets food labelling requirements
- Develops codes of hygienic practice
- Harmonizes food regulations worldwide

Importance:

- Protects consumers from unsafe or adulterated food
- Facilitates international food trade
- Supports national food laws and regulations
- Recognized by the World Trade Organization (WTO)



Safe & Quality Food Supply

⬇

Consumer Health Protection

Flowchart 2.1: WHO–Codex Food Safety Framework

TOPIC 3. NSF INTERNATIONAL AND ITS ROLE IN NUTRACEUTICAL INDUSTRY

Figure 2.3: NSF Internationals Role in the Nutraceutical Industry

- NSF International, originally founded in 1944 as the National Sanitation Foundation, is a global, independent, non-profit organization dedicated to protecting public health. It develops consensus-based public health and safety standards and provides testing, inspection, auditing, and certification services.
- In the nutraceutical and dietary supplement industry, NSF plays a vital role in ensuring that products are safe, high-quality, accurately labelled, and compliant with regulatory requirements.
-

Aspect	Description
Full Name	NSF International
Founded	1944
Original Name	National Sanitation Foundation
Nature	Independent, global, non-profit organization

Headquarters	United States
Core Function	Development of public health standards, testing, auditing, and certification
Industry Coverage	Nutraceuticals, dietary supplements, food, water, medical devices

Table 2.9: Overview of NSF International

3.1 Objectives of NSF International

1. To safeguard public health by ensuring nutraceuticals and dietary supplements meet national and international safety standards.
2. To provide independent, scientifically validated certifications that verify the quality, purity, and authenticity of nutraceutical products.
3. To assist manufacturers in achieving and maintaining Good Manufacturing Practice (GMP) compliance, especially in line with FDA and international regulations.
4. To foster consumer confidence and transparency by ensuring truthful labelling, ingredient disclosure, and product consistency.
5. To reduce the risk of adulteration, contamination, and misbranding in dietary supplements.

- Supports harmonization of global safety and quality standards, enabling international market access.
- Assists companies in meeting export and import compliance requirements.

Area	**Role of NSF**
Standard Development	Formulates science-based and consensus standards
Testing	Verifies identity, purity, potency, and safety
Certification	Provides third-party product certification
Facility Auditing	Conducts GMP inspections and compliance audits
Label Review	Confirms accuracy of ingredient listing and claims

Table 2.10: Role of NSF in the Nutraceutical Industry

3.2 Role of NSF in Nutraceutical Industry

3.2.1 Development of Standards

- Develops science-based standards for dietary supplements, functional foods, water, and related products.
- Participates in ANSI-accredited consensus standards development, ensuring global acceptance.

3.2.2 Testing and Certification

- Conducts laboratory testing to:
  - Verify ingredient identity and purity
  - Detect contaminants such as heavy metals, pesticides, microbes, and banned substances
  - Confirm potency and dosage claims
- Provides certifications such as:
  - NSF Dietary Supplement Certification
  - NSF Certified for Sport® (critical for athletes to avoid banned substances)

3.2.3 Facility Auditing

- Performs on-site audits of manufacturing facilities to evaluate:
  - GMP compliance
  - Sanitation and hygiene practices
  - Quality control systems
  - Traceability and documentation
- Helps prevent cross-contamination and adulteration.

3.2.4 Label Verification

- Ensures that product labels:
  - Accurately reflect ingredient composition
  - Contain ingredients only as declared
  - Comply with regulatory labelling requirements
- Helps reduce false or misleading health claims.

3.2.5 Global Collaboration and Regulatory Support

- Collaborates with regulatory bodies such as the FDA, WHO, and international agencies.

3.3 Additional Importance of NSF in Nutraceuticals

Enhances brand credibility and market acceptance

- Supports risk management and product recalls
- Provides training and education on quality systems and regulatory compliance
- Plays a key role in sports nutrition safety

Stakeholder	Benefits
Consumers	Safe, high-quality, and trustworthy products
Manufacturers	Regulatory compliance and market credibility
Regulators	Improved industry oversight
Athletes	Protection from banned substances
Retailers	Reduced risk and improved brand trust

Table 2.11: Benefits of NSF Certification

NSF International serves as a trusted authority in the nutraceutical industry, ensuring product safety, quality, and regulatory compliance. Its certification programs and GMP audits significantly enhance consumer trust and support manufacturers in maintaining high industry standards.

TOPIC 4: NSF CERTIFICATION PROCESS

Figure 2.4: NSF Certification Process

The NSF Certification Mark signifies that a product complies with applicable NSF standards and has undergone independent, third-party verification for quality, safety, and Good Manufacturing Practices (GMP). Certified products are listed in NSF's publicly accessible online certification database, ensuring transparency and traceability.

4.1 Steps in the NSF Certification Process

Certification Stage	Key Requirements	Responsible Party
Application Submission	Product formulation, label claims, supplier documentation	Manufacturer
Product Testing	Ingredient verification, contaminant testing, compositional limits	NSF Laboratory
Facility Audit	GMP compliance, SOPs, training records, traceability	NSF Auditors
Corrective Actions	CAPA implementation and documentation	Manufacturer
Certification Approval	Final technical review and approval	NSF Certification Body

Surveillance	Annual audits, random product sampling	NSF

Table 2.12: Key Requirements at Each NSF Certification Stage

1. **Application Submission**

The manufacturer submits a formal application that includes:

- Complete product formulation and composition
- Ingredient specifications and supplier documentation
- Product labelling and marketing claims
- Manufacturing process details
  - This step also identifies the applicable NSF/ANSI standard or certification programme.

2. **Product Evaluation and Laboratory Testing**

NSF conducts analytical testing to:

- Verify the presence and quantity of declared ingredients
- Confirm the absence of harmful contaminants (e.g., heavy metals, microbes, banned substances)
- Ensure compliance with established compositional and safety limits
  - Label claims are reviewed to confirm accuracy and regulatory compliance.

3. **Facility Audit (GMP Inspection)**

An on-site audit is performed to assess compliance with GMP requirements, including:

- Manufacturing and quality control procedures
- Equipment calibration and maintenance
- Personnel training and qualifications
- Documentation, recordkeeping, and traceability systems
  - Any non-conformances identified must be addressed through corrective actions.

Document Type	**Purpose**
Master Manufacturing Records	Verifies controlled production processes
Batch Production Records	Ensures product traceability
SOPs	Confirms standardized operations
Equipment Calibration Logs	Verifies equipment accuracy
Training Records	Confirms staff competency

Table 2.13:Documentation Reviewed During NSF Certification

4. **Corrective Actions and Compliance Review**

If deficiencies are identified during testing or auditing, the manufacturer must:

- Implement corrective and preventive actions (CAPA)
- Provide documented evidence of compliance
- NSF reviews and verifies the effectiveness of these actions before proceeding.

5. **Certification Decision**

Upon successful completion of testing, auditing, and compliance review:

- The product is approved
- Authorization is granted to use the NSF Certification Mark

- The product is listed in the official NSF certification database

Verification Activity	Purpose	Frequency
Laboratory Testing	Confirms product safety, identity, and label accuracy	Initial (before approval) + Random (post-marketing checks)
GMP Audit	Ensures consistent manufacturing quality	Annual (once every year)
Label Review	Confirms truthful and compliant claims	Initial (before release) + Updates (whenever label changes)
Product Sampling	Verifies ongoing compliance	Unannounced (without prior notice)
Database Listing	Public transparency of certified products	Continuous (regularly maintained and updated)

Table 2.14: Types of NSF Verification Activities

6. **Continuous Surveillance and Re-Certification**

To maintain certification validity, NSF conducts:

- Annual or periodic facility audits
- Ongoing GMP compliance assessments
- Random product sampling and laboratory testing

❖ Failure to maintain compliance may result in suspension or withdrawal of certification.

Area	Outcome
Product Quality	Independently verified for safety and composition
Regulatory Confidence	Demonstrates GMP compliance
Market Credibility	Authorized use of NSF Certification Mark
Transparency	Product listed in public NSF database
Risk Reduction	Continuous monitoring minimizes quality failures

Table 2.15: Outcomes of NSF Certification

TOPIC 5: NSF STANDARDS FOR FOOD AND DIETARY SUPPLEMENTS

- NSF International establishes standards to ensure that food products and dietary supplements are safe, properly labelled, and manufactured according to stringent quality criteria.
- These standards are critical for maintaining consumer confidence, supporting regulatory compliance, and ensuring product efficacy.
- NSF standards cover identity, purity, composition, strength, and Good Manufacturing Practices (GMP) for dietary supplements and related products.
- By minimizing risks related to contamination, adulteration, and misrepresentation, NSF standards promote trust in dietary supplements and nutraceutical products.

Aspect	Description
Purpose of NSF Standards	Ensure food products and dietary supplements are safe, properly labeled, and manufactured according to stringent quality and safety requirements
Regulatory Alignment	Supports compliance with FDA regulations, including 21 CFR Part 111 for dietary supplements
Quality Focus	Emphasizes identity, purity, composition, strength, labeling accuracy, and adherence to Good Manufacturing Practices (GMP)
Risk Reduction	Minimizes risks related to contamination, adulteration, misrepresentation, and undeclared ingredients
Consumer Confidence	Promotes trust in dietary supplements, functional foods, and nutraceutical products
Global Recognition	NSF certification is widely accepted by regulators, retailers, manufacturers, and consumers worldwide

Table 2.16: Overview of NSF Standards for Food and Dietary Supplements

5.1 Key NSF Standards

Figure 2.5: Key NSF Standards Applicable to Dietary Supplements and Related Products

- **NSF/ANSI 173 – Dietary Supplements**
  Specifies requirements for ingredient identity, purity, composition, strength, label claims, and GMP compliance. It is the primary standard used for dietary supplement certification.
- **NSF/ANSI 455-2 – Dietary Supplements GMP**
  Defines manufacturing system requirements aligned with FDA 21 CFR Part 111**,** including quality management systems, documentation, sanitation, training, and process controls.
- **NSF/ANSI 455-3 – Cosmetics**
  Establishes safety and quality standards for cosmetics and personal care products, including nutracosmetic products that overlap with nutrition-related claims.
- **NSF/ANSI 220 – Health and Fitness Facilities**
  Covers health, safety, and operational management systems for fitness facilities. While it does not directly regulate supplements, it supports quality assurance in environments where sports nutrition products are stored, handled, or distributed.
- **NSF Certified for Sport® Program (Additional Important Program)**
  A specialized certification ensuring dietary supplements are free from substances banned by major athletic and anti-doping organizations. This program is widely recognized in professional and competitive sports.

Standard Code	Title	Scope and Application
NSF/ANSI	Dietary Supplements	Specifies requirements for identity, purity, composition,

173		strength, and GMP of supplements.
NSF/ANSI 455-2	Dietary Supplements GMP	Defines manufacturing system requirements aligned with FDA 21 CFR Part 111.
NSF/ANSI 455-3	Cosmetics	Sets standards for personal care and nutracosmetic products.
NSF/ANSI 220	Health and Fitness Facilities	Includes quality and safety assurance for supplements used in sports nutrition.

Table 2.17: Key NSF Standards Applicable to Dietary Supplements and Related Products

TOPIC 6: GOOD MANUFACTURING PRACTICES (GMP) FOR NUTRACEUTICALS

Good Manufacturing Practices (GMP) are internationally recognized regulations that define the minimum requirements manufacturers must meet to ensure that products are consistently produced and controlled to quality standards appropriate for their intended use.

GMP helps to:

- Prevent contamination and mix-ups
- Ensure product consistency and traceability
- Protect consumer safety
- Meet regulatory compliance across markets

Figure 2.6: Global Frameworks for Nutraceuticals

6.1 Key Elements of GMP

1. Quality Management System (QMS)

- Establishes overall quality policies, objectives, and responsibilities
- Includes SOPs, quality assurance (QA), quality control (QC), change control, deviations, and CAPA (Corrective and Preventive Actions)

2.Personnel Training and Hygiene

- Adequate qualification and continuous training of staff
- Personal hygiene programs, protective clothing, and health checks
- Training records must be maintained

3.Raw Material Control

- Supplier qualification and approval
- Testing and verification of identity, purity, strength, and safety of raw materials
- Proper storage to prevent contamination or degradation

4. Premises and Equipment

- Hygienic facility design to prevent cross-contamination
- Adequate space, lighting, ventilation, and sanitation
- Equipment qualification, calibration, cleaning, and maintenance

5. Production and Process Control

- Validated manufacturing processes
- In-process quality checks
- Control of critical process parameters
- Batch manufacturing records

6. Packaging and Labelling

- Packaging materials must protect product quality and stability
- Accurate, compliant labelling (ingredients, dosage, warnings, shelf life)
- Prevention of label mix-ups

7. Documentation and Record Keeping

- SOPs, batch records, test results, deviations, and change controls
- Records must be accurate, legible, contemporaneous, and traceable
- Data integrity principles (ALCOA: Attributable, Legible, Contemporaneous, Original, Accurate)

8. Stability Studies

- Establish product shelf life and storage conditions
- Ongoing stability testing to ensure quality throughout product life

9. Complaint Handling and Product Recall

- Written procedures for receiving, investigating, and responding to complaints
- Effective recall system for rapid removal of defective products
- Root cause analysis and corrective actions

10. Sanitation and Cleaning Programs

- Cleaning SOPs for facilities and equipment
- Prevention of microbial and chemical contamination

11. Supplier and Contract Manufacturer Management

- Qualification and auditing of vendors and contract manufacturers

- Quality agreements defining responsibilities

12. Risk Management

- Use of risk-based approaches (e.g., HACCP, risk assessments)
- Identification and control of critical quality risks

6.2 Global GMP Frameworks for Nutraceuticals

Region/Agency	Guideline/Regulation	Key Reference
WHO	WHO GMP Guidelines for Herbal Medicines	WHO Technical Report Series No. 937
USA	21 CFR Part 111	Dietary Supplement GMP Regulations
European Union	EFSA GMP and HACCP Guidelines	Regulations (EC) No. 852/2004
India	FSSAI Nutraceutical Regulations, 2016	Schedule IV – GMP and Quality Assurance

Table 2.18: Global GMP Frameworks for Nutraceuticals

6.3 SUMMARY

The global regulation of nutraceuticals requires coordinated and harmonized efforts among international regulatory and standard-setting organizations to ensure product safety, quality, and consumer confidence. Key agencies such as the World Health Organization (WHO), Codex Alimentarius Commission, and NSF International play complementary roles in establishing global benchmarks.

The WHO provides scientific and public health–based guidance on nutrition, traditional medicines, and herbal products, forming the foundational regulatory framework. The Codex Alimentarius Commission, jointly established by WHO and FAO, develops international food standards, labelling requirements, and safety limits, facilitating global trade and consumer protection. NSF International supports the industry through independent testing, auditing, and certification, ensuring compliance with GMP and regulatory standards.

In addition, Good Manufacturing Practices (GMP) serve as the backbone of nutraceutical quality assurance by controlling every stage of production—from raw material sourcing and processing to packaging and distribution. Together, these regulatory frameworks ensure that nutraceutical products are consistently manufactured, scientifically validated, properly labelled, and safe for human consumption, thereby promoting global market acceptance and protecting public health.

Role of Key International Organizations in Nutraceutical Regulation

Organization	Primary Role	Contribution to Nutraceutical Quality & Safety

WHO	Global public health authority	Develops nutritional guidelines, herbal medicine GMP, and safety frameworks
Codex Alimentarius (FAO/WHO)	International food standards body	Sets standards for food safety, contaminants, additives, and labelling
NSF International	Independent certification body	Provides third-party testing, GMP certification, and product verification
National Regulatory Authorities (FDA, EFSA, FSSAI)	Country-specific regulation	Enforce compliance, approvals, market surveillance, and recalls
GMP Systems	Manufacturing quality framework	Ensures consistency, traceability, and contamination control

Table 2.19: Role of Key International Organizations in Nutraceutical Regulation

UNIT – 3rd

TOPIC 1: FOOD SAFETY AND STANDARDS ACT (FSSA), 2006: ORGANIZATION AND FUNCTIONS, REGULATIONS FOR NUTRACEUTICALS, AND RDA IN INDIA

1.1 Introduction

The Food Safety and Standards Act (FSSA), 2006 is the primary legislation governing all aspects of food safety, standards, and regulation in India. It consolidates multiple older food laws and establishes the Food Safety and Standards Authority of India (FSSAI) as the apex regulatory body to ensure safe, wholesome, and quality food for the population. The Act covers manufacture, storage, distribution, sale, and import of food and related products, including nutraceuticals, dietary supplements, and functional foods.

1.2 Objectives of the Food Safety and Standards Act, 2006

The objectives of the Food Safety and Standards Act, 2006 are to ensure the availability of safe, wholesome, and quality food for consumers by regulating the manufacture, storage, distribution, sale, and import of food. The Act aims to establish a single, science-based authority for food regulation, replace multiple older food laws, promote transparency and accountability, and protect public health while building consumer confidence in food safety.

The key objectives of the FSSA are:

1. To ensure availability of safe and wholesome food for human consumption.
2. To establish a single reference point for all food safety issues.
3. To integrate and replace multiple older food laws such as the Prevention of Food Adulteration Act, Fruit Products Order, and Milk and Milk Products Order.
4. To set science-based standards for food quality.
5. To promote consumer confidence and awareness in food safety.

1.3 Salient Features of the FSSA, 2006

- Establishes an independent statutory body (FSSAI).
- Introduces uniform standards for all food categories.
- Mandatory licensing/registration for all Food Business Operators (FBOs).
- Provides for scientific risk assessment, recall systems, and safety audits.
- Specifies penalties and punishments for non-compliance.
- Ensures transparency and accountability in food regulation.

1.4 Organization and Structure of FSSAI

The organization and structure of FSSAI refer to the administrative setup and framework through which the Food Safety and Standards Authority of India functions. It includes its establishment under the Food Safety and Standards Act, 2006, its governing body consisting of a Chairperson and members from various ministries and expert institutions, its headquarters in New Delhi, regional offices across India, and the supporting scientific panels and committees that help in formulating food safety standards and regulations.

1.4.1 Establishment

FSSAI was established under Section 4 of the FSSA, 2006 and operates under the Ministry of Health and Family Welfare, Government of India.

1.4.2 Headquarters and Regional Offices

Headquarters: New Delhi. Regional offices are located in Mumbai, Chennai, Kolkata, and Guwahati.

1.4.3 Composition

FSSAI consists of a Chairperson (appointed by the Central Government) and 22 members representing various ministries, industries, and scientific institutions.

Level	Authority	Key Role
Central Level	FSSAI (Chairperson & Members)	Policy making, standard setting
Advisory	Scientific Panels & Committees	Risk assessment, expert advice
State Level	State Food Safety Commissioner	Enforcement of FSSA
District Level	Designated Officer	Supervision and coordination
Field Level	Food Safety Officer (FSO)	Inspection, sampling, prosecution

Table 3.1: Organizational Structure of FSSAI

1.4 Functions of FSSAI

FSSAI performs scientific, regulatory, and advisory functions, which include:

- Standard Setting - Develops science-based food standards and sets limits for contaminants and additives.
- Licensing and Regulation - Issues licenses to manufacturers and importers and monitors compliance.
- Data Collection and Risk Analysis - Collects data on food consumption and performs risk assessment.
- Laboratory Infrastructure - Establishes and accredits food testing laboratories across India.
- Public Awareness and Training - Promotes education on labeling, hygiene, and nutrition.
- Monitoring and Enforcement - Coordinates with state authorities for enforcement and recall systems.

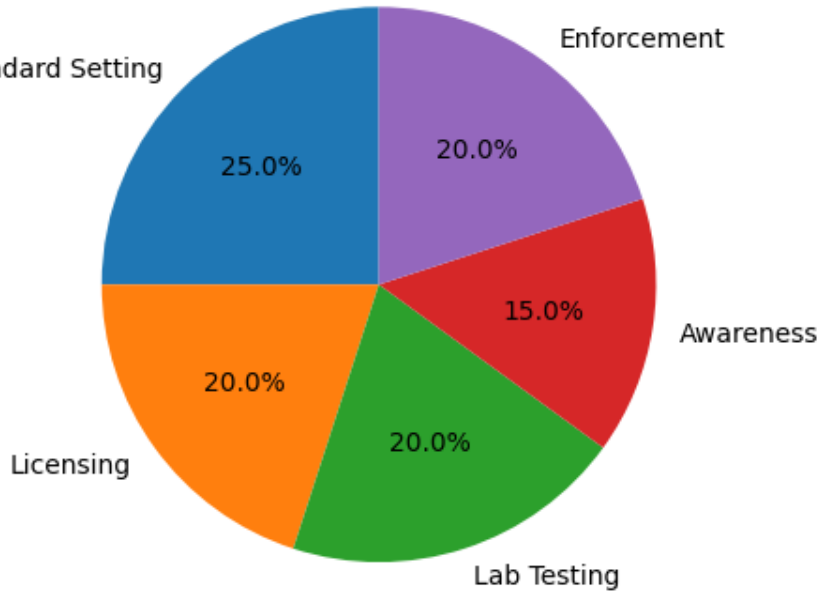


Figure 3.1 Functions of FSSAI

1.6 Regulations for Import, Manufacture, and Sale of Nutraceutical Products in India

Nutraceuticals are products derived from food sources that provide health and medical benefits, including prevention or treatment of disease. They are regulated under the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Functional Food, and Novel Food) Regulations, 2016.

1.6.1 Classification of Nutraceutical Products

According to FSSAI regulations, nutraceuticals fall into the following categories: Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Foods, and Novel Foods.

Category	Description
Health Supplements	Vitamins, minerals, amino acids
Nutraceuticals	Products with physiological benefits
Functional Foods	Foods providing additional health benefits
Food for Special Dietary Use (FSDU)	For specific dietary needs
Food for Special Medical Purpose (FSMP)	For patients under medical supervision
Novel Foods	New or innovative food ingredients

Table 3.2: Categories of Nutraceutical Products under FSSAI

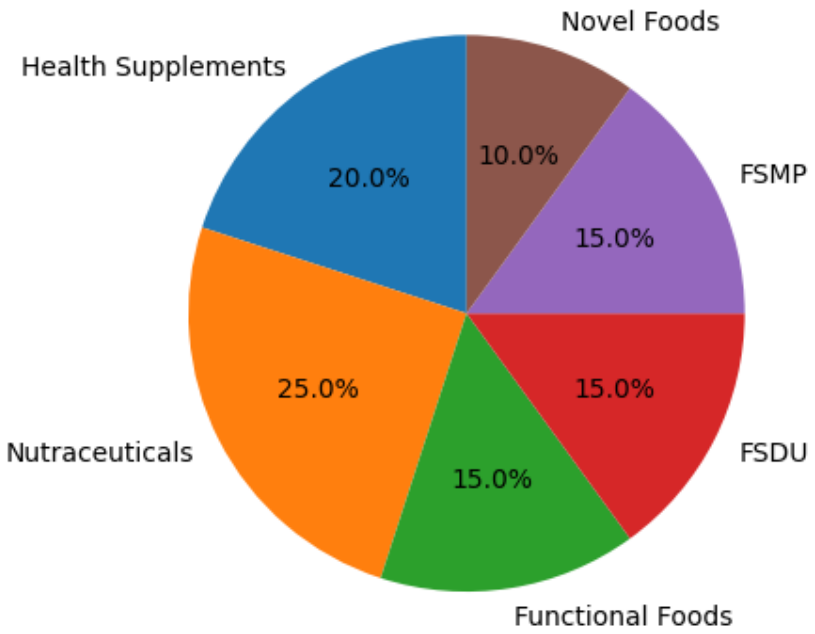


Figure 3.2: Categories of Nutraceutical Products under FSSAI

1.6.2 Manufacturing Regulations

1. **FSSAI License:** Manufacturers must obtain a valid license.
2. **Approved Ingredients:** Only approved vitamins, minerals, botanicals, and bio-actives are allowed.
3. **GMP Compliance:** Production must follow Good Manufacturing and Hygienic Practices.
4. **Labelling:** Must include product name, ingredients, dosage, warning, and "Not for medicinal use."

1.6.3 Import Regulations

1. Importers must register under the Food Import Clearance System (FICS).
2. Labels must comply with Indian standards.
3. Samples undergo laboratory testing before clearance.
4. FSSAI issues No Objection Certificate (NOC) after safety verification.

1.6.4 Sale and Distribution Regulations

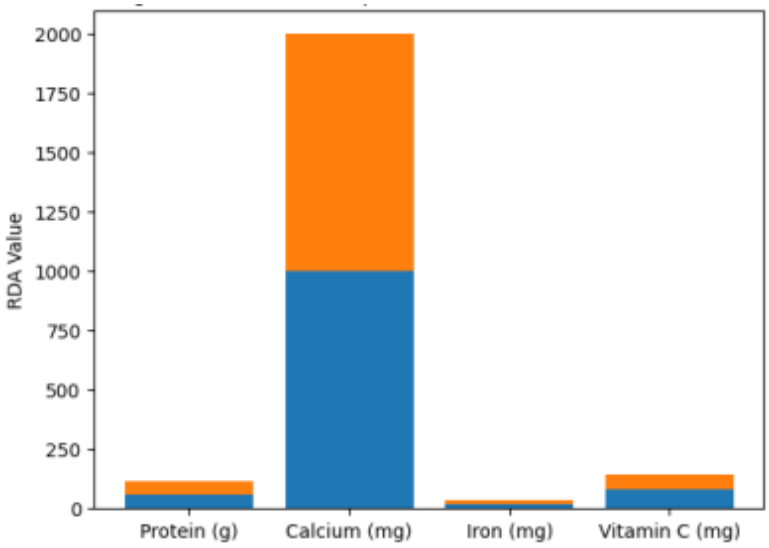
1. Only licensed distributors and retailers can sell nutraceuticals.
2. Claims must be scientifically supported and not misleading.
3. Hormones or steroids are prohibited.
4. Shelf-life and storage instructions must be stated clearly.

1.7 Recommended Dietary Allowances (RDA) in India

RDA refers to the daily nutrient intake level required to meet the needs of nearly all healthy individuals. It is issued by the Indian Council of Medical Research (ICMR) and National Institute of Nutrition (NIN), Hyderabad, and provides guidelines for safe formulation of nutraceuticals.

Nutrient	RDA (Adult Men)	RDA (Adult Women)
Energy	2300 kcal/day	1900 kcal/day
Protein	60 g/day	55 g/day
Fat	25–30% of total energy	25–30% of total energy
Calcium	1000 mg/day	1000 mg/day
Iron	17 mg/day	21 mg/day
Vitamin C	80 mg/day	65 mg/day
Vitamin D	10 µg/day	10 µg/day
Zinc	12 mg/day	10 mg/day

Table 3.3: RDAfor Adult Men and Women in India



Graph 3.1: RDA Comparison for Adult Men and Women

1.8 Enforcement Mechanism under FSSA, 2006

The enforcement mechanism under the Food Safety and Standards Act, 2006 refers to the system and authorities responsible for implementing and enforcing food safety laws. It includes Food Safety Officers, Designated Officers, State Food Safety Commissioners, food analysts, adjudicating officers, and special courts, who together ensure inspection, sampling, testing, compliance, and punishment of violations to protect public health.

1.8.1 Food Safety Authorities at State Level

- Each state appoints a State Food Safety Commissioner.
- Responsible for implementation and enforcement of FSSA within the state.
- Supported by Designated Officers and Food Safety Officers (FSOs).

1.8.2 Role of Food Safety Officers (FSOs)

- Conduct inspections of food business premises.
- Collect food samples for analysis.

- Investigate complaints related to unsafe or substandard food.
- Initiate prosecution in case of violations.

1.8.3 Food Analysts and Adjudicating Officers

- Food Analysts test samples in FSSAI-notified laboratories.
- Adjudicating Officers impose penalties for minor offenses.
- Serious cases are referred to Special Courts.

Food Safety Officer	Inspection, sampling
Food Analyst	Laboratory testing
Adjudicating Officer	Imposes penalties
Special Court	Serious offences
State Commissioner	Overall state enforcement

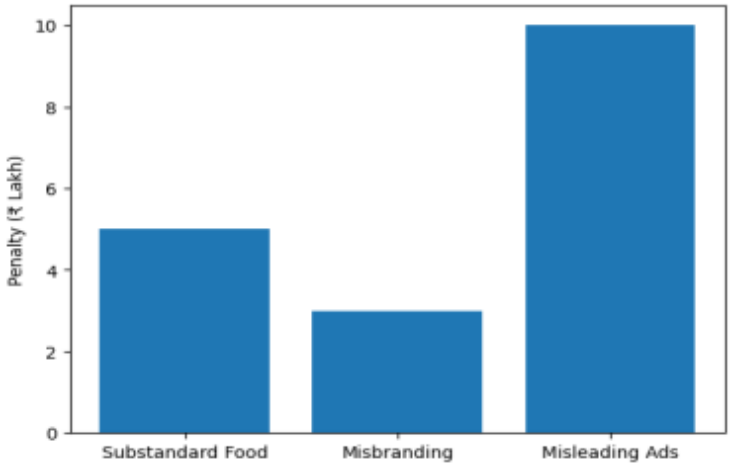
3.4 Enforcement Authorities and Their Regulatory Functions

1.9 Offences and Penalties under FSSA, 2006

- Offences and penalties under the Food Safety and Standards Act, 2006 refer to the punishments imposed for violating food safety laws.
- These include fines and imprisonment for activities such as selling unsafe, substandard, misbranded, or adulterated food.
- Minor offences attract monetary penalties, while serious offences causing injury or death can lead to heavy fines and imprisonment. The aim is to ensure compliance with food safety standards and protect public health.
-

Offence	**Penalty**
Sale of substandard food	Fine up to ₹5 lakh
Misbranding	Fine up to ₹3 lakh
Misleading advertisements	Fine up to ₹10 lakh
Unsafe food causing injury	Imprisonment + fine
Unsafe food causing death	Life imprisonment + fine

Table 3.5:Offences and Penalties under FSSA, 2006



Graph 3.2 Penalties under FSSA, 2006

1.10 Labelling and Claims Regulations for Nutraceuticals

- Labelling and claims regulations for nutraceuticals are prescribed by FSSAI to ensure that consumers receive clear, accurate, and non-misleading information. Every nutraceutical product must carry a proper label mentioning the product name, category, list of ingredients with quantities, recommended daily usage, RDA percentage, storage conditions, and statutory warnings such as "Not for medicinal use".
- Claims made on nutraceutical labels or advertisements must be scientifically substantiated and limited to health maintenance or nutrient function claims. Disease cure, prevention, or therapeutic claims are strictly prohibited. These regulations help prevent false advertisements, ensure consumer safety, and distinguish nutraceuticals from pharmaceutical drugs.

1.10.1 Mandatory Label Declarations

- Name of food category (e.g., "Nutraceutical").
- Complete list of ingredients with quantities.
- Recommended usage and dosage.
- Warning:
  "This product is not intended to diagnose, treat, cure or prevent any disease."
- RDA percentage per serving.
- "Not for medicinal use".

Requirement	Purpose
"Not for medicinal use"	Distinguishes from drugs
RDA percentage	Prevents overconsumption
Recommended usage	Ensures safe intake
Disclaimer statement	Prevents misleading claims

Table 3.6: Key Label Warnings Required for Nutraceuticals

1.10.2 Permitted and Prohibited Claims

Permitted:

- Health maintenance claims (e.g., "supports immunity").
- Nutrient function claims.

Prohibited:

- Disease cure claims (e.g., "treats diabetes").
- Claims comparable to pharmaceutical drugs.
- Exaggerated or misleading advertisements.

1.11 Upper Limits (UL) and Safety Considerations of RDA

Upper Limits (UL) and safety considerations of RDA refer to the maximum safe level of daily nutrient intake that should not be exceeded to avoid adverse health effects. While RDA indicates the recommended amount needed for normal health, UL defines the highest permissible intake level. In nutraceutical formulations, nutrients must be within RDA and UL limits, as excessive intake especially of vitamins and minerals can cause toxicity. These limits ensure product safety and protect consumers from overconsumption.

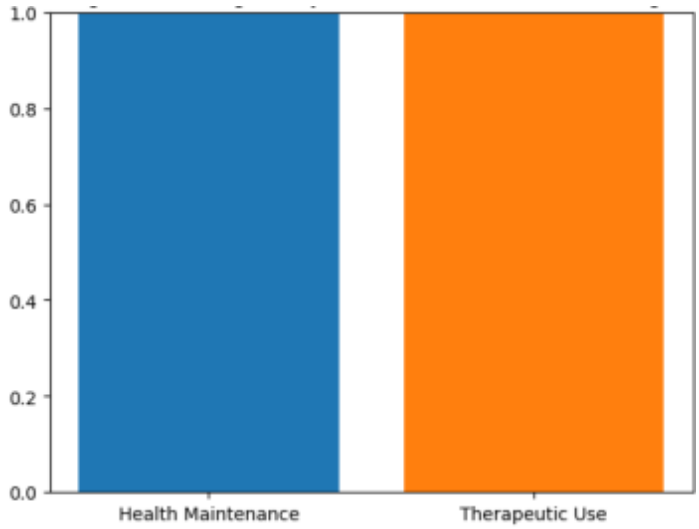
- RDA values are used as reference limits for formulation.
- Nutraceuticals should not exceed the Tolerable Upper Intake Level (UL).
- Excess intake of fat-soluble vitamins (A, D, E, K) can cause toxicity.
- FSSAI mandates:
  - Maximum % of RDA per daily dose
  - Scientific justification for higher levels if required
  -

1.12 Difference Between Nutraceuticals and Drugs (Regulatory Perspective)

- The difference between nutraceuticals and drugs from a regulatory perspective lies in their purpose, claims, and governing laws.
- Nutraceuticals are regulated as foods under the Food Safety and Standards Act, 2006 and are intended for health maintenance and nutritional support, with no therapeutic or disease-curing claims allowed.
- Drugs are regulated under the Drugs and Cosmetics Act, 1940 and are intended for the diagnosis, treatment, or prevention of diseases, supported by clinical trials and permitted therapeutic claims.

Aspect	Nutraceuticals	Drugs
Governing Law	FSSA, 2006	Drugs & Cosmetics Act, 1940
Purpose	Health maintenance	Diagnosis and treatment
Claims	Limited, non-therapeutic	Therapeutic claims allowed
Approval	Ingredient-based	Clinical trial-based
Label	"Not for medicinal use"	Prescription/OTC labelling

Table 3.7:Difference Between Nutraceuticals and Drugs (Regulatory Perspective)



Graph 3.3: Regulatory Focus-Nutraceuticals vs Drugs

1.13 Recent Regulatory Developments

Recent regulatory developments refer to the latest updates, amendments, and new measures introduced by regulatory authorities to improve the safety, quality, and control of food and nutraceutical products. In the context of FSSA, 2006, this includes new FSSAI regulations, stricter labeling and advertising norms, digital systems for licensing and imports, enhanced surveillance, and updated standards to align with scientific advancements and public health needs.

- Introduction of Food Import Clearance System (FICS) for faster imports.
- Increased focus on e-commerce regulation of nutraceuticals.
- Stricter surveillance on misleading advertisements (ASCI + FSSAI).
- Push towards fortified foods and nutrition security.

1.14 Challenges in Regulation of Nutraceuticals in India

The regulation of nutraceuticals in India faces several challenges, including unclear distinction between nutraceuticals and drugs, misleading health claims, lack of consumer awareness, rapid market growth, limited scientific data for some ingredients, and difficulties in enforcement, especially in online and e-commerce sales. These challenges make consistent regulation and consumer protection more complex.

- Overlapping boundary between food and drug categories.
- Consumer confusion due to aggressive marketing.
- Limited awareness among small-scale manufacturers.
- Need for harmonization with global standards (Codex, WHO).

1.15 Summary

- The Food Safety and Standards Act, 2006 represents a paradigm shift from adulteration control to preventive, science-based food regulation.
- Through FSSAI, India has established a structured system for regulating nutraceuticals, ensuring consumer safety while promoting innovation.
- Understanding organizational structure, regulatory provisions, RDA limits, labelling norms, and enforcement mechanisms is essential for pharmacy professionals involved in formulation development, quality assurance, regulatory submissions, and public health protection.

TOPIC 2: FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA (FSSAI): ORGANIZATION, FUNCTIONS

2.1 Food Safety and Standards Authority of India (FSSAI): Organization and Functions

The Food Safety and Standards Authority of India (FSSAI) is an autonomous statutory body established under the Food Safety and Standards Act (FSSA), 2006. It functions under the Ministry of Health and Family Welfare, Government of India and serves as the apex authority for food safety regulation in the country.

The primary objective of FSSAI is to lay down science-based standards and regulate the manufacture, processing, storage, distribution, sale, and import of food to ensure the availability of safe, wholesome, and nutritious food for human consumption.

2.1.1 Organization Structure of FSSAI

FSSAI is headquartered in New Delhi and operates through six regional offices located at Delhi, Mumbai, Kolkata, Chennai, Guwahati, and Cochin, ensuring uniform implementation of food safety regulations across India.

The organizational structure of FSSAI includes:

- **Chairperson**
  Appointed by the Central Government; responsible for overall leadership and policy direction.
- **Members (22) Representing:**
  - Central and State Governments
  - Food processing industry
  - Consumer organizations
  - Farmers and agricultural sectors
  - Scientific, technical, and research institutions
- **Chief Executive Officer (CEO)**
  Responsible for administration, execution of policies, coordination with stakeholders, and day-to-day functioning of the Authority.
- **Scientific Committee and Scientific Panels Provide expert scientific advice on:**
  - Food additives
  - Contaminants and residues
  - Pesticides and antibiotics
  - Nutrition and functional foods
  - Food labelling
  - Risk assessment and risk analysis

- **Central Advisory Committee (CAC)**
  Facilitates coordination between FSSAI and State Food Safety Authorities and advises on policy matters.
- **State Food Safety Authorities (SFSAs)**
  Responsible for enforcement of food safety laws at the state level through designated officers.
- **Food Safety Officers (FSOs)**
  Conduct inspections, collect food samples, investigate complaints, and ensure compliance at the field level.

Flowchart 3.1: Organisation Structure of FSSAI

2.1.2 Functions of FSSAI

The major functions of FSSAI include:

- Framing, notification, and periodic revision of science-based food safety standards and regulations.
- Licensing and registration of Food Business Operators (FBOs).
- Monitoring and enforcement through inspections, surveillance, audits, and sampling of food products.
- Regulation of food imports and coordination with customs authorities to ensure safety of imported food.
- Accreditation and recognition of food testing laboratories and research institutions.
- Risk assessment, risk management, and risk communication related to food hazards.

- Collection, analysis, and dissemination of data on food consumption patterns, contaminants, residues, and emerging food safety risks.
- Training and capacity building programs for food safety officials, laboratory personnel, and food business operators.
- Consumer awareness and education initiatives such as:
  - *Eat Right India Movement*
  - *Clean Street Food Initiative*
  - *Food Safety on Wheels (FSW)*
- Promotion of nutrition, hygiene, and food safety culture across India.
- Collaboration with international organizations including:
  - World Health Organization (WHO)
  - Food and Agriculture Organization (FAO)
  - Codex Alimentarius Commission

Figure 3.3 Functions of FSSAI

Thus, FSSAI plays a central role in protecting public health by ensuring food safety, improving nutritional quality, harmonizing food laws, and promoting consumer awareness, thereby contributing to a safer and healthier food ecosystem in India.

2.2 Regulations of FSSAI

Figure 3.4: Regulations of FSSAI

The Food Safety and Standards Authority of India (FSSAI) enforce food safety through a comprehensive set of Food Safety and Standards Regulations, notified under the Food Safety and Standards Act (FSSA), 2006. These regulations ensure uniform standards for food quality, safety, hygiene, labelling, and nutrition across India.

2.2.1 Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011

- Governs licensing and registration of Food Business Operators (FBOs).
- Categorizes businesses into Basic Registration, State License, and Central License.
- Specifies eligibility, application procedure, validity, renewal, and suspension of licenses.
- Ensures traceability and accountability of food businesses.

2.2.2 Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011

- Prescribes standards for various food products such as dairy, oils, cereals, beverages, meat products, and processed foods.
- Specifies permitted food additives, their maximum limits, and conditions of use.
- Ensures prevention of adulteration and misuse of additives.

2.2.3 Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011

- Lays down maximum permissible limits for:
  - Heavy metals (lead, mercury, arsenic)
  - Pesticide residues
  - Antibiotics and veterinary drug residues
  - Naturally occurring toxins
- Protects consumers from chemical and biological hazards.

2.2.4 Food Safety and Standards (Prohibition and Restrictions on Sales) Regulations, 2011

- Prohibits sale of unsafe, misbranded, adulterated, or substandard food.
- Restricts sale of food containing unsafe additives, colours, or contaminants.
- Includes restrictions on food near educational institutions (e.g., junk food).

2.2.5 Food Safety and Standards (Packaging and Labelling) Regulations, 2011

(Now integrated into Labelling & Display Regulations, 2020)

- Specifies requirements for **food labels**, including:
  - Name of food
  - Ingredient list
  - Nutritional information
  - FSSAI logo and license number
  - Date of manufacture and expiry
- Prevents misleading claims and ensures consumer transparency.

2.2.6 Food Safety and Standards (Labelling and Display) Regulations, 2020

- Introduced clear front-of-pack labelling norms.
- Mandatory declaration of veg/non-veg symbol.
- Regulates nutritional claims, health claims, and advertisements.
- Enhances consumer awareness and informed food choices.

2.2.7 Food Safety and Standards (Food Import) Regulations, 2017

- Regulates import of food articles into India.
- Ensures imported food complies with Indian food safety standards.
- Covers procedures for clearance, inspection, sampling, and rejection of unsafe imports.

2.2.8 Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose and Functional Foods) Regulations, 2016

- Regulates health supplements, nutraceuticals, and functional foods.
- Specifies permitted ingredients, vitamins, minerals, and botanical extracts.
- Prevents false therapeutic claims and misuse of supplements.

2.2.9 Food Safety and Standards (Alcoholic Beverages) Regulations, 2018

- Prescribes standards for alcoholic drinks such as beer, wine, spirits, and country liquor.
- Regulates alcohol content, additives, labelling, and quality parameters.

2.2.10 Food Safety and Standards (Hygiene and Sanitary Practices) Regulations

- Specifies Good Manufacturing Practices (GMP) and Good Hygiene Practices (GHP).
- Covers hygiene requirements for food premises, equipment, personnel, and transportation.
- Essential for preventing microbial contamination.

The FSSAI regulations form a comprehensive legal framework that ensures:

- Food safety and quality
- Consumer protection
- Transparency in food labelling
- Control over contaminants and additives
- Regulation of imports and special foods

These regulations collectively support the goal of "Safe and Nutritious Food for All."

2.3 Application Procedure for FSSAI Licence

The Food Safety and Standards Authority of India (FSSAI) mandates that every Food Business Operator (FBO) obtain registration or a licence before commencing food-related activities.
The procedure for applying for an FSSAI licence is explained below.

Step 1: Business Registration / Eligibility Identification

The food business operator must first determine the category of registration required based on:

- Nature of food business
- Annual turnover
- Scale of operation

Accordingly, the FBO applies for:

- Basic Registration
- State Licence
- Central Licence

Step 2: Application Submission

The applicant must submit the FSSAI licence application:

- Online through the FoSCoS (Food Safety Compliance System) portal
- By filling the prescribed form and uploading required documents

Step 3: Document Verification

Submitted documents are verified by the concerned licensing authority. Documents generally include:

- Identity and address proof
- Food safety management plan
- List of food products
- Layout plan of premises (if applicable)

Step 4: Inspection

In certain cases, the Food Safety Officer (FSO) conducts an inspection of the food premises to verify:

- Hygiene and sanitation practices
- Infrastructure and equipment
- Compliance with food safety norms

Step 5: Approval and Fee Payment

Once the application and inspection (if any) are satisfactory:

- The licensing authority approves the application
- The applicant pays the prescribed licence fee

Step 6: Issue of FSSAI Licence

After successful approval and payment:

- The FSSAI Licence or Registration Certificate is issued
- The FBO receives a 14-digit FSSAI licence number

This licence must be displayed at the food premises and printed on food labels.

Note:

The FSSAI licensing system ensures that all food businesses operate in compliance with food safety laws, thereby protecting public health and ensuring the supply of safe and wholesome food.

Figure 3.4: FSSAI Licence Process

TOPIC 3. REGULATIONS FOR IMPORT, MANUFACTURE, AND SALE OF NUTRACEUTICAL PRODUCTS IN INDIA

FSSAI regulates nutraceuticals under the "Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Foods, and Novel Foods) Regulations, 2016". These regulations define the standards for safety, labeling, claims, and permissible ingredients. Nutraceuticals in India are regulated under the, along with subsequent amendments issued by FSSAI.

Flowchart 3.2: Regulatory Framework of Nutraceuticals in India

3.1 Nutraceuticals

Nutraceuticals are foods or food ingredients that provide physiological and health benefits beyond basic nutritional functions, and are intended to supplement the normal diet. They help in the maintenance of health, prevention of nutritional deficiencies, and reduction of risk of diseases, but are not meant for medicinal or therapeutic use.

According to FSSAI, nutraceuticals are:

Foods or parts of foods, other than normal foods, that have health benefits and are used to supplement the diet, containing one or more ingredients such as vitamins, minerals, amino acids, botanicals, or other substances with nutritional or physiological effects.

Parameter	Food	Nutraceutical	Drug
Main use	Nutrition	Health support	Disease treatment
Regulation	FSSAI	FSSAI	DCGI
Claims	Nutritional	Health claims	Therapeutic
Prescription needed	No	No	Yes

Table 3.8: Difference Between Food, Nutraceuticals and Drugs

3.2 Import of Nutraceutical Products in India

The import of nutraceutical products into India is regulated by the Food Safety and Standards Authority of India (FSSAI) under the Food Safety and Standards Act, 2006 and the Food Safety and Standards (Import) Regulations, 2017, along with the Health Supplements and Nutraceuticals Regulations, 2016.

Authority	Role
FSSAI	Regulates safety & standards
Customs	Clears imported goods
FICS	Online import clearance
Approved Labs	Testing of samples

Table 3.9: Authorities Involved in Import of Nutraceuticals

These regulations ensure that imported nutraceuticals are safe, properly labeled, and compliant with Indian food laws.

3.2.1 Import Licensing and Registration

- Import licensing and registration are mandatory requirements for importing nutraceutical products into India. Any entity intending to import nutraceuticals must obtain a Central FSSAI License prior to initiating import activities. This license authorizes the importer to legally bring, store, and distribute nutraceutical products within the country.
- The Central FSSAI License is issued only after verification of the importer's business details, premises, food safety management system, and compliance capability. Each importer is accountable for ensuring that imported products meet Indian food safety and regulatory standards.
- The FSSAI license number must be prominently displayed on the product label**,** along with importer details, to ensure traceability and regulatory transparency. Import of nutraceutical products without a valid FSSAI license is strictly prohibited and may result in rejection of consignments, penalties, or legal action.
- Thus, import licensing and registration serve as a critical regulatory control to ensure that only compliant and safe nutraceutical products enter the Indian market.

3.2.2 Compliance with Indian Standards

- All nutraceutical products imported into India must strictly comply with Indian food safety and quality standards, regardless of their approval status in the country of origin. The regulatory framework mandates adherence to the Food Safety and Standards Act, 2006 and the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose and Functional Foods) Regulations, 2016.
- Imported nutraceuticals are required to contain only permitted ingredients as notified by FSSAI, and these ingredients must be used within the prescribed maximum limits. The inclusion of any prohibited substances, pharmaceutical drugs, hormones, or steroids is strictly forbidden. Products making therapeutic or medicinal claims beyond permitted nutritional or functional benefits are also not allowed.
- In addition, imported products must meet Indian standards for safety, purity, and quality, including limits for contaminants such as heavy metals, pesticides, mycotoxins, and microbiological parameters. Compliance with labelling regulations is mandatory, ensuring

accurate declaration of ingredients, nutritional information, usage instructions, warnings, and importer details as per Indian norms.

- Failure to comply with Indian standards may lead to detention, rejection, or destruction of consignments, along with regulatory penalties. Therefore, compliance with Indian standards is essential to safeguard consumer health and maintain regulatory conformity in the import of nutraceutical products.

3.2.3 Food Import Clearance System (FICS)

- The Food Import Clearance System (FICS) is an online platform established by the Food Safety and Standards Authority of India (FSSAI) to regulate and streamline the import clearance of food and nutraceutical products into India. FICS ensures that imported products comply with Indian food safety standards before they are released into the domestic market.
- Under FICS, importers are required to submit an online application for clearance of each consignment through the FSSAI portal. The system facilitates document verification, risk-based sampling, laboratory testing, and regulatory decision-making in a transparent and time-bound manner.
- Key documents submitted through FICS include the Bill of Entry, product label, ingredient list, Certificate of Analysis, Country of Origin certificate, and manufacturer's authorization**.** Based on the risk assessment, consignments may be approved directly or selected for physical inspection and laboratory analysis.
- Only after satisfactory compliance with all regulatory requirements does FSSAI issue a No Objection Certificate (NOC)**,** allowing the consignment to be cleared by customs. In cases of non-compliance, consignments may be rejected, re-exported, or destroyed.
- Overall, FICS plays a vital role in ensuring food safety, regulatory compliance, and efficient import processing, thereby protecting public health and facilitating legitimate trade.
-

Document	Why needed
Bill of Entry	Customs processing
Product label	Label compliance
Certificate of Analysis	Quality proof
Country of Origin	Product traceability
Manufacturer authorization	Authenticity

Table 3.10: Documents Required for Import (FICS)

3.2.4 Labelling Requirements

Imported nutraceuticals must comply with Indian labelling regulations. Labels should include:

- Product name and category
- Nutritional information based on Indian RDA
- Recommended usage and dosage
- Warning statements, if applicable
- Declaration "NOT FOR MEDICINAL USE"
- Name and address of the importer
- FSSAI logo and license number

Label Information	Mandatory
Product name	Yes
Nutritional information	Yes
Usage & dosage	Yes
Warning statement	Yes
"NOT FOR MEDICINAL USE"	Yes
FSSAI logo & license no.	Yes

Table 3.11: Labelling Requirements for Imported Nutraceuticals

Correction of Non-Compliant Labels

Non-compliant labels may be corrected only at FSSAI-approved bonded warehouses means that if an imported product's label does not meet FSSAI labeling requirements, the importer is not allowed to modify or relabel the product at any random location.

- If the label has errors (missing information, incorrect claims, wrong format)
- The product cannot be sold or cleared directly
- Label correction is permitted only inside warehouses approved by FSSAI
- These warehouses are called bonded warehouses and are under customs and regulatory supervision

Rationale for the Regulation

- To prevent unauthorized tampering or misuse of imported products
- To maintain regulatory oversight and product traceability
- To ensure that corrected labels fully comply with Indian food safety and labeling standards

Practical Implementation

- The importer submits a formal request for label correction
- The consignment is transferred to an FSSAI-approved bonded warehouse
- Relabelling is carried out under official regulatory supervision
- Upon satisfactory compliance, FSSAI grants clearance for sale in the Indian market

3.2.5 Sampling and Testing

- Sampling and testing are done to check whether imported food or nutraceutical products are safe and meet Indian standards. After the importer submits documents through the FICS portal, FSSAI officials review the consignment.
- If required, a sample is taken by authorized FSSAI officers from the imported consignment in the presence of customs or the importer. The sample is properly sealed and sent to an FSSAI-approved laboratory**.**
- The laboratory tests the sample for ingredient compliance, safety, quality, and contamination such as microbes or harmful substances. Based on the test results, FSSAI decides whether the product can be allowed into the market.
- If the product meets all standards, it is cleared for sale. If not, it may be rejected, returned, or destroyed. This process helps protect consumer health and ensures product safety.

3.2.6 Shelf-Life Requirements

Imported nutraceutical products must have at least 60% of their original shelf life remaining at the time of import. Shelf life must be supported by stability data.

3.2.7 Novel Foods and Ingredients

Nutraceuticals containing novel foods or ingredients require prior approval from FSSAI before import. Importers must submit scientific safety and efficacy data for such ingredients.

3.2.8 Restrictions and Prohibitions

- Therapeutic or disease-curing claims are strictly prohibited.
- Products containing banned substances or pharmaceutical ingredients are not allowed.
- Genetically modified ingredients require specific approvals.

3.2.9 Post-Import Surveillance and Enforcement

FSSAI conducts market surveillance and post-import monitoring of nutraceutical products. Non-compliant products may be recalled, and penalties may be imposed under the Food Safety and Standards Act, 2006.

Thus, the import of nutraceutical products in India is governed by a robust regulatory framework to ensure consumer safety, transparency, and compliance with national food standards.

3.3Manufacture of Nutraceutical Products in India

3.3.1 Introduction

Nutraceuticals are products derived from food sources that provide additional health benefits beyond basic nutritional value. The term "nutraceutical" is a combination of "nutrition" and "pharmaceutical" and represents a rapidly growing segment of the healthcare industry. In India, nutraceuticals bridge the gap between conventional foods and pharmaceuticals, playing a crucial role in preventive healthcare, wellness promotion, and management of lifestyle-related disorders.

With increasing health awareness, aging population, and preference for natural and preventive therapies, the nutraceutical industry in India has witnessed significant growth. The manufacture of nutraceutical products requires strict adherence to regulatory guidelines, quality standards, and scientific validation to ensure safety, efficacy, and consumer trust.

3.3.2 Regulatory Framework in India

3.3.2.1 Governing Authority

The manufacture, distribution, and marketing of nutraceutical products in India are regulated by the Food Safety and Standards Authority of India (FSSAI) under the Food Safety and Standards Act, 2006.

3.3.2.2 Applicable Regulations

The primary regulation governing nutraceuticals is:

- Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations

These regulations define nutraceuticals, specify permitted ingredients, nutrient limits, labelling requirements, and restrictions on claims. Nutraceuticals are regulated as foods, not as drugs, and therefore therapeutic claims such as cure, prevention, or treatment of diseases are strictly prohibited.

3.3.3 Classification of Nutraceutical Products

Nutraceutical products manufactured in India may be classified as:

1. **Dietary Supplements**
   Vitamins, minerals, amino acids, fatty acids, and antioxidants.
2. **Herbal and Botanical Nutraceuticals**

Products containing plant extracts such as ashwagandha, turmeric, ginseng, and garlic.

3. **Functional Foods**
   Foods fortified with bioactive compounds providing health benefits.
4. **Probiotics and Prebiotics**
   Live microorganisms or substrates that promote gut health.
5. **Specialty Nutraceuticals**
   Products for sports nutrition, weight management, and immune support.

3.3.4 Licensing and Approval for Manufacturing

3.3.4.1 FSSAI License

Any entity involved in the manufacture of nutraceutical products must obtain an FSSAIlicense through the Foscos portal.

- **Basic Registration** -Small-scale manufacturers
- **State License** - Medium-scale manufacturers
- **Central License** - Large-scale manufacturers and exporters

Most nutraceutical manufacturing units require a Central FSSAI License, irrespective of turnover.

3.3.4.2 Product Approval

- Only ingredients listed in FSSAI schedules are permitted.
- Novel ingredients require prior approval with documented safety data.
- Nutrient levels must comply with ICMR-recommended dietary allowances (RDA).

License Type	Who needs it
Basic	Small manufacturers
State	Medium manufacturers
Central	Large manufacturers / exporters

Table 3.12: FSSAI Licenses for Manufacturing

3.3.5 Manufacturing Standards and Quality Requirements

3.3.5.1 Good Manufacturing Practices (GMP)

Manufacturing facilities must comply with **GMP for food products**, ensuring:

- Hygienic premises and controlled environment
- Trained technical personnel
- Validated manufacturing processes
- Proper sanitation and waste management

3.3.5.2 Quality Control

Quality control is a critical component of nutraceutical manufacturing and includes:

- Raw material testing (identity, purity, microbial limits)
- In-process quality checks
- Finished product testing (assay, stability, contamination)

Implementation of HACCP (Hazard Analysis and Critical Control Points) and Food Safety Management Systems (FSMS) is recommended.

3.3.6 Manufacturing Process of Nutraceutical Products

3.3.6.1 Formulation Development

Formulation involves selection of active ingredients, excipients, dosage form, and stability considerations. Nutrient compatibility, bioavailability, and shelf life are key factors.

3.3.6.2 Raw Material Procurement

Raw materials must be sourced from approved vendors and accompanied by certificates of analysis. Herbal ingredients should be standardized for active constituents.

3.3.6.3 Processing and Production

Depending on the dosage form, manufacturing may involve:

- Powder blending
- Granulation
- Tableting
- Encapsulation
- Liquid filling

Strict control of processing parameters is essential to maintain uniformity and potency.

3.3.6.4 Packaging and Storage

Packaging materials must be food-grade and protect the product from moisture, light, and contamination. Storage conditions should ensure product stability throughout shelf life.

3.3.7 Labelling and Claims

3.3.7.1 Labelling Requirements

Mandatory label information includes:

- Product category (Nutraceutical / Health Supplement)
- Ingredient list and nutritional information
- Recommended usage and warnings
- FSSAI license number

3.3.7.2 Claims and Advertisements

Health claims must be scientifically substantiated and compliant with FSSAI Advertising and Claims Regulations. Misleading or medicinal claims are prohibited.

3.3.8 Challenges in Nutraceutical Manufacturing

- Regulatory complexity and frequent updates
- Ensuring quality consistency of herbal ingredients
- Scientific validation of health benefits
- Consumer awareness and trust issues

3.3.9 Future Prospects

The Indian nutraceutical industry is poised for substantial growth due to increasing demand for preventive healthcare, functional foods, and natural products. Advances in formulation technology, personalization of nutrition, and integration of traditional knowledge with modern science are expected to drive innovation.

The manufacture of nutraceutical products in India is a regulated, science-driven process requiring compliance with FSSAI regulations, GMP standards, and quality assurance practices. With appropriate regulatory adherence and technological advancements, nutraceuticals hold immense potential as safe, effective, and sustainable healthcare products

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3.4 Sale of Nutraceutical Products in India

3.4.1 Introduction

The sale of nutraceutical products in India forms a vital component of the rapidly expanding preventive healthcare sector. Nutraceuticals, positioned between foods and pharmaceuticals, are marketed to promote health, enhance physiological functions, and reduce the risk of lifestyle-related disorders. Unlike drugs, nutraceuticals are regulated as food products, and their sale is governed primarily by food safety laws rather than pharmaceutical legislation.

The legal sale of nutraceutical products in India requires strict compliance with regulatory provisions concerning licensing, labelling, claims, advertising, and distribution channels to ensure consumer safety and prevent misleading practices.

3.4.2 Regulatory Authority Governing Sale

The sale and distribution of nutraceutical products in India are regulated by the Food Safety and Standards Authority of India (FSSAI) under the Food Safety and Standards Act, 2006.

Key regulations applicable to sale include:

- Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations
- Food Safety and Standards (Health Supplements and Nutraceuticals) Regulations
- Food Safety and Standards (Labelling and Display) Regulations
- Food Safety and Standards (Advertising and Claims) Regulations

3.4.3 Licensing Requirements for Sale

3.4.3.1 FSSAI Registration / License

Any entity involved in the sale, distribution, wholesale, or retail of nutraceutical products must obtain a valid FSSAI license or registration, depending on the scale of business:

- **Basic Registration** - Small retailers with limited annual turnover
- **State License** - Medium-scale wholesalers and distributors
- **Central License -** Large distributors, importers, exporters, and e-commerce platforms

Sale of nutraceuticals without a valid FSSAI license is considered illegal and punishable under the Act.

Business Type	License Required
Retail shop	FSSAI Registration
Distributor	State / Central License
E-commerce	Central License

Table 3.13: Licensing for Sale

3.4.4 Sale Through Different Channels

3.4.4.1 Retail Sale

Nutraceuticals may be sold through:

- Pharmacies and drug stores
- Supermarkets and health food stores
- Ayurvedic and wellness outlets

A drug license is not mandatory, as nutraceuticals are not classified as drugs; however, compliance with FSSAI norms is compulsory.

3.4.4.2 Wholesale and Distribution

Wholesalers and distributors must ensure:

- Products are sourced from licensed manufacturers
- Proper storage and transportation conditions are maintained

- Batch numbers and expiry dates are traceable

3.4.4.3 Online and E-Commerce Sale

The sale of nutraceutical products through e-commerce platforms is permitted, provided:

- The seller holds a valid FSSAI license
- Product labels and claims comply with regulations
- No misleading or medicinal claims are made

E-commerce operators are considered food business operators (FBOs) and are responsible for regulatory compliance.

3.4.5 Storage and Handling Requirements

Proper storage is essential to maintain product quality and safety. Requirements include:

- Clean, dry, and hygienic storage conditions
- Protection from moisture, heat, and direct sunlight
- Segregation of expired or damaged products

Failure to maintain storage conditions may lead to product deterioration and regulatory action.

Channel	Allowed
Pharmacies	Yes
Supermarkets	Yes
Online platforms	Yes
Without license	No

Table 3.14: Sale Channels of Nutraceuticals

3.4.5 Labelling Compliance at Point of Sale

At the point of sale, nutraceutical products must display:

- Name of the product and category (Nutraceutical/Health Supplement)
- Ingredient list and nutritional information
- Recommended daily usage and warnings
- FSSAI logo and license number

Products with incomplete or misleading labels are prohibited from sale.

3.4.7 Advertising and Promotional Restrictions

3.4.7.1 Permitted Claims

Only general health, nutritional, and functional claims supported by scientific evidence are permitted.

3.4.7.2 Prohibited Claims

- Claims of curing, preventing, or treating diseases
- Claims equating nutraceuticals with pharmaceutical drugs
- Misleading endorsements or exaggerated benefits

Sales promotion must comply with the Advertising and Claims Regulations, ensuring truthful and ethical communication.

3.4.8. Pricing and Taxation

- Nutraceutical products are subject to Goods and Services Tax (GST), typically ranging between 12%–18%, depending on product classification.
- Unlike essential medicines, nutraceuticals are not subject to price control under the Drugs (Prices Control) Order (DPCO).

3.4.9 Inspection, Enforcement, and Penalties

FSSAI and state food safety authorities conduct inspections to ensure compliance. Non-compliance may result in:

- Product recall
- Suspension or cancellation of license
- Monetary penalties or prosecution

Violation	Action Taken
No license	Fine
False claims	Product recall
Unsafe product	Prosecution

Table 3.15: Penalties for Non-Compliance

3.4.10 Ethical Considerations in Sale

Ethical sale practices include:

- Transparent labelling and communication
- Avoidance of misleading health claims
- Consumer education on appropriate usage

Healthcare professionals and retailers play a crucial role in promoting rational and safe consumption of nutraceutical products.

3.4.11 Challenges in Sale of Nutraceutical Products

- Misclassification as drugs or Ayurvedic medicines
- Proliferation of unapproved products
- Consumer confusion due to aggressive marketing
- Regulatory enforcement across online platforms

Figure 3.5 Regulatory Frame work in India

The sale of nutraceutical products in India is governed by a robust regulatory framework aimed at ensuring safety, quality, and consumer protection. Compliance with FSSAI licensing, labelling, storage, and advertising regulations is essential for lawful sale. As demand for preventive healthcare continues to rise, ethical and regulated sale of nutraceutical products will play a significant role in public health promotion.

TOPIC 4. RECOMMENDED DIETARY ALLOWANCES (RDA) IN INDIA

Recommended Dietary Allowances (RDA) represent the average daily nutrient intake level sufficient to meet the requirements of nearly all healthy individuals in a particular life stage and gender group. RDAs are designed to prevent deficiency diseases, promote optimal health, and support growth and physiological functions.

In India, the Indian Council of Medical Research (ICMR) - National Institute of Nutrition (NIN) is the statutory authority responsible for determining and updating RDA values. The latest comprehensive RDA recommendations in India were published in 2020 by ICMR-NIN.

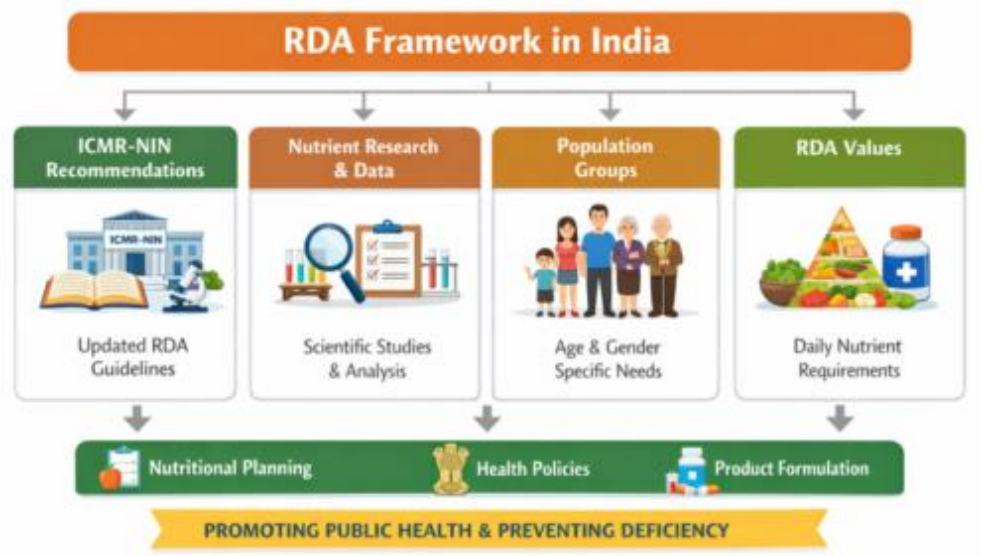

Figure 3.6: RDA Framework in India

4.1 Importance of RDA

1. Nutritional Planning: Helps dietitians and healthcare professionals design balanced diets for different population groups.
2. Public Health Policy: Guides national food fortification, supplementation programs, and dietary guidelines.
3. Product Formulation: Ensures nutraceuticals and fortified foods comply with safe nutrient limits.
4. Preventing Deficiency & Toxicity: Avoids under- or over-consumption of essential nutrients.

4.2 Basis for Determination of RDA

The determination of RDA values is based on extensive epidemiological, clinical, and biochemical research and depends on several factors:

- Age, gender, and physiological status such as infancy, childhood, adolescence, adulthood, pregnancy, and lactation.
- Energy expenditure and metabolic rate, influenced by body composition and physical activity levels.
- Bioavailability of nutrients, considering dietary sources and absorption efficiency.
- Environmental and lifestyle factors, including climate, occupational activity, and socio-economic conditions.
- Health status of the population, including prevalence of nutritional deficiencies.

These parameters ensure that RDA values are population-specific and scientifically robust.

4.3 Components of RDA

RDA values are provided for: 1. Macronutrients - Carbohydrates: Energy source; generally 50-60% of total calories. - Proteins: Based on body weight and growth requirements. - Fats: Essential fatty acids and energy balance.

- Micronutrients
  - Vitamins: Water-soluble (B-complex, Vitamin C) and fat-soluble (A, D, E, K).
  - Minerals: Major (Calcium, Phosphorus, Magnesium) and trace elements (Iron, Zinc, Iodine).
- Other Nutrients
  - Fiber: Prevents constipation and supports gut health.
  - Water: Daily fluid requirements based on climate, activity, and body weight.
- **Note:** Full RDA tables include infants, children, adolescents, pregnant, and lactating women, and elderly population.

Note:RDA values may vary based on revised ICMR–NIN guidelines and specific population subgroups.

4.4 Role of RDA in Nutraceutical Regulation

RDA plays a critical role in the regulation and safe use of nutraceutical products in India:

- FSSAI regulations mandate that the levels of added vitamins, minerals, and nutrients in nutraceuticals must comply with ICMR/NIN-recommended RDA limits.
- Nutrient content generally should not exceed the RDA, except where higher limits are scientifically justified and permitted under regulations.
- Prevents nutrient toxicity, hypervitaminosis, and mineral overload, especially with long-term consumption.
- Assists manufacturers in designing safe, balanced, and scientifically justified formulations.
- Provides a standardized reference for nutritional labeling and health claims, ensuring transparency and consumer awareness.
- Supports regulatory scrutiny during product approval, inspection, and post-marketing surveillance.

4.5 Importance of RDA in Nutraceutical Formulation and Quality Assurance

RDA acts as a benchmark for dose selection in nutraceutical formulations.

- Helps in maintaining uniformity and consistency across batches.
- Facilitates risk assessment during formulation development.
- Ensures compliance during quality audits and regulatory inspections.
- Enhances consumer trust by ensuring evidence-based nutrient levels.

The Food Safety and Standards Authority of India (FSSAI) play a pivotal role in ensuring the safety, quality, and regulatory compliance of nutraceutical products through structured legislation, scientific evaluation, and enforcement mechanisms. The integration of ICMR–NIN Recommended Dietary Allowance (RDA) guidelines ensures that nutraceutical products deliver health benefits while minimizing risks associated with excessive nutrient intake.

4.7 Examples of RDA for Key Nutrients

Nutrient	Adult Male	Adult Female	Pregnant Women
Energy (kcal/day)	2450	1900	2230
Protein (g/day)	60	55	65
Iron (mg/day)	17	21	35
Calcium (mg/day)	600	600	1200
Vitamin C (mg/day)	80	80	100
Vitamin A (µg/day)	1000	840	900

Table 3.16: RDA for Key ingredients

4.8 Application of RDA

- Dietary Planning: Ensures diets meet the nutritional needs of the population.
- Fortification and Supplementation: Nutraceutical and health supplement products are designed based on RDA to avoid nutrient excess or deficiency.

- Research and Clinical Nutrition: Used as reference values for evaluating nutrient intake in epidemiological studies.

4.9 Differences from International RDA

- Indian RDA considers Indian dietary habits, food availability, and bioavailability, which may differ from WHO, FAO, or US RDA values.
- For example, iron RDA in India is higher due to predominantly plant-based diet and lower absorption rates.

RDA values are essential for maintaining health, preventing deficiencies, and guiding nutraceutical formulation. Indian RDAs, established by ICMR-NIN, provide a science-based framework for dietary planning, health policies, and product development, making them indispensable for nutritionists, pharmacists, and healthcare professionals.

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UNIT – 4th

REGULATION OF NUTRACEUTICALS AND DIETARY SUPPLEMENTS IN THE UNITED STATES

TOPIC 1: US FDA FOOD SAFETY MODERNIZATION ACT (FSMA)

Figure 4.1: FSMA - From Reactive Food Safety to Preventive Regulatory Control

1.1 Introduction

- The Food Safety Modernization Act (FSMA), enacted in 2011, represents the most significant reform of United States food safety legislation in more than seven decades. The primary objective of FSMA is to transform the food safety regulatory system administered by the United States Food and Drug Administration (US FDA) from a reactive, incident-driven approach to a science-based, preventive framework aimed at minimizing foodborne illnesses and enhancing consumer protection.
- FSMA applies to all FDA-regulated food products, including nutraceuticals, dietary supplements, functional foods, and food ingredients, covering both domestic and imported products. The Act emphasizes preventive controls, risk-based inspections, supply chain accountability, and strengthened regulatory oversight to ensure food safety across the entire food production and distribution chain.
- Prior to the implementation of FSMA, the food safety regulatory system in the United States was largely reactive, focusing mainly on responding to food safety incidents after they occurred. Regulatory actions were typically initiated only after outbreaks, contamination events, or consumer complaints were reported. This approach often resulted in delayed interventions, limited preventive measures, and reduced accountability of manufacturers. FSMA introduced a preventive, risk-based regulatory framework that emphasizes early hazard identification, enhanced FDA authority, improved inspection systems, and increased responsibility for manufacturers and importers.

Parameter	Before FSMA (Reactive Approach)	After FSMA (Preventive Approach)
Regulatory focus	Responding to food safety incidents	Preventing food safety hazards
FDA authority	Limited recall power	Mandatory recall authority
Hazard control	Not systematically required	Mandatory hazard analysis & preventive controls
Inspection system	Periodic inspections	Risk-based inspection frequency
Import safety	Limited oversight	Foreign Supplier Verification Program (FSVP)
Manufacturer responsibility	Limited accountability	Full responsibility for safety & compliance

Table 4.1: Comparison of Pre-FSMA and Post-FSMA Food Safety Approach

Figure 4.2: Pre-FSMA approach vs Post-FSMA approach

Impact of FSMA on Nutraceuticals and Dietary Supplements

The implementation of the Food Safety Modernization Act (FSMA) has had a significant impact on the regulation of nutraceuticals and dietary supplements in the United States. FSMA has transformed the regulatory framework from a reactive, post-market approach to a preventive, science-based system, ensuring that nutraceutical products are manufactured under controlled, hygienic, and quality-focused conditions.

The Act requires manufacturers to implement preventive controls, follow current Good Manufacturing Practices (cGMP), and conduct thorough hazard analysis and risk-based preventive controls (HARPC). These measures significantly reduce the risk of contamination, adulteration, and misbranding, enhancing the overall safety and reliability of nutraceutical products.

FSMA has also strengthened supply chain oversight, particularly for products relying on imported raw materials, through the Foreign Supplier Verification Program (FSVP). Importers are now responsible for verifying that foreign suppliers meet US food safety standards, ensuring ingredient safety and accountability throughout the supply chain.

Additional provisions, including mandatory recall authority, risk-based inspections, and detailed record-keeping, have further enhanced regulatory oversight. According to FSMA impact assessments, key areas influenced include hazard prevention (90%), supply chain oversight (75%), and enhanced safety standards (65%), demonstrating measurable improvements in product safety and quality.

Overall, FSMA has led to greater transparency, higher product quality, strengthened regulatory compliance, improved consumer safety, and increased confidence in nutraceuticals and dietary supplements marketed in the United States.

Figure 4.3: FSMA impact on Nutraceuticals

1.2 Key Provisions of FSMA

Figure 4.4: Key Provisions of FSMA

The major provisions of FSMA that are particularly relevant to the manufacture and marketing of nutraceuticals and dietary supplements include:

1.2.1 Preventive Controls for Human Food

FSMA requires food facilities to implement preventive controls to identify and minimize potential biological, chemical, and physical hazards. Manufacturers must develop and maintain a Food Safety Plan based on systematic hazard identification and control.

- ❖ FSMA requires food manufacturers to prevent food safety problems instead of reacting after they occur.
- ❖ Food facilities must prepare a written Food Safety Plan.

- ❖ Manufacturers must identify possible hazards such as:
- ❖ Biological (bacteria, fungi)
- ❖ Chemical (pesticides, heavy metals)
- ❖ Physical (glass, metal pieces)
- ❖ Preventive controls must be applied to control these hazards.
- ❖ Facilities must monitor the controls regularly to ensure they are working properly.
- ❖ Corrective actions must be taken if any safety issue is identified.
- ❖ Proper records and documents must be maintained for FDA inspection.
- ❖ A trained and qualified person must oversee the food safety system.
- ❖ These controls help ensure safe, high-quality nutraceutical and dietary supplement products.

1.2.2 Current Good Manufacturing Practices (cGMP)

FSMA strengthens compliance with current Good Manufacturing Practices (cGMP) by mandating hygienic facility design, personnel training, sanitation controls, and equipment maintenance to ensure consistent product quality and safety.

- ❖ FSMA strengthens the implementation of Current Good Manufacturing Practices (cGMP) to ensure food safety and quality.

- Manufacturing facilities must maintain clean and hygienic premises to prevent contamination.
- Personnel must receive proper training in hygiene and safe handling of materials.
- Sanitation controls must be followed for equipment, utensils, and processing areas.
- Equipment used in manufacturing must be properly designed, cleaned, and maintained.
- Raw materials and finished products must be stored under suitable conditions.
- Proper documentation and records must be maintained to demonstrate compliance.
- Compliance with cGMP ensures consistent quality, safety, and reliability of nutraceutical and dietary supplement products.

1.2.3 Hazard Analysis and Risk-Based Preventive Controls (HARPC)

Facilities must conduct Hazard Analysis and Risk-Based Preventive Controls (HARPC), which involves:

- Identification of known or reasonably foreseeable hazards
- Implementation of preventive controls
- Monitoring and verification procedures
- Corrective actions and record-keeping

HARPC forms the scientific foundation of FSMA's preventive approach.

- HARPC is a systematic method to identify and control food safety risks.
- Facilities must identify known or reasonably foreseeable hazards at every stage of manufacturing.
- Appropriate preventive controls are applied to reduce or eliminate identified hazards.
- Monitoring procedures are carried out to ensure controls are working effectively.
- Verification activities confirm that preventive controls are adequate and properly implemented.
- Corrective actions are taken immediately if any deviation or failure occurs.
- All activities must be properly documented and recorded.
- HARPC is mandatory under FSMA and focuses on prevention rather than detection.
- It helps reduce the risk of contamination, adulteration, and product recalls.
- HARPC is especially important for nutraceuticals and dietary supplements due to complex raw materials.

1.2.4 Foreign Supplier Verification Program (FSVP)

Under FSMA, importers are responsible for ensuring that foreign suppliers meet US food safety standards. The Foreign Supplier Verification Program (FSVP) requires verification of supplier compliance, significantly impacting nutraceutical manufacturers sourcing raw materials globally.

- FSVP is a requirement under FSMA for imported food products.
- Importers must ensure that foreign suppliers follow US food safety standards.
- Importers are responsible for the safety and quality of imported ingredients.
- Verification activities include:
  - Reviewing supplier documents
  - Conducting audits or inspections
  - Testing and evaluation of imported materials
- FSVP helps ensure that imported nutraceutical raw materials are safe and of good quality.
- Proper records and documentation must be maintained by importers.
- This program improves supply chain transparency and accountability.

- ❖ FSVP reduces the risk of adulteration, contamination, and substandard imports.

1.2.5 Mandatory Recall Authority

FSMA grants the FDA mandatory recall authority, enabling the agency to recall unsafe or adulterated food products when voluntary recall by manufacturers is inadequate, thereby enhancing consumer protection.

- ❖ FSMA gives the US FDA the power to order mandatory recalls of unsafe food products.
- ❖ This authority is used when a manufacturer fails to recall a product voluntarily.
- ❖ FDA can recall products that are adulterated, misbranded, or harmful to health.
- ❖ Mandatory recall helps quickly remove unsafe products from the market.
- ❖ It reduces the risk of foodborne illness and consumer harm.
- ❖ Manufacturers must have a recall plan in place.
- ❖ This provision strengthens regulatory enforcement and consumer protection.
- ❖ It is especially important for nutraceuticals and dietary supplements used regularly by consumers.

1.2.6 Risk-Based Inspection and Compliance

FSMA mandates risk-based inspection frequency, prioritizing facilities that manufacture high-risk products. This ensures efficient regulatory oversight and prompt corrective action against non-compliant facilities.

- ❖ FSMA gives the US FDA the power to order mandatory recalls of unsafe food products.
- ❖ This authority is used when a manufacturer fails to recall a product voluntarily.
- ❖ FDA can recall products that are adulterated, misbranded, or harmful to health.
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- ❖ This provision strengthens regulatory enforcement and consumer protection.
- ❖ It is especially important for nutraceuticals and dietary supplements used regularly by consumers.

FSMA Provision	Description	Relevance to Nutraceuticals
Preventive Controls	Identification & control of hazards	Ensures product safety
cGMP Compliance	Hygiene, sanitation, equipment control	Maintains quality consistency
HARPC	Risk-based hazard management	Prevents contamination
FSVP	Verification of imported raw materials	Ensures ingredient safety
Mandatory Recall	FDA can recall unsafe products	Protects consumers
Risk-Based Inspections	High-risk facilities inspected more frequently	Improves compliance

Table 4.2: Key FSMA Provisions Applicable to Nutraceuticals and Dietary Supplements

1.3 Significance of FSMA

The implementation of FSMA has strengthened the regulatory landscape for nutraceuticals and dietary supplements by ensuring:

- **Improved food safety systems** through preventive, science-based controls
- **Enhanced traceability and supply chain accountability**, including imported ingredients
- **Reduced risk of contamination, adulteration, and misbranding**
- **Greater transparency and documentation** across manufacturing operations
- **Stronger enforcement mechanisms**, including warning letters, recalls, and facility suspension
- **Increased consumer confidence** in food and nutraceutical products marketed in the United States

1.4 Relevance of FSMA to Pharmaceutical and Nutraceutical Professionals

For pharmacy and nutraceutical professionals, FSMA is critically important as it:

- Guides regulatory compliance in nutraceutical manufacturing and import/export operations
- Influences quality assurance and risk management strategies
- Supports global harmonization of food safety standards
- Provides a foundation for regulatory affairs and inspection readiness

The Food Safety Modernization Act represents a paradigm shift in food and nutraceutical regulation in the United States by emphasizing prevention rather than reaction. Through stringent preventive controls, supplier verification, and enhanced enforcement powers, FSMA ensures higher safety standards for nutraceuticals and dietary supplements.

TOPIC 2: DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT (DSHEA), 1994

2.1 Introduction

- The Dietary Supplement Health and Education Act (DSHEA) of 1994 is the principal legislation governing the regulation of dietary supplements in the United States. Enacted as an amendment to the Federal Food, Drug, and Cosmetic Act (FD&C Act), DSHEA established a distinct regulatory category for dietary supplements and defined the scope of FDA oversight.
- Under DSHEA, dietary supplements are regulated as a subcategory of food, rather than as pharmaceutical drugs. This regulatory classification provides dietary supplements with greater market accessibility while simultaneously placing the responsibility for product safety, quality, and labelling on manufacturers.

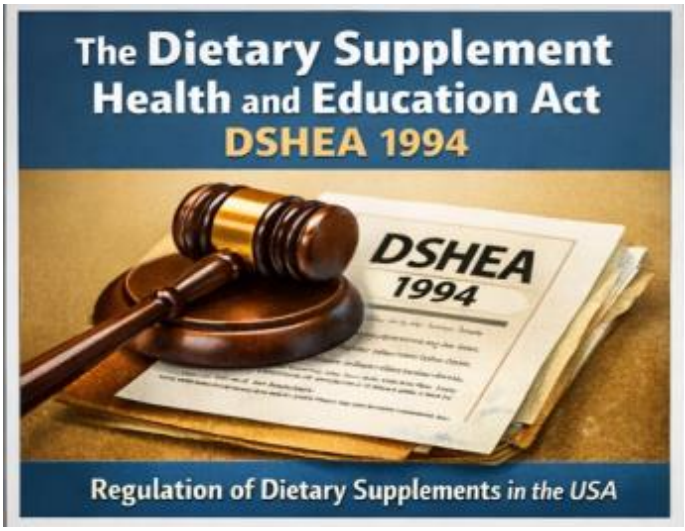

Figure 4.5: Overview of the Dietary Supplement Health and Education Act (DSHEA), 1994

Definition of Dietary Supplement (DSHEA)

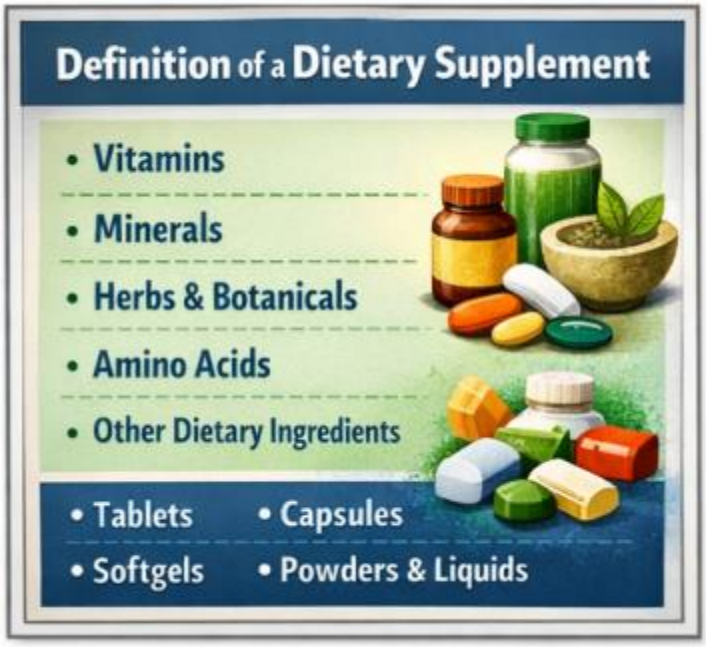

Figure 4.6: Dietary supplement ingredients and dosage forms as defined under DSHEA

According to DSHEA, a dietary supplement is a product intended to supplement the diet and contains one or more of the following dietary ingredients:

- Vitamins
- Minerals
- Herbs or botanicals
- Amino acids

- Other dietary substances used to increase total dietary intake
- Concentrates, metabolites, constituents, extracts, or combinations of the above ingredients

Dietary supplements are intended for oral administration in dosage forms such as tablets, capsules, powders, soft gels, or liquids, and must be labelled as a "Dietary Supplement."

2.2 Regulatory Responsibilities under DSHEA

The Dietary Supplement Health and Education Act (DSHEA), 1994, establishes a shared regulatory responsibility model involving manufacturers, the US Food and Drug Administration (FDA), distributors, and consumers. Unlike pharmaceutical products, dietary supplements are not subject to pre-market approval; therefore, DSHEA places the primary responsibility for safety and quality on manufacturers, while empowering FDA with post-market regulatory authority.

1. Manufacturer Responsibilities

Under DSHEA, manufacturers bear the primary legal responsibility for dietary supplement safety and compliance before the product enters the market.

Manufacturers must ensure that:

- Dietary supplements are safe for consumption under recommended conditions of use.
- Products are manufactured in compliance with Current Good Manufacturing Practices (cGMPs) specific to dietary supplements.
- All ingredients used are lawful dietary ingredients, and New Dietary Ingredients (NDIs) are notified to FDA at least 75 days prior to marketing, supported by adequate safety data.
- Labelling is truthful, accurate, and not misleading, including:
  - Proper identification as a "Dietary Supplement"
  - Complete Supplement Facts panel
  - Mandatory FDA disclaimer for structure/function claims
- Products are free from adulterants, contaminants, and prohibited substances.
- Failure to meet these responsibilities may result in regulatory actions such as warning letters, recalls, or product seizures.

2. FDA Responsibilities

The US FDA acts as the post-market regulatory authority under DSHEA.

FDA responsibilities include:

- Conducting post-market surveillance to monitor product safety.
- Reviewing New Dietary Ingredient (NDI) notifications submitted by manufacturers.
- Taking enforcement actions against adulterated or misbranded dietary supplements.
- Issuing warning letters, initiating product recalls, and conducting seizures when necessary.
- Investigating serious adverse event reports (SAERs) associated with dietary supplement use.
- Providing regulatory guidance on labelling, GMP compliance, and claims.
- Importantly, under DSHEA, the burden of proof lies with FDA to demonstrate that a dietary supplement is unsafe after it has entered the market.

3. Distributor Responsibilities

Distributors play a crucial role in ensuring the integrity of dietary supplements during the supply chain.

Distributor responsibilities include:

- Ensuring proper storage, handling, and transportation of dietary supplements.
- Avoiding the distribution of adulterated, expired, or misbranded products.
- Maintaining traceability and cooperating with FDA recall procedures when required.
- Ensuring that distributed products meet labelling and packaging requirements.

4. Consumer Responsibilities

While regulatory oversight exists, DSHEA also emphasizes consumer awareness and informed usage.

Consumers are responsible for:

- Using dietary supplements according to label directions.
- Understanding the limitations of structure/function claims.
- Reporting adverse events associated with supplement use to healthcare professionals or FDA.
- Avoiding misuse or overconsumption of dietary supplements.

➢ Stakeholder	Regulatory Responsibility
Manufacturer	Safety assurance, truthful labelling, GMP compliance
FDA	Post-market surveillance, enforcement, recalls
Distributor	Proper handling and distribution
Consumer	Responsible use based on label information

Table 4.3: Regulatory Responsibilities under DSHEA

DSHEA establishes a balanced regulatory framework that promotes consumer access to dietary supplements while maintaining public health protection. By assigning pre-market responsibility to manufacturers and post-market enforcement authority to FDA, DSHEA ensures regulatory flexibility without compromising safety. A clear understanding of these responsibilities is essential for pharmacy professionals involved in regulatory affairs, quality assurance, formulation development, and patient counselling.

Figure 4.7 Stakeholder-wise regulatory responsibilities under DSHEA

2.3 Key Features of DSHEA

The major regulatory features of DSHEA include:

- **Manufacturer Responsibility for Safety**
  Manufacturers are legally responsible for ensuring that dietary supplements are safe, properly manufactured, and accurately labelled before marketing.
- **No Pre-Market Approval Requirement**
  Unlike drugs, dietary supplements do not require FDA pre-market approval, except in the case of New Dietary Ingredients (NDIs).
- **New Dietary Ingredient (NDI) Notification**
  Dietary ingredients not marketed in the US before October 15, 1994 require NDI notification to FDA at least 75 days prior to marketing, along with safety data.
- **Post-Market FDA Enforcement**
  FDA has the authority to take action after the product enters the market if it is found to be unsafe, adulterated, or misbranded.
- **Permitted Claims with Disclaimer**
  DSHEA allows structure/function claims, provided they are truthful, not misleading, and accompanied by the mandatory disclaimer:
  "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."
- **Burden of Proof**
  Under DSHEA, the burden of proof lies with FDA to demonstrate that a dietary supplement is unsafe.

Figure 4.8: Major regulatory features of DSHEA

2.4 Significance of DSHEA in Dietary Supplement Regulation

- DSHEA has played a crucial role in shaping the dietary supplement industry in the United States by:
- Encouraging consumer access to dietary supplements
- Promoting innovation and market growth
- Clearly distinguishing dietary supplements from drugs
- Establishing a balance between regulatory oversight and industry flexibility
- Enhancing consumer awareness through labelling and disclaimers

2.5 Limitations and Challenges of DSHEA

- Limited pre-market FDA control
- Increased risk of adulteration or misbranding
- Heavy reliance on post-market surveillance
- Potential for misleading claims if not properly enforced

The Dietary Supplement Health and Education Act (DSHEA), 1994, provides the legal foundation for the regulation of dietary supplements in the United States. By classifying dietary supplements as food products, DSHEA facilitates market access while placing primary responsibility for safety and labelling on manufacturers. A thorough understanding of DSHEA is essential for pharmacy professionals involved in regulatory affairs, nutraceutical formulation, quality assurance, and product marketing.

2.6 Regulatory Framework under DSHEA

- **Dietary Supplement vs. Conventional Food:** DSHEA establishes dietary supplements as a distinct category separate from conventional foods, allowing for specialized labelling and claims.
- **Dietary Supplement Label Requirements:** Labels must include:
  - Statement of identity ("Dietary Supplement")
  - Net quantity of contents
  - Supplement Facts panel with ingredients and serving size
  - Manufacturer, packer, or distributor name and address
  - Directions for use
  - Structure/function claim disclaimer (if applicable)
- **Good Manufacturing Practices (GMPs):**
  - DSHEA mandates compliance with Current Good Manufacturing Practices (cGMPs) specific to dietary supplements to ensure quality, purity, and consistency.
  - These GMPs include proper ingredient testing, record-keeping, and facility sanitation.

2.7 Types of Claims Allowed under DSHEA

1. **Health Claims:** Describe a relationship between a dietary supplement and a reduced risk of a disease or health-related condition.
2. **Nutrient Content Claims:** Describe the level of a nutrient (e.g., "high in vitamin C").
3. **Structure/Function Claims:** Describe the effect on normal body structure or function (e.g., "supports bone health").
   - **Must include the FDA disclaimer:** *"This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."*
4. **Prohibited Claims:** Claims implying disease treatment or cure are not allowed.

Type of Claim	Description	Example
Health Claims	Link supplement to reduced disease risk	"Calcium may reduce risk of osteoporosis"
Nutrient Content Claims	Describe nutrient level	"High in Vitamin C"
Structure/Function Claims	Support normal body functions	"Supports immune health"
Prohibited Claims	Disease treatment or cure	"Treats arthritis" (Not allowed)

Table 4.4: Types of Claims Permitted under DSHEA

2.8 New Dietary Ingredient (NDI) Notification

- Any ingredient not marketed in the US before October 15, 1994 is considered a New Dietary Ingredient (NDI).
- Manufacturers must submit safety data and notification to the FDA 75 days before marketing.

- Failure to comply may result in the product being considered adulterated.

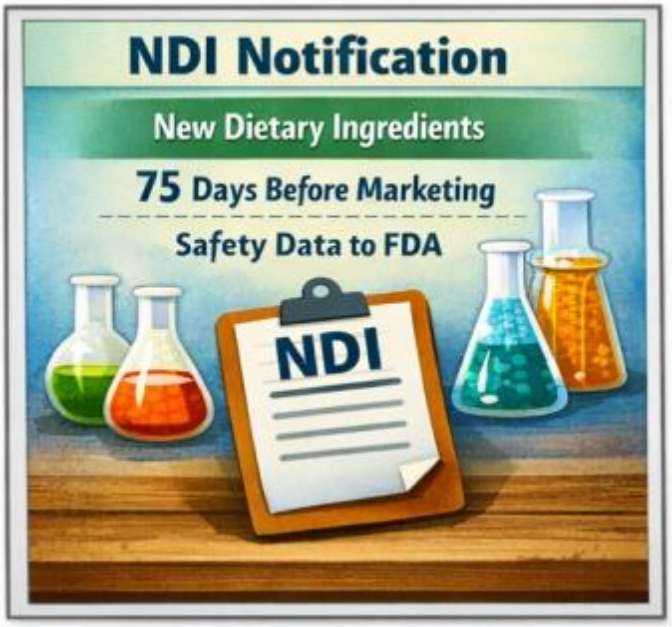

Figure 4.9: FDA New Dietary Ingredient (NDI) notification process

2.9 FDA's Role Post-Market

- FDA does not approve dietary supplements before they reach the market.
- FDA actions include:
  - Product recalls if unsafe or adulterated
  - Warning letters for misbranding or misleading claims
  - Seizure of non-compliant products
  - Investigations into adverse event reports

2.10 Impact on the Dietary Supplement Industry

- **Market Growth:** DSHEA enabled rapid growth of the nutraceutical and dietary supplement sector in the US.
- **Innovation:** Encouraged development of new formulations and herbal combinations.
- **Consumer Empowerment:** By allowing structure/function claims, consumers can make informed choices.

2.11 Criticisms and Challenges

- **Safety Concerns:** Limited pre-market oversight increases risk of adverse effects.
- **Labelling and Misbranding:** Despite disclaimers, some products may still make misleading claims.
- **Global Implications:** DSHEA influences international trade and marketing of US supplements.

- **Regulatory Ambiguity:** Differentiating between drugs and supplements can be challenging, especially for herbal or bioactive compounds.

Figure 4.10: Benefits and challenges of DSHEA in dietary supplement regulation

2.12 Key References for Further Study

- FDA, Dietary Supplement Labelling Guide
- Office of Dietary Supplements (ODS), National Institutes of Health
- Cohen PA, "The DSHEA 25 years later: Impact and regulatory challenges," Journal of Dietary Supplements, 2019
- New Dietary Ingredient (NDI) Guidance, FDA

2.13 Practical Implications for Pharmacy Professionals

- **Regulatory Affairs:** Ensuring compliance with labelling, GMP, and NDI requirements.
- **Quality Assurance:** Testing for purity, potency, and absence of contaminants.
- **Formulation Development:** Designing supplements with safe and effective doses of vitamins, minerals, herbs, and other bioactive compounds.
- **Patient Counselling:** Educating consumers about benefits, limitations, and potential interactions.

TOPIC 3: US REGULATIONS FOR MANUFACTURE AND SALE OF NUTRACEUTICALS

3.1 Regulatory Status of Nutraceuticals in the United States

The term "nutraceutical" does not have a formal legal definition under United States law. The US FDA does not recognize nutraceuticals as a separate regulatory category. Instead, products marketed as nutraceuticals are regulated under existing FDA frameworks, depending on their composition, intended use, and claims.

Figure 4.11: Regulatory Categories

Regulatory Category	Legal Status	Governing Law / Regulation	Key Characteristics	Examples
Conventional Foods	Legally defined	FD&C Act	Consumed as part of normal diet; no disease claims	Fortified cereals, probiotic drinks
Dietary Supplements	Legally defined	DSHEA, 1994	Intended to supplement diet; tablets, capsules, powders	Vitamins, minerals, herbal supplements
Functional Foods	Not legally defined	Regulated as foods	Provide health benefits beyond basic nutrition	Omega-3 enriched foods
Medical	Legally	FD&C Act	Used under medical	PKU formulas

Foods	defined	(Section 5(b))	supervision for disease management	

Table 4.5: Regulatory Classification of Nutraceutical Products in the United States

Nutraceutical products may be regulated as:

- Foods - conventional foods or beverages with health benefits
- Dietary Supplements - regulated under DSHEA, 1994
- Functional Foods - foods providing physiological benefits beyond basic nutrition (not a legally defined category)
- Medical Foods (in limited cases) - intended for dietary management of specific diseases under medical supervision

Regulatory classification depends on product claims, labelling, and route of administration, rather than the term "nutraceutical" itself.

3.2 Manufacturing Regulations for Nutraceuticals

Manufacturers of nutraceutical products must comply with FDA manufacturing and safety regulations, primarily applicable to food and dietary supplement categories.

Figure 4.12: Manufacturing Requirements

Key Manufacturing Requirements

- **Current Good Manufacturing Practices (cGMP):**
  - **21 CFR Part 110** - (Earlier Food cGMP – now replaced)
  - **21 CFR Part 117** - GMP, Hazard Analysis, and Risk-Based Preventive Controls for Human Food
- **Food Safety Modernization Act (FSMA):**
  - Mandatory hazard analysis
  - Implementation of preventive controls
  - Sanitation and allergen control programs
- **Facility Registration:**
  - All manufacturing, processing, packing, or holding facilities must be registered with FDA under the Bioterrorism Act.

- **Quality & Safety Controls:**
  - Raw material testing
  - Process validation
  - Sanitation and hygiene controls
  - Record keeping and documentation

3.3 Regulations for Sale and Distribution of Nutraceuticals

Nutraceutical products can be marketed and sold through:

- Retail stores
- Online platforms
- Pharmacies and healthcare outlets
- Key Sale and Marketing Requirements
- Products must not claim to diagnose, treat, cure, or prevent diseases, as such claims would classify the product as a drug.
- Only nutritional, structure/function, or general wellness claims are permitted.
- Claims must be truthful, substantiated, and non-misleading.
- Labelling must comply with:
  - FDA labelling regulations
  - Ingredient declaration
  - Nutrition Facts or Supplement Facts (as applicable)
- Advertising is regulated by both:
  - FDA (labelling)
  - Federal Trade Commission (FTC) (advertising claims)

Authority	Regulatory Scope
FDA	Product safety, labelling, compliance
FTC	Advertising and promotional claims
CBP	Import compliance
State authorities	Retail compliance

Table 4.6: Role of Regulatory Authorities in Marketing and Advertising

Figure 4.13: Sales & Labelling Regulations

Regulation	CFR Reference	Applicability
Food cGMP (old)	21 CFR Part 110	Replaced
Food cGMP (current)	21 CFR Part 117	Foods & functional foods
Dietary Supplement cGMP	21 CFR Part 111	Dietary supplements
FSMA	Public Law 111-353	Preventive food safety
Bioterrorism Act	Section 305	Facility registration

Table 4.7: Applicable FDA Manufacturing Regulations for Nutraceuticals

3.4 Regulatory Enforcement and Compliance

The FDA actively monitors nutraceutical products through post-market surveillance, inspections, and complaint-based investigations.

Enforcement Actions Available to FDA

- Warning Letters for regulatory violations
- Product Seizure for adulterated or misbranded products
- Mandatory or Voluntary Recalls
- Import Alerts to restrict entry of non-compliant products
- Facility Suspension or Registration Cancellation

Repeated non-compliance may lead to civil or criminal penalties.

3.5 Importance of Compliance for Manufacturers

Compliance with US nutraceutical regulations ensures:

- Consumer safety and public health protection
- Legal market access in the United States
- Product quality, consistency, and credibility
- Prevention of regulatory actions and product recalls
- Global acceptance of nutraceutical products

Figure 4.14: Importance of compliance

Although nutraceuticals lack a distinct legal identity in the United States, they are strictly regulated under existing food and dietary supplement laws. Compliance with FDA cGMPs, FSMA requirements, labelling regulations, and post-market surveillance obligations is essential for the lawful manufacture and sale of nutraceutical products. Understanding these regulations is crucial for pharmacy professionals involved in nutraceutical development, quality assurance, regulatory affairs, and international marketing.

TOPIC 4: US REGULATIONS FOR MANUFACTURE AND SALE OF DIETARY SUPPLEMENTS

Dietary supplements in the United States are regulated by the US Food and Drug Administration (US FDA) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as amended by the Dietary Supplement Health and Education Act (DSHEA), 1994. Unlike pharmaceutical products, dietary supplements are regulated as a category of food; however, they are subject to stringent manufacturing, quality, labelling, and post-marketing controls to ensure consumer safety.

4.1 Manufacturing Regulations

Manufacturers of dietary supplements must comply with Current Good Manufacturing Practices (cGMP) as specified under 21 CFR Part 111 – Current Good Manufacturing Practice in Manufacturing, Packaging, Labelling, or Holding Operations for Dietary Supplements.

Regulation / Act	Year	Regulatory Role
Federal Food, Drug, and Cosmetic Act (FD&C Act)	1938	Provides legal authority for FDA oversight
Dietary Supplement Health and Education Act (DSHEA)	1994	Defines dietary supplements as food category
21 CFR Part 111 (cGMP)	2007	Manufacturing, packaging, labelling standards
Dietary Supplement and Nonprescription Drug Consumer Protection Act	2006	Mandatory adverse event reporting

Table 4.8: Key US Laws Governing Dietary Supplements

Key Manufacturing Requirements

1. **Facility and Equipment Standards**
   - Manufacturing facilities must be designed and maintained to prevent contamination.
   - Equipment must be properly calibrated, cleaned, and maintained.
2. **Process Control and Documentation**
   - Proper design, monitoring, and control of manufacturing processes must be established.
   - Written Standard Operating Procedures (SOPs) are mandatory.
   - Batch production records must be maintained for traceability.
3. **Raw Material and Finished Product Testing**
   - Testing is required to ensure identity, purity, strength, composition, and limits on contaminants.
   - Manufacturers may use in-house testing or qualified third-party laboratories.
   - Specifications must be established for each component and finished product.
4. **Quality Control Unit (QCU)**
   - A dedicated Quality Control Unit must be established.
   - The QCU is responsible for approving or rejecting raw materials, in-process materials, packaging materials, and finished products.
   - Investigation of deviations, complaints, and product failures is mandatory.
5. **Personnel and Training**
   - Personnel must be qualified and trained in hygiene and manufacturing practices.
   - Training records must be documented.

Compliance with 21 CFR Part 111 ensures that dietary supplements are consistently produced and controlled according to quality standards appropriate for their intended use

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4.2 New Dietary Ingredient (NDI) Notification

A New Dietary Ingredient (NDI) is defined as a dietary ingredient that was not marketed in the United States before October 15, 1994.

NDI Notification Requirement

- Manufacturers or distributors must submit an NDI notification to the US FDA at least 75 days prior to marketing the dietary supplement.
- The notification must include:
  - Identity and description of the ingredient
  - Conditions of use and recommended dosage
  - History of use or other evidence of safety
  - Toxicological and scientific data supporting safety

Regulatory Significance

- NDI notification is not an approval process, but a safety review mechanism.
- Failure to submit NDI notification may result in the product being considered adulterated under the FD&C Act.
- Ingredients marketed before October 15, 1994, are considered "grandfathered" and exempt from NDI notification.

4.3 Sale and Distribution of Dietary Supplements

4.3.1 Sale Authorization

- Dietary supplements may be sold without a prescription.
- Products may be distributed through:
  - Retail pharmacies
  - Health food stores
  - Supermarkets
  - Online and e-commerce platforms

4.3.2 Online and E-Commerce Sales

- Online sales must comply with:
  - US FDA regulations (product safety, labelling, manufacturing)
  - Federal Trade Commission (FTC) regulations for truthful advertising
- All health-related claims must be truthful, non-misleading, and scientifically substantiated.

4.3.3 Post-Market Surveillance

Dietary supplements are subject to **post-market regulatory oversight**, including:

- Adverse Event Reporting (AER) under the Dietary Supplement and Nonprescription Drug Consumer Protection Act
- Mandatory reporting of serious adverse events by manufacturers and distributors
- FDA inspections and product sampling
- Issuance of warning letters, recalls, or import alerts in case of violations

4.3.4 Prohibited Practices

- Disease cure or treatment claims
- Misbranding or false labelling
- Distribution of adulterated or unsafe products

The manufacture and sale of dietary supplements in the United States are governed by a robust regulatory framework that balances market accessibility with consumer safety. Compliance with 21 CFR Part 111, proper NDI notification, and adherence to labelling, advertising, and post-market surveillance requirements are essential for lawful marketing. These regulations place primary responsibility on manufacturers to ensure product quality, safety, and regulatory compliance.

TOPIC 5: LABELLING REQUIREMENTS AND LABEL CLAIMS FOR DIETARY SUPPLEMENTS (USA)

Figure 4. 15: Labelling Requirement and Label Claim for Dietary Supplements (Usa)

Proper labelling of dietary supplements is a critical regulatory requirement in the United States to ensure consumer safety, transparency, and informed decision-making. The labelling requirements are governed by the Dietary Supplement Health and Education Act (DSHEA), 1994, and enforced by the United States Food and Drug Administration (US FDA) under 21 CFR Part 101.

5.1 Mandatory Label Components

Dietary supplement labels must include the following mandatory components:

1. Statement of Identity

- The product must be clearly identified as a "Dietary Supplement" on the principal display panel.
- The statement of identity may include the common or usual name of the supplement (e.g., "Calcium Dietary Supplement").

2. Net Quantity of Contents

- The label must declare the net quantity of contents (e.g., number of tablets, capsules, or volume for liquids).
- It must be expressed in both metric and US customary units.

3. Supplement Facts Panel

- The Supplement Facts panel is mandatory and must be presented in a standardized format.
- It includes:
    - Serving size
    - Servings per container
    - Amount of each dietary ingredient per serving
    - Percentage of Daily Value (%DV), where established
- Ingredients without established Daily Values must be clearly indicated.

4. Ingredient List

- All dietary ingredients must be listed in descending order of predominance by weight.
- Botanical ingredients must include the plant part used (e.g., root, leaf).
- Excipients, fillers, and additives must also be declared.

5. Name and Address of Manufacturer, Packer, or Distributor

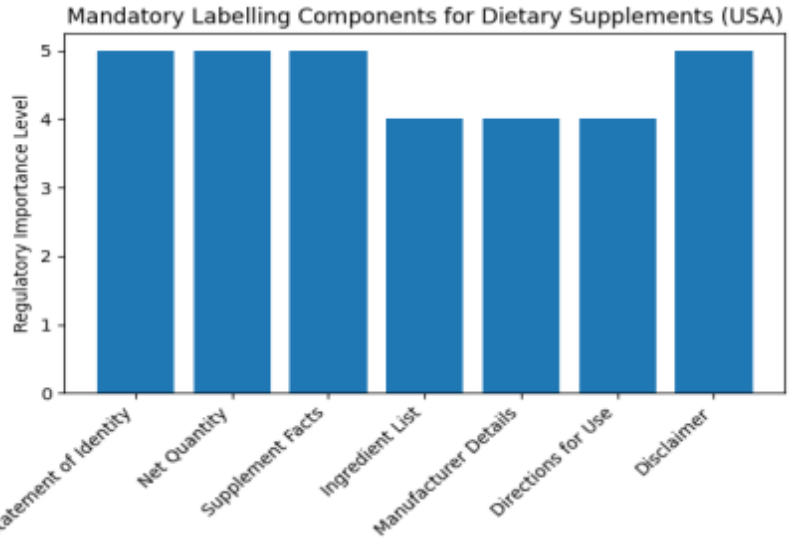
- The label must clearly state the name and place of business of the responsible entity.
- If the manufacturer is not the distributor, qualifying phrases such as "Manufactured for" or "Distributed by" must be used.

6. Directions for Use

- Clear instructions regarding recommended dosage, method of administration, and frequency of use must be provided.
- Warning statements (e.g., use by pregnant women, children, or individuals with medical conditions) should be included where applicable.

7. Mandatory Statements

- Allergen declarations (if applicable) as per FDA guidelines.
- Storage conditions when necessary.
- Lot or batch number for traceability.



Graph 4.1:Mandatory Labelling Components for Dietary Supplements (USA)

5.2 Types of Permitted Claims

Dietary supplement labels may carry specific types of claims, provided they comply with FDA regulations and are not misleading.

5.2.1 Nutrient Content Claims

- These claims describe the relative amount of a nutrient present in the product.
- Examples include:
  - "High in calcium"
  - "Low fat"
- Such claims must conform to FDA-defined criteria for nutrient levels.

5.2.2 Structure/Function Claims

- These claims describe the role of a nutrient or ingredient in supporting normal physiological functions of the body.
- Examples:
  - "Calcium supports bone health"
  - "Fiber helps maintain digestive health"
- These claims must not mention specific diseases.
- Manufacturers must notify the FDA within 30 days of marketing a product bearing a structure/function claim.

5.2.3 Health Claims

- Health claims describe a relationship between a dietary substance and reduced risk of a disease or health-related condition.
- Such claims must be:
  - Authorized by the FDA, or
  - Supported by significant scientific agreement
- Unauthorized or unsubstantiated health claims are strictly prohibited.

5.3 Disclaimer Requirement

All dietary supplements bearing structure/function claims must include the following mandatory disclaimer prominently on the label:

"This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

Significance of the Disclaimer

Clearly differentiates dietary supplements from pharmaceutical drugs.

- Prevents consumers from assuming therapeutic or medicinal benefits.
- Protects public health by discouraging misuse.
- Legally safeguards manufacturers when claims are properly substantiated.

5.4 Regulatory Importance of Labelling

- Ensures consumer protection and informed choice
- Prevents misbranding and adulteration
- Facilitates regulatory inspections and compliance
- Supports transparency and ethical marketing practices
- Enhances credibility of dietary supplement products

Labelling and claim regulations for dietary supplements in the United States are designed to balance consumer access to health-promoting products with robust safeguards against misleading information. Compliance with mandatory labelling components, permissible claim categories, and disclaimer requirements is essential for lawful marketing.

TOPIC 6: RECOMMENDED DIETARY ALLOWANCES (RDA) IN THE UNITED STATES

The Recommended Dietary Allowance (RDA) represents the average daily intake level of an essential nutrient that is sufficient to meet the nutritional requirements of nearly all (97–98%) healthy individuals within a specific life-stage and gender group. RDAs are developed using extensive scientific evidence derived from clinical, epidemiological, and metabolic studies.

Figure 4.16: Part of Dietary Reference Intakes

RDAs serve as a cornerstone of nutritional science and provide the scientific basis for dietary planning, food fortification, dietary supplement formulation, and public health nutrition policies in the United States

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6.1 Authorities Responsible for Establishing RDA

In the United States, RDAs are established by the:

- Institute of Medicine (IOM)

(Now reorganized as the National Academies of Sciences, Engineering, and Medicine – NASEM)

- NASEM develops RDAs as part of a broader framework known as Dietary Reference Intakes (DRIs), which include:
  - Estimated Average Requirement (EAR)
  - Recommended Dietary Allowance (RDA)
  - Adequate Intake (AI)
  - Tolerable Upper Intake Level (UL)

These values are periodically reviewed and updated based on emerging scientific evidence.

6.2 Role of RDA in Dietary Supplement Regulation

RDAs play a critical regulatory and scientific role in the formulation, labeling, and evaluation of dietary supplements in the United States:

- Provide reference standards for determining appropriate nutrient levels in dietary supplement formulations.
- Support the development of safe and effective supplement dosages.
- Assist in the establishment of Daily Values (DV) used on dietary supplement and food labels.
- Help prevent nutrient deficiencies in populations with inadequate dietary intake.
- Reduce the risk of nutrient toxicity and overconsumption, particularly with long-term supplement use.
- Facilitate consumer education by offering science-based benchmarks for daily nutrient needs.
- Aid regulatory authorities during post-market surveillance and safety assessment of dietary supplements.

6.3 Relationship Between RDA and Upper Intake Levels (UL)

The relationship between RDA and UL is fundamental to dietary supplement safety:

- RDA defines the adequate daily intake necessary to maintain optimal health.
- UL (Tolerable Upper Intake Level) represents the maximum daily intake unlikely to cause adverse health effects in the general population.
- Intakes above the UL increase the risk of toxicity, especially for fat-soluble vitamins and minerals.
- Dietary supplements are formulated to meet or moderately exceed the RDA but should not exceed the UL unless supported by clinical evidence and medical supervision.

Understanding this balance is essential to ensure both nutritional adequacy and safety.

6.4 Importance of RDA in Nutraceutical and Supplement Development

Serves as a scientific benchmark during product development.

- Assists in risk–benefit assessment of nutrient levels.
- Supports compliance with FDA labelling regulations.
- Enhances global harmonization, as RDA concepts align with international nutritional guidelines.

- Improves consumer trust through evidence-based formulation.

Parameter	RDA	UL
Definition	Adequate daily intake for health	Maximum safe daily intake
Purpose	Prevent deficiency	Prevent toxicity
Safety Margin	Designed for adequacy	Upper safety boundary
Risk Above Limit	Deficiency below RDA	Toxicity above UL
Importance in Supplements	Guides dose selection	Prevents overconsumption

Table 4.9: Relationship Between RDA and Upper Intake Level (UL)

The United States has a well-structured and science-driven regulatory framework governing nutraceuticals and dietary supplements, primarily enforced by the US Food and Drug Administration (FDA) through legislation such as the Food Safety Modernization Act (FSMA), the Dietary Supplement Health and Education Act (DSHEA), and current Good Manufacturing Practice (cGMP) regulations.

While dietary supplements benefit from regulatory flexibility compared to pharmaceutical products, manufacturers bear the primary responsibility for ensuring product safety, quality, and truthful labelling. A thorough understanding of RDA, UL, and related Dietary Reference Intake concepts is essential for pharmacy professionals engaged in formulation development, regulatory affairs, quality assurance, and international nutraceutical trade.

UNIT – 5th

TOPIC-1: EUROPEAN FOOD SAFETY AUTHORITY (EFSA): ORGANISATION AND FUNCTIONS

1.1 Introduction to European Food Safety Authority (EFSA)

- The European Food Safety Authority (EFSA) is the central scientific authority of the European Union responsible for providing independent scientific advice and technical support in matters related to food and feed safety.
- EFSA plays a crucial role in protecting human and animal health and ensuring consumer confidence in the European food system. It functions as the cornerstone of the EU's risk assessment framework, covering the entire food chain "from farm to fork."
- EFSA operates independently of political, commercial, and industrial interests and bases its opinions strictly on scientific evidence. For pharmacy professionals, EFSA is particularly important due to its role in the evaluation of food additives, nutraceuticals, novel foods, excipients, contaminants, and health claims.

1.2 Establishment and Legal Framework of EFSA

EFSA was established in 2002 under Regulation (EC) No. 178/2002, known as the General Food Law Regulation. This regulation laid down the general principles of EU food law and introduced a structured risk analysis approach comprising risk assessment, risk management, and risk communication.

The authority was created following several major food safety incidents in Europe

Several major food safety incidents in Europe include:

1. **Bovine Spongiform Encephalopathy (BSE)** or *mad cow disease* crisis (1980s - 1990s), which raised serious concerns about meat safety
2. **Dioxin contamination in animal feed** in Belgium (1999), leading to widespread food recalls
3. **Salmonella outbreaks** linked to poultry and eggs across multiple EU countries
4. **E. coli O104:H4 outbreak** in Germany (2011), associated with contaminated sprouts
5. **Listeria monocytogenes outbreaks** in ready-to-eat foods such as dairy and processed meats
6. **Melamine contamination** detected in imported food products affecting European markets
7. **Horse meat adulteration scandal** (2013), involving substitution of beef with horse meat

These incidents which highlighted the need for a transparent and independent scientific body. EFSA is headquartered in Parma, Italy, and functions within the EU institutional framework while maintaining scientific autonomy.

1.3 Mission, Objectives, and Scope of EFSA

The mission of EFSA is to provide high-quality, independent scientific advice to support EU policies and legislation related to food and feed safety.

The major objectives include:

- Protection of human and animal health
- Scientific risk assessment of food-related hazards
- Harmonization of food safety standards across EU member states

- Identification of emerging and future risks
- Transparent communication of scientific findings

The scope of EFSA extends to food, feed, nutrition, animal health and welfare, plant health, pesticides, genetically modified organisms, and environmental risks related to the food chain.

1.4 Organisational Structure of EFSA

EFSA has a multi-tier organisational structure designed to ensure scientific excellence, transparency, and operational efficiency.

1.4.1 Management Board

- The Management Board provides strategic direction and ensures that EFSA fulfills its mandate effectively.
- It includes representatives from EU member states, the European Commission, the European Parliament, and civil society organizations.
- The Board does not interfere in scientific opinions but oversees administrative and financial matters.

1.4.2 Executive Director

The Executive Director is responsible for EFSA's daily operations, implementation of work programs, and external representation. The Director ensures that EFSA's activities comply with EU regulations and scientific standards.

1.4.3 Advisory Forum

The Advisory Forum comprises representatives of national food safety authorities from EU member states. It facilitates scientific cooperation, data exchange, and harmonization of risk assessment methodologies across Europe.

1.5 Scientific Committee and Scientific Panels of EFSA

EFSA's scientific work is conducted through a Scientific Committee and several specialized Scientific Panels composed of independent experts.

The Scientific Committee addresses cross-sectoral and emerging issues, ensures consistency in risk assessment methodologies, and provides guidance on scientific principles.

The major Scientific Panels include:

Scientific Panel	Area of Assessment
FAF	**Food additives, flavourings, enzymes**
NDA	**Nutrition, novel foods, food allergens**
GMO	**Genetically modified organisms**
CONTAM	**Contaminants in the food chain**
BIOHAZ	**Biological hazards**
PPR	**Plant protection products and residues**
ANS*	**Food additives and nutrient sources (*earlier classification*)**

Table 5.1: Major Scientific Panels

These panels are highly relevant to pharmacy and regulatory sciences, particularly in toxicology and safety evaluation.

1.6 Functions of EFSA

EFSA performs several core functions within the EU food safety system. Its primary function is risk assessment, involving scientific evaluation of biological, chemical, and physical hazards in food and feed. EFSA also provides scientific advice to the European Commission, European Parliament, and EU member states.

Additional functions include:

- Data collection and analysis on food consumption and exposure
- Assessment of applications for authorization of novel foods, food additives, enzymes, and health claims
- Identification of emerging risks and early warning support
- Development of scientific guidance documents

EFSA does not perform enforcement or regulatory approval; these responsibilities lie with risk managers, mainly the European Commission and national authorities.

1.7 EFSA and Risk Analysis Framework

EFSA operates strictly within the risk analysis framework, which consists of:

- **Risk Assessment** - conducted by EFSA
- **Risk Management** - undertaken by the European Commission and member states
- **Risk Communication -** shared responsibility

This separation ensures objectivity and prevents conflicts of interest, strengthening the credibility of EU food safety decisions.

1.8 Transparency, Risk Communication, and Public Engagement

- Transparency is a fundamental principle of EFSA. Scientific opinions, methodologies, meeting minutes, and declarations of interest are publicly available.
- EFSA conducts public consultations and stakeholder engagement to enhance scientific robustness and public trust.
- Risk communication aims to deliver clear, accurate, and timely information to consumers, professionals, and policymakers, particularly during food safety emergencies.

1.9 Funding, Independence, and Scientific Integrity of EFSA

EFSA is funded primarily by the general budget of the European Union. Strict rules are in place to ensure independence, including:

- Mandatory declarations of interest
- Conflict-of-interest management policies
- Independent peer review of scientific opinions

These measures ensure that EFSA's assessments remain unbiased and scientifically sound.

1.10 Relevance of EFSA to Pharmacy and Pharmaceutical Sciences

EFSA plays a significant role in pharmaceutical and allied sciences, especially in:

- Evaluation of nutraceuticals and dietary supplements
- Safety assessment of excipients and food additives
- Toxicological risk assessment
- Novel food authorization
- Regulatory affairs and dossier preparation

1.11 Challenges and Future Role of EFSA

EFSA faces emerging challenges such as novel food technologies, nanomaterials, climate change impacts on food safety, and increasing consumer demand for transparency. In the future, EFSA is expected to play a greater role in predictive risk assessment, digital data integration, and global regulatory harmonization.

Note:

The European Food Safety Authority is a scientifically independent and structurally robust organization that forms the backbone of the EU food safety system. Through its expert panels, transparent processes, and evidence-based risk assessments, EFSA ensures high standards of consumer protection and harmonization across Europe. Its role is highly relevant to pharmacy education and practice, particularly in regulatory and safety sciences.

TOPIC-2: EU DIRECTIVES AND REGULATIONS FOR MANUFACTURE AND SALE OF NUTRACEUTICALS

2.1 Introduction to Nutraceutical Regulation in the European Union

- Nutraceuticals occupy an important position at the interface between food and medicine. In the European Union (EU), nutraceuticals are not regulated as medicines but fall primarily under food law, particularly as dietary supplements, fortified foods, or novel foods, depending on their composition and intended use.
- The EU regulatory framework aims to ensure a high level of consumer protection while facilitating free movement of goods within the internal market.
- Unlike some countries that have a separate legal category for nutraceuticals, the EU regulates these products through a harmonized set of directives and regulations applicable to foods, food supplements, and related products.

2.2 Legal Classification of Nutraceuticals in the EU

In the EU, nutraceuticals are regulated under the following classifications:

- Food supplements (vitamins, minerals, botanicals, bioactive substances)

- Fortified or functional foods (foods with added nutrients that help improve health like Milk fortified with vitamin D)
- Novel foods (foods or ingredients without a history of significant consumption in the EU before 15 May 1997)

The regulatory pathway for manufacture and sale depends on the classification, composition, dosage form, and claims made for the product.

2.3 General Food Law Regulation (EC) No. 178/2002

Regulation (EC) No. 178/2002 forms the foundation of EU food law and applies to all nutraceuticals marketed as foods or food supplements. It establishes:

- General principles of food safety
- Risk analysis framework
- Responsibilities of food business operators
- Traceability requirements

According to this regulation, nutraceuticals placed on the EU market must be safe for consumption and supported by scientific evidence. It also established the European Food Safety Authority (EFSA) as the scientific risk assessment body.

2.4 Directive 2002/46/EC on Food Supplements

Directive 2002/46/EC is the primary legislation governing manufacture and sale of food supplements in the EU. This directive harmonizes rules related to:

- Permitted vitamins and minerals
- Approved chemical forms of nutrients
- Maximum and minimum levels of nutrients
- Labelling requirements

Manufacturers must ensure that nutraceuticals marketed as food supplements comply with this directive and are produced using safe and bioavailable forms of nutrients.

2.5 Regulation (EU) 2015/2283 on Novel Foods

Many modern nutraceutical ingredients such as probiotics, plant extracts, algae-derived compounds, and bioactive peptides fall under the Novel Food Regulation (EU) 2015/2283.

This regulation applies to foods and ingredients that:

- Were not consumed significantly in the EU before 15 May 1997
- Are newly developed or produced using novel technologies
- Before marketing, novel nutraceutical ingredients require pre-market authorization, including:
- Safety assessment by EFSA
- Toxicological and nutritional evaluation
- Authorization by the European Commission

2.6 Regulation (EC) No. 1924/2006 on Nutrition and Health Claims

Regulation (EC) No. 1924/2006 governs nutrition and health claims made on nutraceutical products. It ensures that claims are:

- Scientifically substantiated
- Clear and not misleading
- Approved by EFSA

Types of claims include:

- Nutrition claims (e.g., "source of vitamin C")
- Health claims (e.g., "contributes to normal immune function")
- Reduction of disease risk claims

Unauthorized or medicinal claims are strictly prohibited.

2.7 Regulation (EU) No. 1169/2011 on Food Information to Consumers

This regulation specifies labelling requirements for nutraceuticals sold in the EU. Mandatory information includes:

- Name of the product
- List of ingredients
- Allergen declaration
- Nutritional information
- Recommended daily intake
- Warnings and storage conditions

Clear labelling is essential to ensure safe use and informed consumer choice.

2.8 Manufacture of Nutraceuticals in the European Union

2.8.1 Manufacture of Nutraceuticals in the EU

The manufacture of nutraceuticals in the European Union must comply with EU food law and food hygiene regulations. All nutraceutical products must be produced in registered or approved food establishments and follow Good Manufacturing Practices (GMP) and Hazard Analysis and Critical Control Point (HACCP) principles. Manufacturers are responsible for ensuring product safety, quality, traceability of raw materials, and compliance with compositional standards laid down in EU directives and regulations. Ingredients used must be permitted under EU law, and novel ingredients require prior authorization before manufacture.

2.8.2 Good Manufacturing Practices (GMP) for Nutraceuticals

Manufacture of nutraceuticals in the EU must comply with food GMP principles, including:

- Regulation (EC) No. 852/2004 on food hygiene
- Hazard Analysis and Critical Control Points (HACCP)

Manufacturers are responsible for ensuring product quality, safety, traceability, and contamination control throughout the production process.

Good Manufacturing Practices (GMP) Principles for Nutraceuticals

Good Manufacturing Practices (GMP) are a set of guidelines that ensure nutraceutical products are consistently manufactured and controlled to meet quality and safety standards.

1. Quality Management System

A documented quality management system must be in place to ensure that nutraceuticals are produced according to approved specifications and regulatory requirements.

2. Personnel and Training

Manufacturing personnel must be adequately qualified, trained in GMP, hygiene, and safety procedures, and aware of their roles and responsibilities.

3. Premises and Equipment

Manufacturing facilities must be suitably designed, maintained, and cleaned to prevent contamination, mix-ups, and cross-contamination. Equipment should be properly qualified and calibrated.

4. Raw Material Control

All raw materials, including botanicals, vitamins, and excipients, must be sourced from approved suppliers, tested for quality and safety, and properly stored.

5. Production and Process Control

Manufacturing operations must follow validated procedures to ensure batch-to-batch consistency. Critical process parameters should be monitored and documented.

6. Sanitation and Hygiene

Adequate sanitation programs must be implemented to maintain cleanliness of facilities, equipment, and personnel to prevent microbial contamination.

7. Quality Control and Testing

Finished nutraceutical products must be tested for identity, purity, strength, and safety before release. Quality control laboratories should follow standardized testing procedures.

8. Packaging and Labelling Control

Packaging materials must protect the product from contamination and degradation. Labelling must be accurate, approved, and compliant with regulatory requirements.

9. Documentation and Record Keeping

All manufacturing, testing, and distribution activities must be documented to ensure traceability and accountability.

10. Storage and Distribution

Products must be stored under appropriate conditions and distributed in a manner that maintains quality and prevents damage or contamination.

11. Complaints, Recalls, and Corrective Actions

A system must be in place for handling consumer complaints, product recalls, and implementing corrective and preventive actions.

2.8.3 Hazard Analysis and Critical Control Point (HACCP)

Hazard Analysis and Critical Control Point (HACCP) is a systematic, science-based preventive approach used to identify, evaluate, and control hazards that may affect the safety of nutraceutical products during manufacturing, storage, and distribution.

Rather than relying on end-product testing, HACCP focuses on preventing hazards at critical stages of production.

In nutraceutical manufacturing, HACCP is applied to control biological, chemical, and physical hazards that could compromise product safety.

Importance of HACCP in Nutraceutical Manufacturing

HACCP plays a crucial role in ensuring nutraceutical safety by:

- Preventing contamination during production

- Ensuring compliance with EU food safety regulations
- Enhancing consumer confidence
- Reducing product recalls and safety failures

Principles of HACCP

HACCP is based on seven internationally recognized principles, which form the foundation of food and nutraceutical safety management systems.

Principle 1: Conduct Hazard Analysis

Identify potential biological (microorganisms), chemical (toxins, pesticides), and physical (foreign matter) hazards at each stage of nutraceutical production and assess their likelihood and severity.

Principle 2: Determine Critical Control Points (CCPs)

Identify points in the manufacturing process where control is essential to prevent, eliminate, or reduce identified hazards to acceptable levels.

Principle 3: Establish Critical Limits

Set maximum or minimum values (such as temperature, time, moisture level) that must be met at each CCP to ensure hazard control.

Principle 4: Establish Monitoring Procedures

Implement procedures to regularly monitor CCPs to ensure they remain within critical limits.

Principle 5: Establish Corrective Actions

Define actions to be taken when monitoring shows that a CCP is not under control, ensuring safety is restored.

Principle 6: Establish Verification Procedures

Apply methods such as audits, testing, and review of records to confirm that the HACCP system is functioning effectively.

Principle 7: Establish Documentation and Record Keeping

Maintain detailed records of hazard analysis, CCP monitoring, corrective actions, and verification activities to ensure traceability and regulatory compliance.

2.9 Manufacture and Sale of Nutraceuticals in the European Union

2.9.1 Sale and Marketing of Nutraceuticals in the EU

The sale of nutraceuticals in the EU is permitted only after compliance with labelling, safety, and claims regulations. Products must be correctly classified as food supplements or functional foods and must not make medicinal claims. Labels must provide clear consumer information, including dosage instructions and warnings. For most food supplements, prior market authorization is not required; however, manufacturers must notify national authorities before sale. Nutraceuticals lawfully marketed in one EU member state may be sold across other member states under the principle of free movement of goods, subject to safety controls.

2.9.2 Market Authorization and Notification Procedures

For most food supplements, pre-market authorization is not required, but manufacturers must:

- Notify competent authorities in the member state where the product is first marketed
- Submit label samples and product details

For novel nutraceuticals, centralized authorization is mandatory following EFSA evaluation.

2.10 Role of EFSA in Nutraceutical Regulation

EFSA plays a critical role by:

- Conducting safety assessments of novel ingredients
- Evaluating nutrition and health claims
- Advising the European Commission on risk assessment

EFSA does not grant approvals but provides scientific opinions that form the basis of regulatory decisions.

2.11 Free Movement of Nutraceuticals within the EU

Once lawfully marketed in one EU member state, nutraceuticals can generally circulate freely across the EU under the principle of mutual recognition, unless specific safety concerns exist.

This principle supports harmonization while allowing national authorities to impose restrictions if public health risks are identified.

2.11.1 Principles Governing Free Movement of Nutraceuticals within the EU

The free movement of nutraceuticals within the European Union is based on the following key principles:

1. Mutual Recognition Principle

A nutraceutical lawfully manufactured and marketed in one EU member state can be sold in other member states without additional authorization, even if national rules differ, provided the product is safe.

2. Harmonization Principle

EU-wide directives and regulations harmonize safety, labeling, and quality requirements to ensure uniform standards across all member states and facilitate cross-border trade.

3. Non-Discrimination Principle

Member states must treat nutraceutical products from other EU countries in the same manner as domestically produced products, preventing unjustified trade barriers.

4. Proportionality Principle

Any national restriction imposed on the sale of nutraceuticals must be appropriate, necessary, and proportionate to the identified public health risk.

5. Precautionary Principle

When scientific uncertainty exists regarding potential health risks, member states may take temporary protective measures to restrict sale until further evidence is available.

6. Consumer Protection Principle

The free movement of nutraceuticals must not compromise consumer health, safety, or access to accurate product information.

7. Transparency Principle

Decisions to restrict or withdraw nutraceuticals from the market must be transparent, scientifically justified, and communicated clearly to stakeholders.

2.12 Enforcement and Market Surveillance

EU member states are responsible for enforcement through:

- Market surveillance

- Product recalls
- Border controls

Non-compliance can result in withdrawal of products, financial penalties, and legal action.

2.13 Challenges in EU Nutraceutical Regulation

Key challenges include:

- Diverse national interpretations of EU directives
- Classification disputes between food and medicine
- Rapid innovation in nutraceutical ingredients
- Scientific substantiation of health claims

The EU regulatory framework for nutraceuticals is comprehensive, science-based, and consumer-focused. Through a combination of directives and regulations governing safety, manufacturing, labelling, and claims, the EU ensures that nutraceuticals placed on the market are safe, effective, and of high quality. Knowledge of these regulations is crucial for pharmacy professionals engaged in nutraceutical research, development, and regulation.

TOPIC-3: EU DIRECTIVES AND REGULATIONS FOR MANUFACTURE AND SALE OF DIETARY SUPPLEMENTS

3.1 Introduction

Dietary supplements are concentrated sources of nutrients or other substances with nutritional or physiological effects, intended to supplement the normal diet. In the European Union (EU), dietary supplements are regulated as foods, not medicines, provided they do not claim to prevent, treat, or cure diseases.

The EU regulatory framework ensures that dietary supplements are safe, high-quality, properly labelled, and can move freely within the internal market.

Examples: Vitamins, minerals, amino acids, fatty acids, probiotics, plant extracts, botanicals.

3.2 Definition under EU Law

According to Directive 2002/46/EC, dietary supplements are foodstuffs that:

- Supplement the normal diet
- Contain concentrated sources of nutrients or other substances
- Are marketed in dose forms such as capsules, tablets, powders, liquids, or sachet

3.3 Legal Framework

Dietary supplements in the EU are regulated through a harmonized framework including:

- Regulation (EC) No. 178/2002 – General Food Law
- Directive 2002/46/EC – Food Supplements Directive
- Regulation (EC) No. 1924/2006 – Nutrition and Health Claims

- Regulation (EU) No. 1169/2011 – Food Labelling and Information
- Regulation (EU) 2015/2283 – Novel Foods

3.4 Directive 2002/46/EC: Food Supplements

This directive harmonizes rules for dietary supplements regarding:

- Permitted vitamins and minerals
- Authorized chemical forms of nutrients
- Minimum and maximum nutrient levels
- Labelling and consumer information

Note: Only nutrients listed in the annexes of the directive may be used in supplements marketed in the EU.

3.5 Regulation (EC) No. 178/2002: General Food Law

Regulation EC 178/2002 establishes:

- General food safety principles
- Responsibilities of food business operators
- Traceability requirements across supply chains
- Risk analysis framework

All dietary supplements must be safe under normal conditions of use and supported by scientific evidence.

3.6 Manufacture of Dietary Supplements

The manufacture of dietary supplements in the European Union must follow strict regulations to ensure product safety, quality, and compliance with EU directives. Manufacturers are responsible for controlling all stages of production, from raw material sourcing to final product packaging and labelling.

3.6.1 Key Requirements for Manufacturing

- Supplements must be produced in registered or approved food establishments.
- Raw materials must be sourced from approved suppliers and comply with EU standards.
- Manufacturing processes must ensure batch-to-batch consistency, prevent contamination, and maintain nutrient stability.
- Traceability of ingredients and finished products must be maintained throughout the supply chain.
- Novel ingredients require pre-market authorization from the European Commission following EFSA safety evaluation.

Dietary supplements must be manufactured in registered or approved facilities. Manufacturers are responsible for:

- Safety and quality of raw materials
- Compliance with authorized ingredient lists
- Batch-to-batch consistency
- Traceability

- Novel ingredients require pre-market authorization**.**

3.6.2 Good Manufacturing Practices (GMP)

Manufacture must follow GMP principles, ensuring:

- Controlled production processes
- Prevention of contamination
- Product quality, safety, and regulatory compliance

Good Manufacturing Practices (GMP) are a set of systematic guidelines that ensure dietary supplements are consistently produced and controlled to meet quality, safety, and regulatory standards. GMP is mandatory in the EU and forms the backbone of safe supplement manufacturing.

Key Objectives of GMP

- Ensure consistent quality and safety of dietary supplements.
- Prevent contamination, mix-ups, and errors during production.
- Maintain compliance with EU directives and regulations.
- Facilitate traceability of raw materials and finished products.

Key Components of GMP in Dietary Supplement Manufacturing

1. **Quality Management System (QMS)**
   - A documented system to ensure products are manufactured according to approved specifications.
   - Includes procedures for quality assurance, audits, and continuous improvement.
2. **Personnel and Training**
   - All staff must be adequately trained in hygiene, safety, and GMP practices.
   - Responsibilities and duties should be clearly defined to prevent errors.
3. **Premises and Equipment**
   - Manufacturing facilities must be clean, well-maintained, and appropriately designed to avoid contamination.
   - Equipment must be calibrated, validated, and regularly maintained.
4. **Raw Material Control**
   - Only approved and tested ingredients can be used.
   - Proper storage conditions must be maintained to prevent degradation or contamination.
5. **Production and Process Control**
   - Manufacturing operations should follow standard operating procedures (SOPs).
   - Critical process parameters (temperature, humidity, mixing time, etc.) must be monitored and documented.
6. **Sanitation and Hygiene**
   - Strict cleaning protocols for facilities, equipment, and personnel.
   - Reduces the risk of microbial contamination.
7. **Quality Control and Testing**
   - Finished products are tested for identity, potency, purity, and safety before release.
   - Testing ensures compliance with label claims and regulatory standards.
8. **Packaging and Labelling Control**
   - Packaging must protect products from contamination and deterioration.
   - Labels must accurately display ingredients, dosage, warnings, and storage instructions.
9. **Documentation and Record Keeping**

- All manufacturing, testing, and distribution activities must be thoroughly documented.
- Ensures traceability, accountability, and regulatory compliance.

10. **Storage and Distribution**
    - Supplements must be stored under appropriate conditions.
    - Distribution should prevent product damage, contamination, or mix-ups.
11. **Complaints, Recalls, and Corrective Actions**
    - A system must be in place to handle consumer complaints.
    - Non-compliant batches must be recalled and corrective actions implemented.

Note:

- GMP ensures consumer safety and regulatory compliance.
- EU authorities may audit manufacturers, and non-compliance can lead to product recalls, penalties, or market withdrawal.
- Following GMP is essential for international trade and market access.

3.6.3 Hazard Analysis and Critical Control Point (HACCP)

HACCP focuses on preventing hazards at critical points during production, storage, and distribution. It ensures control over:

- Biological hazards (microorganisms)
- Chemical hazards (toxins, pesticides)
- Physical hazards (foreign matter)

HACCP Steps in Dietary Supplement Manufacturing

HACCP (Hazard Analysis and Critical Control Point) is a preventive system to ensure product safety by controlling hazards at critical stages.

Step 1: Conduct Hazard Analysis

- Identify potential biological, chemical, and physical hazards at each stage of production.
- Example: Microbes in raw botanicals, heavy metals in minerals, foreign particles in powders.

Step 2: Determine Critical Control Points (CCPs)

- Identify stages where hazards can be prevented, eliminated, or reduced.
- Example: Pasteurization of herbal extracts, filtration of powders, testing raw materials.

Step 3: Establish Critical Limits

- Set measurable limits for each CCP to ensure safety.
- **Example:**
  - Temperature ≥70°C for pasteurization
  - Moisture ≤5% in powders
  - Heavy metals below EU limits

Step 4: Establish Monitoring Procedures

- Regularly check CCPs to ensure critical limits are met.
- **Example:** Measure temperature, moisture, pH, or filtration efficiency during production.

Step 5: Establish Corrective Actions

- Define actions if critical limits are exceeded.
- Example: Re-process or reject a batch if pasteurization fails or contaminants are detected.

Step 6: Establish Verification Procedures

- Confirm that the HACCP system is working effectively.
- Example: Internal audits, laboratory testing, review of monitoring records.

Step 7: Establish Documentation and Record Keeping

- Maintain records of hazard analysis, CCP monitoring, corrective actions, and verification.
- Purpose: Ensures traceability, accountability, and regulatory compliance.

3.7 Novel Foods Regulation (EU 2015/2283)

Ingredients without a significant history of consumption in the EU before 15 May 1997 are classified as novel foods.

For dietary supplements containing such ingredients:

- Pre-market safety assessment by EFSA
- Centralized authorization by the European Commission

Examples: New botanicals, probiotics, algae extracts, peptides.

3.8 Nutrition and Health Claims (Regulation EC 1924/2006)

Claims on dietary supplements must be:

- Scientifically substantiated
- Clear and non-misleading
- Approved by EFSA

Types of claims:

- Nutrition claims (e.g., "Source of Vitamin C")
- Health claims (e.g., "Supports normal immune function")
- Reduction of disease risk claims

Note: Medicinal claims are strictly prohibited.

3.9 Labelling Requirements (Regulation EU 1169/2011)

Mandatory labelling includes:

- Product name and description
- Ingredient list
- Nutrient content per daily dose
- Recommended daily intake
- Warning statements

Proper labelling ensures safe and informed use.

3.10 Sale and Marketing

3.10.1 Sale Conditions

- Products must comply with safety, labelling, and claims regulations.
- Medicinal claims are prohibited.

3.10.2 Notification and Authorization

- Most dietary supplements: notification to national authority before sale
- Novel ingredients: centralized EU authorization required

3.11 Free Movement within the EU

Dietary supplements lawfully marketed in one member state may be sold in other member states under the mutual recognition principle, unless public health concerns exist.

Principles Governing Free Movement

1. Mutual Recognition – safe products in one country circulate freely
2. Harmonization – uniform EU-wide safety, quality, and labelling
3. Non-Discrimination – imported products treated like domestic ones
4. Proportionality – restrictions appropriate to health risk
5. Precautionary Principle – temporary restrictions allowed if risk uncertain
6. Consumer Protection – safety and accurate information prioritized
7. Transparency – restrictions must be justified and communicated

3.12 Role of EFSA

EFSA:

1. Assesses safety of novel ingredients
2. Evaluates nutrition and health claims
3. Provides scientific opinions to the European Commission

EFSA does not approve products; it provides the scientific basis for decisions.

3.13 Enforcement and Market Surveillance

3.13.1 Enforcement and Market Surveillance – Members Involved

1. **National Competent Authorities (NCAs)**
   - Each EU member state has a designated competent authority responsible for enforcing food law.

     Examples:
     - In Germany – Federal Office of Consumer Protection and Food Safety (BVL)
     - In the UK – Food Standards Agency (FSA)
     - In France – DGCCRF (Directorate-General for Competition, Consumer Affairs and Fraud Control)
   - Roles: Inspections, audits, approvals, recalls, and penalties.
2. **European Commission (EC)**
   - Ensures harmonization and enforcement across all member states.
   - Coordinates actions in case of cross-border non-compliance.
   - Can issue alerts or recommendations via Rapid Alert System for Food and Feed (RASFF).
3. **European Food Safety Authority (EFSA)**
   - Provides scientific advice on safety issues, novel ingredients, or claims.
   - EFSA itself does not enforce, but its opinions guide national authorities.
4. **Rapid Alert System for Food and Feed (RASFF)**
   - A network for sharing information on unsafe products between member states.
   - Helps coordinate recalls, market withdrawals, and preventive actions.
5. **Customs and Border Control Authorities**
   - Monitor imports and exports of dietary supplements.

- Prevent unsafe or unauthorized products from entering the EU market.

Summary

- Member states ensure compliance via:
  - Inspections and audits
  - Market surveillance and recalls
  - Penalties for non-compliance

- Enforcement is multi-level:
  - National Authorities → inspections, recalls, penalties
  - EU Institutions (Commission, EFSA, RASFF) → coordination and scientific guidance
  - Border/Customs → control imports and exports
- Ensures dietary supplements comply with GMP, labelling, claims, and safety regulations.

3.14 Challenges in Regulation

- Differing national rules for botanicals and extracts
- Classification issues between food and medicine
- Rapid innovation in formulations
- Scientific substantiation of claims

The EU provides a robust, harmonized framework for dietary supplements. Knowledge of EU directives, regulations, and EFSA guidance is critical for pharmacy professionals to ensure safety, quality, compliance, and market access for dietary supplements.

TOPIC 4: EUROPEAN UNION (EU) NUTRITIONAL LABELLING

4.1 Introduction to EU Nutritional Labelling

Nutritional labelling in the European Union (EU) is governed by a harmonized legal framework aimed at ensuring consumer protection, transparency, and informed food choices while facilitating the free movement of food products within EU member states.

Unlike pharmaceutical labelling, nutrition labelling falls under food law, and nutraceuticals, food supplements, and functional foods are regulated accordingly. The EU framework emphasizes mandatory nutrition information, standardized presentation, scientific substantiation of claims, and consumer readability.

4.1.1 Objectives of EU Nutritional Labelling

The primary objectives are:

- To provide clear, accurate, and non-misleading nutrition information
- To enable comparability of food products
- To prevent false or exaggerated health claims
- To support public health and nutrition policies
- To ensure uniform labelling across all EU member states

4.1.2 Legal Basis for Nutritional Labelling in the EU

EU nutritional labelling is mainly regulated under:

- Regulation (EU) No. 1169/2011 *on the provision of food information to consumers (FIC Regulation)*
- Supporting regulations include:
- Regulation (EC) No. 1924/2006 – Nutrition and Health Claims
- Directive 2002/46/EC – Food Supplements
- Regulation (EU) 2015/2283 – Novel Foods

4.2 Regulation (EU) No. 1169/2011 – Food Information to Consumers (FIC)

Regulation (EU) No. 1169/2011 forms the cornerstone of EU nutritional labelling, making nutrition declaration mandatory for most pre-packed foods.

4.2.1 Scope and Applicability

This regulation applies to:

- All pre-packed foods
- Foods sold in retail, catering, and online markets
- Imported food products marketed in the EU

Exemptions include:

- Unprocessed single-ingredient foods
- Herbal infusions
- Foods sold in very small quantities directly to consumers

4.2.2 Mandatory Nutrition Declaration

The nutrition declaration must include the following mandatory parameters:

Nutrient	Unit
Energy	kJ / kcal
Fat	g
Saturated Fat	g
Carbohydrate	g
Sugars	g
Protein	g
Salt (NaCl equivalent)	g

Table 5.2: Mandatory Nutrient Declaration (EU)

4.2.3 Expression of Nutritional Values

Nutrition information must be expressed:

- Per 100 g or 100 ml (mandatory)
- Per portion (optional, with portion size defined)
- Using SI units
- In numerical format

Energy must be declared in both kJ and kcal.

4.2.4 Presentation and Format Requirements

- Nutrition information must appear in a tabular format
- Font size: minimum 1.2 mm (x-height)
- Must be placed in the same field of vision
- No misleading emphasis or graphical exaggeration

4.3 Voluntary Nutrition Information

In addition to mandatory elements, voluntary declaration may include:

- Mono-unsaturated fat
- Poly-unsaturated fat
- Polyols
- Starch
- Fibre
- Vitamins and minerals (only if present in significant amounts)

4.3.1 Declaration of Vitamins and Minerals

Vitamins and minerals may be declared if present at:

- ≥ 15% of Nutrient Reference Value (NRV) per 100 g/ml
- Declared as:
  - Amount per 100 g/ml
  - Percentage of NRV (%)

4.4 Nutrition Claims under EU Law

- Nutrition claims are governed by Regulation (EC) No. 1924/2006

4.4.1 Definition of Nutrition Claims

A nutrition claim states that a food has beneficial nutritional properties, such as:

- "Low fat"
- "Sugar-free"
- "High fibre"
- "Source of protein"

4.4.2 Conditions for Use of Nutrition Claims

Claim	Condition
Low fat	**≤ 3 g fat / 100 g**
Sugar-free	**≤ 0.5 g sugars / 100 g**
High fibre	**≥ 6 g fibre / 100 g**
Source of protein	**≥ 12% energy from protein**

Table 5.3: Examples:

- Only authorized claims listed in EU annexes may be used.

4.5 Health Claims and Scientific Substantiation

- Health claims suggest a relationship between a food and health.

4.5.1 Categories of Health Claims

- Article 13 claims – General function claims
- Article 14 claims – Disease risk reduction and children's development claims

4.5.2 Role of EFSA

The European Food Safety Authority (EFSA):

- Evaluates scientific evidence
- Assesses safety and efficacy
- Authorizes or rejects claims
- Ensures claims are truthful and evidence-based

4.6 Labelling of Food Supplements

- Food supplements are regulated under Directive 2002/46/EC.

4.6.1 Mandatory Statements for Supplements

Labels must include:

- "Food supplement"
- Recommended daily dose
- Warning not to exceed stated dose
- Statement that supplements are not a substitute for a balanced diet
- Storage and safety warnings

4.7 Front-of-Pack Nutrition Labelling (FoPNL)

The EU encourages voluntary front-of-pack labelling systems such as:

- Nutri-Score
- Reference Intake (RI) labels
- Color-coded schemes (voluntary)

These aim to improve consumer understanding.

4.8 Enforcement and Penalties

- Enforcement is carried out by national authorities of EU member states
- Non-compliance may lead to:
  - Product recall
  - Fines
  - Market withdrawal
  - Legal prosecution

4.9 Importance of EU Nutritional Labelling for Pharmacy and Regulatory Professionals

For Pharmacy and Regulatory Professionals, understanding EU nutritional labelling is critical for:

- Regulatory affairs
- Nutraceutical product development

- Global market authorization
- Label compliance audits
- Research and policy formulation

TOPIC 5: EUROPEAN REGULATIONS ON NOVEL FOODS AND NOVEL FOOD INGREDIENTS

5.1 Introduction to Novel Foods

- Novel foods are foods or food ingredients that were not consumed to a significant degree within the European Union before 15 May 1997 (the date when the first Novel Food Regulation came into force).
- The regulation of novel foods ensures that innovative foods entering the EU market are safe for consumers, properly labelled, and do not mislead the public. This regulation is especially relevant for nutraceuticals, functional foods, bioactive compounds, and traditional foods from non-EU countries.

5.1.1 Objectives of Novel Food Regulation

The key objectives include:

- Ensuring high level of consumer safety
- Supporting innovation in the food sector
- Harmonizing approval procedures across EU Member States
- Preventing misleading or unsafe novel ingredients
- Providing scientific risk assessment prior to market authorization

5.1.2 Legal Framework Governing Novel Foods

The primary legislation is:
Regulation (EU) 2015/2283
on novel foods, which repealed Regulation (EC) No. 258/97.
Supporting legal instruments:

- Implementing Regulation (EU) 2017/2469 - Administrative & scientific requirements
- Regulation (EU) 2017/2470 - Union List of Novel Foods
- Regulation (EC) 1924/2006 - Nutrition and health claims
- Regulation (EU) 1169/2011 - Food information to consumers

5.2 Definition of Novel Foods

According to Regulation (EU) 2015/2283, a novel food is any food that was not used for human consumption to a significant degree in the EU before 15 May 1997 and falls into specified categories.

Category	Description
New molecular structures	Newly developed or modified molecules
Foods from microorganisms	Bacteria, fungi, algae
Foods from plants or animals	Not traditionally consumed
Foods from cell culture	Cell-based or tissue culture products

Nanomaterials	Engineered nanomaterials
Modified foods	Produced by new production processes
Vitamins/minerals	New sources or forms

Table 5.4: Categories of Novel Foods

Novel Food	Category
Chia seeds (initially)	**Traditional food from third country**
Algal oils	**Microorganism-derived**
CBD isolate	**New molecular structure**
Insect protein	**Animal-derived novel food**
Phytosterol esters	**Modified food ingredient**

Table 5.5: Examples of Novel Foods

5.3 Novel Food Ingredients

Novel food ingredients refer to individual substances or components used in food formulations that are novel in nature or origin.

5.3.1 Types of Novel Food Ingredients

- Bioactive plant extracts
- New probiotic strains
- Synthetic analogues of natural nutrients
- Nano-encapsulated nutrients
- Fermentation-derived compounds

5.3.2 Distinction Between Novel Foods and Novel Ingredients

Aspect	Novel Food	Novel Ingredient
Scope	**Finished food product**	**Component of food**
Regulation	**Requires authorization**	**Authorization as part of food**
Evaluation	**Safety + use conditions**	**Safety + exposure assessment**

Table 5.6: Comparison between Novel Foods and Novel Food Ingredients under EU Regulations

5.4 Union List of Authorized Novel Foods

The Union List is a centralized positive list of all authorized novel foods permitted for marketing in the EU.

5.4.1 Regulation (EU) 2017/2470

This regulation establishes:

- Approved novel foods
- Conditions of use
- Labelling requirements

- Specifications

5.4.2 Importance of the Union List

- Eliminates duplicate authorizations
- Enhances regulatory transparency
- Facilitates innovation
- Ensures uniform application across EU

5.5 Authorization Procedure for Novel Foods

- Authorization follows a centralized EU procedure.

5.5.1 Application Submission

- The applicant submits a dossier to the European Commission, including:
- Identity and composition
- Production process
- Specifications
- Proposed uses and intake levels
- Toxicological and safety data
- Nutritional information
- Allergenicity assessment

5.5.2 Scientific Risk Assessment by EFSA

The European Food Safety Authority (EFSA) evaluates:

- Toxicological safety
- Nutritional adequacy
- Absorption, distribution, metabolism, and excretion (ADME)
- Human exposure levels

EFSA must provide an opinion within 9 months.

5.5.3 Authorization Decision

Based on EFSA's opinion:

- European Commission drafts implementing act
- Standing Committee on Plants, Animals, Food and Feed (PAFF) approves
- Novel food added to Union List

5.6 Traditional Foods from Third Countries

Traditional foods with history of safe use outside the EU may follow a simplified route.

5.6.1 Simplified Notification Procedure

Requirements include:

- At least 25 years of safe use
- Data on composition and consumption
- Absence of safety objections

5.6.2 Objection-Based Assessment

- If no objections → authorization granted
- If objections raised → full EFSA assessment required

5.7 Data Protection and Proprietary Data

5.7.1 Data Protection Period

- Approved applicants may receive 5 years of data protection
- Protects proprietary scientific data
- Encourages innovation

5.8 Labelling Requirements for Novel Foods

- Novel foods must comply with general EU food labelling laws.

5.8.1 Additional Labelling Requirements

Labels must specify:

- Nature of the novel ingredient
- Specific conditions of use
- Target population restrictions
- Warnings if necessary

5.9 Post-Market Monitoring

Post-market surveillance may be required when:

- Safety uncertainties exist
- Long-term exposure effects are unknown

5.9.1 Responsibilities of Food Business Operators

- Monitor consumption patterns
- Report adverse effects
- Maintain traceability

5.10 Comparison: Old vs New Novel Food Regulation

Feature	Regulation 258/97	Regulation 2015/2283
Authorization	Decentralized	Centralized
Union List	Not available	Available
Transparency	Limited	High
Innovation support	Low	High
Traditional foods	Complex	Simplified

Table 5.7: Comparison of Old and New EU Novel Food Regulations

5.11 Importance of Novel Food Regulation for Pharmacy and Nutraceutical Professionals

- Essential for nutraceutical development
- Regulatory compliance for EU market entry
- Risk assessment and dossier preparation
- Product innovation and global trade

5.12 Summary

The EU Novel Food Regulation ensures that new and innovative foods and ingredients are thoroughly evaluated for safety, scientifically substantiated, and transparently authorized before entering the EU market. Regulation (EU) 2015/2283 represents a robust, science-driven, and harmonized framework, balancing consumer safety with innovation.

TOPIC 6: EUROPEAN REGULATORY DIETARY ALLOWANCES (RDA) IN EUROPE

6.1 Introduction to Dietary Allowances in the European Union

- Dietary Allowances in Europe represent science-based reference values established to guide adequate nutrient intake for healthy populations. Unlike pharmaceutical dose recommendations, RDAs in Europe are designed to prevent deficiency, maintain physiological function, and support long-term public health.
- In the European Union (EU), the concept of Regulatory Dietary Allowances is implemented through Dietary Reference Values (DRVs), which form the basis for nutrition labelling, food fortification, dietary guidelines, and health policy decisions.

6.1.1 Objectives of European Dietary Reference Values

The major objectives include:

- Establishing safe and adequate intake levels of nutrients
- Supporting nutritional labelling and consumer information
- Preventing nutrient deficiencies and toxicities
- Providing scientific reference points for food supplements and fortified foods
- Assisting regulatory authorities, clinicians, and researchers

6.1.2 Evolution of RDA Concept in Europe

Initially, European countries followed national RDAs, leading to regulatory inconsistency. To harmonize nutrition policy:

- The European Food Safety Authority (EFSA) was mandated to develop pan-European reference values
- RDAs evolved into Dietary Reference Values (DRVs) covering a wider scientific scope

6.2 Regulatory Authority for RDA in Europe

6.2.1 Role of European Food Safety Authority (EFSA)

The European Food Safety Authority (EFSA) is the central scientific authority responsible for establishing dietary reference values in the EU.

EFSA's responsibilities include:

- Reviewing epidemiological, clinical, and biochemical data
- Assessing nutrient bioavailability
- Evaluating deficiency and excess risks
- Publishing scientific opinions on nutrient requirements

6.2.2 Legal and Regulatory Framework

Although RDAs are not legally binding doses, they are embedded within EU legislation, including:

- Regulation (EU) 1169/2011 – Food Information to Consumers
- Regulation (EC) 1924/2006 – Nutrition and Health Claims
- Directive 2002/46/EC – Food Supplements
- Regulation (EU) 2015/2283 – Novel Foods (when nutrients are novel sources)

6.3 Terminology Used in European Dietary Reference Values

Europe uses a multi-parameter DRV system, rather than a single RDA.

Term	Definition
AR (Average Requirement)	Intake sufficient for 50% of population
PRI (Population Reference Intake)	Intake sufficient for nearly all (≈97.5%)
AI (Adequate Intake)	Intake assumed adequate when data insufficient
RI (Reference Intake)	Used for nutrition labelling
UL (Tolerable Upper Intake Level)	Maximum safe intake

Table 5.8: Key Terminology Used in European Dietary Reference Values (DRVs)

6.3.2 Relationship Between RDA and PRI

In EU terminology:

- PRI ≈ RDA
- PRI is the primary regulatory reference used for policy and labelling
- RDAs as a term are avoided to ensure scientific precision

6.4 Scientific Basis for Setting RDAs in Europe

6.4.1 Data Sources Used by EFSA

EFSA considers:

- Human intervention studies
- Balance and depletion–repletion studies
- Biomarkers of nutrient status
- Population intake surveys
- Toxicological data

6.4.2 Risk–Benefit Assessment Approach

EFSA establishes intake values by balancing:

- Risk of deficiency
- Risk of excess intake
- Inter-individual variability
- Life-stage and physiological conditions

6.5 European RDAs (PRIs) for Macronutrients

6.5.1 Energy Intake

Energy requirements are expressed as Average Requirements (AR) rather than PRI, based on:

- Age
- Sex
- Body weight
- Physical activity level (PAL)

6.5.2 Protein Requirements

Population	PRI
Adults	**0.83 g/kg/day**

Pregnant women	**+1 to 28 g/day**
Elderly	**Higher recommended due to muscle loss**

Table 5.9: European Population Reference Intake (PRI) for Protein

6.5.3 Fat and Carbohydrates

Nutrient	Recommended Intake
Total fat	**20–35% of energy**
Saturated fat	**As low as possible**
Carbohydrates	**45–60% of energy**
Dietary fibre	**≥25 g/day**

Table 5.10: Recommended Intake Levels for Fats and Carbohydrates in Europe

6.6 European RDAs (PRIs) for Vitamins

6.6.1 Fat-Soluble Vitamins

Vitamin	PRI (Adults)
Vitamin A	**650–750 µg RE**
Vitamin D	**15 µg**
Vitamin E	**11–13 mg**
Vitamin K	**AI basis**

Table 5.11: European Population Reference Intake (PRI)

for Fat-Soluble Vitamins

6.6.2 Water-Soluble Vitamins

Vitamin	PRI
Vitamin C	90–110 mg
Thiamine (B1)	0.1 mg/MJ
Riboflavin (B2)	1.6 mg
Vitamin B12	4 µg
Folate	330 µg DFE

Table 5.12: European Population Reference Intake (PRI)
for Water-Soluble Vitamins

6.8 European RDAs (PRIs) for Minerals

6.7.1 Major Minerals

Mineral	PRI
Calcium	**950 mg**

Phosphorus	**550 mg**
Magnesium	**300–350 mg**
Sodium	**As low as possible**
Potassium	**3500 mg**

Table 5.13: European Population Reference Intake (PRI) for Major Minerals

6.7.2 Trace Elements

Element	PRI
Iron	**11–16 mg**
Zinc	**7–16 mg**
Iodine	**150 µg**
Selenium	**70 µg**

6.8 RDAs and Nutrition Labelling in Europe

6.8.1 Reference Intakes (RI) for Labelling

For food labelling, simplified Reference Intakes (RI) are used instead of PRIs.

Nutrient	RI Value
Energy	**8400 kJ / 2000 kcal**
Fat	**70 g**
Saturated fat	**20 g**
Sugars	**90 g**
Salt	**6 g**

6.9 RDAs and Food Supplements Regulation

6.9.1 Minimum and Maximum Levels

EU regulates supplements by:

- Minimum level: ≥15% of NRV
- Maximum level: Below UL to prevent toxicity

6.9.2 Risk of Excess Intake

Supplements must not:

- Exceed UL
- Mislead consumers regarding necessity
- Replace balanced diet

6.10 RDAs for Vulnerable and Special Populations

6.10.1 Life-Stage Specific Recommendations

EFSA sets distinct DRVs for:

- Infants
- Children
- Adolescents
- Pregnant women

- Lactating women
- Elderly population

6.10.2 Clinical and Public Health Significance

Special RDAs help prevent:

- Neural tube defects
- Osteoporosis
- Anaemia
- Sarcopenia

6.11 Comparison of EU RDAs with Other Regions

Aspect	EU	USA
Authority	EFSA	IOM/FDA
Terminology	PRI/DRV	RDA/AI
Labelling	RI	%DV
Legal role	Scientific reference	Regulatory guidance

6.12 Challenges and Future Directions

- Inter-individual variability
- Aging population
- Nutrigenomics
- Personalized nutrition
- Sustainability-based dietary guidelines

6.13 Importance of European RDAs for Pharmacy and Regulatory Professionals

European RDAs are critical for:

- Nutraceutical formulation
- Regulatory submissions
- Health claim substantiation
- Clinical nutrition
- Public health policy development

6.14 Summary

European Regulatory Dietary Allowances, expressed through EFSA-established Dietary Reference Values, form the scientific backbone of nutrition regulation in the EU. They ensure consumer safety, harmonized labelling, rational supplementation, and evidence-based public health nutrition, making them indispensable for pharmacy, nutraceutical, and regulatory professionals.

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