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INNOVATIVE FOOD PRODUCTS – NUTRACEUTICALS AND FUNCTIONAL FOODS

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Review Based Book Chapter

CONSUMER TRENDS AND NUTRIFIED FOOD

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REVIEW BASED BOOK CHAPTER**CONSUMER TRENDS AND NUTRIFIED FOOD**

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Abstract

This chapter explains the market situation, the latest consumer trends, and the positive impact of nutrified foods on human health and well-being. Consumers' increasing awareness of the health benefits of food and its nutritional value is fueling the global nutrified food market. The demand for nutrified foods is rising in developed countries due to growing knowledge of the health benefits of nutrified foods. In 2021, the nutrified foods market reached USD 462.24 billion and is projected to reach USD 721.65 billion by 2027. The market is expected to grow at an annual growth rate of 7.71% between 2022 and 2027. Despite increasing consumer trends, the market faces several challenges that need to be addressed, such as country-specific regulations and health claim substantiation, cost, consumer trust, awareness, and limited availability of nutrified foods. The current chapter explores the opportunities and strategies for developing and promoting innovative and personalized nutrified foods using novel technologies by balancing taste and nutrition, educating consumers, and sustainable practices. This chapter also concludes by proposing a future outlook and recommendations for the nutrified food market, such as technology integration, 3D and 4D food printing, nanotechnology, sustainability focus, and growth and diversification continuation.

Keywords

Nutrified Dense Foods, Healthy Foods, Nutraceutical, Functional Foods, Market Trends

1. Introduction

The nutrified food and consumer trends are key factors in the food industry's change. Consumer trends relate to the patterns of behavior, inclinations, and mindsets that have a substantial influence on the decisions and choices made by consumers in the marketplace. Numerous causes, such as changes in the population, improvements in technology, environmental concerns, cultural values, and personal motives, all have an impact on these patterns. Furthermore, unique desires and standards for food items and services might be created by consumer trends. Nutrified food, on the other hand, refers

to food items that have been enhanced with useful components like vitamins, minerals, probiotics, antioxidants, or plant extracts, providing additional advantages over mere sustenance [1-3].

Originating in Asia, the notion that "food and medicine are one" is now frequently acknowledged in the West. This is in line with a quotation from the classical Greek physician Hippocrates who said, "Let food be thy medicine" [4, 5]. Consumers are increasingly choosing natural and organic foods for their health benefits, and the food industry is offering more options that are rich in nutrients. The nutraceutical revolution has also changed people's eating habits and behaviour, as they seek foods and supplements that can prevent or treat chronic diseases [6, 7].

The growing demand for nutraceutical and nutrified foods requires the industry to establish new global supply chains. Foods are not only meant to satisfy hunger but also to promote health and wellness. Research has shown that diet is related to many chronic diseases, such as heart disease, diabetes, and cancer, and that these can be prevented or reduced by eating foods with more antioxidants and less fat, exclusively saturated fat [5]. The report of FAOSTAT 2023 concerning the prevalence of undernourishment illustrated in Figure 1 emphasizes the critical necessity for interventions that enhance accessibility to nutrified foods, presenting a crucial avenue for addressing undernourishment and its associated health implications [8].

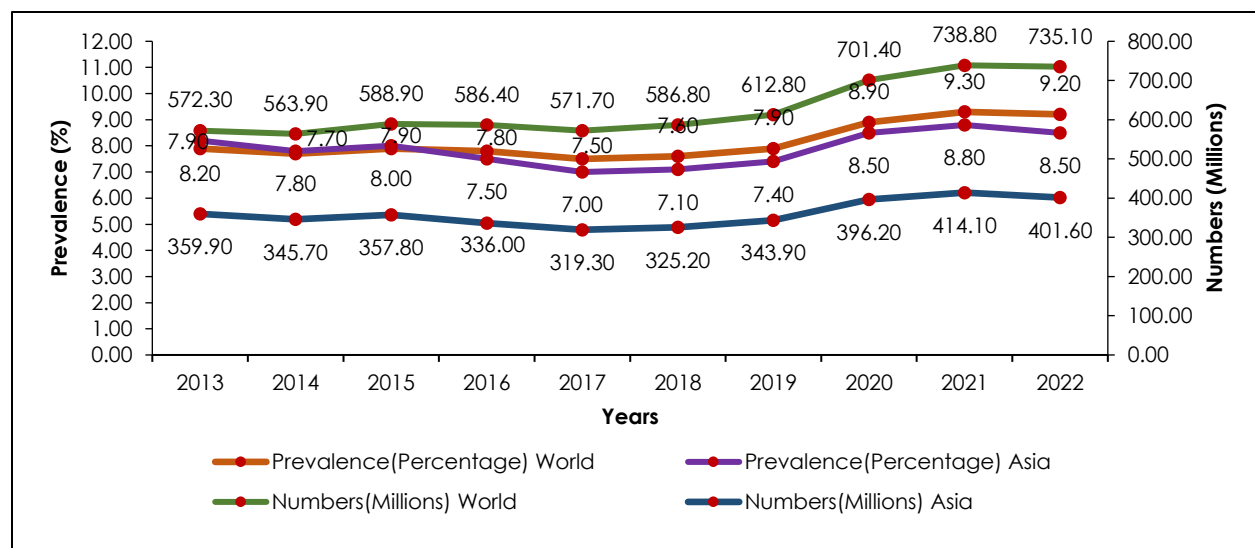


Figure 1 Prevalence of undernourishment in the world and Asia, and the number of undernourished in Asia [8]

Therefore, agriculture and food processing are shifting towards providing foods with added health and nutritional value [4]. Farmers are producing high-yielding and resilient crops and crops with more nutrients to prevent disease and malnutrition. Food manufacturers add value to their products by incorporating specific nutrients or functional ingredients to improve nutrition, immunity, energy, health, and longevity. Various old and new food technologies are used to produce nutritious food and ingredients for healthy food products. Innovation in food technology is vital for transforming nutrition information into consumer products. People want to live long and healthy lives and look for nutritious and functional food that supports their well-being, enjoyment, and active lifestyle [9]. The food industry prioritizes developing healthy foods that provide extra health benefits and incorporates dietary supplements into new food products. For example, breakfast cereals are enriched with minerals and multivitamins, and fruit juices contain glucosamine and chondroitin, which are natural substances that improve joint health. Modern food technology allows people who cannot prepare their healthy foods to get the supplements or nutrients they need from ready-made foods and beverages [4]. This chapter explores the key consumer trends that are shaping the demand and acceptance of nutrified food products and the opportunities and challenges for innovation in this field.

2. Benefits of Nutrified Food

Nutrified foods are enhanced with vital micronutrients that can enhance growth, development, and health while reducing the risk of diseases related to inadequate nutrition; they are particularly advantageous for low- and middle-income nations where nutrient-dense foods are scarce. Nutrified foods can also be tailored to the dietary requirements and preferences of different target groups, such as athletes, vegetarians, vegans, and people with intolerances or allergies [10]. Growing consumer demand in health and wellbeing has raised the demand for and its market capitalization of nutrified foods. Some potential health benefits of nutrified food are shown in Figure 2. Numerous aspects, including the kind, quantity, and bioavailability of the substances, the safety and quality of the food matrix, and any potential interactions or negative effects of the nutrients, affect the nutritional and health results, effectiveness, and quality of nutrified foods. When assessing the effects of nutrified foods, these variables

should be taken into account and suitable methodologies should be applied. Additionally, functional qualities of enriched foods may aid in the management or prevention of chronic conditions like cardiovascular disease, cancer, diabetes, and obesity [11]. Through immune system modulation, molecular mechanism influence, inflammation reduction, cholesterol lowering, blood sugar regulation, gut health promotion, and oxidative stress protection, they achieve this. By offering nutrients that encourage the growth of advantageous bacteria and protect the GI tract from infection, nutrient-rich diets can improve immune function. By incorporating meals high in fiber and fermented foods, they can help improve the function of the digestive tract and aid in digesting. Furthermore, by offering nutrients that enhance the composition and performance of brain cells, nutrified meals can promote brain health. For people of all ages, maintaining a healthy weight, preventing diseases like osteoporosis, hypertension, cardiovascular disease, diabetes, and some types of cancer, and providing energy are all made possible by a good diet [12, 13].

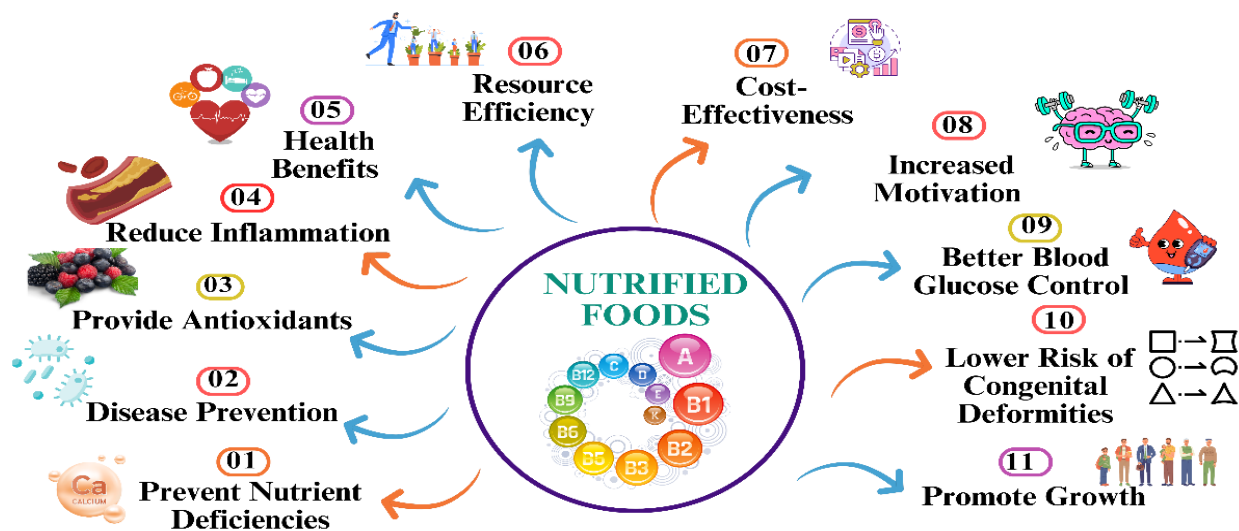


Figure 2 Potential health benefits of Nutrified foods [11-13]

3. Nutrified Food: Market Scenario and Competitive Analysis

Numerous changes in society and demography bolster Nutrified Food, suggesting that its market trend would continue. The aging population, increased consumer interest in health, a movement in nutritional research paradigms to examine the connections

between diet and disease prevention, and support from a range of stakeholders, including the food business, merchants, scientists, and consumer groups, are some of these. The concept of "Nutrified Food" is widely accepted, even though there may not be much consumer awareness of it. Despite low awareness with the word, surveys conducted in several European nations reveal substantial support with fortifying Nutrified components in specific food products [14].

Nutrified foods have become increasingly popular in many spheres of society in recent years for a variety of reasons. First off, a major factor in this expansion has been the rising desire from consumers for items that are enticing, nourishing, and handy. In addition, an aging population has demonstrated a strong conviction in the therapeutic benefits of particular foods and a preference for safer nutritional options requiring less medical intervention. Furthermore, improvements in components, goods, operations, and packaging have made it possible for the food industry to provide additional choices for value-added products thanks to breakthroughs in food technology. Moreover, continuous advancements in the field of nutrition science have expanded our comprehension of the connection between nutrition and overall health. Finally, customers are now aware of the health benefits of specific foods or ingredients thanks to legislative reforms that allow for the increased use of health claim declarations on food products. These various factors have collectively contributed to the tremendous growth of nutrified foods in recent years [15, 16].

According to a report issued by Variant Market Research, the global market is projected to develop at a compound annual growth rate (CAGR) of 7.2% from 2016, increasing \$340 billion in 2024 from \$195 billion in 2016. Geographically, the world's economies are predicted to expand at a CAGR of 7.6% for Asia-Pacific and 7.7% for the rest of the world [5]. Moreover, A report by Precedence Research illustrated in Figure 3 reveals that the size of the worldwide nutraceuticals market was estimated at USD 462.24 billion in 2021 and is projected to grow at a compound annual growth rate (CAGR) of 7.71% to reach USD 721.65 billion by 2027 [17].

The North American region is expanding due to the existence of large producers, ample disposable income, and growing emphasis on looks. In 2021, North America dominated the nutraceuticals market due to increasing health awareness, rising

disposable incomes, a growing ageing population, and increasing sales. Prior to the onset of the pandemic, the U.S. witnessed a steady increase of 5% (\$345 million) in dietary supplement sales in 2019 juxtaposed to the earlier year. However, during the first wave of the pandemic, specifically in the six weeks preceding April 5th, 2020, a significant surge of 44% (\$435 million) in sales indicated a heightened demand for dietary supplements. Notably, demand for multivitamins surged significantly in March 2020, accounting for 51.2% of the total revenue of dietary supplements and vitamins, which came to close to 120 million units during that time. This highlights the increased consumer interest in and reliance on dietary supplements during the early stages of the pandemic in the U.S [17, 18].

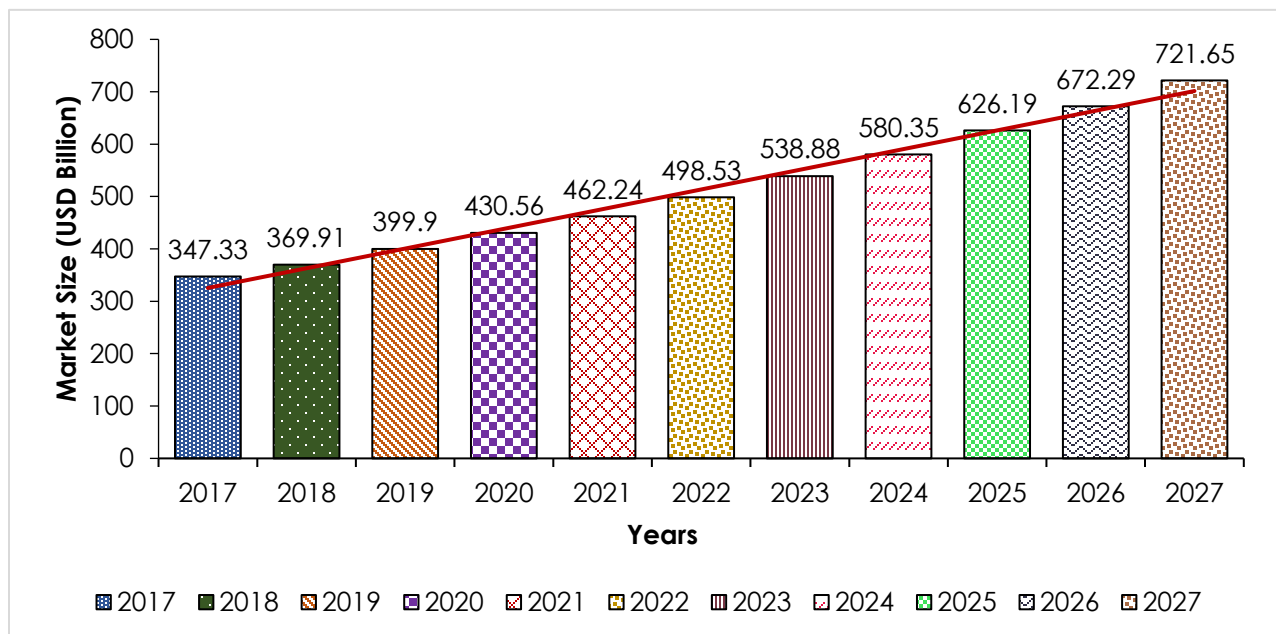


Figure 3 Nutraceutical Market Size 2017 to 2027 (USD Billion) [17]

Conversely, the Indian nutraceuticals market is predicted to grow from \$4 billion in 2017 to \$18 billion in 2025 due to the middle class and upper class' increasing demand for dietary supplements. Furthermore, the market for dietary supplements in India was estimated to be worth USD 3924.44 million in 2020; forecasts indicate that by 2026, it is expected to grow to USD 10,198.57 million. It projects a 22% annual growth rate for the industry [19]. According to a different Precedence Research analysis, the size of the global market for herbal nutraceuticals was predicted to be US\$ 64 billion in 2022 and is

expected to reach approximately US\$ 122.98 billion by 2032, rising at a CAGR of 6.80% from 2023 to 2032, as displayed in Figure 4 [20].

Herbal nutraceuticals are natural supplements that offer health benefits and prevent diseases. They are popular among consumers who want to improve their well-being and avoid chemicals. The global market for herbal nutraceuticals is expected to grow as more people in emerging countries can afford them and access them online. The demand is also driven by the aging population and the prevalence of chronic diseases. Herbal nutraceuticals can help with cholesterol, digestion, and stress. The market will expand as consumers recognize the advantages of herbal products [20, 21].

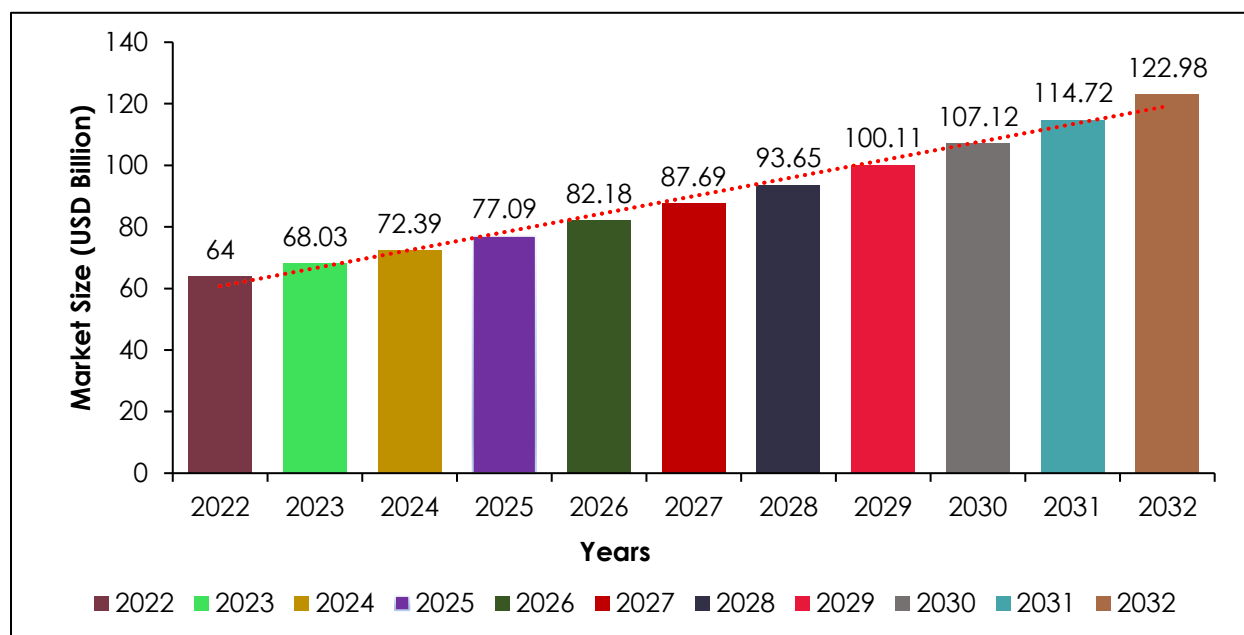


Figure 4 Herbal Nutraceutical Market Size 2022 to 2032 (USD Billion) [20]

4. Challenges of Nutrifed Foods in the Global Market

Nutrified foods can provide various advantages for consumers, such as enhancing immune function, improving cognitive performance, promoting well-being, or preventing or curing diseases. However, in the market, nutrified foods also face a number of challenges and impediments, including those related to availability, price, regulation, customer trust, and knowledge [22].

4.1. Cost Barrier

Nutrified foods face several obstacles, one among them is the high cost of manufacturing and marketing, which can limit consumer availability and affordability, especially in low- and moderate-income areas. Compared to traditional meals, nutrified foods frequently require additional R&D, quality assurance, packaging, and marketing, which drives up costs and decreases profitability. For instance, a study showed that the average retail price of fortified foods in India was 24% higher than that of non-fortified foods [23].

4.2. Regulatory and Ethical Issues

Food safety, quality, labelling, health claims, environmental effect, welfare of livestock, and social responsibility are some of the issues that nutrified foods must contend with. Their validity, credibility, responsibility, and the rights and interests of producers, consumers, and other stakeholders may all be impacted by these issues. It also encounters a complex and diverse regulatory environment, creating uncertainty and inconsistency for producers and consumers. Countries or regions have different regulations and standards for nutrified foods, depending on how they are classified, labelled, and marketed [24, 25]. Table 1 presents regulatory agencies and regulations of different countries regarding nutrified foods.

4.3. Consumer Awareness

Another barrier to nutrified food is low consumer knowledge and awareness, which can influence their adoption and acceptance. Consumers may not have enough education or information about the quality, risks, or benefits of nutrified foods and may not understand or recognize them. For instance, a survey in China disclosed that only 38% of consumers knew about functional foods, and only 17% could recognize some examples [26, 27].

4.4. Consumer Trust

Some consumers are doubtful, wary, and opposed to nutrified foods due to their perceived artificiality, safety, and ethical issues. Consumers may also challenge the accuracy and credibility of the health claims made by the manufacturers. This can influence consumer loyalty, behaviour, and attitude towards nutrified foods and lower the consumer willingness to pay for and buy nutrified foods. For instance, a study in

Brazil showed that 52% of consumers were worried about the possible side effects of functional foods, and 49% were doubtful about the health claim [28, 29].

Table 1 Nutrient Food Regulations and Standards in different countries [25]

Country	Regulatory Body	Regulations
United States	Several laws and regulations	The Federal Food Drug and Cosmetic Act addresses all foods and food additives, whereas the Dietary Supplement Health and Education Act (DSHEA) regulates dietary supplements. Whereas, manufacturing techniques are covered by the Good Manufacturing Techniques regulations. Additionally, the designation of an orphan medication also promotes the creation of therapeutic foods
European Union	European Food Safety Authority (EFSA)	The EFSA regulates and evaluates claims and sets limits for supplement ingredients. Labels cannot make disease claims; only authorized health claims are allowed. Around 10% of evaluated general health claims were supported by scientific evidence
China	State Food and Drug Administration (SFDA)	The Ministry of Health is in charge of authorizing novel food ingredients, whereas the SFDA is in charge of dietary supplement registration. Imports and exports are strictly regulated by the Administration of Quality Supervision, Inspection, and Quarantine
Japan	Ministry of Health, Labor and Welfare (MHLW)	Nutrient function claims have minimal regulation and require only meeting daily vitamin and mineral levels. Foods for Specialized Health Uses (FOSHU) necessitate pre-marketing consent and promote health benefits. Disease risk reduction claims are not permitted
India	Food Safety and Standards Authority of India (FSSAI)	Compared to medicines, nutraceuticals are subject to less surveillance during manufacturing in India and are governed by the Food Safety and Standards Act (FSSA). The ability of Indian producers to export nutraceuticals might be affected by this

4.5. Availability of Nutrified Foods

Nutrified foods are foods with improved nutritional or functional properties. Due to the lack of infrastructure, consumer demand and distribution channels, they face the challenge of low availability in some regions and markets. This can create a discrepancy between the supply and demand of nutrified foods and reduce its potential impact on public health. For example, a survey of Kenya found that regardless of the compulsory fortification policy, only 36% of households had access to fortified maize flour [30, 31].

5. Motivators of Nutrified Food Market

Nutrified foods have many opportunities and strategies to overcome challenges and barriers and succeed in the market. Some of the opportunities and strategies are:

5.1. Innovations

Nutrified foods can use the advances in technology and science to develop new methods, processes, and products that can improve their diversity, functionality, and quality. For instance, nanotechnology can create nano-encapsulated nutrients that can improve nutrified foods' delivery, bioavailability, and stability [32-34].

5.2. Differentiation

Nutrified foods can provide superior or unique value propositions that satisfy consumers' expectations, preferences, or needs. For instance, nutrified foods can target niche markets or segments with underserved or unmet nutritional needs, such as children, the elderly, pregnant women, or athletes [35]. They can also tailor or customize their services or products to fit consumers' goals or characteristics, such as their lifestyle, health status, or genetic profile. Social responsibility, credibility, or quality can be identified by enhancing or creating their brand image [36-39].

5.3. Personalization

Nutrified foods can use analytics and data to provide personalized nutrition solutions that suit individual needs, preferences, and behaviour, and improve loyalty and satisfaction. Personalized nutrition depends on various factors, such as diet, food, recipes, nutrition, host, microbiome, and environment, and can be delivered through digital health technologies and the NCP. Personalized nutrition services, especially

those based on nutrigenomics and adiposity markers, are becoming more popular, but still not widespread, in the nutrition industry [40-44].

5.4. Educating Consumers

One of the key strategies to increase the consumption and acceptance of nutrified foods is to educate consumers about their nutritional value and health benefits using various channels, formats, and media. Education can raise consumers' awareness, knowledge, and understanding, affecting their perception, preference, and behaviour towards nutrified foods [45-47]. Figure 5, demonstrates many effective strategies that can be adopted to proliferate consumers' sentience.

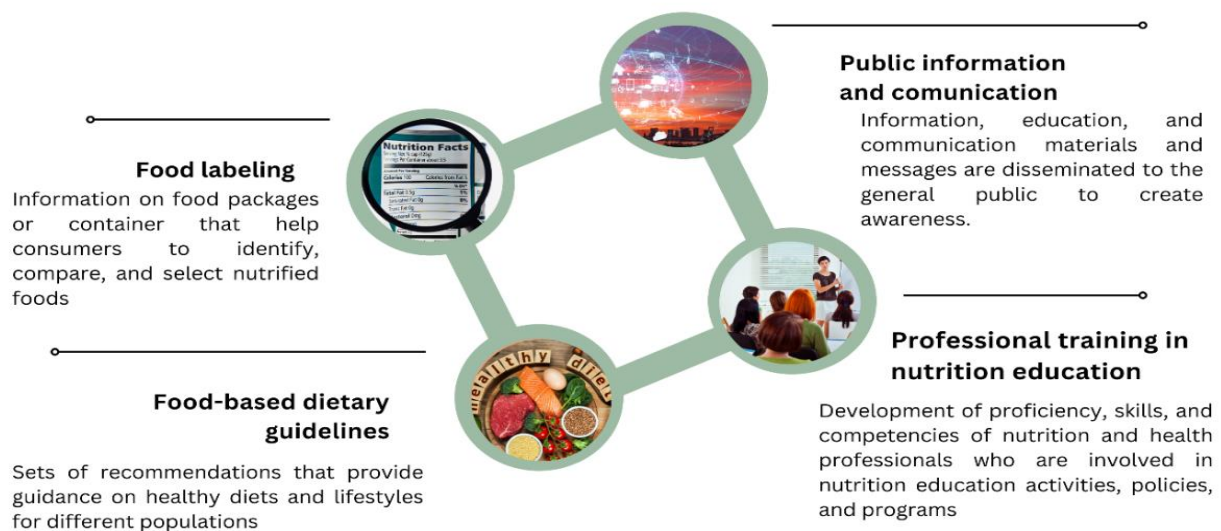


Figure 5 Effective strategies to increase consumer awareness of Nutrified Foods [45-47]

5.5. Balancing Taste and Nutrition

Nutrified foods that boast value-added nutritional or functional properties must strike a balance between taste and nutrition in order to satisfy consumers. However, this can pose a challenge, as certain nutrients may compromise the taste, texture, colour, or smell of foods or require unique methods to maintain their quality. For instance, iron can impart a metallic or bitter taste to foods, omega-3 fatty acids can cause foods to emit a fishy or rancid odour, and probiotics may necessitate refrigeration or fermentation, which can alter their visual or textural properties. Nutrified foods can use a variety of techniques to improve or maximize their nutritional profile and flavour in order to get beyond these obstacles. These tactics include the creation of suitable food matrices or

carriers that either enhance or conceal the flavour or aroma of nutrients or protect them from deterioration or spoiling. Furthermore, natural or synthetic flavourings, sweeteners, or boosters can be added to nutrients to improve or change their flavour or aroma or to satisfy the sensory or hedonistic expectations of the customer [48-50].

5.6. Application of Novel Technologies

Nutrified foods can be improved by regulating the release or delivery of Flavors or nutrients through the use of cutting-edge or unique methods or technology. For example, nano- or micro-sized structures or particles that can encapsulate Flavors or nutrients in nutrified foods at particular locations or times or in response to specific stimuli like enzymes, temperature, or pH can be created using 3D printing, nanotechnology, or microencapsulation. Nutrified foods also contain elements that have been modified through the application of current food biotechnology, fat replacement, enzyme technology, fermentation, and decaffeination. Moreover, nanotechnology and encapsulation are important for safeguarding components and managing their distribution. All these techniques and technologies work synergistically to enhance or create consumers' emotional or sensory experiences [51, 52].

5.7. Safety and Quality Assurance

Nutrified foods must ensure the quality and safety of their platforms, processes, and products using various technologies, tools, and methods, such as certification, tracing, monitoring, and testing. This can prevent the potential hazards and risks of nutrification, such as adulteration, contamination, toxicity, and allergenicity, and ensure nutrified foods' efficacy, reliability, and consistency [53].

5.8. Sustainability and Food Security

Nutrified foods should contribute to society's food security and sustainability, using different indicators, measures, and approaches, such as economic, social, and environmental goals, outcomes, and impacts. This can improve and change the food system and address local and global opportunities and challenges like poverty, malnutrition, population growth, and climate change. For example, a company developed a food ingredient based on microalgae that provides fiber, omega-3, and high-quality protein, using a resource-efficient and low-carbon production process [54-56].

6. Future Perspectives of Nutrified Food

6.1. Technology Integration

Incorporating technology is anticipated to play a critical role in enhancing the accessibility and relevance of personalized nutrition and nutrified food options. Several technologies are poised to significantly impact the future of the nutrified food industry. Digital platforms and apps can facilitate consumers in purchasing nutrified food products, monitoring their health results and food intake, and receiving personalized nutrition guidance [57]. Another example of such technologies is wearable devices and sensors, which can also be utilized to check consumers' metabolic and physiological indicators, such as temperature, heart rate, and glucose levels, and provide feedback and advice on their nutrified food options [58]. Furthermore, the development of smart machines and algorithms that can handle massive data sets and produce the best nutrified food solutions can be greatly aided by machine learning and artificial intelligence technologies [59, 60]. The nutrified food sector is expected to undergo a transformation with the incorporation of these technologies, enabling consumers to access and value nutrified food options and individualized nutrition more than before.

6.1.1. Nanotechnology

Although nanotechnology is not new, the food industry has begun to devote more attention recently because of its several innovative uses and advantages in food processing, packaging, nutrition, and safety. For example, the technology can be applied to distribute and encapsulate nutrients such as vitamin supplements using nano-carriers. The long-term impact of nano-particles in human tissues and any possible safety concerns, when swallowed, still remain ongoing research topics [61, 62].

6.1.2. 3D and 4D Printing of Food

A large number of 3D printers used for food applications are extrusion-based, meaning that a moving nozzle extrudes edible "ink" in a pattern chosen by the 3D model [63]. Additionally, food products can be made more varied and personalized using 3D printing employing co-extrusion printing, which combines many substances, including vitamins and probiotics that are encapsulated. With the increasing popularity of plant-based diets, textures resembling "meat" can be produced using plant-based materials through 3D bio-printing [64]. Four-dimensional food printing, which advances 3D food

printing, is currently being developed. The main uses for 4D printing include modifying food's colour, form, or flavour in reaction to environmental factors like pH, heat, moisture, etc. For example, Ghazal et al. observed colour variations caused by anthocyanins reacting to pH stimuli in a 4D-printed potato-starch meal [61, 65].

6.1.3. Handheld Devices

Compared to laboratory-based testing, food sensing technology on portable analyzers may identify different toxins in food in real time. With point-of-care diagnostics, customers may quickly and easily test their food for particular substances, such as food allergies (like eggs, gluten, or peanuts), on-site. Food allergies are becoming a major public health concern, so these gadgets can also be employed in medical facilities where quick and inexpensive food allergy screening is possible. Given that many people with allergies frequently experience multiple food allergies, various kinds of allergen identification are probably a feature that users of such devices would desire. [66-68].

However, emerging technologies, by definition, come with challenges and opportunities, and a critical understanding is required to balance the benefits with the risks [61].

6.2. Sustainability Focus: Food Security and Environment Protection

The growing demand for sustainable and ethical food practices will shape the future of nutrified food. Consumers will expect more accountability and transparency from nutrified food suppliers and producers and seek products with a positive social and environmental impact. Key sustainability aspects that will influence the future of nutrified food include food waste and loss reduction, greenhouse gas emissions and water footprint reduction, and social and economic development support [69]. Nutrified food products will use new technologies and methods, such as upcycling, bio-preservation, and smart packaging, to reduce food waste and loss along the food supply chain and extend their quality and shelf life [70, 71]. To lower their environmental impact, nutrified food products will utilize alternative protein sources, such as plant-based, insect-based, or cultured meat, that emit fewer greenhouse gases and use less water than animal-based protein [72]. Nutrified food products will also prioritize fair

trade and labour, local and organic farming, and food security and nutrition to support their regions' and communities' social and economic development [73].

6.3. Growth and Diversification Continuation

The nutrified food market is expected to continue growing, with new categories and products emerging to meet the evolving demands of consumers. Various trends and drivers will influence the growth and diversification of the nutrified food market. The growing wellness and health consciousness of customers is one of these factors. Food items with supplementary nutrients will address a range of health objectives and demands, including immune system support, weight control, cognitive function, and athletic performance, as customers look for goods that can improve their overall health and either prevent or treat chronic illnesses [74, 75]. The growing desire for ease and personalization is another motivator. Customers are looking for products that are easy to prepare and consume, fit into their lifestyles and preferences, and offer a variety of ways to consume them and format, such as bars, shakes, powders, and capsules. Nutrified food products will also let consumers choose their Flavors, ingredients, and nutrient levels [76, 77]. Lastly, the growth and diversity of the nutrified food sector will be propelled by the growing demand for unique and unusual ingredients. Nutritious foods, adaptogens, probiotics, and nootropics which provide extra functional and health benefits, will be used in nutrified food products. Customers are eager to try novel and unique substances, particularly those with unusual or exotic origins, benefits, or stories [78].

7. Conclusion

In summary, the food industry is undergoing a significant transformation due to evolving consumer trends and heightened demand for nutrified foods. The increasing popularity of nutrified foods among health-conscious consumers has resulted in a positive perception and a surge in demand, with the market projected to reach billions of dollars in the coming years. Nonetheless, the industry is not without its challenges, and it is prioritizing food technology innovation to combat these challenges. However, it is paramount to consider the safety and effectiveness of nutrified foods, and appropriate methods should be employed to assess their outcomes. The future prospects for the

nutrified food market appear bright, with further innovation and diversification of products on the horizon.

Author Contributions

Conceptualization, F.S, A.G.; validation, S.P, A.S and K.M; writing—original draft preparation, Z.A, S.P, and A.S.; writing—review and editing, F.S, K.M and S.P; visualization, Z.A and A.G.

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Conflicts of Interest

The authors declare no conflict of interest.

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INNOVATIVE FOOD PRODUCTS - NUTRACEUTICALS AND FUNCTIONAL FOODS

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Review Based Book Chapter

**ANTI-DENGUE POTENTIAL OF THE PAPAIN PROTEIN OF
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REVIEW BASED BOOK CHAPTER**ANTI-DENGUE POTENTIAL OF THE PAPAIN PROTEIN OF CARICA PAPAYA**

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Abstract

Dengue hemorrhagic fever (DHF) kills estimated 390 million people yearly throughout the world, according to the WHO in 2019. The *Aedes aegypti* mosquito, which carries the dengue virus, is the source of this illness. Thrombocytopenia and dehydration are two clinical signs of this illness to be concerned about. There are currently only two treatment approaches: fluid replacement and symptomatic therapy. Consequently, a therapeutic that can get around this restriction is needed. The thrombocyte count rises because the papain in *Carica papaya* L. can stimulate the release of thrombocytic cytokines including IL-6 and thrombopoietin. Megakaryocyte and thrombocyte production can both rise with the expression of ALOX 12, which papain can do. Using the aqueous two-phase system and the TPP (Three Phase Partitioning) system for extraction process, papain, extracted from *Carica papaya* L. Papain may be effective in treating dengue fever and restoring normal platelet counts. Further in-depth studies can suggest the dosage and potential adverse effects of papain drug for treating dengue fever.

Keywords

Dengue Fever, Anti-dengue, Papain, *Carica Papaya*, Cytokines, Protein Purification

Introduction***Carica papaya***

The tree like herbaceous plant that belongs to the family is known more widely as papaya. Its scientific name is *Carica papaya* [1]. A member of the *caricaceae* family, *C. papaya* is widely distributed in the tropics and subtropics [2]. Over 6.8 million tonnes of the fruit are produced annually worldwide, as reported by the Food and Agriculture Organization of the United Nations (FAO) [3]. The *C. papaya* plant, which is well-known for its usage in traditional remedies, was discovered to be the most effective anti-

dengue agent. The papaya fruit also contains riboflavin, folate, and niacin in addition to vitamin C, vitamin A, vitamin E, vitamin K, vitamin B 12, and vitamin B6. Macro and micronutrients including salt, potassium, magnesium, iron, copper, and zinc may all be found in plenty. There are many bioactive chemicals, and the primary source is thought to be medicinal plants. A wide variety of insecticides, microbicides, and medicinal medications are derived from secondary metabolites such alkaloids, tannins, proteins, carbohydrates, terpenoids, steroids, and flavonoids [4]. Enzymes such as papain and chymopapain can be found in abundance in papaya leaves [2].

Papain

Latex from the papaya (*Carica papaya* L.) plant is the source of papain (EC 3.4.22.2), an endolytic plant cysteine protease enzyme [5]. Most cysteine proteases belong to the papain family [6]. Papain is extracted by slicing the peel off of an unripe papaya and drying the latex that drains out. Papain's activity increases as fruit ripens, so choose fruit that still has some green on it. As a proteolytic enzyme, papain plays a fundamental role in many essential biological processes in all organisms and is a member of the papain superfamily [5]. Wurtz and Brochut coined the word papain to describe the proteolytic principle found in papaya latex [7]. Important features of papain like molecular weight, number of amino acids, optimum temperature, optimum PH, binding affinity etc. are describe in Table 1.

Structure

In proteins and polypeptides, it acts as a sulfhydryl protease, hydrolyzing the carboxyl terminus of arginine and lysine. It works in a wide pH range (5-8) and is stable even at higher temperatures (65°C) [8]. The structure of papain is given in Figure 1.

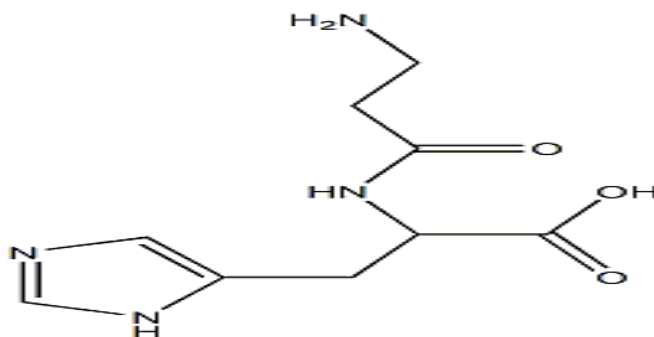


Figure 1. Structure of papain

Table 1. Features of papain

No. of amino acids	212 [9]
Molecular formula of papain	C ₁₉ H ₂₉ N ₇ O ₆
Molecular weight of papain	23KDa
Optimum temperature	50°C - 59°C [10]
Optimum PH	pH 4.5 – 6.6 [10]
Co factor	Mg ²⁺ [10]
Catalytic efficiency (Kcat/Km)	59.776 - pmL/mg.min [7]
Binding affinity	(Km - 0.83 mg/mL) [7]

Extraction of Papain from Papaya Latex

Fruits contain a fluid called latex. The nutrients in this latex promote in fruit development and ripening. The papain enzyme is found in the latex of papaya fruits, which is harvested by cutting or incising the fruits with a sharp stainless-steel device. It's important to keep a few things in mind while collecting latex from papaya fruit: the incision shouldn't be deeper than 2 mm, the latex shouldn't be soaked in water, and the juices shouldn't be combined with it otherwise the quality of the crude papain enzyme will be compromised. As latex dries quickly following an incision, it's important to collect it as soon as possible and keep an eye out for any foreign debris or contamination as you do so. It is recommended to add 0.3M NaOH to latex before storing it to prevent oxidation. Papaya latex is also sold as a spray-dried form on the marketplace [11].

Papain Isolation and Purification

It is critical to purify and isolate papain from fresh latex in its native crystalline form. The aqueous two-phase system and the TPP (Three Phase Partitioning) system have been reported as common methods for the isolation and purification of papain. TPP, on the other hand, is a simple, low-cost, scalable technique that can be used directly with crude suspensions [12].

The Aqueous Two-phase System (ATPS)

To fulfil these requirements, the aqueous two-phase system (ATPS) might be used. The inexpensive material prices, quick processing time, minimal energy requirements, and low denaturation of proteins are the primary reasons for this. By combining clarification, concentration, and purification of the target product into a single unit operation, aqueous two-phase systems (ATPS) have demonstrated their utility in downstream

protein processing. These systems typically comprise two polymers or a single polymer and a salt solution in water (Figure 2). ATPS has been used effectively for enzyme separation and purification at high throughput. When employing such systems, the desired protein partition may be achieved by adjusting a variety of processing parameters. The cheap cost and low viscosity of polymer-salt water systems make them preferable to polymer-polymer-water and polymer-polymer-salt-water systems. Among the latter, the polyethylene glycol (PEG)-phosphate system describe in Figure 2 is the most popular, while other multivalent anion salts have proven helpful as well [13].

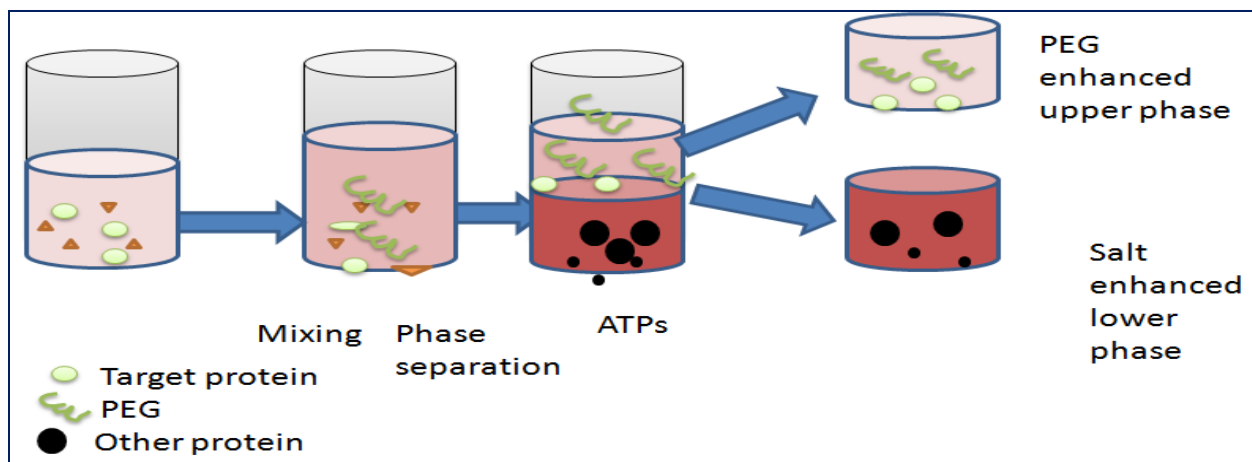


Figure 2. The Aqueous Two-phase System (ATPS)

Three Phase Partitioning (TPP)

Aqueous separation technologies like Three Phase Partitioning (TPP) have been successfully used to extract enzymes from a wide range of biological fluids, tissues, and cells, including those of plants, animals, and microbes, as well as from common surroundings and fermentation broths. TPP was initially reported by Lovrien's lab and is now widely utilized to purify a variety of target macromolecules for a variety of purposes as a result of its versatility and status as an early-exploratory technique. According to a study of the relevant literature, over 70% of TPP-based investigations have concentrated on protein and enzyme recovery, while the remaining 30% have dealt with oils, lipids, small-molecule chemical substances, DNA, and carbohydrates.

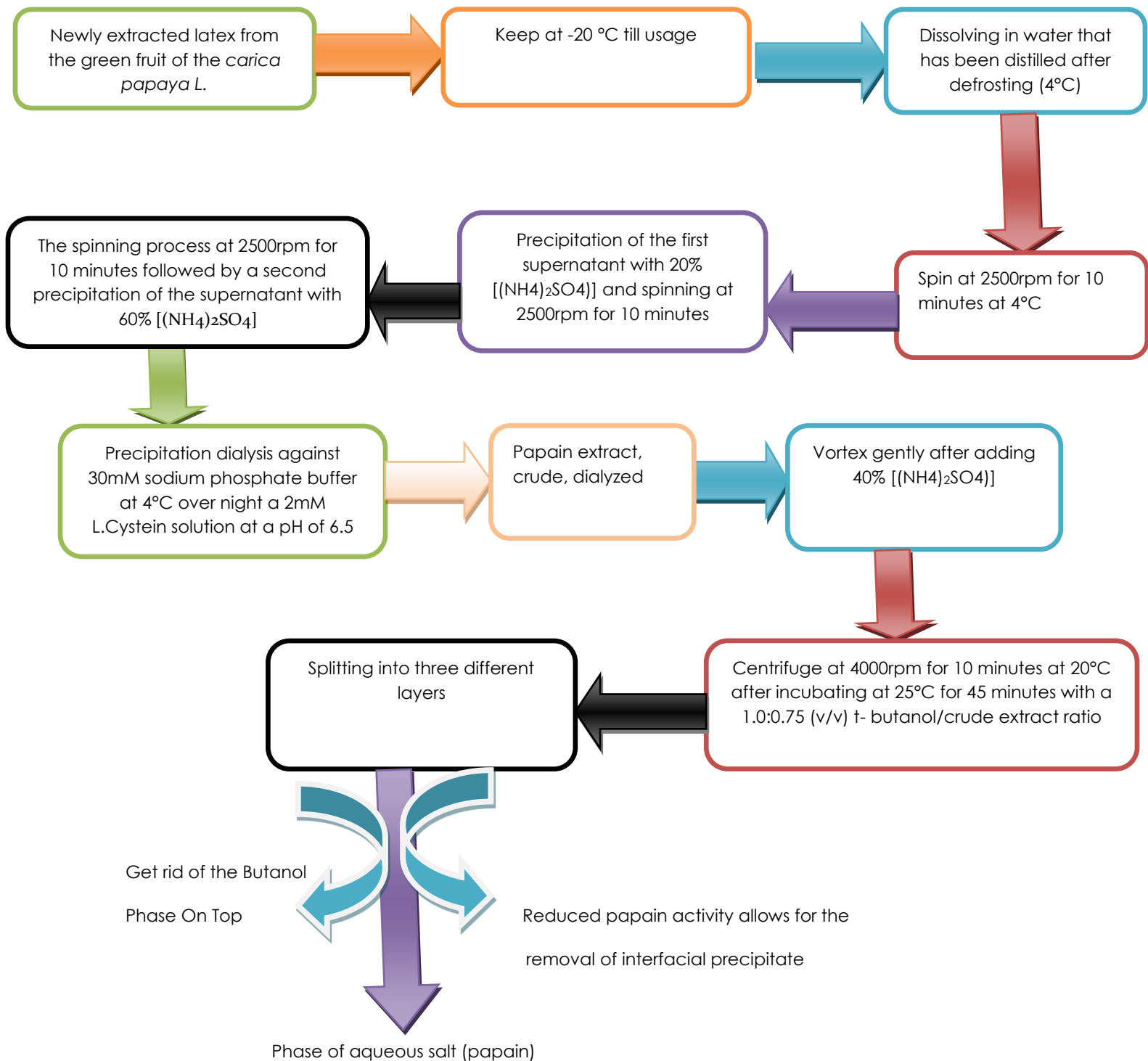


Figure 3. Process employing the Three Phase Partitioning technique that highlights the key steps used to extract papain from the raw papaya latex

The TPP was characterized as a three-stage recovery batch process depicted in Figure 3, combines alcohol precipitations with salting out to extract, dewater, purify, and concentrate the proteins of interest for use in either small- or large-scale production settings. The basic premise is to combine the crude slurry (protein extract) with a solid salt, often ammonium sulphate $[(\text{NH}_4)_2\text{SO}_4]$, and an organic solvent, typically t-BuOH (tert-butanol), to form a three-phase mixture shown in Figure 3. This method relies on the salt's capacity to partition an otherwise miscible t-BuOH-water combination into an organic-rich upper phase and a water-rich lower phase. Proteins provide a protein layer in which the desired macromolecule can precipitate and be readily removed. The mechanisms of salting out, isoionic precipitation, cosolvent precipitation, osmolytic, kosmotropic precipitation, protein hydration changes, and conformation tightening all work together in a complex interaction way to recover the target protein throughout the TPP process. TPP was employed to isolate many types of enzymes since it is effective at doing so, as seen by the observed rise in overall activity. A wide variety of proteases have been isolated and purified, including ficain, zingibain, cucumisin, papain from dried papaya peels, alkaline proteases from farmed giant catfish, proteinase, and calotropain from *Calotropis procera* latex, and many more [14].

Importance of Papain

Papain has attracted a lot of attention because of its remarkable properties, which include high enzymatic activity, a broad pH range of action, high-temperature stability, low cost, and non-toxicity. The US Food and Drug Administration (FDA) has acknowledged this enzyme preparation as a generally recognized as safe (GRAS) chemical [5, 6] and it has been put to use in the dietary sector to create bio-peptides by hydrolysis of food proteins [3, 4]. Consequently, papain was utilized as a food ingredient in the meat tenderization, baking, and milk industries [5, 6]. Papain is an enzyme having antibacterial, anti-inflammatory, and debridement properties that has been shown to enhance tissue regeneration when used in biomedical therapeutic settings. Wound healing ointments and gels containing this ingredient are currently commercially available [8–10]. Papain is one of the probable active components, and it has been shown to reduce the scar and improve the cosmetic appearance of the

treated area by encouraging local cell multiplication through the increased production of cytokines [11]. Figure 4 shows the use of papain in different industries.

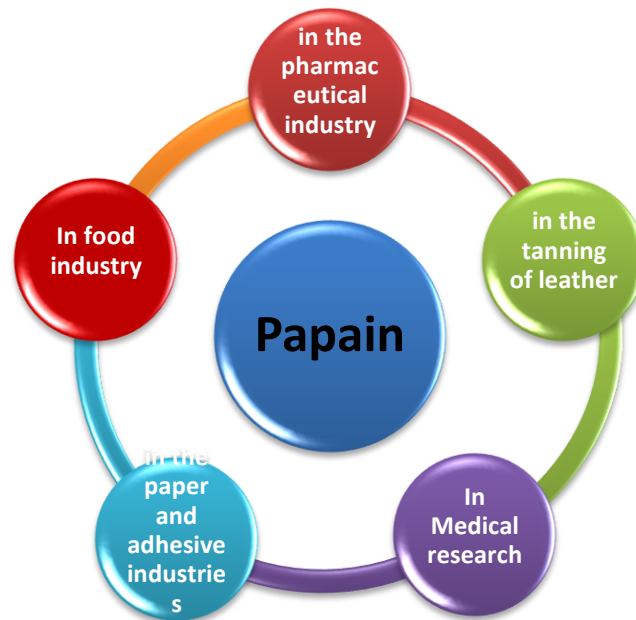


Figure 4. Importance of papain in different industries

Dengue Fever

After malaria, dengue fever is the second most prevalent human illness spread by mosquitoes [15]. Dengue fever, an infection caused by the dengue virus and carried mostly by female *Aedes aegypti* mosquitoes, is a serious and sometimes fatal disease [16]. Dengue fever is caused by a virus in the family *Flaviviridae* that is spread via the bite of an infected mosquito [17]. Severe instances of this viral illness were reportedly first discovered in 1950 during an outbreak in Thailand and the Philippines. It has now been discovered in several other countries. The economic and public health consequences of dengue's rapid worldwide expansion as a result of rising global temperatures are already being felt. In 2021, the epidemic of dengue fever reaches the countries of Reunion Island, Peru, Paraguay, Kenya, Fiji, Colombia, the Cook Islands, and Brazil. Dengue fever can cause severe debilitating symptoms such as severe weakness, extreme malaise, red eyes, red face, vomiting, discomfort behind the eyes, nausea, muscle aches, skin rash, high temperature, back pain, and even death. The mosquito becomes infected by sucking blood from a person who already has the virus. Viruses

can remain dormant in vector mosquitoes for years after infection, and in both circumstances, vertical transfer is extremely rare [16].

Epidemiology

Recent years have seen a rise in the occurrence of dengue fever over the world, putting almost half of humanity at risk. Over 80% of the 100-400 million annual illnesses are considered moderate or asymptomatic. Because of this, dengue instances are frequently underreported. Additionally, many instances are misdiagnosed. One modeling estimate places the number of dengue virus infections at 390 million per year (95% confidence interval: 284-528 million), of which 96 million (range: 67-136 million) show clinical symptoms of the illness. While there is a potential for infection in 129 different nations, the real impact is concentrated in Asia (70%) rather than elsewhere. World Health Organization data show that in the last two decades, the number of dengue cases has increased from 505,430 in 2000 across over 2.4 million in the year 2010 and 5.2 million in 2019 worldwide. There was a dramatic rise in deaths among young people between 2000 and 2015, with the number of reported deaths going from 960 to 4032 during that time period. In both 2020 and 2021, there appeared to be a decline in both the overall number of cases and the number of recorded deaths [15].

Population growth, unchecked urbanization in tropical and subtropical areas with poor sanitation, unreliable water supply systems, poor solid waste disposal, an increase in non-biodegradable containers in endemic areas leading to the proliferation of Aedes mosquito breeding sites, a lack of effective mosquito control programs, and human travel are all potential causes of the global resurgence and spread of dengue fever. The fast dissemination of the illness may also be attributed to the rapid development of dengue viruses with much more virulent genotypes. Every year, about 500,000 individuals with severe dengue need treatment; a significant percentage of these patients are children. Nearly 5% of those afflicted pass away. The yearly number of patients expected to die is 25,000 [15].

Treatment

Numerous studies have been conducted to create a vaccine against dengue viral illness because of its increasing importance in recent decades. However, there is currently no 100% efficient vaccine on the market, though some are available in various

locations. In order to eradicate this viral infection, researchers have relied on optimal control and management strategies [15]. The possible mode of action of such enzymes show that these are useful for enhancing the blood platelet count and blood clotting factor in human [2].

The bone marrow microenvironment is essential for the formation of platelets, which are cellular effectors of mammalian hemostasis. Thrombopoietin (TPO) is principally responsible for controlling the varied and intricate process that produces platelets. A synergistic role is also played in the release of platelets from megakaryocytes by other cytokines, including interleukin-1 (IL-1), IL-3, and IL-6, stem cell factors, fibroblast growth factor (FGF), and erythropoietin (EPO). A powerful phospholipid mediator called Platelet Activating Factor (PAF) also has an impact on platelet aggregation and degranulation.

The Papain Mechanism in the Hemorrhagic Fever of Dengue

The ability of papain to stimulate thrombocytes' production of cytokines like IL-6 is its mechanism of action in dengue hemorrhagic fever is depicted in Figure 5. According to Aziz et al. [18] secretion of this kind is carried out by mesenchymal stem cells, such as SHED, and haematopoietic stem cells. It will directly promote proliferation, maturation, and stimulation platelet production by increasing the secretion of thrombopoietin in the liver, leading to an increased platelet count. Mast cell proteases, tryptases, and chymase, which can cause plasma leakage, can also be broken down by the proteolytic enzyme papain (Figure 5). RNA analysis of study participants by Subenthiran et al. [19] reveals the presence of Arachidonate 12-lipoxygenase (ALOX12) and Platelet-Activating Factor Receptors (PTAFR) genes. At the conclusion of the third day of this investigation, the ALOX12 gene had grown by 15-fold; it is known that these genes are associated with enhanced megakaryocyte formation, followed by platelet creation, via the 12- Hydroxyeicosatetraenoic acid, as well as 12-HETE. The target of RUNX1 transcription, which controls the expression of haemopoietic-specific genes in megakaryocytes and platelets, is known to be ALOX12. Despite this, direct connections between DENV and ALOX12/PTAFR are not mentioned by a number of authors.

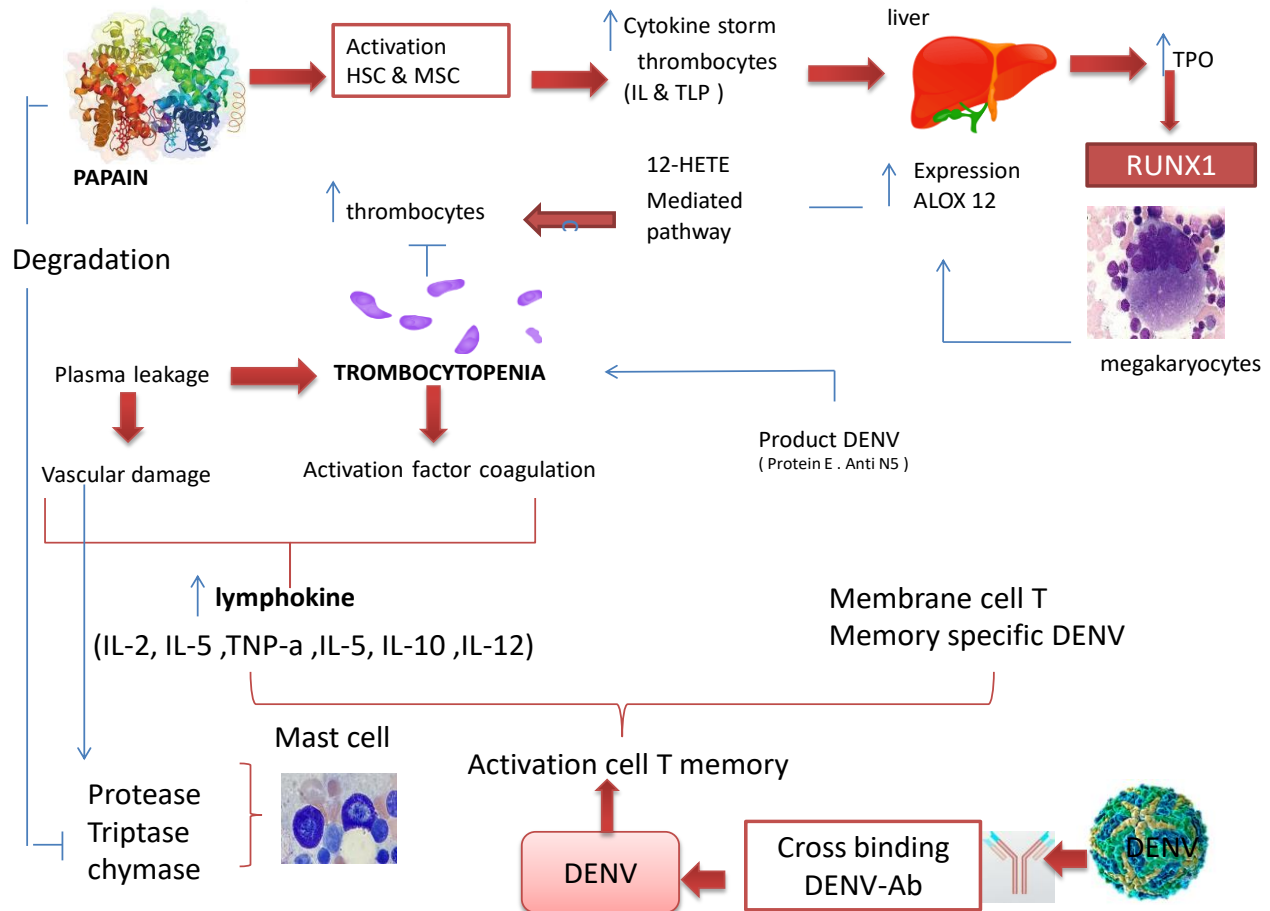


Figure 5. Mechanism of papain to enhance the platelets count

Conclusion

Papain has great potential for treating dengue fever and restoring normal platelet counts. Papain stimulates thrombocytes' production of cytokines. Three phase partitioning method of Papain enzyme purification is more suitable for research purpose. Papain's structure, isolation and function in dengue fever have been reviewed well and will help in the future studies linked with drug design to treat dengue fever.

Conflicts of Interest

The authors declared no conflict of interest.


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INNOVATIVE FOOD PRODUCTS - NUTRACEUTICALS AND FUNCTIONAL FOODS

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Review Based Book Chapter

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REVIEW BASED BOOK CHAPTER**PRODUCTION, NUTRITION AND NUTRACEUTICALS**

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Abstract

Nutraceuticals include various bioactive compounds present in edible natural sources like anti-oxidants, phytochemicals, probiotics, amino acids and fatty acids. In 1989, De Felice first described the term "Nutraceutical" that comes from the terms "Nutrition" and "Pharmaceutical". According to him, nutraceutical as a component of food plays an important role to prevent and treat different illnesses. Currently, nutraceutical business is increasing fast as people are very much concern about their health. The international market of nutraceutical is expected to rise from \$241 billion to \$373 billion from 2019-2025. Nutraceuticals are capable of providing additional health benefits when taken as part of daily diet. Nutraceuticals are critically important in normal physiological functions of human body and also minimize the danger of life-threatening ailments. Nutraceuticals are derived from both plant and animal sources. Nutraceuticals are globally used as dietary supplements, herbal products, probiotics, prebiotics and medicinal foods to treat and prevent various health problems like overweight, CVD, cancer, bone problems, diabetes, insomnia, gastrointestinal issues, various types of cancers, blood pressure, hyperlipidemia, pain management and depression. Mostly, nutraceuticals as dietary supplements are available in the concentrated form as pills, powders, liquid, capsule and soft gels which can be utilized orally along with daily food. Nutraceuticals offer a safer and more natural substitute to synthetic drugs with no or fewer side effects. In conclusion, nutraceutical industry has become well-known and popular all over the world due to its therapeutic benefits.

Keywords

Nutraceuticals, Functional Foods, Phytochemicals, Probiotics, Herbs, Supplements

1. Overview

Industrialization may result in air, water, soil pollutions and food contamination due to their wide spread usage of chemicals, heavy metals and pollutants made by human.

These problems increased the prevalence of problems related to blood sugar, overweight, different types of cancers and many health issues related to functioning of human body. The cost of medicines may increase due to elevated demands of health care. Therefore, for the safety and better quality of life, people start consuming natural sources like vegetables, fruits, and other plant foods, taking dietary supplements or nutraceuticals with no side effects to body. Due to more public awareness about nutraceuticals, the industry of supplements, phytonutrients and natural therapeutic services, have been growing very fast [1].

The intake of health and nutrient-dense foods items may affect the overall health and wellness of human beings. Foods may comprise different nutrients that have lot of health benefits and able to improve human health. Naturally occurring health-enhancing substances come from plant sources, animal sources may also contain various nutritious components that need attention of community for their significant role in improving human health. Eating fruits and vegetables rich in nutrients have been associated with combating illnesses like cancer, cardiovascular disease (CVD), obesity, and disorders related to Gastro-Intestinal tract (GIT) [2].

Phytochemicals present in the food that are linked with numerous health benefits are glucosinolates, flavonoids, terpenoids and polyphenols. In the recent years, nutraceuticals have received much attention from the researchers, consumers, and food producers. The well-known nutraceutical compounds like vitamins, probiotics, bioactive peptides, antioxidants are able to support the health due to presence of health-promoting food ingredients. Functional foods are the therapeutic foods when administrated daily may exert a specific positive health effect beyond their nutritional properties [3].

2. Methodology

Electronic databases including Google Scholar, online library of Willey, Scopus, Science Direct, PubMed and Springer Link were used for searching the data. Data was explored using keywords including "Nutraceutical", "functional food", "dietary supplement", "dietary fiber", "bioactive compounds", "essential fatty acid", "probiotics", "prebiotics", "human Gut", "antioxidants", "polyphenols", "cardiovascular health", "immune system" and "formulation of nutraceutical". Finally, appropriate researches

published before January 2025 were selected, assessed and estimated for the final version.

3. Nutraceuticals

The idea of "Nutraceuticals" is as old as 3000 years ago. Hippocrates stated that the food must be drug and the drug for the treatment of any ailment must be the food. The word "Nutraceutical" was discovered in 1989 by DeFelice. According to him, nutraceutical can be a part of food that delivers health benefits to prevent and treat various diseases. Nutraceuticals as a food products old in the forms of pills, powders, capsules and soft gels [4].

The term "nutraceuticals" comes from two words "nutrition" and "pharmaceuticals," representing a fascinating intersection of food and medicine. It encompasses a diverse array of products derived from specialized diets, dietary supplements, herbal sources, and processed foods like cereals, beverages, and soups. These products serve purposes beyond basic nutrition, doubling as medicinal aids, by virtue of their dual roles, offer a compelling synergy between nutrition and healthcare, embodying a holistic approach to wellness. Nutraceuticals are renowned for their multifaceted therapeutic properties, garnering significant attention in recent years for their potential nutritional, safety, and therapeutic benefits [5].

4. Classification of Nutraceuticals

Nutraceuticals are made from the plant and animal source. Currently, the health problems dedicated the important role of nutraceuticals in social well-being of human beings due to their additional health benefits without any adverse effects [6].

The nutraceuticals used in daily life fall into following categories on the basis of various criteria:

4.1. Classification Based on Food Availability

4.1.1 Traditional Nutraceuticals

Traditional nutraceuticals are one of the major categories of nutraceuticals. Under this category unchanged foods are made. It is totally natural. The nutrition of actual food remains same even after processing and dietary modification. Numerous fruits, vegetables, cereals, fish, milk and meat products contain several natural components. Traditional nutraceuticals are generally obtained directly from nature [7].

Different types of traditional nutraceuticals are given below:

4.1.1.1. Based on Chemical Constituents

i. Nutrients

Nutrients are the substances like fatty acids, amino acids, vitamins and minerals that have strong nutritional profile. Plant and animal products are rich in macronutrients and micronutrients that have various health benefits. They help in curing diseases related to vital organs. Nutrients like vitamins, amino acids, and fatty acids have specific roles in the pathways involved in the metabolism. Natural products from plants are used in treating various illnesses like diseases related to heart and central nervous system. Furthermore, they also strengthen the bones and muscles. Essential fatty acids have great impact on inflammation, brain functionality and reduced the blood cholesterol level. Vegetables, wholegrain cereals, milk products, fruits having vitamins are able to cure many diseases common all over the world. Not only the plant products but also animal products like meat, poultry are widely used to cure various disorders. Minerals mostly present in plant, animal and milk products are beneficial in numerous health-related issues. Fat-soluble vitamins, antioxidant, and water are most commonly known nutrients. Antioxidants have many potential benefits in the form of supplementation or dietary intake. Cancer and cerebrovascular diseases may be prevented by antioxidants. The vitamin E intake in greater amount as part of regular diet may prevent from disorders related to nervous system. Supplementation with selenium in genetically predisposed patients may help to prevent from pancreatic cancer having low level of Se. Zinc is one of the essential components in hundred enzymes which involve digestion, metabolism and wound healing [8].

ii. Herbals

Herbals are as old as human civilization and are utilized for the treatment of almost all the serious and life-threatening illnesses. Nutraceuticals obtained from herbs are able to improve health and save the humans from chronic ailments. Parsley contains flavonoids that increase the urine output, decreased the inflammation and GIT related problems. Menthol in Peppermint is an active constituent that helps to cure cough and fever. Lavender contains tannin and helps to treat depression, hypertension, cough and respiratory ailments. Cranberries contain proanthocyanin which are useful in cancer,

ulcers and urinary tract infection. Herbals are widely used to prevent and cure countless ailments from ancient times [9].

iii. Phytochemicals

Phytochemicals are vital for various physiological activities. Carotenoids are present in vegetables and have the ability to improve the immune system, due to its strong anti-cancer properties. Carotenoids in legumes, palm oil and grains reduced the blood cholesterol level according to previous research. More than 4000 Flavonoids have been identified that are capable to prevent degenerative illnesses [10].

Flavonoid and polyphenols are primarily present in fruits, vegetables and legumes and have strong anti-inflammatory, anti-oxidants, and anti-clotting attributes. Phenols are the largest class of secondary metabolites. They also show anti-cancer and anti-tumor property. Phytochemicals protect against metabolic disorders, microbial infection and mental ailments that had been proven scientifically. Phytochemicals when enter into our bodies, are able to improve optimal health and cure numerous ailments [11].

4.1.1.2. Probiotic Microorganisms

The term was coined by Metchnikoff. It has capacity of forming the friendlier in intestine for break down and absorption of food. Probiotics remove the toxic flora of intestine for making life smoother and maintain friendly environment. The meaning of word 'Probiotics' is 'for life' and is described as alive microbes, which when taken in tolerable quantities, acted effectively on the host. They are beneficial bacteria that elevate the breakdown and absorption of essential nutrients. They act to force out pathogens which may cause diseases and develop synergetic association with the human GIT. They also have an anti-microbial effect. They compete with pathogens and prevent their bonding to the epithelial cells of intestine, also produce an anti-toxin effect and reverse the negative impact of infection on the epithelial cells of intestine. Moreover, probiotics are helpful in lactose intolerance to break down the lactose into its sugar components by the release of β -galactosidase [12].

4.1.1.3. Nutraceutical Enzymes

Enzymes are biocatalyst which are formed by the cell and are protein in nature. Enzyme supplements are used for the treatment of gastrointestinal tract (GIT) related medical issues like gastroesophageal reflux disease, diarrhea, constipation and

ulcerative colitis. At present time, numerous rare ailments can be treated with enzyme therapies. Enzymes are the vital part of life; without enzyme human body is unable to do proper function. The people with the health problems such as anti-hyperglycemia, digestive problems and obesity, when utilized enzyme supplements with their diets may results in the elimination of severe symptoms. The enzymes used for the cure of numerous diseases mostly come from plant, animal and microbial sources [13].

4.1.2. Non-traditional Nutraceuticals

Non-traditional nutraceuticals are the food products synthesized artificially, produced by using biotechnology or agriculture breeding. These techniques include addition of nutrients for upgrading the food properties and improving the human health. On the basis of processing techniques, non-traditional nutraceuticals may be distinguished into fortified and recombinant nutraceuticals [14]. Examples of fortified and recombinant nutraceuticals are given in Table 1.

Table 1. Classification of Nutraceuticals based on Food Availability and Chemical Nature [5]

Nutraceuticals		
Fortified Nutraceuticals	Based on Chemical Nature	Recombinant Nutraceuticals
Calcium in Orange Juice	Carotenoids	Yoghurt
Vitamins and Minerals in Cereals	Polyphenolic Compounds	Cheese
Folic acid in Flour	Phytoestrogens	Vinegar
Cholecalciferol in Milk	Dietary Fibers	Fermented Starch
<i>Bifidobacterium lactisin</i> Milk	Fatty acids	Bread

Non-traditional nutraceuticals are classified as follows:

4.1.2.1 Fortified Nutraceuticals

The fortified food originates from agricultural breeding e.g., calcium is fortified in orange juice; micronutrients are added in cereals and folic acid fortified in wheat flour. Other examples include milk fortified with cholecalciferol to prevent and treat vitamin D deficiency. Fortified nutraceuticals comprise addition of well-suited nutrients as a chief element to prevent and treat different nutritional deficiencies [15].

4.1.2.2. Recombinant Nutraceuticals

Recombinant nutraceuticals are food products that are formed by utilization of genetic engineering and biotechnology. The health benefits related to different foods and crops are enhanced by genetic modification in which recombinant compounds and proteins are added. Biotechnology is widely applied for the development of energy-giving food products (bread, alcohol, fermented starch and fermented milk products), production of probiotics and plant-based extract containing bioactive components [16].

4.1.3. Classification Based on Mechanism of Action

Nutraceuticals may also classify on the basis of their specific mechanism of action into different categories (Figure 1). Due to these attributes, nutraceuticals have strong capability to reduce the microbial infections, inflammation and boost immunity.

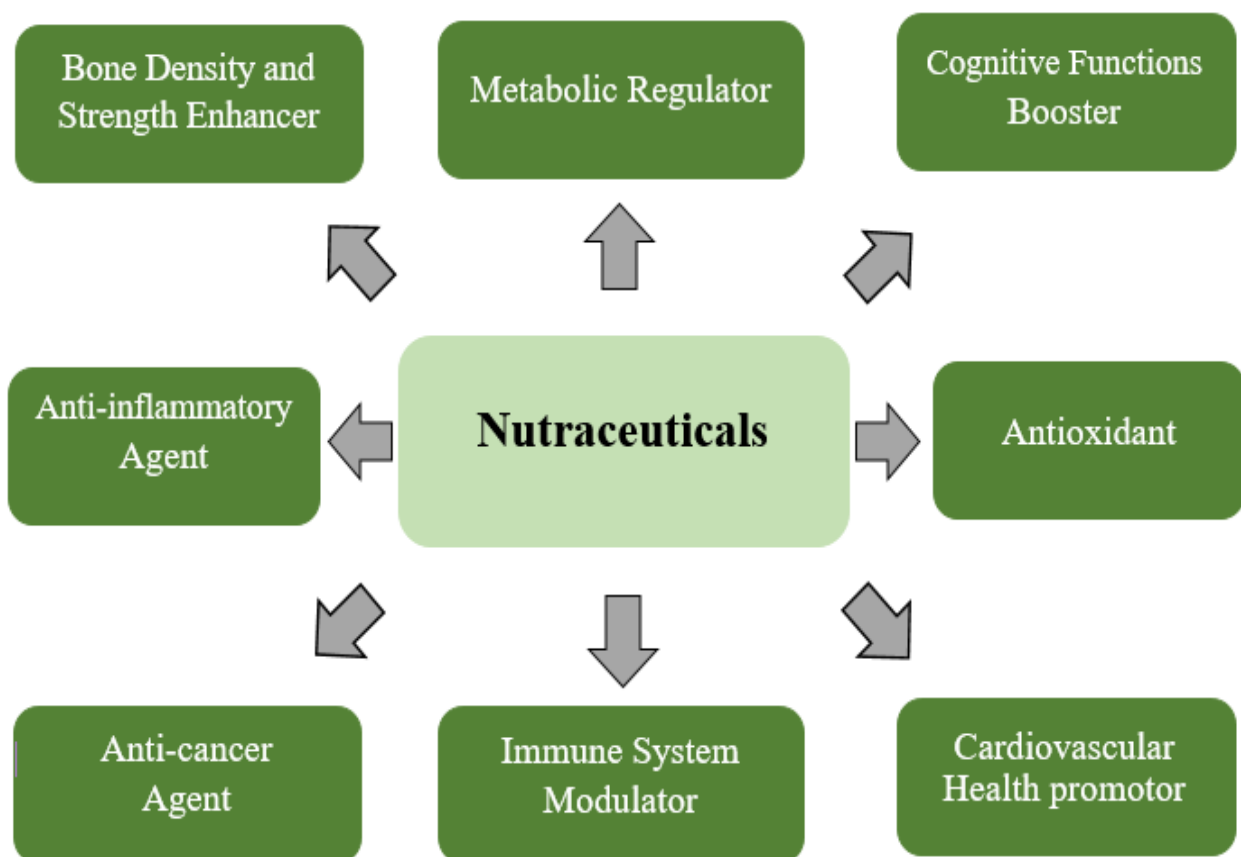


Figure 1. Classification of Nutraceuticals on the basis of Mechanism of Action

4.1.4. Classification Based on Chemical Nature

Nutraceuticals may be classified on the basis of presence of primary and secondary metabolites such as phenolic constituents, isoprenoid by-products, amino acids, fatty acids, and carbohydrates-based elements [16].

4.1.4.1 Food Sources of Nutraceuticals

The food sources from which all nutraceuticals come from are natural and can be characterized as:

i. Dietary Fiber

Dietary fiber are indigestible carbohydrates and lignins that comes from plant sources. Functional fiber contains non-digestible carbohydrates which have advantageous impact on the body functions. Total fiber is made of dietary and functional fiber. Starches, oligosaccharides and other non-digestible carbohydrates are all functional fibers. Dietary fiber is digested by the action of gut microflora, as the enzymes released by the digestive tract are not able to break down the fiber [17]. Dietary fiber comprises non-starch polysaccharides, resistant dextrin and starches. Foods containing soluble fiber contain fruits, cereals and beans. Chemically, dietary fibers do not break down and absorbed in the small intestine as they are complex carbohydrate.

On the basis of solubility in water, dietary fibers are classified into two types; soluble and Insoluble dietary fiber. These two types of dietary fibers also known as non-starch polysaccharides [18].

ii. Probiotics

A probiotic is live microbial feed supplement when taken in enough quantity. It boosts the intestinal microbial balance by giving the host animal good effects. Commonly, different classes of bacteria comprise of probiotics [19] (Figure 2).

Probiotics are present in several forms like liquid form, powdered form, pasted or gel form, granular form and capsule form. Probiotics are usually used in treatment of GIT conditions (acute diarrhea, lactose intolerance) and anti-biotic related GI adverse effects. Probiotic agents are non-toxic and non-pathogenic. They are resistant to the gastric acid. They adhere to anti-bacterial constituent forming gut epithelial tissues. Previous studies showed that intake of probiotics declines the danger of respiratory infections, urinary tract infections, different food and non-food allergies [20].

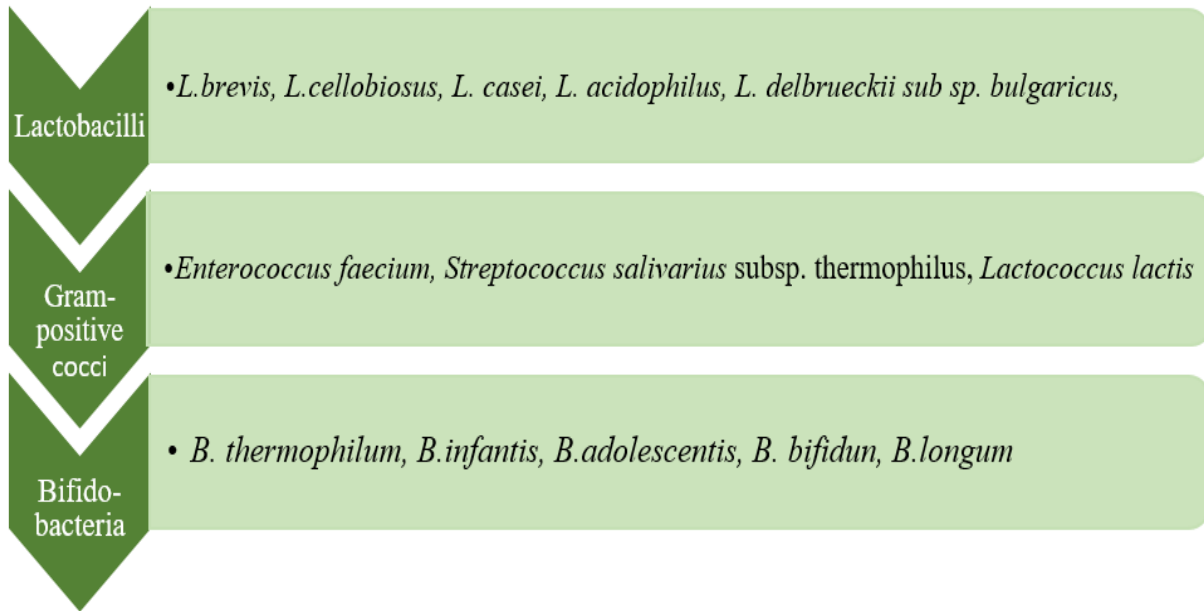


Figure 2. Common Classes of Bacteria used as Probiotics with Examples

iii. **Prebiotics**

Prebiotics are dietary constituents which positively affect the host by breakdown of the gut microbiota or selective alteration in chemical moieties. These are short-chain polysaccharides that have unique chemical structures which are not assimilated by humans; specifically, fructose-based oligosaccharides that occur naturally in food or are added in the food. Normally, the growth of *Bifidobacterial* and *Lactobacillus* in the gut is enhanced by the utilization of prebiotic that help in breakdown. Vegetables like banana, tomato, alliums contain fructo-oligosaccharides. Raffinose in beans and stachyose present in peas are some other examples of these oligosaccharides. The prebiotics enhanced the lactose tolerance, anti-tumor activities, toxins neutralization, and intestinal immune system stimulations, decrease of constipation, complete lipid profile. The growth of bifidobacterial is raised by the everyday consumption of 5g to 20g of insulin and oligosaccharides. Oligosaccharides intake in large quantities may cause flatulence diarrhea, and abdominal discomfort [21].

iv. **Polyunsaturated Fatty acids**

Polyunsaturated fatty acids (PUFAs), come from diet and are vital for the functioning of human body, are called as "essential fatty acids" (EFAs). PUFAs fall within two classes

Omega-3 fatty acids (N-3) and Omega-6 fatty acids (N-6). DHA, EPA, and ALP are the three main example of omega-3 fatty acids. The main sources of these essential fatty acids (DHA & EPA) are fish oils and fatty fish. Moreover, Plant-based oils are rich in LA. PUFA have anti-inflammatory activity that results in the reduction of triglycerides, blood pressure levels, and platelet accumulation. Depending on the double bond's location and number, PUFAs control number of biological functions that includes reduction of blood pressure and blood clotting. Furthermore, they also play a vital role in the normal development and physiological functions of brain and other parts of nervous system [22].

Overall health and nutritional well-being are affected by the location of double bond, the level of unsaturation, and the fatty acid's chain length. Fatty acids are building blocks of various dietary oils and (fats) lipids that originates from both plant and animal sources. As the chief constituents of phospholipids, triglycerides, and cholesterol esters, fatty acids play important structural, functional, and metabolic roles in the body [23].

v. Antioxidants

All the metabolic reactions in the human body takes place in the presence of oxygen. Free radicals are produced during oxidation when oxygen reacts with body compounds. These unstable molecules (free radicals) attack the human body's healthy cells and affects the structure and function of these cells. When anything come in contact with free radicals at a molecular level, they destroy them. More production of free radical, more damage may occur and various health issues can develop. Oxidative stress due to increased formation of free radicals, may results in low cognitive performance, fasten aging process and develop degenerative diseases like cancer, arthritis, cataracts, and heart disease.

Antioxidants can deactivate the free radicals before they attack the healthy cells and lessen the oxidative damage. Antioxidants have the ability to inhibit the oxidants chain reactions and finally rebuild the damaged membranes. Antioxidants avert against free radical damage, and are life-threatening for keeping optimal health and wellbeing. It involves various endogenous and exogenous components, that are involved in the neutralization of free radicals [8].

Antioxidants inactivate ROS at cellular and molecular level and under specific low concentration delay oxidative processes. Examples of anti-oxidants are polyphenols, carotenoids, tocopherols, ascorbates and lipoic acids that have strong free radical scavenging activities. Earlier investigations confirmed that many known diseases are cured by the utilization of antioxidants. The importance of antioxidants makes them crucial part of the nutraceutical industry [24].

Antioxidants are also present in the vegetable oils. Antioxidants are used in the treatment of all the chronic diseases that occurs mostly due to oxidative stress. Oxidative stress plays a main role in the different neurodegenerative diseases. The ageing process fastens due to deficiency of anti-oxidants and increased oxidative stress [19].

vi. Polyphenols

Plants as secondary metabolites, forms a large group of phytochemicals “Polyphenols” that give protection against oxidative stress due to production of ROS. There are almost 8,000 different types of polyphenols, among all flavanones. Flavones, flavan-3-ols, flavonols, and anthocyanin are the most common polyphenols. Most of the polyphenols are formed by the pathway of branched phenylpropanoid. The flavonoids and phenols are the most common examples of polyphenols present in food items. Polyphenols also have anti-inflammatory, cardio protective, antioxidative, and anti-microbial properties and play a pivotal role in preventing diabetes and diseases related to central nervous system. In vitro studies found that on the molar basis, polyphenols are more effective antioxidants than vitamin E and C. Biological activity of polyphenols is determined by using bioavailability of polyphenols, their chemical properties, enzymes available for breakdown, and intestinal absorption rate [25].

vii. Spices

Since 5000 BC spices have been utilized as part of daily diets. Traditionally, spices are used in the various food recipes as flavoring agents due to their therapeutic importance and positive impact on human health. Spices that are rich in bioactive compounds recognized as first functional food and have a noteworthy valuable influence on the health of human beings [26].

Spices enhanced the sensory attributes of foods and give them specific color, flavor, taste aroma, and texture. Most of the spice constituents are terpenes and essential oils which have been found to be useful in many forms. Consumption of garlic with fish oil may reduce the complete lipid profile of patients with hyperlipidemia. As a part of food, spices and herbs are non-toxic and safe. Interactions of spices with synthetic medicines may results in toxicity, or when used as natural drug in higher dose. Spices may improve the digestion, treat digestive issues, and also have anti-bacterial, cardioprotective, anti-diabetic, anti-cancer and anti-inflammatory properties [27].

5. Production and Formulation Process of Nutraceuticals

Dietary supplements come from foods or other natural and nontoxic sources, that are generally concentrated in different forms [28], as shown in Figure 3.



Figure 3. Concentrated Forms of Dietary Supplements

Dietary supplements are sold in the concentrated form as minerals, vitamins, amino acids, herbs secondary metabolites, enzymes and organ tissues. Medical food is defined as a modified food used for the cure of specific health condition along with fulfilling the nutritional needs. As components of medical value, pharmaceuticals have been defined by merging the terms "farm" and "pharmaceuticals", produced from the alteration of plant and animal sources. Functional foods and dietary supplements are the major types of nutraceuticals. Functional foods are taken as part of daily diet and have additional health benefits apart from the basic benefits as proved by scientific researches. The role of functional foods other than physiological benefits also have capability to lessen the dangers of various aliments [29]. Nutraceuticals as a part of food have medicinal and physiological properties, and present in the form of pills, powders, and capsules. Nutraceuticals' effectiveness mainly depends on their sources and constituents, with their division chiefly linked with their origin, chemistry and pharmacology [30].

6. Nutraceuticals and Diseases

Following are some ailments where nutraceuticals play a significant role:

6.1. Anti-diabetic Activity

Diabetes is a metabolic illness which happens when the body do not secrete adequate insulin or cannot utilize it efficiently. Approximately 422 million persons are affected from diabetes internationally. Furthermore, diabetes may result in the death of 1.5 million people annually. The main barriers to widespread access are high cost and inadequate supply of human insulin. Previous researches showed that plant-based diets provide micronutrients and phytochemicals that have anti-diabetic properties. Additionally, adverse effects of artificial medicines are reduced due to utilization of natural food sources [31].

Genistein in soybean seeds, has been revealed to be an active drug for the management of diabetes. According to previous investigations, genistein enhanced the secretion of insulin in animal modelling. In a human study, genistein therapy may also significantly lowered the fasting blood sugar levels of diabetic females. In another animal study, grape seed extracts noticeably lowered the blood glucose levels in type

2 diabetic rats. Furthermore, Sage extract have been noted to decreased the blood glucose levels in patients with diabetes [32].

6.2. Anti-hypertensive Activity

Globally, hypertension is one of the most common causes of serious health issues. Numerous studies showed relation of different dietary components with decreasing the hypertension. *Hibiscus* tea is rich in various bioactive compounds that play a vital part in declining blood pressure. Animal studies have confirmed that intake of sour tea containing *Hibiscus sabdariffa* extract lowered the levels of systolic and diastolic blood pressure. Ginger as a food supplement has a beneficial impact on the functioning of endothelial cells and blood pressure. 2g/day to 6g/day ginger addition in daily diet significantly reduced the LDL and cholesterol levels of hyperlipidemic rats [33]. Additionally, ginger is rich in potassium, due to which it can control blood pressure. Recent investigations depicted that saffron has ability to protect against cardiovascular diseases due to its strong antioxidant potential. In hypertensive rats, saffron administration for five weeks can prevent from increase of blood pressure [34]. The older studies investigated that cinnamon has ability to treat metabolic disorders. Furthermore, cinnamon's polyphenols help in the normal regulation of blood pressure levels [35].

6.3. Anti-hypercholesterolemic Activity

Previous studies suggested that total cholesterol levels dropped significantly in the experimental group that take red-yeast-rice when compared to the control group. Berberine an alkaloid is found in many medicinal plants like *Coptis chinensis* may decrease the lipid profile by lessening the production of liver's cholesterol and triglycerides [36]. Human blood lipid levels, intake of plant based and animal-based protein were studied and compared. The investigations found that plant-based protein consumption as compared to protein from animal source significantly reduced lipid profile of individuals with hyperlipidemia. The impact of the drink made from herbal plant "Tiwai" on hypercholesterolemic patient's lipid profiles were evaluated. The results concluded that taking the herbal drink for 7 days reduced the total cholesterol levels of patients. Findings related to impact of eating tree nuts on lipid profile depicted that the tree nuts reduced triglycerides, LDL and total cholesterol levels [37].

6.4. Cardioprotective Activity

Omega-3 polyunsaturated fatty acids, dietary fibers, antioxidants, and many micronutrients are mostly used for the prevention and treatment of CVD. Many reports show that low consumption of fruits and vegetables are related with a high death rate in CVD. Rice bran helps lowering serum cholesterol and LDL levels in the blood and rises the HDL levels. Rice bran contains lutein as well as Zeaxanthin, which improves eyesight. Important factors responsible for CVD include obesity, increased blood cholesterol level, increased blood pressure and type 2 diabetes. Consumption of poor diets and lifestyle habits strengthens the risk of CVD. People who take a healthy diet, do not smoke and consume less amount of alcohol tend to have a reduced risk of CVD. Food sources can elevate complete lipid profile except lead HDL levels. While treating hypercholesterolemia, increase of cholesterol and bile acids in the fecal excretion may be observed. Diet modification helps to reduce the formation of cholesterol in human liver. People with family history of CVD, must take diet rich in calcium, phosphorus and magnesium. Alcoholic beverages and sodium consumption should be less in these people [38].

6.5. Anti-microbial Activity

An experimental data showed that tannins and other phytochemicals from different medicinal plants may include abundant natural anti-microbial and anti-fungal agents used in the formulation of energy-rich tea formulations. The anti-bacterial activity of larch bark extract was checked on the pathogens that results in respiratory-tract infection in an investigation, and the outcomes confirmed that extract of larch bark had stronger anti-microbial activity than the extract containing grapefruit seed powder. Phytochemicals from LBE can therefore be utilized as active anti-bacterial in the formulation of nutraceuticals. Quercetin, a flavonoid, found mainly in vegetables and fruits has anti-viral, anti-atopic and anti-inflammatory activities. *Thymus vulgaris* essential oil confirmed very noteworthy bactericidal and anti-fungal activity. Apigenin (bioactive compound) in parsley, shows strong activities against inflammation [39].

6.6. Anti-cancer Activity

Laboratory research confirmed that many natural food products rich in bioactive components have strong anti-cancer capabilities. Nutraceuticals also help in

diminishing the side effects of cancer treatment and improving the over-all health of patient. Some research estimates that one-third of all cancer's deaths are preventable by life-style changes, which include appropriate nutrition. Botanicals are widely used in the treatment of cancer. There are many nutraceuticals available for the reduction of the risks of cancer [40]. Preventing the cancer by dietary modifications generally highlights the food items from plant, marine and animal sources and skipping the refined and processed food products. In addition, carotenoids from plant nutraceuticals having anti-oxidant activities are effective for the prevention of cancer. Many phytochemicals including polyphenols and flavonoids have strong anti-cancer potential. Flavonoids present in citrus fruit, also have anti-tumor activities [41]. Alkaloids are effective in treatment of cancer disease. Turmeric is rich in bioactive compound "Curcumin" which possess free radical scavenging, anti-inflammatory, and anti-cancer activities. Nutraceuticals may also help to reduce the toxicity, associated with cancer therapies [42].

7. Conclusion

In conclusion, nutraceuticals have additional nutrients that play vital role for promoting health, preventing disease, and managing various health conditions. Bioactive compounds, that are derived from natural sources such as plants and animals as dietary supplements, offer a wide-ranging therapeutic benefit; from anti-oxidant and anti-inflammatory effects to immune support and detoxification. Furthermore, nutraceuticals are helpful in modulating the bodily functions, support vital organs and immune system, and contribute to overall optimal health. Nutraceuticals may also offer a safer and more natural substitute to synthetic drugs with fewer side effects and a lower risk of toxicity when used in appropriate dose. Overall, nutraceuticals have potential to be used as therapeutic agents to support health and prevent from diseases.

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Author Contributions

Conceptualization, writing – original draft, U.A.; Writing – review and editing, M.; visualization, F.N and R. R.

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The authors declared that they have no conflict of interest.

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INNOVATIVE FOOD PRODUCTS - NUTRACEUTICALS AND FUNCTIONAL FOODS

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Review Based Book Chapter

SAFETY AND QUALITY OF NUTRACEUTICALS

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REVIEW BASED BOOK CHAPTER**SAFETY AND QUALITY OF NUTRACEUTICALS**

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Abstract

Nutraceuticals, derived from bioactive compounds, offer health benefits and serve as natural alternatives to traditional pharmaceuticals. Despite their appeal, these products face significant challenges in safety and quality due to less stringent regulations and inconsistent standards globally. The examination of current regulatory frameworks in various countries, utilizing official sources and databases, reveals the complexities of quality, safety, product development, regulatory discrepancies, and authenticity affecting nutraceuticals. The global expansion of the nutraceutical market further complicates regulatory enforcement and the substantiation of efficacy and safety claims. To address these issues, the establishment of an effective system promoting cooperation among consumers, healthcare professionals, and government entities is imperative. Such a system would contribute to the creation of international standards and botanical references, thereby increasing transparency and trust in both processes and products. Additionally, the role of emerging technologies in enhancing systems engineering through information sharing and resource utilization across nations is explored. In conclusion, the current state of nutraceutical regulation is insufficient, leading to questionable claims often unsupported by robust evidence. Strengthening regulatory frameworks and fostering a culture of integrity are crucial to guarantee product efficacy and safety, facilitate monitoring, and bolster the confidence of both consumers and healthcare providers.

Keywords

Nutraceutical, Therapeutic Effect, Quality, Safety, Regulations

1. Introduction

Nutraceuticals are products with naturally occurring, biologically active ingredients that are good for consumers [1]. Depending on the nation and its laws, they may be categorized as functional foods, medicines, dietary supplements, or therapeutic foods. Nutraceuticals can be obtained from a variety of sources, including dietary fibers, fatty acids that are polyunsaturated, antioxidant vitamins, probiotics, prebiotics, polyphenols,

or spices, and herbs. Nutraceuticals are said to have some physiological effects, including enhancing immunity, treating chronic pain, and enhancing general well-being [2]. Nonetheless, the business and authorities must address the significant issues surrounding the quality and safety of nutraceuticals. Nutraceuticals are not under stringent safety and efficacy testing or pre-market approval, in contrast to pharmaceuticals. Furthermore, there is a great deal of variation in the laws and guidelines governing nutraceuticals in various nations and areas, which leaves both producers and customers perplexed and inconsistent [3]. As a result, methods for quality assurance and control are required to guarantee the identity, potency, purity, equilibrium, and safety of nutritional supplements at every stage of the supply chain, which ranges from the raw material to the finished product. The present state and concerns regarding the safety and quality of nutraceuticals, as well as the most effective approaches and methods for enhancing the quality assurance process of these products, has been covered in this chapter.

Nutraceuticals including antioxidants, omega-3 fatty acids, plants like wheatgrass, aloe vera, and other types of seaweed, and algae, as well as teas and herbs like ginseng and Echinacea, continue to enjoy a healthy and expanding market. According to a recent assessment, the nutraceutical business is predicted to grow to a potential value of \$340 billion by 2024, indicating that it is now experiencing global expansion [4]. From 2016 to 2024, the cumulative annual growth rate (CAGR) for nutraceuticals is projected to be 7.2% [5]. This increase in the nutraceuticals-based industry's growth is linked to a few variables, including an increase in consumer demand for nutraceuticals, increased knowledge of the health advantages of nutrition, and an incremental rate seen in the healthcare graph [6]. Over 90% of the worldwide nutraceutical industry is currently accounted for by Europe, the United States, and Japan. At a compound annual growth rate of 8%, the market is expected to grow from \$247 billion in 2019 to \$336 billion by 2023 [6, 7]. Now that the global markets have reached a certain level of maturity, developing economies, particularly those in Asia Pacific, including India, are the focus of nutraceutical companies. In 2017, the market share of the Indian nutraceutical industry was a mere 2% of the worldwide market [8].

2. Efficacy and Safety Aspects of Nutraceuticals

2.1. Efficacy

The efficacy of nutraceuticals is the degree to which they produce the desired health effects in the prevention or cure of various diseases. Nutraceuticals are natural substances that may have health benefits beyond their nutritional value, such as anti-inflammatory, anti-cancer, antioxidant, and prebiotic effects [9].

Figure 1 describes a few instances of how some nutraceuticals can be beneficial. After carefully weighing the costs and benefits and taking the preferences of the patient into account, a meta-analysis of 12 research revealed that cinnamic acid decreased inflammatory indicators and may be utilized as a potential adjunct in oxidative stress and inflammation [9]. A meta-analysis was conducted on 86 RCTs with 162,796 individuals to compare the effects of high versus low levels of omega-3 fatty acid intake on cardiac and circulatory illness over a minimum of one year. 8672 individuals in 31 RCTs were used in a meta-analysis to assess the effects of probiotic-treated adults and children on the incidence of *Clostridium difficile*-associated diarrhea (CDAD) [9, 10]. 23 RCTs involving 1513 participants were meta-analyzed to determine the effect of dietary fiber on coronary heart disease and associated risk variables. To ascertain if dietary iron therapy prevents and controls anemia in a healthy population, a summary of the data from 75 systematic reviews has been conducted. 19 RCTs were meta-analyzed to ascertain the effectiveness of antioxidant vitamins and/or mineral supplements in slowing the advancement of age-related macular degeneration (AMD) [11].

2.2. Safety: Issues and Potential Risk

Consumers use nutraceuticals, which are sold as over-the-counter products, as supplements [12]. As a result, their safety must be prioritized, or else fatal consequences could happen. The three most often reported problems are contamination, adulteration (deliberate or accidental), and deceptive labeling as shown in Figure 2.

Three distinct detection procedures can be used to show adulteration: (1) the existence of an undocumented drug; (2) the deviation of a component from its usual concentration (content); and (3) the likelihood that a profile will not occur [13]. One can intentionally or unintentionally commit adulteration. Various circumstances may

lead to unintentional adulteration. For example, contamination with chemical fertilizers, heavy metals, fertilizers, or microbiological agents may occur during storage, the formulation and manufacture of nutraceuticals, or the many stages of plant growth. Insects, rodents, parasites, fungi, mold, poisons, heavy metals, dust, pollens, artificial substances, and insects can all be used as adulterants [14]. Any of these contamination types could result in infections or even more serious ailments like gastritis and its aftereffects, liver damage, and even potentially fatal diseases. The stability of the active chemical or compounds, microbiological control, and specifications given in specific monographs may therefore be used to determine the need for raw material and finished product quality control. Intentional adulteration of vitamins or herbal treatments might have very negative effects. It frequently happens with synthetic substances, most of which are not reported [15]. It typically has the goal of changing the pharmacological response and generates financial gains. Nutraceuticals derived from plants are frequently very hard to come by, and extract manufacturing is expensive and time-consuming. Consequently, regulatory agencies do not permit these adulterations [16].

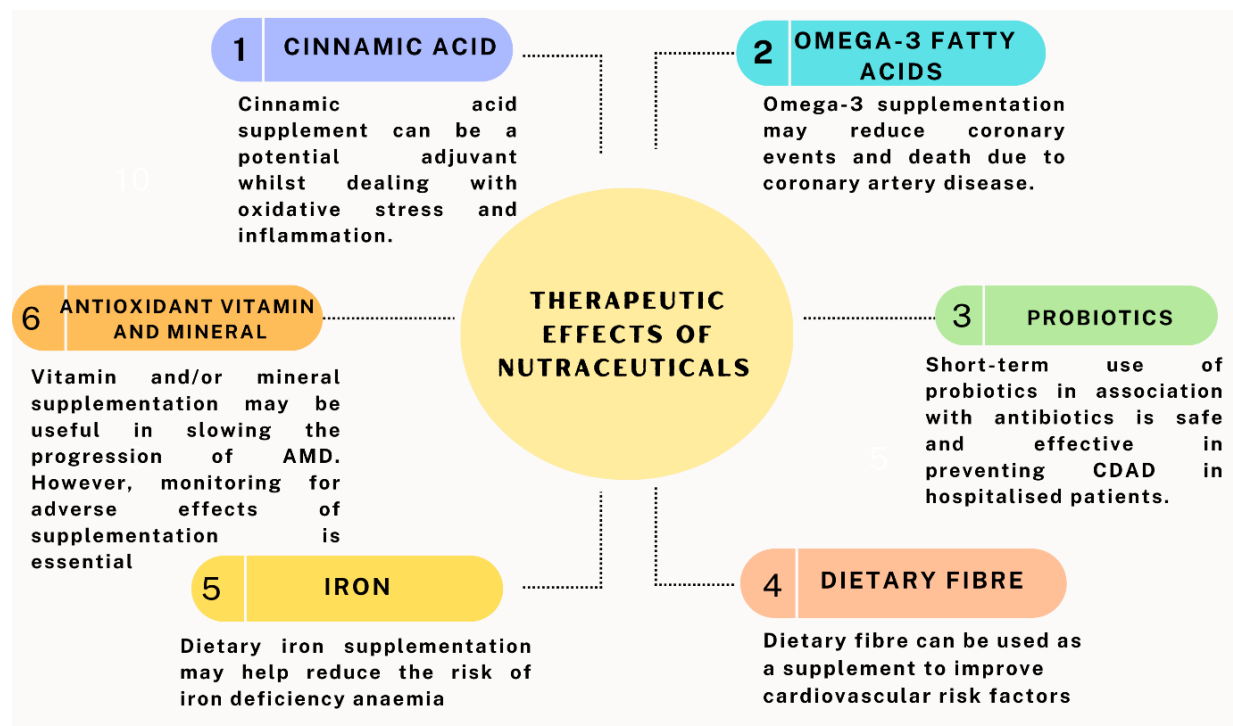


Figure 1. Potential Therapeutic Effects of Nutraceuticals [9]

Deceptive labeling is another source of harm to human health. In one study, the isoflavone content was analyzed and contrasted with the label information on five different types of dietary supplements made from soy [17]. Two of the alleged isoflavones, genistein and daidzein, were found to be missing from three of the five supplements [18].

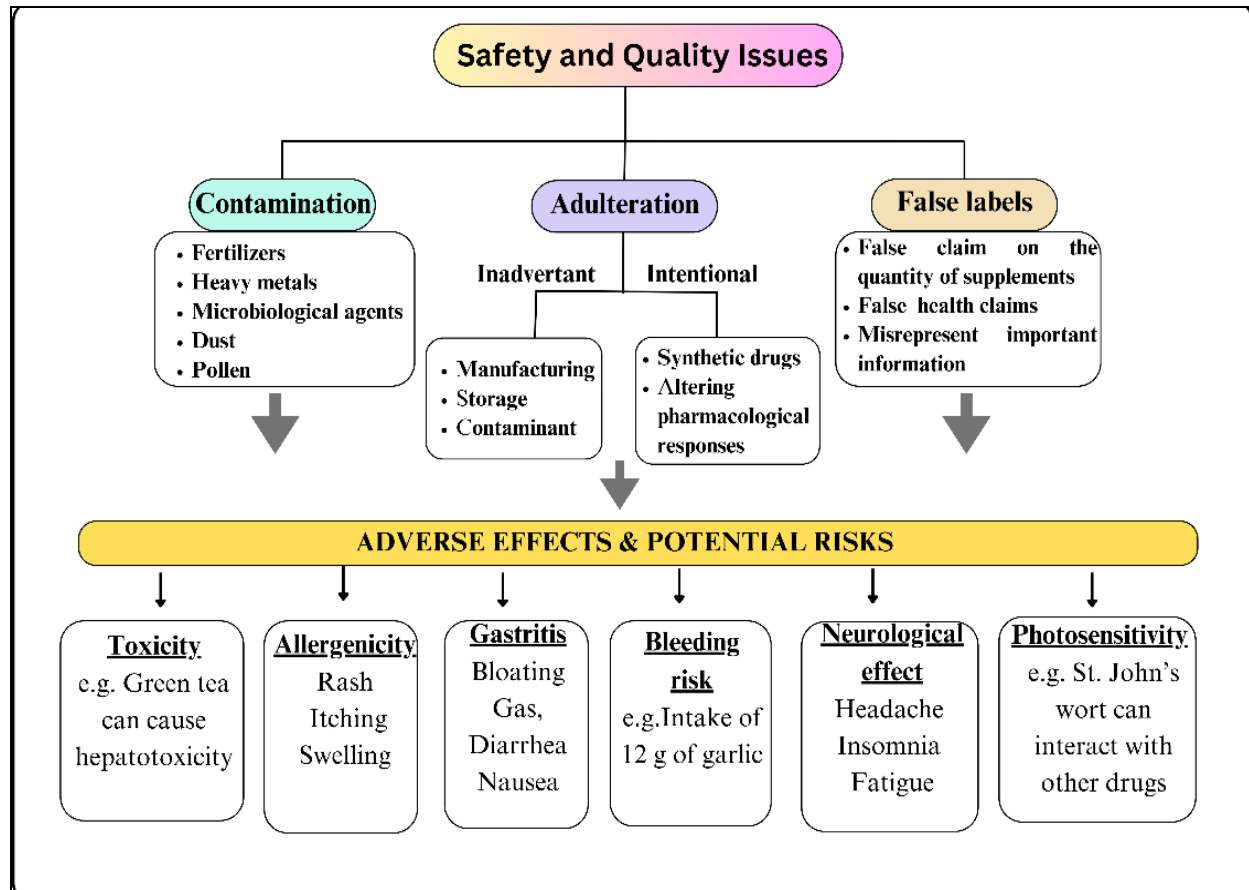


Figure 2. Schematic Illustration of Safety, Quality and Potential Effects and Risks of Nutraceutical [12-15]

Furthermore, an HPLC investigation of one of the compositions revealed that each pill contained 1.538 mg of genistein, rather than the 60 mg of isoflavone that had been calculated based on genistein [19]. However, nutraceuticals have the potential to cause toxicities even at recommended concentrations. The main reason for this is that there aren't enough controlled or long-term human clinical research studies to establish the ideal dosage [20]. For example, there have been reports of hepatotoxicity associated with green tea [21]. An everyday dosage of about 12 g of cloves of garlic

can have antiplatelet properties and induce abnormal bleeding. Your health may be at danger due to incorrect ingredient identification, incomplete ingredient lists, and dosage errors, in addition to potential allergic reactions. It may also have an impact on the effectiveness of other drugs and prescriptions. Supplements containing omega-3 and fish oil may intensify bleeding, which is particularly elusive for people on other anticoagulants [22]. For many supplements, there are recommended dosages available; nevertheless, they differ significantly. Nutraceuticals in pharmaceutical or a greater concentration of supplementation may have unexpected detrimental consequences through pro-oxidative or other mechanisms.

3. Safety Assessment of Nutraceuticals

FAO/WHO mandates that producers of nutraceuticals or functional foods carry out placebo-controlled clinical studies and evaluate the results in four phases [23].

1. Safety
2. Efficiency
3. Effectiveness
4. Surveillance

Investigating the safety of dietary supplements is still ongoing. Table 1 demonstrate that it is necessary to assess the possible dietary impact, the novelty of the constituents and preparation techniques, and both [24]. The safety of any innovative food ingredients and their production techniques is guaranteed by several rules [25].

To assess the safety of functional ingredients, which are added to foods for health benefits, four steps are followed: identifying hazards, characterizing hazards, assessing exposure, and characterizing risks [26].

- **Step 1: Hazard Identification.** This step aims to identify the potential hazards of the functional ingredients, such as their biological activity, toxicity, impurities, and interactions with other substances. Different types of functional ingredients have different safety issues, such as single compounds, herbal extracts, or novel products. Historical exposure and scientific studies can help identify hazards [27].

Table 1. Questionnaire for Healthcare Experts to Assess the Safety of Nutraceuticals

A registered dietitian, a food scientist, a nutritionist expert, or another healthcare provider must be able to respond to several questions to assess the safety of a functional food	
i.	Which ingredient(s) serves a purpose?
ii.	What quantity of the substance is included in each serving?
iii.	How big of a serving is normal?
iv.	What is the average amount of eating the functional food? e) Has the company tested the ingredient(s) in both people and animals for safety?
v.	Are there any published, peer-reviewed studies on the substance or ingredients?
vi.	Will the company give you background on studies that have been published or safety information?
vii.	Does the active component conflict with medications prescribed by a doctor?
viii.	What is the scientific basis for the effectiveness of functional food?
ix.	What is the scientific basis for the effectiveness of functional food?
x.	Have carefully planned and supervised clinical intervention studies involving humans been carried out?
xi.	Do studies appear in journals that undergo peer review?
xii.	Should it be shown successful, is one serving sufficient to give the active ingredient in a way that is noticeable?

- **Step 2: Hazard Characterization.** This step aims to determine the dose-response relationship of the functional ingredients, that is, how the level of exposure affects the severity and probability of adverse effects [28]. Depending on the amount and mode of action, functional substances can produce a variety of effects in the body, ranging from therapeutic effects to outright toxicity. Research on animal toxicology can yield valuable insights into toxicological endpoints of interest, including but not limited to target organ assessment, genetic mutation, carcinogenicity, developmental toxicity, and so on.

- **Step 3: Exposure Assessment.** This step aims to estimate the amount and frequency of exposure to the functional ingredients, considering the intended use and probable experience [29]. The safe level of intake of functional ingredients must be compared to its purpose of use and exposure level. This can be done by looking at past data or using scientific studies (clinical trials, animal toxicology, digestion, distribution, metabolism, excretion, or ADME) to determine the safe level [30]. There may be very little safety buffer between the planned intake amount and a potentially dangerous level. The safe level may be very close to the toxic level, so there is a narrow margin of safety. Drug and food interactions could affect the exposure level and the risk.
- **Step 4: Risk Characterization.** This phase aims to integrate the data from the previous stages and assess the overall threat of the functional ingredients, considering the uncertainty and variability of the data [31]. Human clinical trials are essential to confirm the safety of functional ingredients, due to the limitations of animal models in predicting the effects in humans [32]. When deciding if the results of an animal study may be applied to humans, great effort must be taken to ensure that the design of the study—including the species being studied, dose level, duration, mode of administration, and control groups—matches the human scenario as closely as possible. The complexity and composition of the mixture that the functional ingredient is part of, as well as the presence of impurities, must also be considered [33].

4. Regulation of Nutraceuticals

Different countries have different regulatory bodies that set common principles and responsibilities for nutraceuticals and dietary supplements as explained in Table 2 [34]. These regulations aim to enhance the value of these products and safeguard their safety and effectiveness for consumers. The Table 2 below shows the product characterization and regulations applicable to each country.

4.1. European Union

Nutraceuticals are defined and governed by the European Food Safety Authority (EFSA) as food supplements, which are concentrated nutrient doses intended to

augment a regular diet and offer physiological and/or nutritional advantages [35]. The primary emphasis lies in the components of the supplement, such as minerals, vitamins, and amino acids, as well as the concentrations of each. The materials used in EU-produced nutraceuticals can only be those authorized and listed in Directive 2002/46/EC [36]. A corporation can apply to the EC for consideration if it wants to incorporate a nutritional supplement, minerals, or another material that isn't on this list [37].

This law provides the legal framework that food business operators utilize when they wish to emphasize on the goods labeling or in its advertising the specific health and nutritional benefits of their products. The Regulation's guidelines cover both nutrition and health claims, such as "low fat," "high fiber," and "Vitamin D is crucial for the usual development and growth of bone in children. These regulations aim to guarantee that any claims made about food in the European Union on its label, in its presentation, or its advertising are truthful, precise, and supported by data from science. The EU wants to safeguard food industry operators' quality standards and safeguard consumers [38].

4.2. USA

Depending on the claims and intended usage of nutraceuticals, the US has two primary authorities involved in their regulation. They're The government organization in charge of ensuring the efficacy, safety, and quality of medications, food, cosmetics, biologics, medical equipment, and animal products is the U.S. Food and Drug Administration (FDA) [39]. The government organization that oversees the promotion and marketing of goods and services as well as the enforcement of consumer protection laws is the government Trade Commission (FTC) [40].

The Federal Food, Drug, and Cosmetic Act (FD&C Act) was revised by the Dietary Supplement Health and Education Act of 1994 (DSHEA), creating a new legal framework in the US for the regulation of nutraceuticals [41]. Dietary supplements, as defined by the DSHEA, are goods that include one or more dietary elements, which include minerals, vitamins, herbs, proteins, enzymes, etc., and are meant to be taken in addition to a regular diet [42]. Additionally, the DSHEA gives the Food and Drug Agency

and the FTC the power to supervise the regulation of dietary supplements in areas like safety, labeling, and advertising.

4.3. Japan

Japan regulates nutraceuticals—products with health advantages beyond their nutritional value—under a complicated regulatory framework [43]. Numerous organizations and legal frameworks, including the Food Safety Commission (FSC), the Ministry of Health, Labour, and Welfare (MHLW), the Pharmaceuticals and Medical Devices Agency (PMDA), the Food Sanitation Act, the Health Promotion Act, the Food Labeling Act, and others, regulate nutraceuticals [44]. Nutraceuticals are divided into four groups based on their claims and approval process: foods with function claims, foods for specific health uses, foods with health claims, and foods with nutrient function claims [45]. Notification and approval criteria vary for each category based on the type of claim, degree of scientific proof, and labeling regulations.

4.4. China

China's primary regulatory body for nutraceuticals is: The National Health Commission (NHC) oversees creating and upholding the rules and guidelines about food and medical supplies [46]. Food and healthcare product quality, safety, and efficacy regulations are handled by the State Administration for Market Regulation (SAMR), the central government organization that manages China's market administration and supervision. A wide range of rules and regulations covering all areas of nutraceuticals, including categorization, labeling, marketing, registration, and monitoring, make up China's extensive legal framework for these products [47]. Nutraceuticals are defined in China as health foods with health benefits or as vitamin or mineral supplements. Depending on their contents and claims, these foods may be certified or listed with the relevant authorities. Based on the product's components, claims, dose, intended purpose, target population, and other factors, China makes a distinction between healthy foods and other types of goods [48].

4.5. India

Nutraceuticals are regulated in India by two primary agencies: CDSCO for medicines and medical devices and Food Safety and Standards Authority of India (FSSAI)

concerning food and nutraceuticals [49]. India boasts an extensive legal framework pertaining to nutraceuticals, comprising multiple legislation and rules that establish guidelines and requirements for various categories and varieties of nutraceuticals. According to several variables like intended purpose, target demographic, dosage, claims, and ingredients, food items that offer health and medical advantages are classified as either novel foods, functional food items, dietary supplements, or nutraceuticals in India [50].

4.6. Australia

Nutraceuticals are regulated in Australia as either foodstuff or medicines, based on the contents, dose, claims, and intended application [51]. The Therapeutic Goods Administration, known as the TGA, oversees overseeing nutraceuticals with therapeutic claims. Pre-market authorization and post-market monitoring are necessary for these goods. Food Standards Australia New Zealand (FSANZ) regulates nutraceuticals without therapeutic claims. FSANZ establishes guidelines and standards for food and food additives. A few laws and regulations, including the Food Standards Code, the Therapeutic Goods Regulations of 1990, and the Therapeutic Goods Act of 1989, regulate nutraceuticals [52]. The standards and requirements for the categorization, labeling, promotion, registration, and oversight of nutraceuticals are outlined in these laws and regulations.

5. Quality Management of Nutraceuticals

A comprehensive strategy is required to ensure the quality of nutraceuticals, starting with improving the agricultural crop [53]. According to the ideology of smart product delivery systems, crop identification must be done botanically, using biodata documentation and agronomic practice data (Good Agricultural Practices), and farm site awareness (via Global Positioning Systems). Analyses and monitoring of the biologically active nutraceutical compounds and/or biomarkers are required for phytochemical fingerprinting data [54]. This data necessitates the creation of quick assay techniques and instruments to guarantee compliance and uniformity in real time, together with documentation and change detection during handling, harvesting, processing, and production (manufacturing into product). Rapid tests can also be used

to guarantee chemical and microbiological safety for the duration of the product's shelf life.

5.1. The Role of Intelligent Product-Delivery Systems in Optimizing Product Quality and Accountability

A program called IPDS uses IT to increase product value through the resource/product supply network [55]. Present-day global sourcing requires a certain level of scientific foundation, which traceability both facilitates and assures. Up until now, most of the standardization has relied on data from biomarkers and plants, paying little attention to the precise origin, the conditions there, or the article's "journey" through the market. Table 3 reveals the standardizations required for different aspects of the safety and quality of nutraceuticals [56]. A resource traceability system (RTS), which is a component of an intelligent product-delivery system (IPDS), can enhance the important quality attributes assuring safety (microbiological, chemical, and physical), as well as quality assuring the efficiency of the product (or its components) [56]. By having these processes in place from the field (farm gate) to the table and household disposal, the provider delivers a high degree of responsibility and significantly raises the chance that the product will meet predetermined requirements. Furthermore, if a recall is required, it may be carried out quickly and effectively. By gathering data (identification labels in the form of chips, portable data files, etc.) from point of origin to point of disposal, IPDS enables product tracking and, consequently, traceability. Incorporating I.D. tags with portable data and the compilation of relevant information detailing the product's origin, harvest, and history, IPDS enables fast traceability between agriculture and consumption.

Another issue is the lack of traceability. Three technologies currently in use can be combined to ensure traceability: (1) global origin positioning and lot tracking during transport phases; (2) bar-coding advancement from radiofrequency identity to chip coding; and (3) hazard analysis and critical control point (HACCP) management connection to FDA, or similar international databases, for adverse effect observation [57]. These could be used in conjunction with the quick development of marker assays based on nanotechnology.

Table 2. Nutraceuticals Regulations among Different Countries [34]

Region	Regulatory body	Regulations	Product Characterization
European Union	European Food Safety Authority (EFSA)	Directive 2002/46/EC, which establishes a harmonized list of vitamins and minerals Regulation (EC) No 1924/2006 on nutrition and health claims made on foods	Nutraceuticals are substances that have both nutritional and physiological effects, and can be used as food supplements, feed additives, or medicinal products
United States	Food and Drug Administration (FDA), DSHEA)	Dietary Supplement Health and Education Act of 1994, Federal Food, Drug, and Cosmetic Act, Federal Trade Commission Act	Nutraceutical foods are supplements that contain one or more food ingredients, such as vitamins, minerals etc.
Japan	Ministry of Health, Labour and Welfare (MHLW)	Food with Health Claims, Food with Nutrient Function Claims, Foods for Specified Health Uses, Foods with Function Claims	Nutraceuticals are functional foods that have health benefits beyond basic nutrition, and can be classified into four categories based on their claims and approval process
China	NHC and the SAMR	Food Safety Law, Administrative Measures for Registration and Filing of Health Food, Administrative Measures for Registration and Filing of New Food Raw Materials	Nutraceuticals are health foods that have specific health functions or supplement vitamins or minerals, and can be registered or filed with the authorities depending on their ingredients and claims
India	Food Safety and Standards Authority of India (FSSAI)	Food Safety and Standards Act, 2006, Food Safety and Standards Regulations, 2011, Drugs and Cosmetics Act, 1940, Drugs and Cosmetics Rules, 1945	Nutraceuticals are dietary supplements that offer medical and health advantages, such as illness prevention and treatment and can be categorized as nutraceuticals, functional foods, dietary supplements, or novel foods
Australia	Food Standards Australia New Zealand (FSANZ)	Therapeutic Goods Act 1989, Therapeutic Goods Regulations 1990, Food Standards Code	Nutraceuticals are products that have both nutritional and therapeutic properties, and can be regulated as either foods or medicines depending on their ingredients, dosage, claims, and intended use

Table 3. Standardization for Quality and Safety Management [56]

To ensure safety and quality, standardization is essential for the following aspects:	
1.	The Latin name of the plant materials, the CAS number of the chemical entity, and the origin or synthesis location of the source
2.	The GIS descriptors of the plant material
3.	The sample verification of the plant material by a systematic botanist or a chemical certification
4.	The certification of the tolerance levels below the limit for organics (such as pesticide residues)
5.	Heavy metals (such as lead, and mercury) and microbiological pathogens
6.	The content of bioactive(s)/biomarker(s), if identified
7.	The digital documentation of GMPs, compliance with HACCPs, and monitoring of the US FDA database for adverse effects

6. Regulatory Reforms for Advancing Consumer Protection and Product Quality

A model for collaborative open database creation and nutraceutical development procedure modified from a suggestion by Santini et al. [41]. They suggest a safe development procedure that entails post-marketing monitoring, feedback to regulatory bodies for quality assurance, evaluation of effectiveness, and detection of adverse effects as illustrated in Figure 3 [41]. In addition to safeguarding consumers, this perpetual feedback loop aids in the production of superior analogs and nutraceuticals.

7. Nutraceutical Product Transparency: Challenges and Solutions from Serialization and Blockchain Technology

There is a trust gap between customers and nutraceutical makers, mainly stemming from the uncertainty of the origin and composition of the products, as well as the lack of sufficient proof for the alleged benefits of the products [58]. Regulatory oversight can mitigate the doubts regarding the benefits, but verifying the origin and composition necessitates inventive technological approaches. Serialization, which entails assigning distinct codes and security features to the products, has already demonstrated its effectiveness in preventing falsification in the pharmaceutical sector [59]. Blockchain

technology affords an extra level of security and clarity by generating a distributed, immutable ledger of transactions, enabling the tracing of products from origin to end-user [60]. Incorporation of blockchain with deep learning can yield supplementary advantages, such as forecasting adverse effects, suggesting withdrawals, and even customizing dosage prescriptions. With the global nutraceutical packaging market estimated to attain US\$5 billion by 2029, the implementation of these technologies has the capacity to considerably augment trust and transparency in the sector, benefiting both consumers and producers [61].

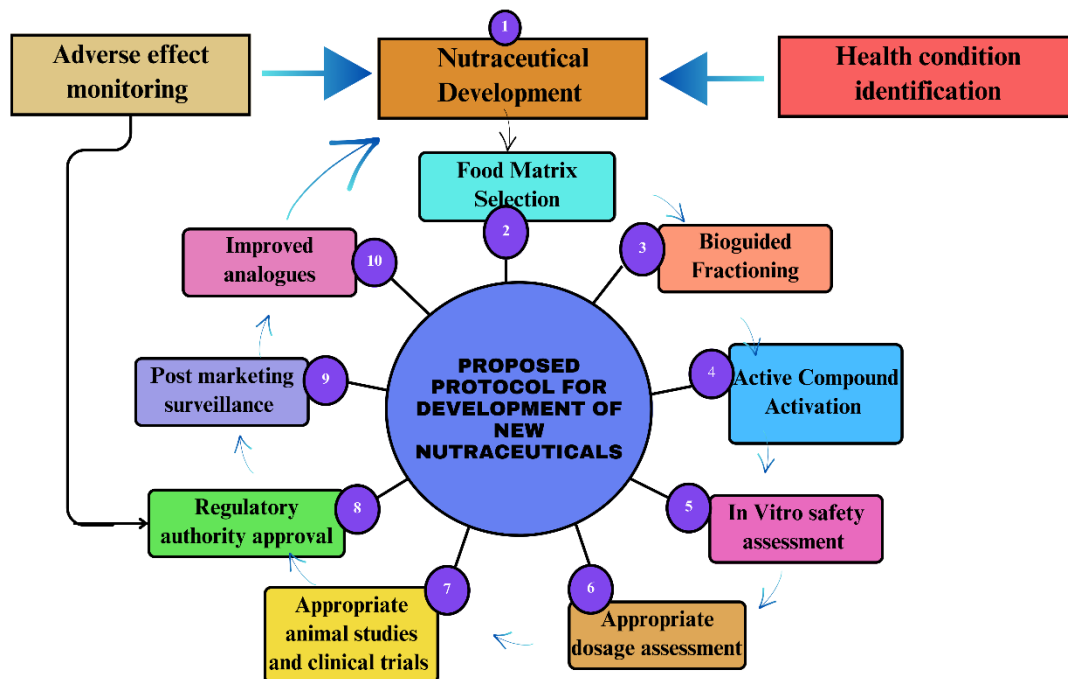


Figure 3. Proposed Protocols for the Development of New Nutraceuticals [41]

Practical examples are already reinforcing the argument for blockchain incorporation in nutraceuticals [62]. Carrefour SA, a French retailer, witnessed sales growth after employing blockchain to trace 20 items such as meat, milk, and fruit in partnership with IBM. They intend to extend that to 100 items, comprising baby and organic products, this year. Likewise, Walmart is experimenting with blockchain with 10 companies after effectively tracking mangoes and pork. This cooperative method, driven by blockchain,

can create the conditions for a future where consumers have ultimate trust in the genuineness and origin of their nutraceuticals.

8. Conclusion

In summation, consumers are interested in health-promoting products that contain dietary ingredients, such as dietary supplements and nutraceuticals. However, in various countries, these products are regulated differently, which creates gaps and challenges in quality and safety. Nutraceuticals have potential advantages, but they require an entire framework of integrity to accomplish them. This requires education, good manufacturing practices, monitoring, protocol development, harmonization, and risk assessment. Product traceability and blockchain technology can enhance transparency and security. The nutraceutical industry also needs novel quality management approaches, such as IPDS and RTS, to reduce chronic disease and healthcare costs and improve quality of life.

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Authors Contributions

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Conflict of Interest

The authors declared that they have no conflict of interest.

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INNOVATIVE FOOD PRODUCTS - NUTRACEUTICALS AND FUNCTIONAL FOODS

Editors

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Review Based Book Chapter

**FUNCTIONAL FOODS, EFFICACY AND DISEASE
PREVENTION**

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REVIEW BASED BOOK CHAPTER**FUNCTIONAL FOODS, EFFICACY AND DISEASE PREVENTION**

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Abstract

The increasing global trend of chronic diseases has promoted remarkable interest in functional foods, defined as foods with health benefits other than basic nutrition. This chapter provides comprehensive analysis of functional foods with respect to their classification, bioactive compounds, and mechanisms of functioning, with special emphasis on functional foods for cardiovascular diseases, cancer, diabetes, obesity, and cognitive impairment. Functional foods, derived from plant-based, animal-based, modified, and nutraceutical sources, contain bioactive compounds such as phytosterols, omega-3 fatty acids, antioxidants, and probiotics, which contribute to various physiological functions, including gut microbiota modulation, immune system enhancement, cognitive support, and physical performance optimization. The broader environmental and economic implications of functional foods are also explored, highlighting their potential to support sustainable health solutions. The emerging areas of research are expected to enjoin personalized nutrition, subsequent development of biotechnology, and new technological insights in nutrition to fast-track the effectiveness and affordability of functional foods. The chapter reinstates the scientific and real-life importance of functional foods and calls for their incorporation in mundane diets while acknowledging the need for sustained research toward optimizing their health-promoting potential.

Keywords

Functional Foods, Bioactive Compounds, Personalized Nutrition, Disease Prevention, Immune System

Introduction of Functional Foods

Functional foods are modified or fortified foods that provide a health benefit beyond their basic nutritional value. They are designed to improve overall health and well-being, reduce the risk of chronic diseases, or enhance physical and mental

performance [1]. The concept of functional foods was first introduced in Japan in the 1980s and has since gained popularity worldwide [2]. These foods typically contain added ingredients such as: Examples of functional foods includes yogurt with live cultures (probiotics), energy bars with added omega-3 fatty acids, fortified cereals with vitamins and minerals, juice beverages with added antioxidants, bread with added fiber (prebiotics). Following are characteristic functions that are played by functional foods in human body: Functional foods may assist in the prevention or management of long-term health conditions such as: heart disease (e.g., omega-3 fatty acids, plant sterols), type 2 diabetes (e.g., fiber-rich foods, probiotics) and certain cancers (e.g., antioxidants, phytochemicals) [3].

Functional foods are defined as foods that provide additional health benefits beyond basic nutrition. Our daily needs for macronutrients (proteins, fats, and carbohydrates) and micronutrients (vitamins and minerals) can be met by a traditional diet, however, functional foods benefits are above all this and they yield benefits such as improved health conditions successively less chances of getting diseases. Encompassing sustained immunity, bolster gut health, lower cholesterol levels, and layout horde of other advantages, making them a vital part of the diet of people who care about their health [4]. Consumers are incorporating functional foods into their diets more frequently as evidence shows their impact on overall health. The market for these foods has grown significantly, providing a diverse selection of options, ranging from probiotic-rich yogurts to antioxidant-packed berries. Integrating functional foods into one's diet is not just a matter of following trends; it's a conscious decision that is based on understanding their profound benefits.

Functional foods can be characterized in various ways which include conventional foods and modified foods. By definition conventional foods are unmodified foods that can be used by individuals in daily life such as vegetables, grains, nuts, seeds, dairy, fish, meat and legumes. On the contrary, modified foods are described as foods that have been modified through various processes which include fortification, enrichment this can be done at various level of processing which can be at agricultural level by enzymatic, chemical or technological means. Examples of modified foods includes

calcium fortified orange juice, margarine that has been enriched with omega 3 fatty acid, eggs enriched with omega-3 fatty acids and fermented foods. There is a third class of functional food which involve isolated or synthesized food ingredients i.e., indigestible carbohydrates (e.g. resistant starch and oligosaccharides) these compounds provide prebiotic effects [5]. Figure 1 shows the classification of functional foods.

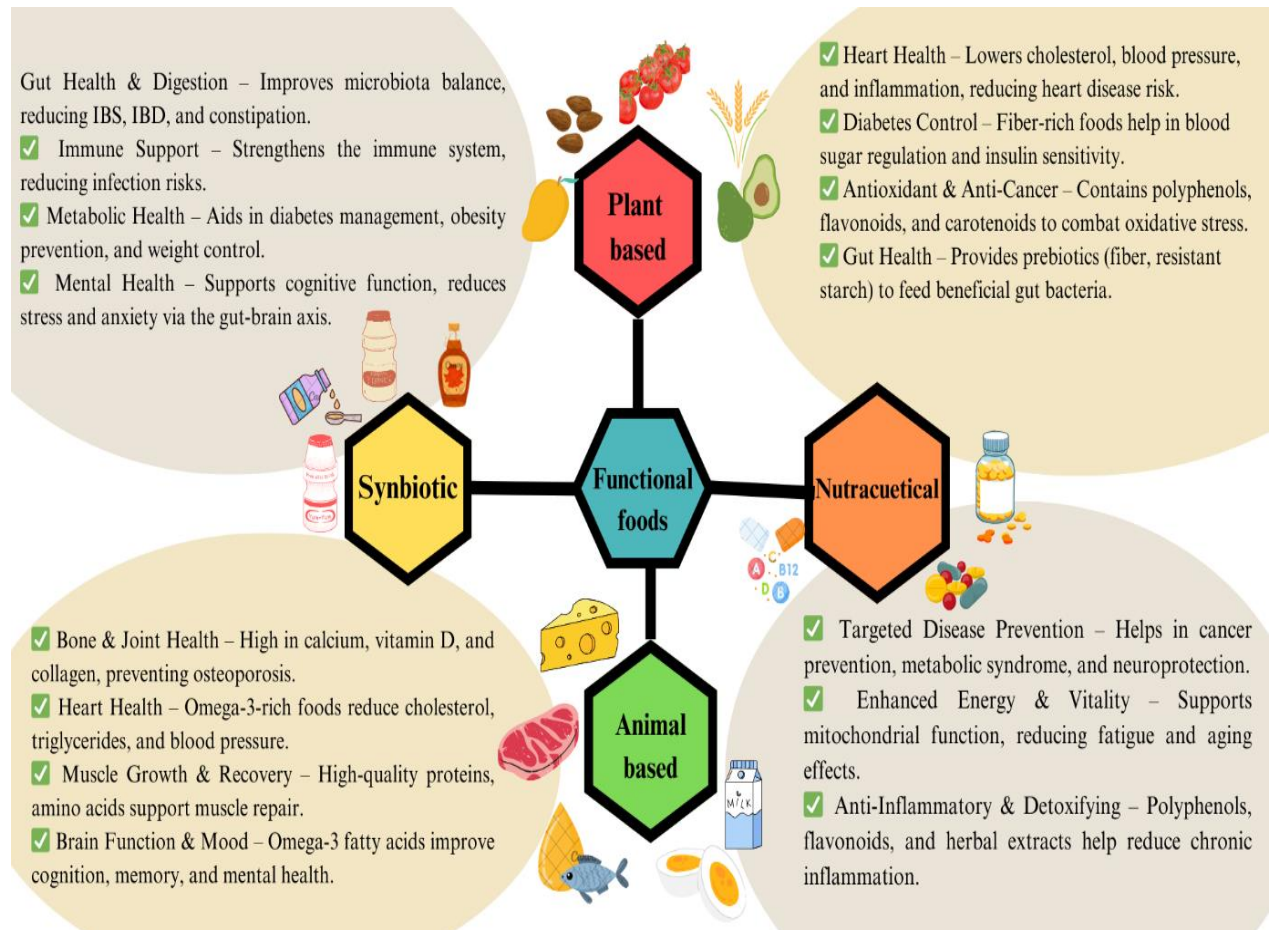


Figure 1. Classification of Functional Foods

Functional foods comprising of prebiotics, probiotics and fiber can contribute to improved gut microbiome, which is prerequisite for, immune system function, digestion and nutrient absorption and production of certain vitamins. In addition, functional foods can aid in improving physical performance by; supplying energy and endurance (e.g., sports drinks, energy bars), assisting muscle growth and repair (e.g., protein-rich

foods, creatine) and improving mental focus and concentration (e.g., omega-3 fatty acids, caffeine). Functional foods also support mental health and cognitive function by lowering stress and anxiety (e.g., adaptogenic herbs, omega-3 fatty acids), improving mood (e.g., serotonin-boosting foods, vitamin D) as well as enhancing cognitive function (e.g., omega-3 fatty acids, antioxidants). Functional foods can allow a suitable and approachable way to assimilate essential nutrients and health-promoting elements into an industrious lifestyle. Customized functional foods can be used to meet individual nutritional needs and health goals, conceding personalized approach to nutrition. Functional foods can proceed toward sound aging by: reducing inflammation (e.g., omega-3 fatty acids, antioxidants), supporting bone health (e.g., calcium, vitamin D) and enhancing cognitive function (e.g., omega-3 fatty acids, antioxidants). Amalgamation of functional foods and balanced diet can subsequently result in advanced health conditions and overall well-being of individuals [6]. Figure 2 shows the key health benefits of functional foods.

1. Bioactive Compounds in Functional Foods

The two types of bioactive compounds in functional foods are from plant-based sources and animal-based sources.

1.1 Bioactive Compounds from Plant-based Sources

Plant based bioactive compounds present in food are beneficial to human health via lowered disease risk. These bioactive compounds are what gives plant-based foods their numerous health benefits. These bioactive compounds are phytosterols, glucosinolates, terpenes and terpenoids, alkaloids, isothiocyanates and polysaccharides to name a few.

1.1.1 Phytosterols

Phytosterols are natural plant compounds that are structurally similar to cholesterol and are from triterpene family. Phytosterols have many health benefits such as anti-inflammatory properties, lowering cholesterol and improving immunity via antioxidant properties. Till now, approximately 250 phytosterols have been identified. Most common phytosterol type in diet is campestral, β -sitosterol and stigmasterol. They are essential

structural components of the cellular membrane and have many important functions, which include membrane fluidity and permeability modulation. They promote health by their antioxidant properties and cholesterol lowering effects by lowering cardiovascular disease risk. They are present in fruits and vegetables, nuts, sunflower seeds, whole grains vegetable oils and legumes [7].



Figure 2. Health Benefits of Functional Foods

1.1.2 Terpenes and Terpenoids

Terpenes are naturally occurring compounds that have simple hydrocarbons structures while terpenoids are known as modified class of terpenes, which have different structure. Terpenes are pinene, myrcene, terpinene, p-cymene and limonene. They have shown antimicrobial activities against the different bacterial strains including antibiotic resistant bacteria and antibiotic susceptible strains of bacteria. Their antimicrobial potential is due to their ability to inhibit synthesis of DNA and protein as well as their ability to enhance cell rupture. *Staphylococcus aureus* is bacterial species against which terpenes (geraniol, thymol, eugenol, carvone and carvacrol) have shown antibacterial action. Terpenoids on the other hand are the aromatic and medicinal plants secondary compounds and have shown disease resistance. For instance, terpenoids such as monoterpenoids caused microbial population to decrease via interfering with microbial metabolic activities as well as disruption in microbe multiplication and development thus justifying its' antimicrobial action [8].

1.1.3 Alkaloids

These are naturally occurring phytochemicals present as secondary metabolites in plants and animals. Alkaloid's chemical structure contain nitrogen. In plants, alkaloids concentrate in various organs such as fruits, roots, leaves, tubers. They have a significant role in protecting the plant against parasites, specifically bacteria and fungi. Studies show that alkaloids concentrate in the unripe fruit of lobeira plant. Extracts from lobeira fruit that were rich in alkaloids as well as extracted and isolated alkaloids have many health benefits including antiparasitic effects as well as hypoglycemic and anticarcinogenic effects [9].

1.1.4 Glucosinolates

Glucosinolates are naturally occurring phytochemicals commonly found in cruciferous vegetables such as broccoli and cauliflower. They have many health benefits such as protection from various cancers like breast cancer, colorectal and prostate cancer. They are also cardioprotective providing protection against myocardial infarction. Glucosinolates are compounds that contain sulfur (S) and nitrogen (N) and are generally present in vegetables as well as plants. They primarily derived from glucose

and amino acids. They are extracted from Brassica genus which includes Brussels sprout, kale, cabbage, broccoli, turnip, swede and cauliflower. They are hydrolyzed in human gut into isothiocyanates. The breakdown products of glucosinolates which are indole and isothiocyanates products have shown to prompt apoptosis (cell death) thereby lowering the growth of tumor via alteration of estrogen metabolism and by blocking the cell cycle as well as by blocking phase 1 enzyme. They also have inflammation lowering capacity via blocking histamine release [10].

1.1.5 Isothiocyanates

Isothiocyanates are byproducts of hydrolysis of glucosinolates in human gut. They are phytochemicals that are highly reactive. Glucosinolates are present mainly in the cruciferous vegetables. Isothiocyanates are possessing health promoting qualities such as neuroprotective properties as well as anti-inflammatory and anti-cancer properties. According to experimental evidences and epidemiological evidences, isothiocyanates lower oxidative stress and acts as antioxidants indirectly and they also show anti-microbial potential, thus, recently they have been shown increased attention due to their research potential and industrial application to different fields such as pharmacy and food industry. Irrespective of these benefits, their application is very challenging due to their volatile nature and increased sensitivity to heat. Also, processing of these bioactive compounds makes them less bioavailable due to sub-optimal conditions of processing. Isothiocyanates shows many health benefits and disease lowering potential due to their antimicrobial activity. This is due to their potential to lower oxygen consumption as well as depolarizing the membrane of mitochondria the bacterial cells. Isothiocyanates are commonly safe compounds (GRAS generally recommended as safe) and therefore are safe to be used in food industrial application as food preservatives. Isothiocyanates are also incorporated to food-packaging films due to their antimicrobial activity. They are also applied to food industry due to their potential of extending shelf life. This is due to their acting as a substrate in order to activate lactoperoxidases (LPO) for shelf-life extension of various dairy-products; which can be attributed to their bacteriostatic properties and bactericidal properties [11].

1.1.6 Polysaccharides

Polysaccharides are naturally existing biochemical compounds that are made up of greater than 10 monosaccharide units which are interconnected via glycosidic linkages. They are the most abundant and commonly available carbohydrates type present in different organisms such as algae, fungi and plants. Their classification is dependent on composition of monosaccharides. Polysaccharides are having two classes which are: heteropolysaccharides, that comprise of two or more than two different monomeric units (like pectin) and homo-polysaccharides, that consists of a single type of monosaccharide (like starch). Polysaccharides are structurally complex and can store carbohydrates in plants. Oral consumption of polysaccharides is followed by absorption and utilization in intestines. Polysaccharides are beneficial for the human bowel movements. Polysaccharides consists of fibers which is beneficial for gut health and is fermented in human gut by the microorganisms present in gut. The microbiota of human gut as well as their derived metabolites positively impacts human health. Hence research focuses on the interaction between microbes and polysaccharides. Deficiency of dietary fiber deficiency negatively impacts gut microbiota and is a precursor to diseases such as metabolic diseases and gut dysbiosis. This also leads to higher resistance of insulin thus increasing obesity. This is primarily due to inflammation caused by excretion of endotoxins by bacterial cells. Improving gut health via consumption of polysaccharide to positively impact gut microbiota can have a beneficial effect on metabolic disease [12].

1.2 Bioactive Compounds from Animal Sources

Like the bioactive compounds that are sourced from plants, bioactive compounds of animal origin are also having positive health benefits. For instance, Marine fishes contain a variety of bioactive compounds; such as increased amount of long chain omega 3 PUFAs (polyunsaturated fatty acids). These PUFAs are beneficial as they can become a part of cell membranes which lowers the inflammation. This is done by lowered synthesis of pro inflammatory cytokines. Another animal derived bioactive compounds from meat and its products are peptides, vitamins, fatty acids and minerals, that have a positive impact on human health. In addition, meat contains essential amino acids, thus

giving essential and quality proteins. Bioactive compounds rich in meat are coenzyme Q10, bioactive peptides, l-carnitine, choline, glutathione, taurine, alpha-lipoic acid, conjugated linoleic acid, and creatine. Milk produced by mammals contains bioactive peptides that positively impacts immunity. Cow produces milk that has whey protein rich in bioactive peptides that modulates immune responses. Similarly, Bioactive compounds in egg have anti-inflammatory effects. Egg whites are rich in bioactive proteins, which includes avidin, ovalbumin, Ovo transferrin, ovomucin and lysozyme; which have shown positive effect on immunity as well as anti-bacterial effects. Therefore, animal derived bioactive compounds should be studied and isolated to maximize their health benefits [13].

2. Role of Functional Foods in Disease Prevention and Management

A functional food provides potential health benefits owing to essential nutrients they encompass. These foods are valuable for the inhibition, prevention and treatment of various maladies. The body utilizes minerals, vitamins, omega 3 fatty acids, fiber, phenolic compounds and antioxidants existing in plants-based food items including vegetables, nuts, fruits, beans and herbs to combat numerous illnesses like cancer, diabetes, obesity and cardiovascular diseases [14].

2.1 Cardiovascular Diseases

Cardiovascular ailments (CVDs) are the primary reason of mortality and morbidity globally and a noteworthy contributor to disability, particularly coronary heart disease (CHD) and stroke. Data reclaimed from the World Health Organization have publicized that in the last two eras, the total of deaths instigated by CVDs amongst adults exceeded 350,000,000 internationally [15].

To reduce the rate of morbidity and mortality attributable to cardiovascular diseases it's significant to lessen the ingestion of sodium and fat. Scientific researches have proven in various studies that vitamin E reduces the risk of cardiovascular diseases. It is also demonstrated the vitamin E supplementation lessen the severity of atherosclerosis by reducing lipid composition of plaque [16]. Vitamin E enriches food sources comprise of lupin, pea, cowpea, moonbeam, soyabean and lentils have several health benefits. Frequent consumption of legumes reduced LDL, VLDL and cholesterol levels of blood

and HDL levels improved. Hydrolysates protein of beans drops cholesterol levels of blood showed hypocholesterolemia activity and also prevented inflammation and oxidative stress by improving the regulation of a compound adipocytokines. It displayed hypoglycemic activity by inhibiting SGLT1 and GLUT2 glucose transporters. Black beans protein hydrolysates also displayed hypoglycemic activity [17]. Polyphenols including flavones, flavonoids, flavanones and flavanols are bioactive compounds of legumes. These bioactive compounds improve the hyperglycemia and hypercholesterolemia. Since, it enhances the activity of adenosine monophosphate protein kinase [18]. Chickpeas comprise of saponins which decreases activity of pancreatic lipase. Also decline the deposition of lipid in 3T3-L1 and adipocytes. Functional foods are beneficial for the promotion of the functionality of HDL-C and the advancement of its levels. The mechanisms comprise of their influence in reverse cholesterol transfer and the enhancement of anti-inflammatory effects and antioxidant effects of HDL-C [19].

2.2 Cancer

Cancer is vigorous and long-term process with the involvement of many factors leading to growth of uncontrolled and inactive cells known as cancerous cells. The uncontrolled spread of cells is through the progression of metastasis. Dietary phytochemicals, generally flavonoids, polyphenols, isothiocyanates, organosulfur compounds, and tetraterpenoids, characterized biologically active compounds present in vegetables, medicinal plants, fruits, and beverages. These natural organic bioactive compounds display epigenetic modulatory properties by inducing the activity of epigenetics crucial enzymes, for instance histone acetyltransferases, DNA methyltransferases, demethylases, deacetylases and histone methyltransferases. Owing to the reversibility of the alterations that they induce, their insignificant adverse effects, and their effective epigenetic regulatory property, dietary bioactive phytochemicals hold noteworthy potential as antitumor agents [20]. Cereals are beneficial for the deterrence of spread of cancerous cells. Cereals food items comprise of barley, wheat and rice are the key source of macronutrients required for providing energy daily. Whole grains reduce the risk of progress of cancer cells. One of the whole grain bioactive compounds lunasin isolated from rice, barley, and wheat is a peptide which is valuable for reducing

inflammation and cholesterol in blood and also has cancer preventive outcome. Highest levels of lunasin are present in oat named ivory [21].

Various bioactive components are present in wheat straw including phytosterols, triterpenoids, policosanols and phenolics, have numerous health benefits like anti-inflammatory, antioxidants, anticancer, antiatherogenic, antiallergic, antimicrobial, antiviral, vasodilatory and cardioprotective effects. Germinating brown rice is a common functional food. It has numerous health beneficial bioactive compounds which have various physiological effects including antioxidant, hypoglycemic, anticancer, hypocholesterolemia effects. Brown rice contains tannins, sterols, GABA, essential oils, amino acids, sterols and flavones. Rice bran is also considered as functional food, have anticancer properties. It also encompasses bioactive components phytochemicals for instance tocopherols, ferulic acid, γ -oryzonals, β -sitosterol, phytic acid, tricin and phytic acid. Additional bioactive component of rice bran is cycloartenyl ferulate which has the anticancer properties by impeding human colorectal adenocarcinoma [22].

2.3 Type 2 Diabetes

It is a metabolic disorder, also identified as diabetes mellitus, is a collection of common endocrine ailments considered by continued enhance blood sugar levels. Various factors are involved in development of diabetes including unhealthy diet, stress, excess body weight, infection, physical inactivity, family history and high blood pressure. Functional foods have their prospective health benefits and have been systematically demonstrated; they have protective effectiveness along with physical activity in diabetes type 2 prevention [23]. Mediterranean diet augmented with functional foods is health beneficial meal plans for the prevention and management of Type 2 diabetes; this diet is exceedingly valued in American Diabetes Association reference for T2DM prevention and management. MD diet is enriched with polyphenols bioactive compounds such as fruits, olive oil vegetables, tree nuts and these bioactive components have health protecting benefits. Alongside with polyphenols, alkaloids, flavonoids, terpenoids, pigments, unsaturated fatty acids and sterols displays an essential part in sustaining wellbeing and helping to elude diseases like cancer, asthma depression, obesity, diabetes, and cognitive decline [24]. Nutraceuticals with

Mediterranean diet such as, omega 3 PUFA in tree nuts and EPA, oleic acid in olive oil and DHA found in oily fish and high amounts of fiber found in whole grains with a low glycemic index, this sort of acids and antioxidants inhibits the oxidation, inflammation, and supports to enhancement of the endothelial micro and macro vascular function [25].

2.4 Obesity

Obesity is common all over the world. Owing to the energy disproportions problem of obesity upsurges whereby energy ingestion exceeds energy spending. Functional foods, when taken as a major part of a balanced diet, have been suggested as a potential substitute method of weight management and obesity prevention and of improving metabolic concerns of obesity, as well as augmented glucose and lipid levels in blood [26]. In current years, numerous animal studies, along with human clinical trials and epidemiological researches, have been executed to observe the potential outcome of particular functional foods and their bioactive compounds on weight control and numerous mechanisms of its effect on health have been suggested [27]. Obesity is considered as multifactorial prolonged diseases mostly instigated by an inequity in kcalories intake and expenditure. Obesity and its linked complications are the fifth foremost reason for worldwide mortality. The remunerations of the present obesity treatment routine have been masked by increase several adversarial effects [28]. Consequently, numerous researchers concentrate on plant-derived bioactive compounds, natural products and changed dietary pattern for the treatment, prevention and management of obesity and its related complications (co-morbidities). Numerous epidemiological researches have inveterate that the ingestion of functional foods and nutraceuticals could significantly lessen possibility of numerous chronic and acute diseases like obesity, diabetic mellitus, cardiovascular and cancer [29].

2.5 Immune System

Immune function is influenced by the nutrition. Bioactive compounds in functional foods are responsible for the strengthening of immune system like vitamins, antioxidants, trace elements (zinc, copper and manganese), omega 3 and 6 polyunsaturated fatty acids, nucleotides, L-arginine, nucleosides, probiotics, prebiotics and synbiotics [30]. Immune dysfunction in the body can be initiated by numerous factors. To solve this problem,

plant-based functional foods are utilized for their wide immune-enhancing activities. Consequently, numerous studies have been carried out to interpret the molecular and cellular regulatory mechanisms and signaling pathways of immunoactive constituents to analyze the immune strengthening properties of these active constituents. Contrasting from current synthetic drugs, which are costly and can have numerous side effects, plant-based functional foods have fewer side effects, are constant, stable, and tend to display a permanent effectiveness. Bioactive compounds demonstrate immune strengthening properties by various mechanisms for instance it regulates the levels of cytokines to enhance immunity, by regulating natural killer cells and propagation of T lymphocytes and stimulate cellular and humoral responses to increase immunoregulative effect [31].

2.6 Gut Health

The GI tract is an understandable mark for the bioavailability of functional foods as it is considered crossing point amid the bioactive compounds of diet and all other metabolic roles. GI function depends on a suitable steadiness of healthy microflora to inhibit the entry of harmful and pathogenic bacteria. An utmost promising area for the formation of functional foods lies in the utilization of constituents to amend the metabolic action of the gut residing microflora such as probiotics, prebiotics and symbiotic (mixtures of probiotics and prebiotics) [32].

The health-related benefits of probiotics include decreased in occurrence or severity of GI infections and diseases as well as improvement of lactose intolerance and enhancement in gut function, including decrease in the frequency of constipation and diarrhea. Prebiotics are non-digestible food constituents that can fuel growth of microflora and alter the metabolic related activity of particular bacterial species already residing in the gut and reduces the growth of pathogenic bacteria, leads to improvement of gut health. Microflora also decreases the risk of development of colon cancer. Their capability to upsurge production of short chain fatty acids in the colon is related with amplified absorption of particular minerals for instance magnesium and calcium. Dairy products, baked goods, table spreads and breakfast cereals, breads, and bars, meat products, salad dressings and about confectionery items contain prebiotics [33].

3. Mechanism of Action of Bioactive Compounds

Bioactive constituents are extra-nutritional components that are present in fewer quantities in foods enhance health benefits beyond the basic nutrients. They are being thoroughly considered to assess their impact on health, and bioactive compounds appeared to have favorable behavioral, physiological, and immunological properties. Up to the present time, several bioactive constituents have been investigated and discovered. These compounds differ extensively in chemical structure and function and are assembled accordingly.

Examples related to bioactive compounds are flavonoids, choline, carotenoids, carnitine, phytosterols, polyphenol, phytosterol, dithiolthiones, phytoestrogens, taurine and glucosinolates. Subsequently, vitamins and minerals displayed beneficial pharmacological properties; they can be characterized as bioactive compounds too. These compounds certainly are present in numerous foods, have antioxidant, anti-inflammatory, antitumor, anticarcinogenic, and antimicrobial properties.

3.1 Modulation of Gut Microbiota

The human gastrointestinal gut entails around 100 trillion microorganisms, containing up to 5000 various types of bacteria, in addition to Archaea, parasites, viruses, Eukarya and bacteriophages that collectively called the "gut microbiome". Alterations in gut microorganism composition (dysbiosis) can lead to numerous diseases [34]. Functional foods and natural herbs encompass bioactive molecules capable of enhancing the immune system, anti-bacterial and anti-viral functions. Functional foods, for instance probiotics, prebiotics, and dietary fibers, have been displayed to have beneficial effects on gut microbiota and immune function. The utilization of functional foods has been related to improved regeneration of cells, enhanced cognitive function, strengthen immunity, maintenance of gut microflora, and substantial improvement in overall health [35].

Probiotics are microorganisms that can optimally change the stability of intestinal microflora, improve digestion, inhibit the growth of harmful bacteria and upsurge the body's resistance by reinforcement the immune system. Studies displayed that probiotics are health beneficial owing to antioxidant properties. Antioxidants are

complexes that decrease the hazard of numerous ailments. These compounds, indeed, prevent the action of free radicals and stop their oxidation [36]. The body cells are protected from the disparaging effects of these compounds owing to the antioxidant properties of probiotics. Oxidative stress is a state that happens as a consequence of upsetting the antioxidant-prooxidant equilibrium in the cell, which ultimately leads to apoptosis and cell death. Ingestion of probiotic strains with antioxidant activity can profit human health by decreasing oxidative harm. Meanwhile the usage of probiotics benefits, improves immune responses, hemostasis and stops numerous disorders produced by oxidation in the host [37].

3.2 Anti-inflammatory Effects

Prolonged inflammation is related to various human diseases. Dietary intake of plant-based products full of antioxidant is an approach and a growing trend for fighting the inflammatory responses of numerous communicable and non-communicable ailments and their risk factors [38]. Fruits, herbs, vegetables, spices, and their extracts demonstrated a functional activity enhancing antioxidant status and at the same time improving inflammatory and oxidative stress. It is highly suggested to entirely utilize the "functional heritage" of the extensive collection of diverse phytochemicals with multi-factorial synergistic interactions confined in fruits, herbs, vegetables, and spices and their extracts to capably stop the raise of inflammatory and oxidative stress, major reasons of deteriorating ailments [39].

3.3 Antioxidant Activity

In the preceding era, antioxidants have got a great deal of publicity for their role in decreasing oxidative stress and free radicals, as well as treatment and prevention of cancer. In such situations, polyphenols and phenols are often of great concern; they can be identified by means of enzymes including phenol oxidases, tyrosinase, and even with the plant tissue carrying such enzymes [40]. Some illnesses for instance cancer, hypertension, obesity, coronary heart diseases, type 2 diabetes, and cataract are induced by increase in free radicals leads to increase in oxidative stress and fruits, legumes, cereals, vegetables, provide the greatest defense in contradiction of these diseases [41]. The food related natural antioxidants present in fruits and vegetables have an advantageous health benefit. Some of the antioxidants present in dietary

plants comprise of carotenoids, phenolic compounds, coumarins, stilbenes, flavonoids, benzoic acid derivatives, lignans and proanthocyanidins. Blackberries, walnuts, artichokes, raspberries, strawberries, brewed coffee, cranberries, blueberries, pecans, grape juice, unsweetened chocolate and ground cloves categorized at the highest of the classification owing to normal serving quantities. Antioxidants for instance vitamin C, polyphenols, vitamin E, lycopene and beta-carotene are ample in beverages and fruit juice, have been displayed to lesser mortality and morbidity related with deteriorating illnesses [42].

3.4 Modulation of Gene Expression

Diet related bioactive constituents, in the notion of nutrigenomics and nutrigenetics comprise of food phytochemicals and nutraceuticals, which can transfer information from the exterior atmosphere and impact gene expression in the cell and therefore the function of the organisms. It is vital to honor diet not only as the foundation of calories and basic nutrition, essential for living and development, but also as the feature persuading health, biochemical mechanisms, and activation of pathways. Bioactive constituents of the food control gene expression through variations in the chromatin structure (including DNA methylation), instigation of transcription factors by signaling cascades, non-coding RNA, or straight ligand binding to the nuclear receptors [43]. Bioactive diet related components effect gene expression through diverse mechanisms, mostly by chromatin structure modification, non-coding RNA, direct ligand binding to the nuclear receptor and initiation of transcription factors by signaling cascades. Identifying of these bioactive complexes and elucidating their mechanism of function will permit more actual food recommendation for entire population [44]. Bioactive diet constituents show a significant part in prevention and treatment of many illnesses, for instance circulatory system ailments, cardiovascular diseases, diabetes, cancers and obesity. It appears significant to advance additional awareness on nutrigenetics and nutrigenomics and to inspire dieticians to utilize this information for more effective dietary references and recommendations [45].

4. Safety Considerations of Functional Foods

Functional foods safety considerations include; ingredient safety: be certain that all the ingredients, including additives and supplements, are safe for consumption. Potential

allergens are supposed to be clearly mentioned on the product label for consumer safety such as gluten, nuts etc. While execution of Good Manufacturing Practices (GMPs) is vital to prevent contamination and ensure cleanliness. Stability assessments to verify that products remain safe and effective for the duration of their shelf life and at the end examine the possible interactions between ingredients in functional foods and prescribed medications.

4.1 Regulatory Considerations

Adhere to labeling laws, which encompass nutrition information, ingredient listings, and health assertions. Verify that health assertions are backed by scientific proof and adhere to regulatory standards. Ensure that ingredients used in specific product have GRAS status or has gained acceptance from regulatory agencies. Comply with regulations for novel foods, including approval processes and labeling requirements. Food and Drug administration is the regulatory body in United States for functional foods. European food safety authority is the regulatory body in Europeans union. In Canada, Health is the one who regulates functional foods. National health and medical research council is the regulatory body in Australia for functional foods. Make certain that safety protocols and regulations are fully met. Regulatory changes should be monitored constantly. Collaboration with experts ensure adherence and addresses concerns. Investment in scientific research and development is highly important to support health claims and that to ensure safety. Effective communication with the consumer is important and that being said transparency throughout is important in responding to concerns of consumers and for that products should be labeled properly [46]. In Pakistan, the safety regulations for functional foods are governed by several authorities and regulations. PFA Pakistan food authority was established in 2017 which is responsible for safety and quality of food products which also include functional foods. Ministry of National Health Services, Regulations and Coordination (NHSR&C) is another ministry that keep an eye on the regulations of functional foods and food products. Though, the main role of Drug Regulatory Authority of Pakistan (DRAP) is to monitor the development of pharmaceuticals however, it also observes the regulations of functional foods and food products.

4.2 Safety Requirements

Manufacturers of functional food products must establish ways that certain safety and quality of their products this involves Good Manufacturing Practices GMPs. There is a systematic way to identify and control potential hazards in foods that are identified by HACCP (Hazard Analysis and Critical Control Points). Product producer must specify that their products are allergens and contaminants free this is done by ACC (Allergen and Contaminant control). Production house product labels and advertising claims should be in compliance with the regulations [47].

Table 1. Bioactive Compounds in Functional Foods and their Health Benefits

Food Name	Functional Compound(s)	Health Benefits	References
Turmeric	Curcumin	<ul style="list-style-type: none"> ➤ Reduces inflammation and joint pain ➤ Acts as a powerful antioxidant, combating oxidative stress ➤ Supports brain health by enhancing BDNF levels 	[48]
Garlic	Allicin, Sulfur Compounds	<ul style="list-style-type: none"> ➤ Lowers blood pressure and cholesterol levels ➤ Boosts immune system function, reducing infections ➤ Exhibits anti-cancer properties by inhibiting tumor growth 	[49]
Green Tea	Catechins, Polyphenols	<ul style="list-style-type: none"> ➤ Provides strong antioxidant protection ➤ Enhances fat burning and weight management ➤ Lowers the risk of cardiovascular diseases 	[50]
Yogurt (Probiotic)	Probiotics (<i>Lactobacillus</i> , <i>Bifidobacteria</i>)	<ul style="list-style-type: none"> ➤ Improves gut microbiota balance, enhancing digestion ➤ Strengthens the immune system ➤ Helps in reducing symptoms of lactose intolerance 	[51]

Fatty Fish (Salmon, Mackerel)	Omega-3 Fatty Acids (EPA, DHA)	<ul style="list-style-type: none"> ➤ Reduces inflammation, lowering risk of chronic diseases ➤ Supports heart health by reducing triglycerides and blood pressure ➤ Enhances brain function and reduces cognitive decline 	[52]
Blueberries	Anthocyanins, Flavonoids	<ul style="list-style-type: none"> ➤ Improves memory and cognitive function ➤ Protects against cellular damage with antioxidants ➤ Supports heart health by reducing blood pressure 	[53]
Tomatoes	Lycopene	<ul style="list-style-type: none"> ➤ Lowers risk of prostate and other cancers ➤ Protects skin from UV damage ➤ Supports cardiovascular health by reducing oxidative stress 	[54]
Nuts (Almonds, Walnuts)	Omega-3, Vitamin E, Fiber	<ul style="list-style-type: none"> ➤ Reduces inflammation and oxidative stress ➤ Supports brain health and cognitive function ➤ Improves heart health by lowering cholesterol levels 	[55]
Whole Grains (Oats, Brown Rice)	Beta-glucan, Fiber	<ul style="list-style-type: none"> ➤ Lowers LDL cholesterol, reducing heart disease risk ➤ Supports digestive health by enhancing bowel function ➤ Provides sustained energy and aids in weight management 	[56]
Dark Chocolate (Cocoa)	Flavonoids, Theobromine	<ul style="list-style-type: none"> ➤ Enhances mood and reduces stress ➤ Improves blood flow and lowers blood pressure ➤ Provides antioxidant protection, reducing inflammation 	[57]

Table 2. Effect of Antioxidants and Bioactive Compounds on Health

Bioactive Compounds	Food Sources	Health Benefits	References
Lutein	Green leafy vegetables (spinach, kale, etc.)	Antioxidant (AOX), anti-inflammatory, antiatherogenic, antihypertensive, antidiabetic, antiulcer, reduces cancer risk, prevents eye diseases	[58]
Curcumin	Curcuma (turmeric)	Antioxidant (AOX), reduces diabetes mellitus (DM) risk, neurodegenerative diseases (NDs), cardiovascular diseases (CVD)	[59]
Inulin	Asparagus, garlic, chicory, onion	Prebiotic effect, reduces atherosclerosis, increases satiety	[60]
β -glucan	Yeasts, oats, bacteria	Reduces CVD, controls diabetes, stimulates the immune system	[61]
Isothiocyanates	Brassica family: Brussels sprouts, cabbage, broccoli	Reduces NDs, reduces cancer risk	[62]
Sterols and Stanols	Wheat germ, rapeseed oil, peanuts	Lowers LDL-C, anti-inflammatory, reduces triglycerides (TG), reduces NDs	[63]
Resveratrol	Red grape, blueberries, blackberries, cocoa	Reduces CVD, lowers LDL-C	[64]
Isoflavones	Soy, miso, tofu, soy-based foods, flaxseeds	Reduces CVD, lowers LDL-C, prevents osteoporosis, reduces DM risk, reduces liver disease	[65]
Fructooligosaccharides	Chicory, onions, garlic, Jerusalem artichoke, dandelion	Alleviates depression symptoms, bifidogenic effect, reduces atherosclerosis, increases	[66]

	greens, leeks, asparagus	satiety	
Glucosinolates	Brassica family: Brussels sprouts, cabbage, cauliflower, etc.	Reduces cancer and metastasis risk, protects cells from redox imbalance, reduces chronic inflammatory diseases	[67]
Zeaxanthin	Egg yolk, spinach, kale	Antioxidant (AOX), provitamin A, anti-inflammatory, improves cognitive function, reduces cancer risk, reduces CVD risk	[68]

Table 3. Observed Effect of Bioactive Compounds and Their Mechanisms [69]

Compounds	Observed Effects	Mechanisms
Omega 3 PUFA	Decrease TNF, IL-6, PGE2	Inflammatory pathway inhibition
Anthocyanin	Increase BDNF, lowers the oxidative damage	Cell signaling, antioxidant activity, anti-inflammatory
Inulin	Increase mineral absorption and Bifidobacterium	Prebiotic effect, maintain lipid levels
Ellagitannins	Decrease inflammation	Microbiome modulation
Lycopene	Inhibited tumor growth, prevent DNA mutation	Apoptosis induction
Neoxanthin	Potent antioxidant properties	Antioxidant actions, modulation of signaling pathways
Punicalagin	Supports in decreasing arthritis, hypertension, cancer, oxidative stress, hyperglycaemia and maintaining cholesterol and lipids levels in blood	Processes for instance deglycosylation, demethylation and ring cleavage lead to the generation of bioactive compounds that demonstrate antioxidant, anti-inflammatory, and metabolic modulatory properties
Ellagic acid	Potent antioxidant and anti-inflammatory properties	Improving insulin secretion, insulin receptor substrate protein 1 expression, triglyceride, glucose transporter 4, total cholesterol, LDL, HDL and decreasing TNF- α , interleukin-6 (IL-6), (ROS), malondialdehyde (MDA), and oxidative stress in related tissues

Conclusion

Functional foods represent a promising approach to enhancing health and preventing chronic diseases by providing bioactive compounds with targeted physiological benefits. Despite their significant health benefits, the development and consumption of functional foods require careful consideration of safety aspects, including ingredient stability, allergenicity, and potential interactions with medications. Regulatory legislation assumes a key role in determining product efficacy, safety, and consumer confidence; in the future, personalized nutrition and biotechnological advances, and scientific research will drive the evolution of functional foods and their ability to efficiently address individual health needs. With the enhancement of public understanding of the benefits derived from functional foods and a deeper scientific knowledge of their mechanisms, functional foods will be recognized and integrated into daily diets and healthcare plans, serving a significant purpose in promoting long-term health and well-being. To maximize the global health impact of functional foods, sustained interdisciplinary research efforts and regulatory progress will be imperative in unlocking their full potential for improving public health outcomes worldwide.

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Authors Contributions

Introduction and Safety regulations, A.Z; classification of functional foods and bioactive components, M.F; disease management and mechanism of action, A.S; abstract, conclusion and figures, Z.A; Conceptualization, review and validation, F.S.

Conflict of Interest

The authors declared that they have no conflict of interest.

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INNOVATIVE FOOD PRODUCTS - NUTRACEUTICALS AND FUNCTIONAL FOODS

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Muhammad Haseeb Ahmad & Farzana Siddique

Review Based Book Chapter

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REVIEW BASED BOOK CHAPTER**NUTRACEUTICALS AND DISEASE PREVENTION**

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Abstract

Nutraceuticals, a fusion of "nutrition" and "pharmaceuticals," refer to products derived from food sources that offer health benefits beyond basic nutrition. They encompass dietary supplements, functional foods, medical foods, and pharmaceuticals, aiming to promote general well-being, prevent chronic diseases, and manage various health conditions. The expanding importance of nutraceuticals in illness prevention and health promotion is examined in this chapter. The potential of nutraceuticals—a broad category that includes dietary supplements, functional foods, and bioactive compounds—to prevent chronic illnesses and enhance general health is becoming more widely acknowledged. The chapter explores the scientific underpinnings of nutraceuticals; therapeutic benefits, emphasizing how they might alter biological pathways linked to oxidative stress, inflammation, and metabolic abnormalities. The impact of several nutraceuticals, including, minerals, vitamins, polyphenols, antioxidants, and omega-3 fatty acids, in lowering the risk of diseases like cancer, diabetes, cardiovascular disease, and neurodegenerative disorders is highlighted in this chapter through a review of recent research. It also discusses the difficulties of standardizing, regulating, and using these substances in clinical settings, highlighting the necessity of more research to validate their safety and effectiveness. This chapter concludes by highlighting the potential of nutraceuticals as a preventative measure in contemporary healthcare and providing information on how to incorporate them into dietary plans for illness prevention.

Keywords

Functional Foods, Dietary Supplements, Disease Prevention, Neurodegenerative Disorders, Metabolic Disorders

1. Introduction

Nutraceuticals are special preparations made with an aim to fulfill dietary requirements and often provide preventive therapy. These are the preparation of nutrients which helps disease prevention and treatment along with a supplementary diet. The term nutraceutical is derived from two terms "nutrition" and "pharmaceutical". These are

bioactive compounds derived from food that offer extra health benefits beyond basic nutrition, between food and medicine [1]. They are dietary supplements, functional foods, and botanicals that offer therapeutic benefits or prevention of disease. These compounds, such as vitamins, minerals, fatty acids, antioxidants, and phytochemicals from plants, sustain many body functions, such as immune function, cardiovascular function, cognitive function, and metabolic function [2]. Nutraceuticals are used in the management and prevention of long-term diseases including heart disease, diabetes, cancer, and neurodegenerative disorders. Nutraceuticals exist in a variety of formats including fortified food, supplements, or extracts but their effectiveness will depend on optimal dosing, purity, and patient health needs. Even though, nutraceuticals can be utilized to support a healthy way of life, they must not be utilized instead of conventional medical treatment and must be utilized with caution to avoid drug interactions or side effects [3]. Nutrition science has progressively developed from the eradication of nutritional deficiencies and management of chronic diseases. Contemporary literature has emphasized the need for redefining the definition of nutraceuticals considering their efficacy, safety and toxicity. Nourishing substances that are ingested, imbibed or otherwise introduced in the body to maintain one alive, aid in energy production, and sustain body development constitute food products. Nutrient isolation of food products has been achieved effectively and utilized today [4].

The history of nutraceuticals is traced back to ancient times, as food and herbs have been used for their medicinal values. Nature products such as ginseng and garlic were known to the ancient Greeks and Egyptians and to traditional Chinese medicine for their medicinal properties. In the Middle Ages, herbal medicine was advanced, and renaissance scientific studies laid the foundation for pharmacognosy. In the 20th century, the discovery of the vitamins and the function of disease-fighting elaborated further on food and health connection. The naming of the nutraceutical was established in 1989 by Dr. Stephen DeFelice. The industry developed strongly with an increase in diet foods and functional supplements during the 1990s. Nutraceuticals blend age-old, centuries-old tradition with state-of-the-art science to yield a final element of preventive medicine and overall well-being [5].

2. Types of Nutraceuticals

Nutraceuticals can be classified as functional foods are the normal foods with added nutrients or bioactive compounds, such as fortified breakfast cereals, probiotic milk, or omega-3-enriched foods [6]. Dietary supplements such as vitamin, mineral, herb, amino acid, or fatty acid concentrated products that are available, such as multivitamin, fish oil, or turmeric capsules. Herbal products like ginseng, garlic, or turmeric consumed for their pharmaceutical action. Probiotics and prebiotics including fiber and live healthy bacteria that promotes intestinal health. Animal-derived nutraceuticals extracted from bees, collagen, and fish oil that provide heart, skin, and joint health benefits. Marine-derived nutraceuticals including omega-3 concentrates from fish or algae, and krill oil to support brain and heart health. Functional beverages included healthy ingredients in energy drinks, sport drinks, and herbal teas. Cosmeceuticals are the products which contain pharmaceutical components with cosmetic importance i.e. wrinkle cream or vitamins for hair growth.

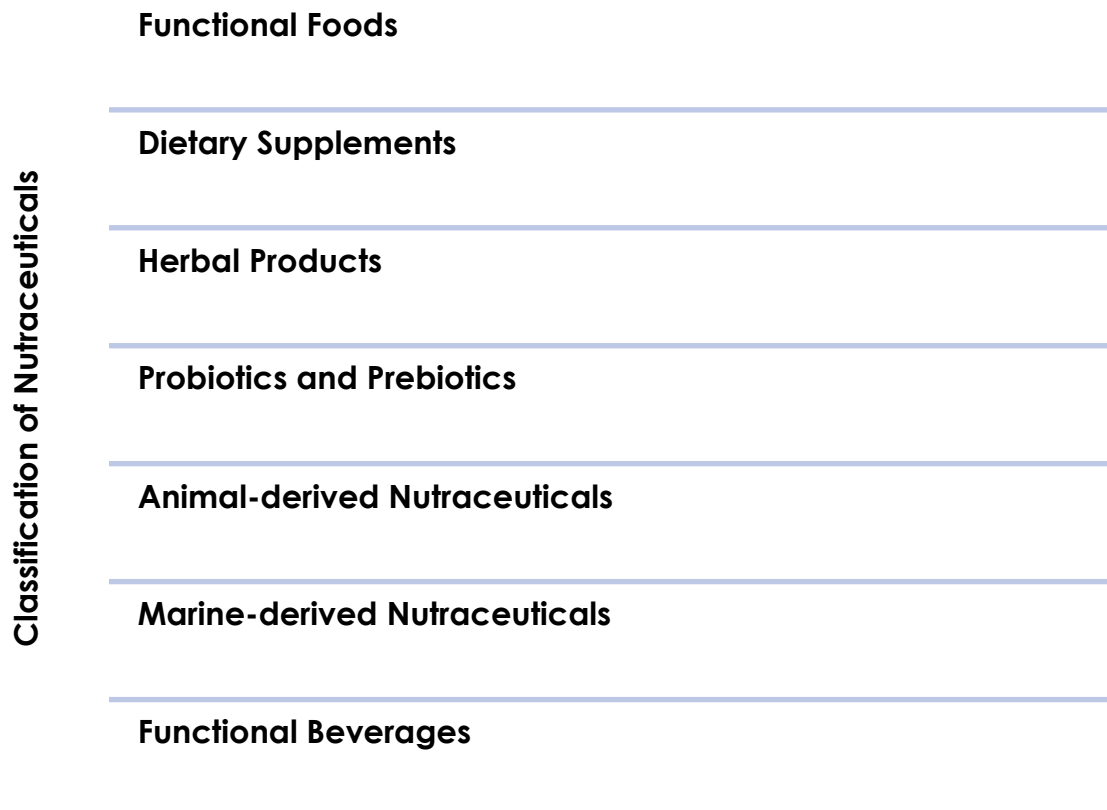


Figure 1. Classification of Nutraceuticals

3. Potential Health Benefits of Nutraceuticals

Nutraceuticals may play a very important role in preventing numerous chronic diseases through maintaining good overall health and eliminating certain risk factors [7]. Following are some diseases and conditions for which nutraceuticals may prevent CVS disorders, omega-3 fatty acids (fish oil or flaxseed) reduce triglycerides, lower blood pressure, and reduce inflammation, lowering the risk of heart disease and stroke. Plant sterols reduce LDL (bad) cholesterol, Coenzyme Q10 (CoQ10) supports cardiovascular health and reduces oxidative stress [8].

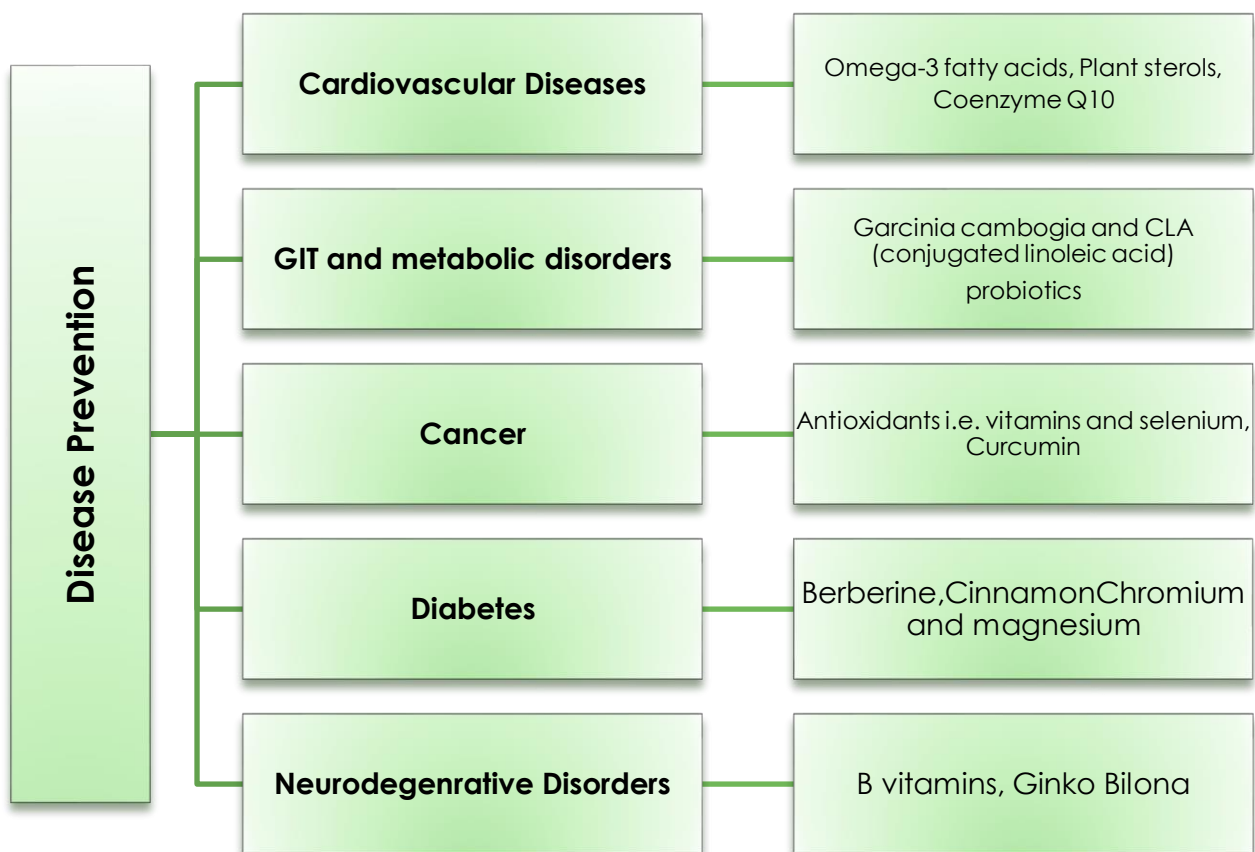


Figure 2. Disease Prevention from Various Types of Nutraceuticals

Chromium and magnesium improve insulin sensitivity and glucose control. Berberine reduces blood sugar and improves insulin action. Cinnamon extract can normalize blood sugar and improve insulin sensitivity [9]. Nutraceuticals also pay significant contribution in preventing cancers i.e. Antioxidants vitamin C, vitamin E, and selenium

inhibit free radicals that harm DNA and contribute to cancer formation. Curcumin (turmeric) has anti-inflammatory and anticancer activity that inhibits cancer cell proliferation. Flavonoids (fruits and vegetables) add to protection from oxidative damage related to cancer [10]. Nutraceuticals also helps improving bone density and osteoporosis, calcium and vitamin D support bone density and strength, magnesium plays a role in mineralization of bone and protects against osteoporosis [11]. DHA and EPA omega-3 fatty acids sustain brain function and are protective against cognitive decline. B vitamins (especially B6, B9, and B12) avoid accumulation of homocysteine, which is a risk for cognitive decline. Ginkgo biloba improves memory and shield against Alzheimer's [12]. Omega-3 fatty acids have anti-inflammatory action, reducing joint pain and inflammation. Turmeric (curcumin) and ginger are both known to have anti-inflammatory activity in alleviating symptoms of arthritis [13]. Green tea extract (high in catechins) may have the ability to increase fat oxidation and lead to weight loss. Garcinia cambogia and CLA (conjugated linoleic acid) may have the ability to reduce body fat and improve metabolic function [14]. Probiotics ensure a balanced gut microbiome, supporting digestion and preventing conditions such as irritable bowel syndrome (IBS), inflammatory bowel disease (IBD), and constipation. Prebiotics stimulate the growth of friendly gut bacteria, enhancing digestive health [15]. Collagen supplements enhance skin elasticity and minimize wrinkles. Vitamin C and vitamin E facilitate skin repair, minimize sun damage, and possess antioxidant properties to protect skin cells from aging. Vitamin C, vitamin D, and zinc enhance immune function, preventing infection and autoimmune disease. Probiotics promote a healthy gut microbiome that is essential to immune function [16]. Stress and mood enhancement is an also a key role of nutraceuticals like ashwagandha known as an adaptogen, ashwagandha may help reduce stress, anxiety, and depression by balancing cortisol levels and supporting the body's stress response. St. John's Wort often used to manage mild to moderate depression, St. John's Wort may help boost mood and alleviate symptoms of depression [17]. Milk thistle known for its active compound silymarin, milk thistle has liver-protective properties and is commonly used to detoxify and support liver function [18].

Table 1. Summarizing the Potential Health Benefits of Various Nutraceuticals

Nutraceutical	Health Benefits	Examples/Source	Reference
Immune System Support	Boosts immunity, protects against infections	Vitamin C, Zinc, Echinacea, Probiotics	[19]
Anti-inflammatory Effects	Reduces inflammation, supports joint and heart health	Omega-3 Fatty Acids, Curcumin (Turmeric)	[5]
Cardiovascular Health	Improves heart function, lowers cholesterol, and regulates blood pressure	CoQ10, Garlic Extract, Flavonoids (Fruits)	[5]
Brain and Cognitive Function	Enhances memory, reduces cognitive decline, and improves mental clarity	Ginkgo Biloba, Omega-3 (DHA & EPA), Phosphatidylserine	[10]
Digestive Health	Improves gut health, supports digestion, and reduces symptoms of IBS	Probiotics, Fiber (Psyllium)	[15]
Weight Management	Aids in fat loss, boosts metabolism, promotes lean body mass	Green Tea Extract, Conjugated Linoleic Acid (CLA)	[5, 14]
Antioxidant & Anti-aging	Fights oxidative stress, reduces aging signs, and protects against age-related diseases	Resveratrol, Vitamin E	[5]
Bone Health	Maintains bone density, supports bone mineralization and strength	Calcium, Vitamin D, Magnesium	[11]

4. Role of Nutraceuticals in Preventing Various Diseases

Now-a-days, there is growing interest in the role of nutraceuticals to enhance health and as remedies to certain diseases. Nutraceuticals are derived with the combination of “nutrition” and “pharmaceuticals” which means bioactive compounds that exist in foods and have potential health or medical benefits in addition to the nutritional

benefits. These substances include vitamins, minerals, antioxidants, polyphenols, probiotics as well as herbs which have been clinically proven to boost human immunities, reduce inflammation and modulate metabolism [20].

Due to the increased incidence of chronic and infectious diseases it is necessary to search for safer ways of treatment instead of conventional chemotherapy and pharmacological effects. Therefore, nutraceuticals provide natural solutions to diseases through enhancing body functions without exposing the patients to other serious side effects of synthetically manufactured drugs. Hence, the utilization of nutraceuticals in preventive medicine has been emphasized, due to their proven benefits by science. They can also lower the risk of viral diseases, allergy, inflammatory response, and metabolic diseases which are prevalent in the modern society [21].

It is possible to build up the human body immunity against diseases through the consumption of functional foods and nutraceuticals. Moreover, systematic diseases, including diabetes, obesity and cardiovascular diseases became major threats to people's health, and nutraceuticals are considered as complementary remedies to traditional medications. Here, an attempt has been made to understand the place of nutraceuticals in the prophylaxis of viral diseases, allergy, inflammation, and metabolic disorders [22].

A benefit accrued from the intake of nutraceuticals is that it cures disease instead of masking symptoms as it deals with the origin of diseases. Most diseases are of a chronic nature, and many of them have their roots in, for instance, oxidative stress, chronic inflammation, compromised immune response, and metabolic disturbances. For this reason, including nutrients or food substances containing compounds that facilitate these processes in nutraceuticals maintains a healthy balance in the body for a decreased chance of diseases [2].

The relation between nutrition and the well-being of an individual has gained the center stage thus creating a great market for nutraceutical products across the developed as well as developing nations. There's awareness on what people take every day thus leading to consumption of foods and supplements that has more than nutritional value. Consumers are being provided with functional foods which contain

bioactive compounds, extracts of herbal products and the dietary supplements thus introducing nutraceuticals to the consumers' meal plans [23].

In the subsequent sections, the discussion has been made regarding the importance of nutraceuticals as an antiviral agent, as an antiallergic, as an anti-inflammatory, and as an anti-metabolic disease agent. It is to understand the workings of such mechanisms and the value that attaches them in enhancing health and human wellbeing [1].

4.1. Viral Diseases

In this case, viral infections still pose a significant threat to the global health of people with contagious diseases like Influenza, COVID-19, and other respiratory infections affect millions of people every year. These infections can be as simple as the flu to as severe as pneumonia and viral hepatitis and other severe diseases. This is so especially because viruses can mutate thus causing the long-term pharmaceutical solutions to be difficult, hence increased importance of preventive measures. As a result, immune systems are the initial line of defense against viral pathogens, and compounds that boost the immune reactions collectively called nutraceuticals are significantly vital constituents of disease precaution procedures [24].

Some of the most popular vitamins that are widely suggested to boost the human immune system include vitamin C and vitamin D. Vitamin C has antiviral effects as it boosts the production and activity of the body's white blood cells – the cells charge with the responsibility of detecting the presence of virus in the body. Also, Vitamin C work against inflammation and oxidative stress, which are other factors that make severe complications in viral infections. Vitamin D that is also called the sunshine vitamin is responsible for the modulation of T cells as well as macrophages that participate in antiviral responses. It looks like excessive intake of vitamin D is associated with increased prevalence of respiratory infections; thereby, beneficial to persons with poor levels of vitamin D [19].

Zinc is a trace element that can be involved in immune signaling and has an effect of peracute and chronic viral disease to decrease its severity and duration. It reduces the chances of viruses getting into host cells, stops the replication process of a virus, and promotes the effectiveness of immune system cells. Most of the reports suggest that Zinc taken as a supplement can helpful in decreasing the frequency of R.T.I, and in addition

it reduces the time taken to cure infections like the flu. Zinc has been therefore considered as an effective remedy as it has antiviral capabilities, which is why it is encouraged in the consumption of immune-booster nutraceutical products [22].

Polyphenols and flavonoids are natural constituents known to possess antiviral activity against various viruses. Such bioactive compounds present in the list of fruits, vegetables, and plant-derived food have a positive influence on antioxidant and anti-inflammatory properties. It is obvious that echinacea, elderberry and garlic are some of the herbs that have been widely used to fight viral infections. This herb is efficient in modulating the immune system and passions and increases the white blood cells number in the body and the capability of fighting infection. In this article, the author was able to explain how elderberry works to prevent virus to enter the host cell thus lower the chances of getting infected when taken early when the symptom starts to appear. Garlic has bioactive compounds such as allicins that possess antimicrobial substances that may combat human viruses with efficacy [25].

Moreover, omega-3 fatty acids, which present in fish oil and flaxseeds, moderates immune and inflammations, which are adverse to the outcome of viral illnesses. This is because inflammation is likely to occur in cases of chronic viral illness, and managing inflammation decreases the risk of developing conditions like ARDS. Curcumin that is found in turmeric also has the anti-inflammatory properties that may affect the body's immune response and suppress the replication of the virus [26].

The substances enriched with bioactive compounds, augmented through proper diet or foods supplements, help in improving the immune system and decrease the chances of viral diseases. Nutraceuticals therefore help prevent viral diseases hence serve as an adjunct to orthodox medicines which have many side effects on the human body. It is only now that the possibility of using nutraceuticals in ASH and antiviral defense is being explored, and thus the subject is an important area of public health interest and disease prevention [27].

4.2. Allergies

Allergies are a condition whereby the body's immune system acts abnormally and reacts to harmless matters like pollen, dust, animal fur, fungus, and some types of food. These allergens are harmless substances which if the immune system perceives them as

a threat, it deploys histamine and other irritant substances. This results to characteristic symptoms like sneezing, nasal issues such as a congested nose, an itching sensation, skin rashes, and breathing problems. Anaphylaxis, which is a life-threatening form of allergy, tends to have severe effects on human beings depending on the cause of the allergy. The symptoms involving allergies can be treated with antihistamines and other drugs, but dietary products may be used to help control allergic reactions and restore immunity [28].

Quercetin for instance is a flavonoid which is an excellent antihistamine found in onions, apples, berries – and citrus fruits. Among the herbs that can alleviate allergic reactions to histamine there are those that directly act as histamine antagonists and those that have indirect antihistamine effects. This helps in stabilizing mast cells so that they cannot release histamine, which is the leading compound to allergic reactions. Specifically, quercetin has been found to have some benefit in improving such conditions as seasonal allergies and asthma due to the regulation of inflammation. Bromelain which is an enzyme obtained from pineapples is also a useful compound in the body since it has anti-inflammatory effects and helps in the treatment of inflammation of nasal passages that result from allergy [29].

Probiotics are one of the essential factors that contribute towards the health of the colon which is directly associated with the immune system. A healthy gut flora ensures immunological tolerance minimalizes and does not allow the immune system to send antibodies against substances that do not pose harm to the organism. Research has indicated that *Lactobacillus* and *Bifidobacterium* tend to alleviate the allergic symptoms mainly among those with hay fever and eczema. Thus, by improving the condition of the guts, the effect of probiotics positively influences the body's immunity and reduces the sensitivity to allergens [30].

Vitamin C and polyphenols have an impact on allergic inflammation since oxidative stress affects cells and tissues. It is also noted that vitamin C helps fight the allergy by lowering histamine concentration in the blood stream. Anti-inflammatory compounds also present in green tea, berries, dark chocolate also modulates allergy responses in body [31].

Omega-3 fatty acids that are present in fatty fishes, flax seeds as well as walnut help decrease inflammation in allergic diseases such as asthma and eczema. Omega-3 reduces the activity of the immune cells and lowers the levels of cytokines – inflammatory molecules that may lead to worsening of the allergenic crisis and decreased respiratory performance [20].

Therefore, these nutraceuticals are beneficial as they help the allergy affected persons develop better immune systems that can handle the allergens. Unlike other anti-allergic medicine that are likely to lead to side effects such as dizziness, sleepiness and other related effects, nutraceuticals are a natural and long-term measure of dealing with allergic diseases. Day by day, knowledge about nutraceutical products as an effective anti-allergic agent with hope for those who are interested on natural products is widening.

4.3. Inflammatory Disorders

Inflammation can become a chronic disease and one that is related to many diseases such as arthritis, asthma, and autoimmune diseases. Nutraceuticals also have the potential of being anti-inflammatory, thus being of value in decreasing inflammation and managing both the conditions that result from it. Curcumin is its active constituent derived from turmeric which has anti-inflammatory properties because it prevents certain activities which trigger inflammation and thus reduces pain. One such compound is resveratrol found in grapes and berries makes every effort to shield the cells from any harm that free radicals meaning chronic inflammation may cause [20].

The epidermal growth factor feeder-size is also reduced and omega-3 fatty acids available in fish oil decrease inflammation through cytokines. Glucosamine and chondroitin sulfate are two nutritional supplements widely used for joint relieve and treatment of osteoarthritis. Vitamin E and selenium also help in offering protection to the carbon body structure against the cause of oxidative stress and prevent inflammation-related damage. They are useful in the treatment of inflammatory diseases and enhancing health standards and wellbeing [5].

Glucosamine and chondroitin sulfate help in improving joint health and joint pain related to osteoarthritis as they were said to have the ability to repair damaged cartilage and decrease inflammation or swelling of the joint. As well, there are such

elements as vitamin E and selenium that can protect cells from oxidative stress, hence, refraining the heart from inflammation related hurt. It also has the effect of lowering the inflammatory markers and helps in giving relief in autoimmune diseases, due to the presence of catechins in the green tea extract. Thus, to help consumers suffering from inflammatory diseases or condition, it is possible through medication via functional food or supplements containing the bioactive compounds mentioned earlier. Apart from playing a role of reducing inflammation, nutraceuticals also play the role of preventing further stress on tissues and diseases that might be caused [32].

4.4. Metabolic Disorders

Pathologies of metabolism such as diabetes, obesity and cardiovascular diseases have become frequent due to inappropriate diet and lack of physical activities. It must be noted that these conditions can be managed through nutraceuticals on basis of glycemic control, lipid panel and weight management. Chromium, alpha-lipoic acid, and berberine are classified to improves insulin and glucose metabolism and hence can be used by diabetic patients. Psyllium and oat beta-glucans help in reduction of cholesterol levels and enhance cardiovascular health. The plant sterols and omega-3 fatty acid help in the prevention of the bad cholesterol also known as LDL while at the same time promoting the good cholesterol, the HDL [5].

To manage weight, green tea extract, congealed linoleic acid, and fibers are useful in the digestion of fats and in appetite regulation which are valuable tools in preventing complications arising out of obesity. Therefore, it can be concluded that addition of these nutraceuticals to their diets would help metabolic disorders subjects to minimize other related health complications [15].

Psyllium and oat beta-glucans are a dietary fiber that has many health benefits on cardiac health through the regulation of cholesterol levels and additionally acts as a prebiotic promoting optimal digestion. Carbohydrate strands also known as fibers help in minimizing level of LDLP (low density lipoprotein) cholesterol on the other hand enhancing level of HDLP (high density lipoprotein) cholesterol decreasing chances of atherosclerosis and heart diseases. Plant steryl esters which can also be obtained from nuts seeds and vegetable oils, lower cholesterol levels by inhibiting cholesterol reabsorption in the small intestine [33].

In weight loss, green tea extract has been also investigated for its impact on fat burning and appetite suppressant effects organs TW, CLA and fiber supplements. Catechins and caffeine present in green tea extract also help in increasing basal metabolic rate and the later enhances fatty oxidation rate for weight reduction. CLA enables the body to have a slimmer look by assisting the loss of body fat particularly the abdominal kind without the loss of lean body mass; it is therefore appropriate for any person with a desire to have a better shape. They also create fullness so that it is easy to avoid over indulgence, thus cutting down on the number of calories consumed [34].

Consuming the mentioned nutraceuticals in their daily diet will enhance an individual's capacity to manage metabolic diseases and thus, the likelihood of other related conditions including hypertension, cardiovascular disease and type-2 diabetes. It is the plausible therefore, that this study re-affirms that dietary intervention, physical activity and nutraceutical intervention, all factors that work synergistically will bring forth a vast improvement on metabolism health [5].

4.5. Cancer

Cancer is a complex disease characterized by uncontrolled cell growth, and nutraceuticals play a role in its prevention by modulating oxidative stress, inflammation, apoptosis, and gene expression. Curcumin, one of the most extensively studied nutraceuticals, has been shown to induce apoptosis (programmed cell death), inhibit the nuclear factor-kappa B (NF- κ B) inflammatory pathway, and suppress tumor growth. Resveratrol, found in red grapes, wine, and berries, influences gene expression, inhibits angiogenesis (the formation of new blood vessels in tumors), and triggers apoptosis in cancer cells. Sulforaphane, a bioactive compound in cruciferous vegetables like broccoli, enhances the detoxification of carcinogens and promotes the death of malignant cells [3].

Green tea is rich in epigallocatechin gallate (EGCG), which inhibits cancer cell proliferation, reduces oxidative stress, and prevents DNA damage. Lycopene, a powerful antioxidant found in tomatoes and watermelon, has been associated with a reduced risk of prostate cancer by lowering oxidative stress and inhibiting tumor growth. Additionally, omega-3 fatty acids, known for their strong anti-inflammatory

properties, have been shown to suppress tumor progression and metastasis, making them valuable in cancer prevention strategies.

4.6. Hypertension

Hypertension is one of the causes of cardiovascular disease, and these nutraceuticals play their vital role in the management of hypertension by enhancing the elasticity of the blood vessel walls and thereby decreasing the stiffness of arteries. There are omega-3 fatty acids found in fish oil and flaxseed which has been proved to have properties such as reducing inflammation, enhance endothelial function and decreased blood pressure levels. Other beneficial compound includes CoQ10; is also involved in antioxidant and energy producing works in the mitochondria; also helps in the release of NO, which causes dilation of blood vessels and therefore better circulation [1].

Catechins, found in green tea, flavonoids found in dark chocolate and berries, sabrosol, brings positive effects on endothelial mechanics and has anti-oxidative effects, which helps in better blood vessels health. One of the most important minerals in our body, magnesium assists the patients by acting like a natural calcium blocker so as to make arteries dilation and reducing the blood pressure. L-arginine which is an antecedent of NO, also enhances the dilation process for increased blood circulation and decreased vascular tone. All the above nutraceuticals are useful in managing hypertension thus lowering the risks of heart diseases and stroke.

4.7. Diabetes Mellitus

Diabetes mellitus is a metabolic disorder, which results from the body's inability to produce enough insulin or the tissues refusing to accept the insulin that is produced. Nutraceuticals have positive effects on glucose control through promoting both insulin sensitivity and decreasing the oxidative stress and carbohydrate digestion and absorption rate. The use of cinnamon has been established to enhance insulin receptor sensitivity which results to increased glucose uptake and low fasting blood glucose level.

Berberine is an active compound derived from plants and has the capacity to straighten the glycolysis pathway by increasing AMPK or the insulin sensitive enzyme which helps to reduce blood glucose level. Alpha-lipoic acid (ALA), an antioxidant,

works to combat the oxidation process and enhanced the glucose transport in the sensitive tissues to insulin. The constituent of curcumin in turmeric works as an anti-inflammatory agent that helps to tackle the problem of insulin resistance [2].

Also, the food also contains soluble fiber which reduces post-meal glycemic index because fenugreek seeds delay release of glucose into the bloodstream. Chromium picolinate as a trace mineral is useful in the regulation of insulin activity, stimulation of glucose uses and control of insulin tolerance. The benefits of the below nutraceuticals include the improvement of blood sugar levels with regard to diabetes and the prevention of complications that may be associated with the disease.

Table 2. Nutraceuticals Source and Mechanism of Action

Key Role	Nutraceuticals	Source	Mechanism of Action	Reference
Modulating Inflammation	Omega-3 Fatty Acids (e.g., EPA, DHA)	fish oil and certain plant sources	Reduce inflammation by inhibiting the production of pro-inflammatory molecules like eicosanoids	[35]
	Curcumin	from Turmeric	Curcumin inhibits inflammatory pathways by targeting molecules like NF- κ B, a key regulator of inflammation	[35]
	Resveratrol	found in grapes and red wine	Resveratrol has anti-inflammatory properties by activating SIRT1, a protein that plays a role in cellular protection and longevity	[36]
Antioxidant Activity	Vitamin C and E	citrus fruit, strawberries, sunflower, olive, nuts like almond, peanuts	These vitamins neutralize free radicals, unstable molecules that can damage cells and contribute to disease	[37]
	Quercetin	found in fruits and vegetables	Quercetin is a flavonoid with potent antioxidant properties, helping to protect cells from oxidative stress	[38]
	Epigallocatechin-3-	green tea	Performs its antioxidant activity by scavenging	[39]

	gallate (EGCG)		free radicals through hydrogen atom transfer (HAT) and single electron transfer (SET) mechanisms, and by chelating metal ions	
Supporting Gut Health	Probiotics (beneficial bacteria)	found in yogurt and fermented foods	Help maintain a healthy gut microbiome, which is crucial for digestion, immunity, and overall health	[40]
	Prebiotics (food for probiotics)	fruits, vegetables, and whole grains	Prebiotics, like fiber, are indigestible foods that serve as fuel for beneficial bacteria in the gut	[41]
Modulating Metabolic Pathways	Chromium	Brewer's yeast, lean meats, whole grains, some spices, and certain fruits and vegetables as well as nuts and seeds	Chromium helps regulate blood sugar levels and improve insulin sensitivity	[42]
	Magnesium	soy products (milk, flour, tofu) Legumes and seeds Fruit (bananas, dried apricots, etc.)	Magnesium plays a role in energy production, nerve function, and muscle function	[43]
	L-Carnitine	red meat, poultry, fish and dairy	L-Carnitine is involved in fatty acid metabolism and energy production	[44]

5. Toxicity Evaluation of Nutraceuticals

While some nutraceuticals are safe, some may be harmful. Due to a dearth of pharmacological and toxicological research, toxicity and safety information are unavailable for a significant proportion of nutraceuticals. The pharmacological and

toxicological assessment of nutraceuticals is more complicated than that of pure synthetic pharmaceuticals because of the following factors: (1) the presence of multiple phytochemicals in a single plant; (2) the variability of phytochemical constituents due to climate, geography, and soil properties; (3) the use of pesticides and fertilizers; (4) harvesting variations throughout the day; (5) stress; and (6) quality control standards. The usage of nutraceuticals for both humans and animals has grown worldwide, and with it, so have the health hazards associated with the supplements' active ingredients and harmful contaminants. Safety is still a major concern because these nutraceuticals have not undergone the same thorough testing as medications and no extensive clinical trials have been conducted. Additionally, because the majority of nutraceuticals are plant extracts, it is highly probable that they contain metals (such as arsenic, cadmium, lead, and mercury), pesticides, mycotoxins, and other plant alkaloids (such as pyrrolizidine alkaloids). Another major worry is the adulteration of nutraceuticals with illegal substances.

6. Regulatory Considerations

The Food and Drug Administration (FDA) does not have a formal definition for the term "nutraceutical". Rather, goods with alleged health advantages fall under the category of dietary supplements. The Dietary Supplement Health and Education Act (DSHEA) of 1994 govern these supplements and require manufacturers to guarantee product safety and correct labeling prior to release. Nevertheless, the FDA does not have to approve them prior to marketing. Standards like ISO 21149, which are relevant to dietary supplements and nutraceuticals, are provided by the International Organization for Standardization (ISO) to guarantee uniformity and quality in production procedures.

7. Conclusion

There exist significant evidences that link nutraceuticals to disease prevention and health enhancement. The substances which are important for the immune function, decreasing inflammation, and regulating metabolism, are crucial for utilizing in the nutrition and diet. From emergence of different bioactive compounds in natural foods, nutraceuticals are increasingly being considered as an effective supplement to pharmaceuticals.

Through incorporating of these food supplements and products into the general dietary systems, persons will be able to boost their health, reduce diseases and have longer and healthy lives. As awareness with improvement in the functionality food products, nutraceutical continues to have a bright future in improving the quality of people's lives and minimizing the impacts of chronic as well as infectious diseases.

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Authors Contributions

All authors contributed equally in writing, drafting and conceptualization.

Conflict of Interest

The authors declare that there is no conflict of interest.

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