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Research Article

# NUTRACEUTICALS: A CONCEPTUAL DEFINITION

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**ABSTRACT**

Nutraceuticals are a diverse product category with various synonyms used internationally. The term 'nutraceutical' has been part of the industry lexicon for almost a decade. Unfortunately, it still seems to be held up in a scrambled web of complementary definitions, regulatory watchdogs and consumer confusion. For an effective regulatory policy framework, nutraceuticals need to move from a blurred idea with varied and sometimes conflicting definitions, to a sharply defined and quantifiable concept. In an effort to clarify the definition of nutraceuticals, three general concepts that should be included in a definition have been identified based on the definitions from literature. The frontiers of the nutraceutical universe were defined using the dimensions of physiological effects, matrix and functional intensity. After an extensive literature review and analysis, a working definition of nutraceuticals is suggested. The need, scope, and importance of this article are clearly evident due to the emerging regulatory regime and recent surge in the growth of nutraceuticals.

**Keywords:** Nutraceutical, Conceptualization.

## INTRODUCTION

The principle, "*Let food be thy medicine, and medicine be thy food*", advocated by Hippocrates (460–377 BC), the well recognized father of modern medicine, emphasize the association between nutrition and human health, and conceptualized the relationship between the use of appropriate foods for health and their therapeutic benefits.

The role of dietary active compounds in human nutrition is one of the most important areas of investigation with the findings having wide-ranging implications for consumers, health care providers, regulators, food producers, processors and distributors[1, 2]. Thus, the concept of 'adequate nutrition' is beginning to be replaced by 'optimal nutrition' with consumer belief increasing at an unprecedented pace[3, 4]. Scientists and food manufacturers have coined several terms to describe these physiologically active components and health benefits of these foods. None have clear and generally accepted definitions[5, 6].

In the past few years, many bioactive constituents of food have been commercialized in the form of pharmaceutical products (pills, capsules, solutions, gels, liquors, powders, granulates, etc.) that incorporate food extracts or phytochemical-enriched extracts to which a beneficial physiological function has been directly or indirectly attributed. This range of products cannot be truly classified as "food" or "pharmaceutical", and a new hybrid term between nutrients and pharmaceuticals, 'nutraceuticals', has been coined to designate them[7]. No official definition exists for the term "nutraceutical", though it is often used to describe a broad list of products sold under the premise of food components with an expressed intent of treatment or prevention of disease and for enhancing the health and wellbeing of an individual[8, 9].

Nutraceuticals are a diverse product category with various synonyms used internationally. The term "nutraceutical" was coined by Stephen DeFelice, founder and chairman of the Foundation for Innovation in Medicine. This term has been part of the industry lexicon for almost a decade. Unfortunately, it still seems to be held up in a scrambled web of complementary definitions, regulatory watchdogs and consumer confusion[10]. "Functional foods," "nutraceuticals," "pharmaconutrients," and "dietary integrators" are all terms used incorrectly and indiscriminately for nutrients or nutrient-enriched foods that can prevent or treat diseases[8].

Since the early 1990s, the world has witnessed the explosive growth of a multi-million dollar nutraceutical industry[11,12]. Nutraceuticals represent a unique intersection of the pharmaceutical and food industries. There is no clear demarcation as such separating food from drugs, but the law mandates such distinctions be made[13]. It appears that the nutraceutical industry has found a comfortable middle ground between the food and drug industries[11]. Nutraceuticals are clearly not drugs, which are potential pharmacologically active substances that will potentiate, antagonize, or otherwise modify any physiological or metabolic function. On the other hand a nutraceutical is evidently a food component that not only maintains, supports, and normalizes any physiologic or metabolic function, but one that also potentiates, antagonize, or otherwise modify physiologic or metabolic functions[19]. Many nutraceuticals are being used as alternatives for both nutrition and medicine[20]. Nutraceuticals are found in a mosaic of products emerging from the food industry, the herbal and dietary supplement industry, the pharmaceutical industry, and the newly merged pharmaceutical/ agribusiness/ nutrition conglomerates[34].

The nutraceutical industry is a dynamic, evolving industry that offers exciting opportunities to merge scientific discovery with growing consumer interest in health-enhancing foods[14]. Nutraceuticals will continue to have great appeal because they are convenient for today's lifestyle[15]. The greatest challenge still remains in the public policy and regulatory arenas, which will encourage research and development of products that provide health benefits and permit truthful, non-misleading communications of these products while protecting public health and maintaining public confidence[16]. The approach to regulating and marketing nutraceuticals is notably heterogeneous on the global level. This is largely due to challenges in classifying these products, absence of a suitable regulatory category for these hybrid products, and varying views on what is considered sufficient scientific substantiation to conclude their functionality[5]. Unfortunately, the absence of a universally accepted definition, great variations between various existing definitions and divergent regulatory frameworks are inadequate to address the full scope of benefits and opportunities for nutraceuticals.

Owing to the lack of a well defined regulatory framework, nutraceuticals in India are not conceptualized in terms of segments, regulations, manufacturing, marketing, exports and imports.[17] For the first time in the Indian regulatory system, the Food Safety and Standards Act, 2006 (FSSA) has formally created a special third category — "Foods for Special Dietary Uses/Functional Foods/Nutraceuticals/Health Supplements" in addition to the first two — "conventional foods" and "drugs". These products are not recognized as a standalone category, instead the FSSA includes them as a special category of products that fall under the general umbrella of foods, that shall have specific regulatory requirements under the forthcoming regulations. The previous food laws of India do not formally recognize and define nutraceuticals[17].

While the FSSA has taken the first step in recognizing nutraceuticals and classifying them under foods, the rules and regulations are yet

to be framed. The formulation of rules and regulations for nutraceuticals is a mammoth task and is anticipated to begin shortly[18]. It is noteworthy that most countries do not formally define or directly regulate nutraceuticals; the regulation of health claims represents the indirect system for these food products.

Appropriately defining the nutraceutical category is the first step in framing a regulatory framework and to protect consumers with accurate, non-misleading information about their health benefits. The appropriate conceptualization and definition of nutraceutical also helps to estimate the scope of the regulatory framework required and also to estimate any potential overlap with other related regulations. An appropriate definition will also serve as a guide for the regulations that one must consider during formulation development, labeling, product claims, and process that must be followed before placing a product onto the market. It also impacts the way a company can promote and distribute the product to the end user. Without the knowledge of the category that the product will be classified under, it is very difficult to assess product regulatory compliance.

A better understanding of the various concepts and principles that should be considered while defining nutraceuticals could increase the uniformity between definitions and, help develop a prospective definition. The aim of this article is to conceptualize the nutraceuticals, and to propose a definition of nutraceuticals. This conceptual paper could be considered as the first of its kind that attempts to conceptually define the frontiers of the nutraceutical universe, and to provide a working definition of nutraceutical. This paper should contribute to the debate surrounding the type of product that should be considered as a nutraceutical and the lack of a common definition for nutraceuticals. The research work of Maurice Doyon and JoAnne Labrecque has been used as a guideline across the various conceptualization components of this paper[19].

## MATERIALS AND METHODS

### Objective of the study

The overarching objective of this study is to identify concepts that should be included in a broadly accepted nutraceutical definition.

The key objectives of this study are:

1. To identify key concepts found in the various definitions of nutraceutical
2. To identify and develop principles those illustrate the frontiers of the nutraceutical universe
3. To propose a working definition of nutraceuticals
4. To attain these objectives, the following methodological steps are taken:
5. Refer to the relevant literature in order to identify key concepts for a broadly accepted definition i.e., should or should not include
6. Analyze relevant literature to identify and develop principles that would contribute to illustrate the frontiers of the nutraceutical universe
7. Propose a working definition of nutraceuticals
8. Explain the various components of the proposed definition

No universally accepted definition for nutraceutical exists. In fact, nutraceuticals are more of a concept than a well-defined group of food products, a working definition rather than a firm definition is preferred for the purposes of this paper.

### Search criteria

The objective was to collect definitions of nutraceutical cited in the literature from various sources. The nutraceutical definitions were identified by examining the following range of sources.

1. Websites of regulatory agencies and government departments responsible for regulating standards of food and related products like nutraceuticals (www.fssai.gov.in, www.fda.gov, www.hc-sc.gc.ca, www.efsa.europa.eu, www.fao.org, www.emea.europa.eu, www.mhlw.go.jp and www.foodstandards.gov.au);
2. Digital archives and databases of biomedical and life sciences journal literature (PubMed (www.ncbi.nlm.nih.gov/pubmed), Ingenta (www.ingenta.com), British Library Direct (http://direct.bl.uk/bld), Google Scholar (http://scholar.google.com) and Scirus (www.scirus.com));
3. Academic journals;
4. Legal texts and literature (e.g. Lexis-Nexis (www.lexisnexis.com) and Global Legal Information Network (www.glin.gov));
5. Internet search (www.google.com, www.altavista.com, www.bing.com and www.lycos.com).

The search terms used were: “Nutraceutical”, “Nutraceuticals”, “Nutraceutical Definition” “Definition of Nutraceutical”, “Nutraceutical Labeling”, “Nutraceutical Regulations” and “Nutraceutical Claims”.

The definitions of product categories considered as synonyms or related to nutraceuticals in the literature are not considered for the purpose of the analysis (for e.g. health supplement)

## RESULTS AND DISCUSSION

### Review of definitions

Originally, the term "nutraceutical" was coined by Dr. Stephen DeFelice, founder and chairman of the Foundation for Innovation in Medicine. According to DeFelice, “a nutraceutical is any substance that is a food or a part of a food and provides medical or health benefits, including the prevention and treatment of disease”[20]. Since the initial conceptualization of nutraceuticals, a range of alternate definitions have been proposed; by either limiting the dosage forms covered by the term (e.g. tablets, capsules), imposing some sort of processing requirements (e.g., must be isolated, purified from foods), confining the criteria of its health benefits (e.g., exert physiological benefit, provide protection against chronic disease), or defining them in relation to other product categories (e.g., referring to dietary supplements, functional foods, bioactives or their modified forms).

The literature reveals varied definitions of nutraceuticals. After reviewing numerous definitions, twenty-five definitions were selected on the basis of their representation. The selected definitions are listed in table 1.

A number of definitions concur or cross reference the original DeFelice definition. Some define a nutraceutical as an objective product with demonstrated health benefits that are generally sold in medicinal forms (definitions one to ten of table 1). A few definitions describe nutraceuticals as bioactive compounds or phytochemicals of food (definitions eleven to nineteen of table 1). A few other definitions characterize nutraceuticals as dietary supplements and functional foods, or as their active components (definitions twenty to twenty five of table 1). While some definitions are quite simple, others are more complex. A majority of the definitions relate nutraceuticals to food, food components, or nutrients providing health or physiological benefits beyond the basic nutritional value of the product

From the selected definitions of table 1, three key concepts were identified.

*The nature of the nutraceutical:* The nature of the nutraceutical appears to be an important concept. The characteristic nature of nutraceuticals is further presented in ‘conventional food’ or as a ‘concentrated, isolated, or purified’ nature. Although most definitions use the word food, almost a half (12/25) denotes nutraceuticals as concentrated, isolated or purified nature of food. Almost one quarter of the definitions (6/25) denotes nutraceuticals as conventional food nature or refers to conventional food nature by relating them to functional foods. Almost one quarter of the definitions (6/25) denote nutraceutical as both conventional foods and concentrated, isolated or purified nature of food.

*The form of nutraceutical:* The form of the nutraceutical appears to be a vital concept. Nearly one half (11/25) denote nutraceuticals as medicinal forms not usually associated with food (e.g. tablets, capsules) or presented in a non-food matrix, by defining them as such or relating nutraceuticals to dietary supplements.

**Table 1: Analysis of nutraceutical definitions**

| S.No. | Definition | Nature | | Form | | Health benefits | | |
|---|---|---|---|---|---|---|---|---|
| | | Conventional food | Isolated/ Purified/ Concentrated form of food | Conventional food form | Medicinal Form | Prevention of disease | Treatment of disease | Reduce the risk of disease |
| 1 | A nutraceutical is any substance that is a food or a part of a food and provides medical or health benefits, including the prevention and treatment of disease. Such products may range from isolated nutrients, dietary supplements and specific diets to genetically engineered designer foods, herbal products, and processed foods such as cereals, soups and beverages[8, 20-25]. | ✓ | ✓ | | ✓ | ✓ | ✓ | |
| 2 | A nutraceutical is a product isolated or purified from foods that is generally sold in medicinal forms not usually associated with food [26-29]. A nutraceutical is demonstrated to have a physiological benefit or provide protection against chronic disease. | | ✓ | | ✓ | ✓ | | |
| 3 | A nutraceutical is, "any nontoxic food component that has scientifically proven health benefits, including disease treatment and prevention"[11]. | | ✓ | | | ✓ | ✓ | |
| 4 | Nutraceuticals are isolates that provide concentrated nutrients in the form of pills, tablets, liquids, or powders for direct consumption or for use as ingredients in functional foods. Nutraceuticals include micro- and macronutrient isolates, herbs and botanicals, and isolated reagents (e.g., hormones) [30]. | | ✓ | | ✓ | | | |
| 5 | Nutraceuticals are commodities derived from foods, but are used in the medicinal form of pills, capsules, portions and liquids and again render demonstrated physiological benefits[31]. | | ✓ | | ✓ | | | |
| 6 | "Nutraceutical" is any substance that may be considered a food or part of a food and provides medical or health benefits, encompassing, prevention and treatment of diseases[32]. | ✓ | ✓ | | | ✓ | ✓ | |
| 7 | Nutraceuticals have been proven to offer physiologic benefits or to reduce the risk of chronic disease, or both, beyond their basic nutritional functions[33]. | | | | | | | ✓ |
| 8 | Nutraceuticals are food or food ingredients that have defined physiological effects. These products in general terms cover health promotion, "optimal nutrition" the concept of enhanced performance – both physically and mentally – and reduction of disease risk factors[34]. | ✓ | | | | | | ✓ |

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| 9 | Nutraceuticals can be formulations or foods, taken orally in addition to the normal diet over prolonged periods at concentrations below RDA norms to prevent nutrition related disorders, provide structure/ function support and fulfill special physiological needs of the body [35]. | ✓ | | ✓ | ✓ | | | |
| 10 | Formulations or foods with health benefits that are taken orally in addition to the normal diet and can even be taken over prolonged periods in concentrations which are lower than the Recommended Daily Allowance (i.e., below the therapeutic range) to; supplement the diet to help prevent nutrition related disorders; provide structure/function support that may help prevent specific diseases like diabetes, cancer, obesity through beneficial and proven effects that go beyond the known nutritional effects; and fulfill special physiological needs of the body such as like pregnancy, lactation, sports, infancy and sedentary lifestyle[36]. Further to this definition. Functional foods, dietary supplements and functional beverages categories have been considered under the purview of "Nutraceuticals"[36]. | ✓ | | ✓ | ✓ | ✓ | | |
| 11 | Nutraceuticals are bioactive natural compounds that have health promoting or disease preventing properties[37]. | | ✓ | | | ✓ | | |
| 12 | Bioactive compounds are also referred to as nutraceuticals, a term (coined in 1979 by Stephan DeFelice) that reflects their existence in the human diet and their biological activity. Bioactive substances present as natural constituents in food provide health benefits beyond the basic nutritional value of the product[38]. Nutraceuticals may range from isolated nutrients, dietary supplements, and diets to genetically engineered ''designer'' foods, herbal products, and processed foods, such as cereals, soups, and beverages | ✓ | ✓ | | ✓ | | | |
| 13 | Nutraceutical generally refers to dietary supplements that contain a concentrated form of a bioactive substance originally derived from a food[39]. | | ✓ | | ✓ | | | |
| 14 | Nutraceutical is the term used to describe a medicinal or nutritional component that includes a food, plant or naturally occurring material, which may have been purified or concentrated, and that is used for the improvement of health, by preventing or treating disease[40]. | | ✓ | | | ✓ | ✓ | |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 15 | Nutraceuticals are chemicals found as a natural component of foods or other ingestible forms that have been determined to be beneficial to the human body in preventing or treating one or more diseases or improving physiological performance. Essential nutrients can be considered as nutraceuticals if they provide benefit beyond their essential role in normal growth or maintenance of human body[41]. | | ✓ | | | | ✓ | ✓ |
| 16 | Dietary supplements deliver a concentrated form of a presumed bioactive ingredient (nutraceutical) from a food, in a nonfood matrix (usually in a tablet or capsule form), to enhance health in dosages that exceed those that can be obtained from normal food[42]. | | ✓ | | | ✓ | | |
| 17 | Nutrients and non-nutrient compounds in food that have health-promoting, disease preventive or medicinal properties. Nutraceuticals can be purified to make a dietary supplement or added to a food to increase the amount of those substances in the diet[43]. | | ✓ | | | ✓ | ✓ | |
| 18 | Nutraceuticals are naturally occurring/derived bioactive compounds that are reported to have health benefits. The delivery systems for nutraceuticals are foods (functional foods), supplements, or both[44]. | | ✓ | ✓ | | ✓ | | |
| 19 | Nutraceuticals also refer to natural functional/medical foods or bioactive phytochemicals that have health promoting, disease preventing or medicinal properties[15, 45]. | ✓ | ✓ | | | | ✓ | |
| 20 | The attempts of the food industry to omit health-adverse compounds, and incorporate constituents with identified beneficial health effects has coined the term 'functional food', encompassing fresh or processed food with health-promoting and/or disease-preventing properties. The active ingredients of these products are known as 'nutraceuticals'[46]. | | ✓ | | | | ✓ | ✓ |
| 21 | Nutraceuticals are foodstuffs, food additives or dietary supplements that make health claims[47]. | ✓ | ✓ | | | ✓ | | |
| 22 | The term "nutraceutical" is used to describe medicinally or nutritionally functional foods[48]. | ✓ | | ✓ | | | | |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 23 | Nutraceuticals are diet supplements that deliver a concentrated form of a presumed bioactive agent from a food, presented in a non-food matrix, and used with the purpose of enhancing health in dosages that exceed those that could be obtained from normal foods[7, 49,50]. | | ✓ | | ✓ | | | |
| 24 | The term 'nutraceutical' means a dietary supplement, food, or medical food, as respectively defined in paragraphs (f) and (ff) and section 5(b)(3) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)), that(1) possesses health benefits; and (2) is safe for human consumption in such quantity, and with such frequency, as required to realize such properties[51]. The term 'health benefit', when used with reference to a nutraceutical, means a benefit which prevents or reduces the risk of a disease or health condition, including the management of a disease or health condition or the improvement of health [51]. | ✓ | ✓ | ✓ | ✓ | ✓ | | ✓ |
| 25 | Functional food provides the body with the required amount of vitamins, fats, proteins, carbohydrates, etc, needed for its healthy survival. When functional food aids in the prevention and/or treatment of disease(s) and/or disorder(s) other than anemia, it is called a nutraceutical[52]. | ✓ | | ✓ | | ✓ | ✓ | |

More than one third (9/25) do not specify the form of nutraceuticals, these definitions describe nutraceuticals as bioactives or food components, and do not indicate the matrix they should be presented. Only two definitions (2/25) relate nutraceuticals to the conventional food format by referring to functional foods. Few definitions (3/25) specify nutraceuticals as both medicinal forms and conventional food forms. Only two definitions (2/25) describe the consumption pattern over prolonged periods at concentrations below the Reference Daily Allowance (RDA) norms in addition to the normal diet. Only two definitions (2/25) specify the amount of consumption to exceed the quantities that cannot be obtained from conventional food either as a concentrated form or as an addition to conventional food.

*The health benefits of nutraceuticals:* A majority of the definitions (23/25) indicate the health benefits of nutraceuticals. The concept of health benefits appears to be central to most definitions. Moreover, the use of the term "health benefit" is not restrictive, and also refers to physiological and medical benefits. In the selected definitions, health benefits when specified are classified as; prevention of disease (2/25), prevention and treatment of disease (7/25), reducing the risk of disease (2/7) and prevention and reduction of the risk of disease (1/25). Some definitions indicate the health benefits (10/25) without mentioning the terms, 'prevention', 'treatment' and 'reducing the risk of disease'. When the term disease is mentioned in the definitions, nearly half of them are non-specific (12/25), two definitions mention "chronic disease" (2/25), one definition specifies "nutritional deficiency disease", and one definition mentioned "specific diseases" like diabetes, cancer, and obesity. Only four definitions (4/25) mention the health benefits should be demonstrated and proven, but they do not specify the type of scientific evidence required. Three definitions (3/25) specifically mentioned that health benefits should be beyond the basic nutritional functions.

**Nutraceutical Boundaries**

From the above observations it appears that one important boundary that defines the nutraceutical universe is physiological effects. The upper bound of the physiological effect dimension would be food that can cure or heal. It has also been established previously that a nutraceutical should have benefits beyond its basic nutritional functions. To better define the boundaries of nutraceuticals, it is important to distinguish nutritional deficiency from other physiological effects such as disease risk reduction. Thus, a food that improves nutritional equilibrium should not be considered as a nutraceutical. The second important boundary that defines the nutraceutical universe is the matrix in which the nutraceutical is presented, "food matrix, i.e., conventional food format" or "non-food matrix, i.e., medicinal forms not usually associated with conventional food". The third boundary of the nutraceutical universe is the functional intensity. This functional intensity is measured through its physiological effects and its concentration of "active" components[19]. Since all foods have some degree of functional intensity; a nutraceutical must have an optimal degree of functional intensity to stimulate physiological effects beyond the basic nutritional functions. The three dimensions used simultaneously should be sufficient to define the nutraceutical universe, as illustrated in figure 1.

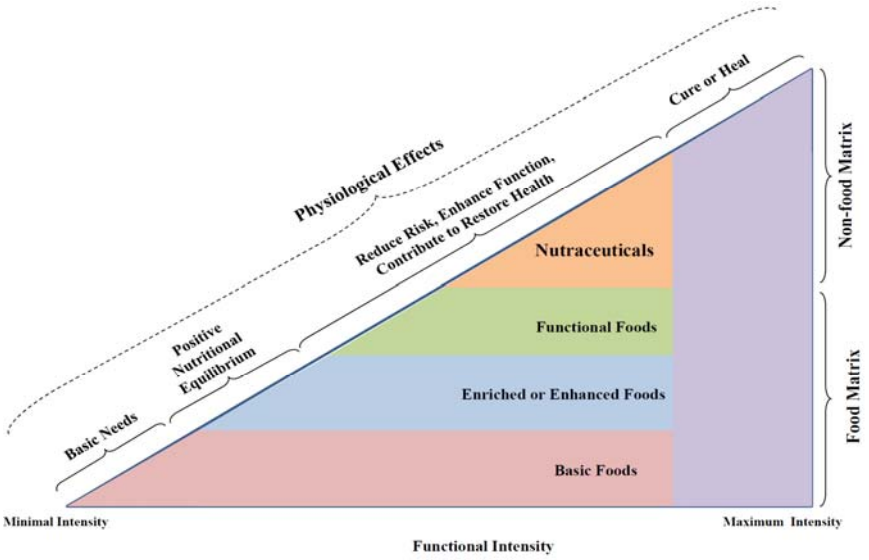


**Fig. 1: Frontiers of nutraceutical universe.**

**Definition of nutraceutical**

From the frontiers of the nutraceutical universe as illustrated in figure 1, the following working definition of nutraceutical is suggested;*"A nutraceutical is a food or a part of a food for oral administration with demonstrated safety and health benefits beyond the basic nutritional functions to supplement diet, presented in a non-food matrix or non-conventional food formats, in such a quantity that exceeds those that could be obtained from normal foods and with such frequency as required to realize such properties, and is labeled as a 'nutraceutical'."*

**Rationalization of the nutraceutical definition**

The first sentence – "*A nutraceutical is a food or a part of a food for oral administration"*–implies that a nutraceutical is considered as food regulated under the umbrella of food regulations and is not strictly a drug. Specifying nutraceuticals as food draws a boundary, and restricts the positioning of a nutraceutical as a drug by any implicit or explicit expressions, for example, use of ingredients or claims specified under drug regulations. The phrase – "*for oral administration"* – restricts a nutraceutical for non-oral administration, for example, parenteral route of administration.

The "*part of a food"* phrase does not exclude the possibility that the essential nutrients and components of food could be concentrated, isolated, purified, enriched, or improved as long as the levels are in the range permitted for food use as specified by relevant national regulations (for example, in amounts not exceeding the Recommended Daily Allowance (RDA) or enzymes (within permissible limits), and are not in the drug range specified by any drug regulations.

The second sentence – "*with demonstrated safety and health benefits beyond the basic nutritional functions to supplement diet"* – integrates the safety and health benefit as an integral component of the definition. The "*demonstrated safety"* phrase does exclude the possibility of any novel food and food ingredient as a nutraceutical for which safety is not assessed under appropriate regulations. Where a certain food or food ingredient is significantly changed in comparison to its equivalent ordinary food, it should be considered as a novel food and any safety issue should be resolved before it is marketed. A novel food can be defined as a type of food that does not have a significant history of consumption or is produced by a method that has not previously been used for food. The concept of novel food is relevant to safety rather than health benefits. Owing to the interest from the industry and scientific community and the dynamic nature of the nutraceutical segment, novel and modification of existing food components could be projected, for example, foods or food ingredients with a new or intentionally modified primary molecular structure, production process not currently used posing a significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value. It is required to establish an independent regulation for novel foods and food ingredients that present a safety concern for the consumer, and regulate foods or food ingredients whose normal consumption would be nutritionally detrimental for the consumer.

The term "health benefits" is not restrictive. It refers to physiological, psychological, and biological benefits as permitted by regulations. Health benefits characterize a relationship between a specific food component or a specific food and a health-related condition, and are supported by scientific evidence. Health benefits are directed to the general population or designated subgroups and are intended to assist the consumer in maintaining healthy dietary practices. Since the scope of this article is to define nutraceuticals using health benefits as one key concept, focus on the presence of health benefits is emphasized, rather on the type of health benefit claims, level of proofs and type of evidence required.

Health claims of foods and nutraceuticals are not permitted to claim the treatment, cure, diagnosis, or mitigation of disease; such statements would be considered as drug claims[53]. Since claims, including health claims are generally regulated; this somehow implies some sort of approval or clearance from a government agency and therefore some level of protection for consumers. The health benefit claims should be governed by appropriate regulations for labeling. Various jurisdictions around the globe have now developed a series of systematic approaches to review scientific data and ascribe links between dietary ingredients and disease risk reduction, as well as performance and well-being, with the common objectives of identifying the threshold of scientific evidence needed to substantiate an authoritative statement to the general public in the form of a label claim for a given marketed product[54].

The phrase "*basic nutritional functions*" refers to the role of nutrients in providing energy for cellular metabolism and repair, organ function, growth, maintenance, and development of the well-being of the human body. Nutraceuticals should offer health benefits beyond what is considered as a basic nutritional function.

The phrase "*to supplement diet"* restricts the representation of nutraceutical for use as a conventional food or as the sole item of a meal or diet. As observed in the term per se, they can only supplement the diet. Nutraceuticals are consumed as a part of a total diet only when required by the physiological condition of individual. The nutraceutical need not be a part of an everyday normal diet or fit a normal consumption pattern in a specific geographic and/or cultural context.

The third sentence – "*presented in a non-food matrix or non-conventional food formats"* – restricts the representation of nutraceuticals in the conventional food form, and imposes the nutraceutical to be in medicinal forms not usually associated with food, such as pills, capsules, etc.

The fourth sentence – "*in such a quantity that exceeds those that could be obtained from normal foods and with such frequency as required to realize such properties"* – specifies the delivery of an adequate quantity of a specific food component or a specific food to realize the health benefits in the regimen supported by scientific evidence. The quantity of a nutraceutical indicated for a health benefit generally exceeds the quantities that could be obtained from a normal diet, and an acceptable variation from the composition of ordinary foods of comparable nature is generally tolerated. The quantity and regimen indicated for specific health benefits should be directed to the general population or designated subgroups and be intentional to assist the consumer in maintaining healthy dietary practices. Nutraceutical ingredient quantities and regimens should restrict quantities specified for a drug or medicinal use.

The last sentence – "*is labeled as a nutraceutical"* – specifies the statement of identity for product that is marketed as a nutraceutical in order to identify the product as such. Labeling with the statement of identity helps to identify the product as a nutraceutical, and clearly distinguishes it from its related and confusing categories like "health supplements", "functional foods", "dietary supplements" and "medical foods". Although there is a statutory distinction between these categories, the actual implementation at the consumer and enforcement level may not be as simple without labeling the statement of identity for a product.

**CONCLUSION**

A clear understanding of nutraceuticals in a regulatory system will reduce the confusion in establishing the policy for nutraceuticals. For an effective regulatory framework, nutraceuticals need to move from a blurred idea with many and sometimes conflicting definitions to a sharply defined and quantifiable concept. However, the regulatory position of nutraceuticals would be different depending on the country's regulatory framework. The examination in this paper is based on the generalized concepts.

In an effort to clarify the definition of nutraceuticals, three general concepts that should be included in a definition have been identified (*nature, form and health benefits)* based on the twenty-five definitions from literature. The frontiers of the nutraceutical universe were defined using the physiological effects, matrix and functional intensity.

The following working definition is suggested after an extensive literature review and analysis: *"A nutraceutical is a food or a part of a food for oral administration with demonstrated safety and health benefits beyond the basic nutritional functions to supplement diet, presented in a non-food matrix or non-conventional food formats, in such a quantity that exceeds those that could be obtained from normal foods and with such frequency as required to realize such properties, and is labeled as a 'nutraceutical'."* Moreover, it can be concluded that a nutraceutical definition need not require naturally occurring component compositions and/or enrichment of ingredients as a condition.

Further work should focus on a detailed scoring system to clarify and refine the frontiers of the nutraceutical universe.

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