



NUTRACEUTICALS: CONCEPT AND REGULATORY SCENARIO

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Received: 25 Dec 2009, Revised and Accepted: 27 Jan 2010

ABSTRACT

Although the term "nutraceutical" is now recognized internationally, there is still no consensus on its definition and meaning. Nutraceutical is recognized as a linguistic combination of "nutrient" and "pharmaceutical", and is accepted as "Any substance that may be considered a food or part of a food and provides medical or health benefits, including the prevention and treatment of disease." Nutraceuticals are a diverse product category with various synonyms that are used internationally. Nutraceuticals create an open environment for new products that promise novel solutions to health-related issues. Nutraceuticals will play important role in future therapeutic developments. The greatest challenge will remain in the public policy and regulatory arenas, which will encourage research and development of products providing health benefits and permit truthful, non-misleading communications of these products while protecting public health and maintaining public confidence. The aim of this article is to discuss the concept and the definition of nutraceuticals in general. This article attempts to provide an initial insight on the recent policy initiatives of Indian regulatory regime. The need, scope and importance of this article are clearly evident due to the emerging regulatory regime and recent surge in growth in the nutraceuticals.

Keywords: Nutraceuticals, Food safety and standards act, 2006

INTRODUCTION

The fact that food and optimal health are closely correlated is not a novel concept. About 2500 years ago, Hippocrates (460–377 BC), the renowned father of modern medicine, conceptualized the relationship between the use of appropriate health foods and their therapeutic benefits and quoted, "Let food be thy medicine, and medicine be thy food"¹.

Understanding of the relationships between foods, physiological function and disease have progressed in recent years, particularly over the past decade. Linkages between diet habits and the quality of life continue to surface on numerous fronts². Modern nutritional science is providing even more information on the functions and mechanisms of specific food components in health promotion and/or disease prevention. Current nutritional approaches are beginning to reflect a fundamental change in our understanding of health. Today, foods are intended to deliver a health benefit beyond providing sustenance and nutrition³. Thus, the concept of 'adequate nutrition' now tends to be replaced by 'optimal nutrition' with consumer belief increasing at an unprecedented pace^{4,5}. Increasing knowledge regarding the impact of diet at the genetic and molecular levels is changing the way we consider the role of nutrition, resulting in new dietary strategies. At the same time, state-of-the-art technologies, including biotechnology, have led to nutritional discoveries, product innovations, and mass production on an unprecedented scale. These developments have spawned an important and dynamic new area of research, resulting in increasing numbers of nutritional products with potential medical and health benefits⁶. Scientific and technologic developments are increasing the possibilities of modifying traditional foods and developing new food sources to meet these newly discovered requirements. Using modern genetics, chemistry and molecular biology, the scientific community is now able to design and manufacture foods having specific characteristics⁶.

In response to the demands from increasingly health conscious consumers, food industries globally are developing products that not only provide superior sensory appeal but also nutritional and health benefits⁷. Scientists and food manufacturers have coined several terms such as, 'functional foods', 'foods for specified health use', 'health promoting foods', 'nutraceuticals', 'health supplements', 'foods for particular nutritional uses', 'medical foods', 'pharma-foods', and so forth, to describe these physiologically active components and the foods that contain them. While none of these have clear and generally accepted definitions, they are commonly used interchangeably⁸. The pharmaceutical companies favor the

terms medical foods, nutraceuticals, and functional foods, whereas the food companies prefer functional foods and nutritional foods. While the food industry's approach is based on a nutritional concept, the pharmaceutical industry's approach is based on a medicine concept¹⁰. These new products represent a major departure from traditional foods, in part because they are based on a new approach to nutrition, i.e., as having the potential to lower the risk of chronic disease. Confusion over the definitions makes it difficult to estimate the exact size of this sector. Estimates range as high as over \$200 billion in sales globally with 10 to 15 percent growth range per annum¹¹.

India is strong and is a growing force in the international health foods market¹². Rapid urbanization, rising incomes, changing lifestyles and dietary patterns, and growing health consciousness have triggered the growth of health and wellness foods in India. The health and wellness foods market is currently estimated to be around US\$ 1.6 billion and is expected to reach US\$ 7.5 to 10 billion by 2015 growing at 25 to 30 percent compound annual growth rate¹³.

What is a Nutraceutical?

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, healthcare providers, regulators and industry¹. Foods and nutrients play a vital role in the normal functioning of the body. They help to maintain the health of the individual and to reduce the risk of various diseases. Worldwide acceptance of this fact formed a recognition link between "nutrition" and "health", and thus the concept of "nutraceuticals" evolved¹⁴. Risk of toxicity or adverse effects of medical drugs led to consider safer nutraceutical and functional food based approaches for health management. This resulted in a world-wide nutraceutical revolution¹⁵. The nutraceutical revolution began in the early 1980s, sparked off when the actual or potential clinical benefits of calcium, fiber, and fish oil were supported by clinical studies published in distinguished medical journals, and when physicians began to educate their colleagues and consumers about these substances via the mass media. The nutraceutical revolution leads into a new era of medicine and health, in which the food industry is expected to become a research-oriented sector similar to the pharmaceutical industry¹⁶. Nutritional genomics is a recent off-shoot of scientific evolution that includes nutrigenomics: the study of interaction of dietary components with the genome and the resulting proteomic and metabolomic changes; and nutrigenetics: understanding the gene-based differences in response to dietary components and

developing nutraceuticals that are most compatible with health based on individual genetic makeup.¹⁷ Nutrigenetics is a nascent area that is developing quickly and riding on the wave of “personalized medicine” providing opportunities in nutraceutical product development¹⁷.

In the past few years, many food bioactive constituents 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 either “food” or “pharmaceutical”, and a new hybrid term between nutrients and pharmaceuticals, ‘nutraceuticals’, has been coined to designate them¹⁸. No official definition exists for the term “nutraceutical”, but is now commonly accepted with enriched foods that are connected with the health and wellbeing of the individual¹⁹. The word is derived from combining elements of the words “nutrient” (a nourishing food or food component) and “pharmaceutical” (a medical drug), and the intended meaning is quite evident, even if these terms encompass very different product categories. Nutraceuticals are considered as pharmaceutical forms (tablets, capsules, powders, etc.) containing bioactive food compounds as active principles¹⁸. The word “nutraceutical” has often been used to describe a broad list of products sold under the premise of being food components, but with the expressed intent of treatment or prevention of disease²⁰. Nutraceuticals have been proven to offer physiologic benefits or to reduce the risk of chronic disease, or both, beyond their basic nutritional functions²¹. Nutraceuticals are being widely adopted as a catchall term to refer to vitamins, minerals, herbs, and various other supplements¹¹.

Nutraceuticals are such a diverse product category with various synonyms that are used internationally. The term “nutraceutical” was coined by 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 disease²². The Food Directorate of Health Canada has proposed the following, “a nutraceutical is a product isolated or purified from food that is generally sold in medicinal forms not usually associated with food. A nutraceutical is demonstrated to have a physiological benefit or provide protection against chronic disease²³. The concept of nutraceuticals is now being started to be acknowledged as a measure to prevent diseases²⁴. Nutraceuticals may range from isolated nutrients, dietary supplements, and diets to genetically engineered “designer” foods, herbal products and processed products like cereals, soups and beverages^{6, 25, 26}. Many of these products possess pertinent physiological functions and valuable biological activities. Bioactive compounds are also referred to as nutraceuticals, a term that reflects their existence in the human diet and their biological activity. Bioactive substances are present as natural constituents in food that provide health benefits beyond the basic nutritional value of the product⁶.

The term ‘nutraceutical’ has been part of the industry lexicon for almost a decade. Unfortunately, it still seems held up in a scrambled web of complementary definitions, regulatory watchdogs and consumer confusion²⁷. “Functional foods,” “nutraceuticals,” “pharmacnutrients,” and “dietary integrators” are all terms used incorrectly and indiscriminately for nutrients or nutrient-enriched foods that can prevent or treat diseases¹⁹. While several terms have been used with similar meanings to the term nutraceutical, one of most frequently used terms is functional food²³. A functional food is, or appears similar to, a conventional food. It is part of a standard diet and is consumed on a regular basis, in normal quantities. It has proven health benefits that reduce the risk of specific chronic diseases or ill states in addition to its basic nutritional function⁹.

The scope of nutraceuticals is significantly different from functional food for several reasons. These include: (i) Prevention and treatment of disease (i.e., medical claims) are relevant to nutraceuticals, but only reduction of disease, not the prevention and treatment of disease, is involved with functional foods. (ii) Nutraceuticals include dietary supplements sold in forms that are

similar to drugs: pills, extracts, tablets, etc as well as other type of foods, functional foods must be in the form of ordinary food^{10, 18}. However, the boundary between nutraceuticals and functional foods is not always clear¹⁸. Since there is no distinct regulatory framework for “functional foods” or “nutraceuticals”, they are both often regulated as foods²⁸.

Nutraceuticals have received considerable interest because of their presumed safety and potential nutritional and therapeutic effects²⁹. A majority of the nutraceuticals claim to possess multiple therapeutic benefits although they lack substantial evidence for the benefits as well as unwanted effects²⁹. With regard to the promise of nutraceuticals, they are generally recognized in two ways — potential nutraceuticals and established nutraceuticals. Established nutraceuticals have sufficient clinical data to demonstrate the promised or labeled benefit. A potential nutraceutical holds a promise of a particular health or medical benefit; a potential nutraceutical becomes an established nutraceutical only after there is sufficient clinical data to demonstrate such a benefit¹⁶.

Since the early 1990s, the world has witnessed the explosive growth of the multi-million dollar nutraceutical industry^{30,31}. Nutraceuticals represents a unique intersection of the pharmaceutical and food industries. There is no “clear line” demarcating food from drugs, but the law mandates such distinctions be made¹. It appears that the nutraceutical industry has found a comfortable middle ground between food and drug industry.³⁰ Food can be distinguished from medicine based on the differences in practical concepts applied in a regulatory system. One of the criteria is intended use, including the timing of targeted effect and the specificity of target population. It would clarify some of the confusion between the concepts of food and drug. Another criterion is the different approaches to safety between food and medicine. Whereas foods are generally presumed safe, considering that they are consumed daily, absolute safety is not applied to medicine. This is evaluated and permitted on the basis of a benefit/risk ratio³². 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 a nutrient that not only maintains, supports, and normalizes any physiologic or metabolic function; it can also potentiate, antagonize, or otherwise modify physiologic or metabolic functions¹⁹. A nutraceutical may be a single natural nutrient in powder or tablet form, not necessarily a complete food, but equally not a drug¹⁹. Many nutraceuticals are being used as alternatives for both nutrition and medicine²⁰.

The pharmaceutical industry is known for the high costs of research and development associated with drug development and the use of patents to protect the discoveries from this research; therefore, the industry is associated with high product margins. The food industry is noted for its low margins and the commoditization of its inputs and in some cases its products. Nutraceuticals fall somewhere in between the two³³. Nutraceuticals are higher priced with greater margins than conventional foods, generating a great incentive for companies to enter this market³³. The ongoing research will lead to a new generation of foods that will certainly cause the interface between food and drugs to become increasingly permeable²⁵. 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 amalgamated pharmaceutical/ agribusiness/ nutrition conglomerates³⁴.

Nutraceutical products represent an excellent growth opportunity but, companies must take appropriate actions to develop, preserve and protect their intellectual property rights in order to stay competitive³⁵. The rational use of nutraceuticals is based on objective evaluation of the clinical evidence as well as subjective evaluation of the risks, benefits, economic costs, and potential drug interactions³⁶. Nutraceuticals, like many substances, may cause problems due to direct toxic effects, or by delay of more appropriate treatment²⁰. Studies on long-term supplementation to evaluate the biological effect of these nutraceutical supplements after regular intake are generally lacking and studies on possible adverse effects, accumulation, and toxicity are urgently required¹⁸. Clinical studies

with both healthy and unhealthy volunteers have shown a large inter-individual variability and lack of consistency in the results. This may be attributed to various factors: (i) differences in the chemical composition of the nutraceutical tested (ii) differences in the pharmaceutical form used (pills, capsules, gels, etc.) which can affect stability and bioavailability of the compounds; and (iii) physiological status of the volunteers¹⁸.

It is clear that the prospects nutraceuticals already stimulated the scientific community into discovering new substances that promise to extend healthy life²⁵. Nutritionists and health professionals are continuing to discover and demonstrate the beneficial role of proper diet and nutrition, nutraceuticals, and health foods in disease prevention and health promotion, which has led to an increase in the number of nutraceutical companies worldwide¹. Public health authorities consider prevention and treatment with nutraceuticals to be a powerful instrument in maintaining health and in acting against nutritionally induced acute and chronic diseases, thereby promoting optimal health, longevity, and quality of life²⁵. Consumer belief in the nutraceutical category has increased significantly in the recent past. The growth in production, distribution, and sales of nutraceuticals in the past decade has been considerable and is an obvious response to burgeoning consumer demand^{31,37}. The nutraceutical industry is a dynamic, evolving industry offering exciting opportunities to merge scientific discovery with growing consumer interest in health-enhancing foods³⁸. Nutraceuticals will maintain their appeal because they are convenient for today's lifestyle³⁴. The greatest challenge will remain in the public policy and regulatory arenas, which will encourage research and development of products providing health benefits and permit truthful, non-misleading communications of these products while protecting public health and maintaining public confidence³⁹. The existing terminology and regulatory framework is inadequate to address the full scope of benefits and opportunities for nutraceuticals.

Nutraceuticals : Global Regulatory Scenario

The approach to regulating and marketing nutraceuticals is notably heterogeneous on the global level. This is largely due to the 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 the functionality⁸. At this juncture, there are no regulations and no regulatory processes that define and explicitly deal with nutraceuticals. There is no indication of if and when specific regulations for nutraceuticals will come into force. This regulatory class shall be dealing with the category containing an extremely wide range of products lacking precise boundaries. An analysis of the legislation underlying nutraceuticals proves to be difficult. Under the current regulatory framework, nutraceuticals appear to have an awkward fit. Although some may appear to consumers as ordinary foods, they are known to produce physiological effects. Others appear to be in a "drug-like" form however, some manufacturers are reluctant to consider them as such²³. Although nutraceuticals comparable to functional foods challenge the regulatory concepts of food and drugs, they seem to be clearly distinguishable in a number of aspects³². For nutraceutical industries, two challenges are apparent: regulatory uncertainty, and credibility of labeling claims. Regulatory uncertainty arises both nationally, given the regulatory quagmire in which the nutraceutical industries have existed recently, and in export markets due to the lack of international agreement on how to define nutraceuticals³⁸.

In most countries these hybrid products are forced under an existing classification of either foods or medicines, and are positioned into a number of existing regulatory categories having their own unique regulatory framework. For example, nutraceuticals in the USA are regulated as dietary supplements, a special category of products classified under the general umbrella of foods; while they are regulated as natural health products classified as a subset of drugs in Canada. The formal recognition of these products and regulatory category across the selected regulatory regime is shown in table 1.

Table 1: Nutraceuticals Statutory Position and Regulatory Category.

Country	Statutory position of nutraceuticals	Regulatory category under which nutraceuticals are regulated
United States.	No legal status or formal definition ⁴⁰ .	"Dietary Supplements" as defined by the Dietary Supplement Health and Education Act of 1994 ³² .
Canada.	No legal status or formal definition ⁴¹ .	"Natural Health Products" as defined by Natural Health Products Regulations of the Food and Drugs Act ⁴² .
European Union.	No legal status or formal definition ^{43,44} .	"Food supplements" as defined in Directive 2002/46/EC ⁴³ .
Japan.	No legal status or formal definition ⁴⁵ .	"Food with Health Claims" (FHC) including "Foods with Nutrient Function Claims" (FNFC) and "Foods for Specified Health Uses" (FOSHU) ⁴⁵ .
CODEX	No Legal Status or formal definition	"Vitamin and Mineral Supplements" ⁴⁶ .

A direct comparison among different jurisdictions is a complex task since different countries have taken very different approaches to developing or applying existing definitions and regulations. Most countries do not formally define these products, and do not regulate these products directly; the regulation of health claims represents an indirect approach for regulating these food products. The control through health claims is widely practiced in the regulatory frameworks of developed countries and is generally accepted as the most appropriate measure⁴⁷.

The absence of proper definitions and regulations confounded issues for the industry and consumers. The existing regulatory frameworks are considered to be inadequate to address the full scope of benefits and opportunities for nutraceuticals or other similar products. The regulatory situation is even more uncertain for firms wishing to export nutraceuticals, with little agreement internationally on the appropriate definition of a nutraceutical, and regulations evolving differently in different markets³⁸.

Nutraceuticals: Indian Regulatory Scenario

Historically, the food sector in India has been governed by multiple laws enacted at different points of time to complement and supplement each other. A variety of laws and regulations that were enacted to address specific food issues, or to assign food-related responsibilities to particular ministries or government units, created

a maze of conflicting or overlapping rules^{48, 49}. Legislations have been in place for decades and do not reflect modern concepts, principles or definitions, nor have they been amended or added to in some parts and not others, creating inconsistencies. The result is that the food sector in India is governed by a number of different statutes rather than a single comprehensive enactment. The multiplicity of ministries and administering authorities at both the central and state level has resulted in a complex regulatory system that is not well integrated, which increases the burden on the food processing industry. In general, this regulatory system resulted in the absence of comprehensive and integrated food law under a single regulatory authority that ensures public health, safety, and also specifies quality norms for meeting the globally recognized standards^{48, 50}. Following pressure from the industry and stakeholders for a single regulatory body and an integrated modern food law, the Food Safety and Standards Act, 2006 (FSSA) was enacted by the Government of India (GOI) after extensive consultation and formal legislative procedures⁵¹. The FSSA has 12 chapters with 101 sections and two schedules. The FSSA incorporates the salient provisions of the Prevention of Food Adulteration Act 1954, and is based on international legislations, instrumentalities, and the Codex Alimentarius Commission⁴⁸.

The FSSA is a major transformation that has happened after decades and promises to bring a paradigm shift in the food regulatory

scenario of the country. The FSSA aims to establish a single reference point for all matters relating to food safety and standards, by moving from multi-level, multi-departmental control to a single line of command. This unified Act, FSSA, will enable unidirectional compliance and address the need for a single regulatory body. The FSSA establishes the Food Safety and Standards Authority of India (FSSAI) as an apex regulatory authority, consisting of a Chairperson and 22 members. In their endeavor to carry out the provisions of the FSSA, the FSSAI shall be assisted by a Central Advisory Committee (CAC), Scientific Panels (SPs), and a Scientific Committee (SC); each with specific responsibilities. On September 5, 2008, the GOI notified the establishment of the FSSAI — consisting of a chairman and members, who in turn will initiate the rule making process⁵². The FSSAI constituted the SC and SPs, and established their administrative procedures⁵³. The FSSAI is expected to lay more emphasis on science based and participatory decisions, while adopting a contemporary approach in both standard setting and implementation. Formulating rules and regulations under the FSSA is a mammoth task and is anticipated to begin shortly. Certain provisions of the FSSA are steadily enforced and are notified by the GOI⁵⁴. The drafts of “Food Safety and Standards Rules and Regulations, 2009” were released by FSSAI in the month of December 2009 for public comments. The implementation of the Act is reportedly in progress, and the FSSAI has notified its intention to the implementation of FSSA in a phased manner starting from January, 2010⁵⁵.

Owing to the lack of a well defined regulatory framework, nutraceuticals in India are not conceptualized in terms of segments, regulations, manufacturing, marketing, and exports and imports. For the first time in the Indian regulatory system, the FSSA has formally created a special third category—“Foods for Special Dietary Uses/Functional Foods/Nutraceuticals/Health Supplements” besides 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, but which shall have specific regulatory requirements under the forthcoming regulations. The previous food laws of India do not formally recognize or define nutraceuticals, or other similar products. Currently, the Nutraceutical sector is predominantly governed by the Prevention of Food Adulteration Act, 1954 and its amendments particularly GSR No. 664(E) that permits certain nutritional and health claims,⁵⁶ and certain provisions of the Drugs and Cosmetics Act⁵⁷. The FSSA is a fundamental food law that consolidates the existing food-related laws and establish the FSSAI that lays science based standards for articles of food and regulates their manufacture, storage, distribution, sale and import, to ensure the availability of safe and wholesome food for human consumption and for matters connected therewith or incidental thereto. The scope of this fundamental food law is wide ranging and is applicable to all foods depending on the nature of the food. The FSSA regulates nutraceuticals as a special category of products classified under the general umbrella of foods, and nutraceuticals come under its wide policy scope.

At this point in time, the FSSA does not differentiate nor does it have specific definitions for functional food, food for special dietary uses, nutraceuticals, and health supplements. Instead it bridges all of them with a common definition. Section 22(1) of FSSA, defines “foods for special dietary uses or functional foods or nutraceuticals or health supplements” as:

- a) *foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition or specific diseases and disorders and which are presented as such, wherein the composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist, and may contain one or more of the following ingredients, namely:-*
 - i. *Plants or botanicals or their parts in the form of powder, concentrate or extract in water, ethyl alcohol or hydro alcoholic extract, single or in combination;*
 - ii. *Minerals or vitamins or proteins or metals or their compounds or amino acids (in amounts not exceeding the Recommended Daily Allowance for Indians) or enzymes (within permissible limits);*

- iii. *Substances from animal origin;*
- iv. *A dietary substance for use by human beings to supplement the diet by increasing the total dietary intake;*
 - b)
 - (i) *a product that is labeled as a “Food for special dietary uses or functional foods or nutraceuticals or health supplements or similar such foods” which is not represented for use as a conventional food and whereby such products may be formulated in the form of powders, granules, tablets, capsules, liquids, jelly and other dosage forms but not parenterals, and are meant for oral administration;*
 - (ii) *such product does not include a drug as defined in clause (b) and Ayurvedic, Sidha and Unani drugs as defined in clauses (a) and (h) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) and rules made thereunder;*
 - (iii) *does not claim to cure or mitigate any specific disease, disorder or condition (except for certain health benefit or such promotion claims) as may be permitted by the regulations made under FSSA;*
 - (iv) *does not include a narcotic drug or a psychotropic substance as defined in the Schedule of the Narcotic Drugs and Psychotropic Substances Act, 1985 and rules made there under and substances listed in Schedules E and EI of the Drugs and Cosmetics Rules, 1945;*

While the FSSA has taken the first step in recognizing functional foods and nutraceuticals and classifying them under foods, the rules and regulations are to be framed yet. The Scientific Panel for functional foods, nutraceuticals, dietetic products and other similar products of the FSSAI shall be responsible for drafting the rules and regulations under the provisions of the FSSA⁵³. This Scientific Panel of the FSSAI had its first meeting on September 03, 2009, and the formulation of rules and regulations is anticipated to begin shortly⁵⁸.

In order to introduce the category of nutraceuticals into the present regulatory system, it is necessary to review the relationships between nutraceuticals and other existing legal or commercial terms, with internationally accepted definitions. Nutraceuticals are also regarded as functional foods, health foods, and novel foods in certain cases. These complex relationships can be one of the reasons why nutraceuticals should be controlled on the basis of horizontal approaches such as health claims¹⁰. A clear understanding of nutraceuticals in the present regulatory system will reduce the confusion in establishing the policy for nutraceuticals.

Although nutraceuticals have significant promise in the promotion of human health and disease prevention, health professionals, nutritionists and regulatory toxicologists should strategically work together to plan appropriate regulations to provide the ultimate health and therapeutic benefits to mankind¹. Since the market for nutraceuticals is booming, many products are available that have not been tested for either safety or efficacy^{20, 55}. Formulating a regulatory regime that comprehensively addresses the pre-market regulation of product safety and post-market regulation of product labeling needs to be emphasized during policy framing. However, ensuring the efficacy and safety of nutraceuticals will largely depend on how these products are defined and classified. Different classifications for nutraceutical products (e.g., foods and drugs) have different standards for safety and pre-market approval.

Nutraceuticals that may be used individually, in combination, or even added to food or beverage for a particular technologic purpose or health benefit, must have an adequate safety profile demonstrating the safety for consumption by humans¹⁵. Proof of efficacy and safety are two key sets of information that underlie the successful use of nutraceuticals for the management of human health and well-being¹⁵. In an attempt to establish product safety and efficacy, extensive safety studies, including acute, sub-acute, sub-chronic, chronic and long-term toxicity studies, genotoxicity, reproductive toxicology, teratogenicity, molecular mechanisms of action (both in vitro and in vivo), as well as supplementation studies in animals and clinical trials in humans could be necessary¹. All nutraceutical claims must be based on sound science. Safety, quality, and cost-effectiveness must remain paramount¹⁹. The straightforward application of pharmaceutical standards, especially across national borders, is likely to be a difficult challenge and could effectively paralyze the industry⁵⁹. Imposing pharmaceutical levels of control and regulation would increase costs and reduce patient

access to new products, but the evidence is compelling that closer monitoring of raw materials, production controls and formulation will be required to maximize the benefits and minimize the risks⁶⁰. A place for nutraceuticals in clinical practice is emerging, but important pharmaceutical and clinical issues need to be addressed by further research⁵⁹. More comprehensive product information and more accurate product labeling is important but better nutrition education of health professionals, the media, and the general population is the key to long-term success. Consumers will need protection from fraudulent claims or inferior quality products without unnecessarily stifling innovation and instituting long, drawn-out marketing approval procedures. Consumers need to be better informed with accurate definitions, and better product information¹⁹.

The policymakers should establish and maintain a stable, transparent and effective regulatory environment governing labeling claims, product safety, and the protection of intellectual property rights so that the nutraceutical sector can continue to grow³⁸. Involvement of industry and other stakeholders at the earliest stages of rule framing, and transparent public consultation, directly or through representative bodies, during the preparation, evaluation, and revision is essential for setting of sound scientific standards and alignment with international standards. The policymakers should identify the broad range of legislative instruments and legislative provisions that may have an impact on nutraceuticals within the broad scope of FSSA. The emerging regulations must ensure that nutraceuticals are regulated in a manner that maximizes health benefits and minimizes health risk for consumers and that claims that are made by the firms producing and selling them are genuine.

CONCLUSION

It was the advances in understanding the relationship between nutrition and health, often at the molecular level, that led to the concept of 'nutraceuticals' as a practical and new approach to achieve optimal health and possibly reduce the risk of disease. Nutraceuticals constitute a rapidly growing focus for research, product development and consumer interest as well as regulatory efforts in recent years. Nutraceuticals represents a unique intersection of the pharmaceutical and food industries with a wide scope.

Nutraceuticals are a diverse product category with various synonyms that are used internationally. Although the term "nutraceutical" or "nutraceuticals" is now recognized internationally, the truth is that there is still no consensus on its meaning. Unfortunately, it still seems held up in a tangled web of complementary definitions and consumer confusion. The approach to regulating and marketing of nutraceuticals is notably heterogeneous on the global level. This is largely due to the 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 the functionality.

For the first time in the Indian regulatory system, the Food Safety and Standards Act, 2006 has formally recognized nutraceuticals. The FSSA is a major transformation that has happened after decades and promises to bring a paradigm shift in the regulatory scenario of the country. The FSSA regulates nutraceuticals as a special category of products classified under the general umbrella of foods, and nutraceuticals fall under its wide policy scope. While the FSSA has taken the first step in recognizing functional foods and nutraceuticals and classifying them under foods, the rules and regulations are to be framed yet. Formulating rules and regulations is a mammoth task and is anticipated to begin shortly.

Nutraceuticals are destined to play an important role in future therapeutic developments and their success will be governed by control of purity, safety and efficacy without inhibiting innovation.

The story of nutraceuticals is the convergence of the following four powerful factors, when adopted together these factors create an

attractive and emerging environment for nutraceuticals which promise novel solutions for health-related issues:

1. Advances in understanding the relationship between nutrition and health, often at the molecular level, that led to a practical and new approach to achieve optimal health and possibly reduce the risk of disease
2. Growing health consciousness and significant increase in consumers belief in the nutraceutical category
3. Emerging regulatory regime creating opportunities for new health-based products
4. An expanding interest of pharmaceutical and food companies looking for new growth opportunities

The greatest challenge for the nutraceutical sector remains in the public policy and regulatory arenas, which will encourage research and development of products providing health benefits and permit truthful, non-misleading communications of these products while protecting public health and maintaining public confidence. The existing terminology and regulatory framework are inadequate to address the full scope of benefits and opportunities for nutraceuticals. It demands that the policymakers establish and maintain a stable, transparent and effective regulatory environment governing labeling claims, product safety and the protection of intellectual property rights so that the nutraceutical sector can continue to grow. A place for nutraceuticals in clinical practice is emerging, but important pharmaceutical and clinical issues need to be addressed by further research.

The views expressed in this article are those of the authors and do not reflect the official policy or position of the government or any other agency. Owing to the emerging regulatory situation and given the voluminous nature of the specific details, the reader is directed to the pertinent GOI and FSSAI publications for the current regulatory scenario. The authors and journal will not be responsible for the accuracy or legality of any statement made during this constantly changing regulatory environment

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