



ISSN (E): 2277- 7695

ISSN (P): 2349-8242

NAAS Rating: 5.03

TPI 2018; 7(8): 448-451

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www.thepharmajournal.com

Received: 07-06-2018

Accepted: 09-07-2018

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## **Nutraceuticals: Meaning and regulatory scenario**

**Amit Kumar Singh, AK Chaturvedani, NP Singh and Amit Baranawal**

#### **Abstract**

Nutraceutical is a term coined to describe substances which are not traditionally recognized nutrients but which have positive physiological effects on the human body. They do not easily fall into the legal category of food and drug and often inhabit a grey area between the two. Risk of toxicity or adverse effect of drugs led us to consider safer nutraceutical and functional food based approaches for the health management. This resulted in a worldwide nutraceutical revolution. The nutraceutical revolution will lead us into a new era of medicine and health. Nutraceutical, a portmanteau of the words “nutrition” and “pharmaceutical”, is a food or food product that reportedly provides health and medical benefits, including the prevention and treatment of disease. A product isolated or purified from foods 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 disease. 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.

**Keywords:** Nutraceutical, dietary supplement, medical foods

#### **Introduction**

The fact that food and optimal health are closely correlated is not a novel concept. About 2500 years ago, Hippocrates, 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”. 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 fronts. 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 nutrition. Thus, the concept of ‘adequate nutrition’ now tends to be replaced by ‘optimal nutrition’ with consumer belief increasing at an unprecedented pace. 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 benefits.

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 characteristics. 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 benefits. 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 interchangeably. 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 concept. 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 annum. India is strong and is a growing force in the international health foods market. 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 rate.

### **Nutraceutical**

The term nutraceutical was originally defined by Dr. Stephen L. Defelice, founder and chairman of the Foundation of Innovation Medicine (FIM), Crawford, New Jersey. Since the term was coined by Dr. Defelice, its meaning has been modified by Health Canada which defines nutraceutical as: a product isolated or purified from foods, and generally sold in medicinal forms not usually associated with food and demonstrated to have a physiological benefit or provide protection against chronic disease. Examples are beta-carotene and lycopene. Dr Stephen Defelice coined the term "Nutraceutical" from "Nutrition" and "Pharmaceutical" in 1989.

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."

### **Classification of Nutraceuticals**

Nutraceuticals is a broad umbrella term used to describe any product derived from food sources that provides extra health benefits in addition to the basic nutritional value found in foods. Products typically claim to There is minimal regulation over which products are allowed to display the nutraceutical term on their labels. Because of this, the term is often used to market products with varying uses and effectiveness. The definition of nutraceuticals and related products often depend on the source. Members of the medical community desire that the nutraceutical term be more clearly established in order to distinguish between the wide varieties of products out there. There are multiple different types of products that may fall under the category of nutraceuticals.

### **Dietary supplements**

Dietary supplements, such as the vitamin B supplement show above, are typically sold in pill form. A dietary supplement is a product that contains nutrients derived from food products that are concentrated in liquid or capsule form. The Dietary Supplement Health and Education Act (DSHEA) of 1994 defined generally what constitutes a dietary supplement. "A

dietary supplement is a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. The "dietary ingredients" in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites. Dietary supplements can also be extracts or concentrates, and may be found in many forms such as tablets, capsules, softgels, gencaps, liquids, or powders. "Dietary supplements do not have to be approved by the U.S. Food and Drug Administration (FDA) before marketing. Although supplements claim to provide health benefits, products usually include a label that says: "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

### **Functional foods**

Functional foods are designed to allow consumers to eat enriched foods close to their natural state, rather than by taking dietary supplements manufactured in liquid or capsule form. Functional foods have been either enriched or fortified, a process called nutrification. This practice restores the nutrient content in a food back to similar levels from before the food was processed. Sometimes, additional complementary nutrients are added, such as vitamin D to milk. Health Canada defines functional foods as "ordinary food that has components or ingredients added to give it a specific medical or physiological benefit, other than a purely nutritional effect." In Japan, all functional foods must meet three established requirements: foods should be

- (1) Present in their naturally-occurring form, rather than a capsule, tablet, or powder
- (2) Consumed in the diet as often as daily; and
- (3) Should regulate a biological process in hopes of preventing or controlling disease.

### **Medical foods**

Medical foods aren't available as an over-the counter product to consumers. The FDA considers medical foods to be "formulated to be consumed or administered internally under the supervision of a physician, and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, on the basis of recognized scientific principles, are established by medical evaluation." Nutraceuticals and supplements do not meet these requirements and are not classified as Medical Foods. Medical foods can be ingested through the mouth or through tube feeding. Medical foods are always designed to meet certain nutritional requirements for people diagnosed with specific illnesses. Medical foods are regulated by the FDA and will be prescribed/monitored by medical supervision.

### **Farmaceuticals**

According to a report written for the United States Congress entitled "Agriculture: A Glossary of Terms, Programs, and Laws", "(Farmaceuticals) is a melding of the words farm and pharmaceuticals. It refers to medically valuable compounds produced from modified agricultural crops or animals (usually through biotechnology). Proponents believe that using crops and possibly even animals as pharmaceutical factories could be much more cost effective than conventional methods.

**Examples:** Broccoli may help in the prevention of cancer. The following is an incomplete list of foods with reported medicinal value:

- Antioxidants: resveratrol from red grape products; flavonoids inside citrus, tea, wine, and dark chocolate foods; anthocyanins found in berries, Vitamin C.
- Reducing hypercholesterolemia <sup>[16]</sup>. soluble dietary fiber products, such as psyllium seed husk.
- Cancer prevention: broccoli (sulforaphane) fiddleheads (Matteuccia Struthiopteus).
- Improved arterial health: soy or clover (isoflavonoids).
- Lowered risk of cardiovascular disease: alpha-linolenic acid from flax or chia seeds, Omega 3 fatty acids in fish oil.

In addition, many botanical and herbal extracts such as ginseng, garlic oil, etc. have been developed as nutraceuticals. Nutraceuticals are often used in nutrient premixes or nutrient systems in the food and pharmaceutical industries.

### Benefits of nutraceuticals

From the consumers' point of view, functional foods and nutraceuticals may offer many benefits:

- May increase the health value of our diet.
- May help us live longer.
- May help us to avoid particular medical conditions.
- May have a psychological benefit from doing something for oneself.
- May be perceived to be more "natural" than traditional medicine and less likely to produce unpleasant side-effects.
- May present food for populations with special needs (e.g. nutrient-dense foods for the elderly).

### Regulatory Perspective of Nutraceuticals in India

Regulatory guidelines since nutraceuticals are not a part of pharma and drugs formulation, rules and regulations also tend to be different for this segment. Indian government has recently implemented the new law FSSAI (Food Safety and Standards Authority of India). As a result, there is some confusion in the minds of new entrants about the do's and don't's of the Indian regulatory system.

The Food Safety and Standards Act, 2006 consolidates eight laws governing the food sector and establishes the Food Safety and Standards Authority of India (FSSAI) and its other allied committees to regulate the sector. The FSSAI comprises a chairperson and 22 members. The chairperson is either an eminent food scientist or a civil servant not below the rank of secretary. Seven of the members would be ex-officio, not below the post of joint secretary, from various ministries. Five members would be appointed by rotation every three years from the States and Union Territories. The authority would have two representatives each from the food industry and consumer organizations, three food technologists and two members from a farmers' organisation and one from retail organisation. FSSAI will be aided by several scientific panels and a Central Advisory Committee to lay down standards for food safety. These standards will include specifications for ingredients, contaminants, pesticide, biological hazards, labels and others. Everyone in the food sector is required to get a license or a registration that would be issued by the local authorities. Temporary stall holders are exempted from the license but need to get their businesses registered with the local municipality or panchayat. The law will be enforced through state commissioners of food safety and local level officials. The Act empowers the FSSAI and state food safety authorities to monitor and regulate the food business operators. The commissioner of food safety of each

state appoints a designated officer (DO), not below the level of sub-divisional officer, for a specific district. His duties include issuing or cancelling licenses, prohibiting sale of food articles that violate specified standards, receiving report and samples of food articles from food safety officers and getting them analysed. The state commissioner, on the recommendation of the designated officer, decides whether a case of violation would be referred to a court of ordinary jurisdiction or to a Special Court. The Act provides for a graded penalty structure where the punishment depends on the severity of the violation.

Offences such as manufacturing, selling, storing or importing sub-standard or misbranded food could incur a fine. Offences such as manufacturing, distributing, selling or importing unsafe food, which result in injury, could incur a prison sentence. The sentence could extend to life imprisonment in case the violation causes death. Petty manufacturers who make their own food, hawkers, and vendors or temporary stall holders could be fined up to Rs 25000 if they violate the specified standards.

### Current scenario

The Food Safety and Standard Rules, 2011 have been issued, effective from 5th May, 2011. The Food Safety and Standard Authority have also issued regulations about licensing and registration of food business, packing and labeling, food products standard and additive etc. These acts, rules and regulations have been implemented from 5th August, 2011. Thus, now there is one single legislation and specified authorities to regulate manufacture, sale and distribution of nutraceuticals, functional food and dietary supplement in India. However, due to lack of clarity of specific regulations for registration of nutraceuticals and permitted additives, entrepreneurs intending to launch nutraceuticals in India are still facing the following challenges.

1. Drugs defined under Section 3(b)(i) of the Drugs and Cosmetics Act, 1940 and also ayurvedic, siddha and Unani drugs are specifically excluded from the scope of the definition of nutraceutical, health supplement etc. under Section 22 of the Act. The definition of drug under Drugs Act is very exhaustive. Taking recourse to the definition of drug, regulatory officers are categorizing nutraceuticals, especially manufactured and marketed in tablet, capsule or liquid oral dosages form containing vitamin and minerals as drugs on the basis of even structure function claims.
2. The regulatory officers also take a view that as empty gelatin capsule itself is covered by the definition of drug, any product marketed in capsule form will also be considered as drug.
3. Some commonly used colours and additives such as binding agents, granulating agents used in formulating tablets do not find place in the list of permitted food additives under the regulations.
4. Though the structure function claims are permitted, there is no clarity as to the permitted structure function claims for nutraceuticals and dietary supplements.

To overcome these difficulties, it would be necessary to amend Schedule K of the Drugs and Cosmetics Rules, 1945 to provide for specific exemption to nutraceuticals, dietary supplements, health supplements from the scope of Drugs and Cosmetics Act, 1940 and Rules, 1945. It is also necessary to have specific regulations for product approval, approval of claims, permitted additives, quantity of vitamins and minerals

etc. for nutraceuticals as it is necessary to treat this segment as an independent and unique entity under the Food Safety Standard Act, 2006.

### Regulatory requirements for India entry

As nutraceutical regulations are evolving in India, it is a possibility that some of the content is conflicting / confusing. Yet, for the Indian industry to take shape, these have to be streamlined. In order to enter the Indian nutraceutical market, some of the very important areas of focus include product evaluation, actual product analysis, procuring licenses and developing India specific health and label claims.

**1. Product evaluation:** In Indian conditions, the classification of formulations is very complex. Hence, due diligence in terms of carving a specific amount for each ingredient and the combination of ingredients becomes very crucial. In order to assess a product as per the Indian regulations, it is very important to examine each active ingredient and additive in the context of permissibility, standards and dosage of vitamins/minerals allowed as per the therapeutic, prophylactic or recommended daily allowance for Indians. Manufacturers are also unclear whether their products will be classified as food or food supplement or drug in the context of the Prevention of Food Adulteration Act, 1954 and Rules, 1955, Food Safety and Standards Act, 2006 and Drugs and Cosmetics Act, 1940 and Rules, 1945. The Food Safety and Standards Rules, 2011 highlights the regulatory enforcement structure and procedures which the Central Government proposes to create. The structure has a hierarchy beginning from the commissioner of food Safety to a number of officers like designated officer, food safety officer, food analyst, etc. who will be involved in the product analysis process at different points.

### Various steps in the product analysis include

- Developing extracts of documents and authenticating the same by the concerned authority.
- Sample collection (in the presence of witnesses)
- Sample dispatch to the concerned authority (different processes for bulk package and single package) • Food analysis
- If analysis is not complete within the stipulated period of time, further action plan by the designated officer
- Adjudication proceedings (holding enquiry, appeal procedure, hearing, etc.)

**2. Licenses:** Though the new FSSA promises to simplify the licensing and registration processes for nutraceuticals, the actual process varies as per the number of parameters. To get a product registered in India, number of licenses (almost 4 - 5) might be required, depending on the actual product status like Number of documents will have to be furnished by the food importer to the government authority along with registration application dossiers Interlink, through its regulatory product portfolio, and provides regulatory support related to these licensing procedures for

- Import licensing
- Manufacturing licensing
- Marketing licensing and
- Other state and national level clearances/licenses required from the regulatory side, which need to be taken care of before launching these products in India.

**3. Health and label claims:** Developing health and label claims, specific to Indian regulatory guidelines, is a major element to be considered while entering the Indian market. International as well as national clients have number of questions about

- India specific labeling and packaging requirements
- Packaging of the consignment composition of the consignment and approach to market the same.
- Need for sample material and declaration for registration
- Label content and claim
- Structure - function claim

Based on the regulatory assessment of the product, India-specific label content and claims needs to be developed. New entrant should also consider the requirements to be met, to make specific product claims.

### References

1. Bhowmik D, Gopinath H, Kumar B, Duraivel S, Kumar S. Nutraceutical–A Bright Scope and Opportunity of Indian Healthcare Market. *The Pharma Inn J.* 2013; 1(11):29-41.
2. Gupta SK, Yadav SK, Patil SMM. Nutraceutical–A Bright Scope and Opportunity of Indian Healthcare Market. *Int. J. Res. Dev. Pharm. L. Sci.* 2013; 2(4):478-481.
3. Palthur MP, Palthur SS, Chitta SK. Nutraceuticals: Concept and Regulatory Scenario. *Int. j. Pharma. and Pharmaceutical. Sci.* 2010; 2(2):14-20.
4. Pandey M, Verma R, Saraf S. Nutraceuticals: new era of medicine and health. *Asian. J of Pharma. and Clin. Res.* 2010; 3(1):11-15.
5. Radhika PR, Singh RBM, Shivakumar T. Nutraceuticals: An area of tremendous scope. *IJRAP.* 2011; 2(2):410-415.