

## **REDEFINING NUTRACEUTICALS**

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### **Introduction**

Today, healthcare market is flooded with different new terminologies like Nutraceuticals, Cosmeceuticals, Biopharmaceuticals, Herbaceuticals, Ayurvedicals, Skinceuticals, Dermaceuticals, Nutri-cosmetics and many more. Among all these new terminologies, nutraceuticals has gained more importance for the industry in India and abroad. Nowadays, nutraceuticals is a buzzword in global healthcare market. There is a growing craze for using nutraceutical products to improve quality of life.

### **Interpretation of definitions**

The concept of nutraceuticals was defined and explained by different scholars and government regulatory bodies of different countries. Though the definitions slightly differs, but essence of all definitions remain same i.e. 'food as medicine'

The commonly adopted definition of a nutraceutical by food marketing industry is, "any food or food ingredient which is considered to have a beneficial effect on health". Such description of nutraceutical is broadly used and can refer to anything from a vitamin supplement pill, to an energy enhancing drink, and more recently to foods which are claimed to have physiological effects.

Term Nutraceutical is coined by Dr. Stephen DeFelice in 1989; he fused two words Nutrition and Pharmaceutical to design the term. He has defined nutraceuticals as, "Food, or parts of food, that provide medical or health benefits, including the prevention and treatment of disease is called as Nutraceuticals"<sup>1</sup> According to this

definition food parts such as garlic, soybean are considered as Nutraceuticals. This definition does not specify that crude or processed food (part of food) would be used as nutraceuticals. As per this definition whatever food we take in any form (crude or processed) would be considered as nutraceuticals. 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. Also this definition does not differentiate between nutraceuticals, functional food, and dietary supplement.

Health Canada has adopted different definition saying “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”<sup>9</sup> Unlike other definitions this definition has clearly specified that nutraceuticals are the isolated or purified products of food. This definition does not include the word ‘treatment’ of disease; it reflects that the concept of

nutraceuticals is confined to ‘health benefits’ and ‘prevention of disease’. As per this definition, if we are using isolated active ingredient of garlic in medicinal form for health benefits then it is categorised as Nutraceuticals. Alike previous definition, this definition also does not differentiate between functional food, dietary supplement, and designer food.

Another widely adopted definition of nutraceuticals is that of Zeisel (1999) who described them as “Diet supplements that deliver a concentrated form of a presumed bioactive agent from a food, presented in a nonfood matrix, and used to enhance health in dosages that exceed those that could be obtained from normal foods.”

Though different scholars have attempted to frame different definitions of Nutraceuticals, essence of all remains same. Several attempts have been made to define Functional food, Designer food, and Dietary supplements but ambiguity exist in interpreting clear differences between Nutraceuticals and these terminologies.

### **Nutraceuticals, Dietary supplement, Functional food**

Nutraceuticals are also been called medical foods, designer foods, phytochemicals, functional foods and nutritional supplements. Many different terms and definitions are used in different countries, which can result in confusion. Nutraceuticals can refer to foods, dietary supplements, medical foods, and functional foods that may provide prevention and treatment of illness or disease. Some of the researchers have classified dietary supplement, and functional food under the term 'Nutraceuticals'. Whereas some researchers are of opinion that nutraceuticals, functional food, and dietary supplements are different terminologies. These terminologies are further discussed as-

### **Dietary Supplements including botanicals**

- Vitamins, minerals, coenzyme Q, carnitine
- Gingsing, Gingko Biloba, Saint John's Wort, Saw Palmetto

### **Functional Foods**

- Oats, bran, psyllium and lignin's for heart disease and colon cancer
- Prebiotics - oligofructose for control of intestinal flora
- Omega-3 milk in prevention of heart disease
- Canola oil with lowered triglycerides for cholesterol reduction
- Stanols (Benecol) in reduction of cholesterol adsorption

### **Medicinal Foods**

- Transgenic cows and lactoferrin for immune enhancement
- Transgenic plants for oral vaccination against infectious diseases
- Health bars with added medications

The term "Functional Foods" was first introduced in Japan in the mid 1980s. It

refers to processed foods containing ingredients that aid specific body functions, in addition to being nutritious<sup>14</sup>. The term nutraceuticals and functional food has no legal significance in the United States. In the United States this industry falls under dietary supplement. The DSHEA formally defined "dietary supplement" using several criteria. A dietary supplement<sup>2,10</sup>-

- is a product (other than tobacco) that is intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients.
- is intended for ingestion in pill, capsule, tablet, or liquid form.
- is not represented for use as a conventional food or as the sole item of a meal or diet.
- is labeled as a "dietary supplement."

- includes products such as an approved new drug, certified antibiotic, or licensed biologic that was marketed as a dietary supplement or food before approval, certification, or license (unless the Secretary of Health and Human Services waives this provision).

In Korea, functional foods are defined as dietary supplement whose purpose is to supplement the normal diet and have to be marketed in measured doses, such as in pill, tablets<sup>14</sup>. Health Canada has defined functional food as "A functional food is similar in appearance to, or may be, a conventional food that is consumed as part of a usual diet, and is demonstrated to have physiological benefits and/or reduce the risk of chronic disease beyond basic nutritional functions, i.e. they contain bioactive compound". Presently, there is no universally accepted term for functional foods<sup>14</sup>.

Health Canada has defined 'Novel Food' as "Products that have never been used as food; foods that result from a process that has not previously been used for food; or, foods that have been modified

by genetic manipulation. This category of foods are also referred as genetically modified foods”.

In the opinion of Ekta K. Kalra, nutraceuticals differ from dietary supplements in the following aspects:

- Nutraceuticals must not only supplement the diet but should also aid in the prevention and/or treatment of disease and/or disorder.
- Nutraceuticals are represented for use as a conventional food or as the sole item of meal or diet.

### **Nutraceuticals and Drugs**

Dictionary definition of drug says “Drug is any substance that, when absorbed into the body of a living organism, alters normal bodily function<sup>12</sup>”. Drug can also be defined as, “A substance used in the diagnosis, treatment, or prevention of a disease or as a component of a medication<sup>13</sup>”.

As per the definition of nutraceuticals given by Dr. Stephen DeFelice, nutraceuticals are food or part of food which is used for health benefits including the prevention and treatment

of disease. As per the definition of nutraceuticals given by Health Canada nutraceuticals are “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”

Comparative analysis of above definitions suggest that nutraceuticals are not drugs but their effect is like drug. As per above discussed definitions nutraceuticals cannot be used in the treatment of the disease but it can be used to prevent the disease and for other health benefits. Therefore nutraceuticals are ‘Quasi Drugs’ i.e. ‘Like Drugs’.

### **Need of harmonized definition**

Today there is a craze for being healthy and maintaining health (baby-boomers), increasing awareness about preventive medicines under the concept of “prevention is better than cure”, heavy cost of allopathic treatment and attractive promises of nutraceuticals, greater acceptance by healthcare community and general perception of

“natural is always good and safe” are a few factors responsible for rapid emergence of the Nutraceutical concept. Therefore nutraceutical products are becoming more popular in healthcare market around the globe. As demand is increasing for nutraceutical products, many pharmaceutical companies started launching the nutraceutical products in the market. As a result, market is flooded with several nutraceutical products. Present regulations for Pharmaceuticals are not applicable for the manufacturing and sale of the nutraceuticals. This has triggered manufacturing activities of nutraceuticals by many companies without considering the regulatory aspects.

As the term Nutraceuticals is not recognised and defined officially by many countries, it remains as a market term. Health Canada has adopted the term and framed certain regulatory guidelines. India Government and US FDA have not yet recognised the term. Absence of regulatory guidelines for nutraceuticals in a country like India results in heavy mushrooming of nutraceutical manufacturers and market

may be flooded with several products with lofty claims without sufficient scientific evidences. In order to survive in competition and to reduce the price, manufacturers may compromise with quality of product, which may lead to disaster of health of society.

Analysis of all these factors suggests that there is a need of harmonized definition of nutraceuticals which would be adopted globally. Such definition should clearly differentiate between the term nutraceuticals, dietary supplement and functional food.

### **Proposed definition**

Still there is an ambiguity in distinguishing dietary supplements, nutrient supplements and drugs from nutraceuticals. We have attempted to frame a comprehensive definition of nutraceuticals.

“Any natural product in its crude or processed form if taken for expected health benefits based on nutrient supplement and its physiological action can be explained scientifically in animals and human being is referred as nutraceutical product”

### **Explanation of terms used in the definition-**

**Natural product:** Product from natural sources including plant, mineral and animal sources

**Expected health benefits:** For expected betterment of health including treatment, cure, mitigation or prevention of disease

**Scientifically explained physiological action:** Scientifically explained mechanism of action of the product which supports the claims of beneficial effects in animals or human being

### **Conclusion**

Though Nutraceuticals is considered as a bright landscape in healthcare market, it is in nascent stage. Many scholars around the world have proposed different definitions but no definition is considered as harmonised definition. This lack of harmonised definition is a major challenge. Absence of regulatory guidelines and lack of general awareness are also considered as challenges in development of the concept of Nutraceuticals. The proposed definition of nutraceutical would help in

differentiating the concept of drug, functional food, dietary supplement and novel food. There is a need of accepting one harmonised definition and framing proper regulatory guidelines to control the excessive mushrooming of nutraceutical manufacturers.

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