

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

SJIF Impact Factor 4.897 Review Article

> ISSN 2394-3211 **EJPMR**

NUTRACEUTICALS: TODAY'S NEED FOR HEALTH CARE

Hitesh Kumar* and Ashok Kumar Rajpoot

Moradabad Educational Trust Group of Institutions Faculty of Pharmacy Ram Ganga Vihar Phase-2, Moradabad, Uttar Pradesh, India-244001.

*Corresponding Author: Hitesh Kumar

Moradabad Educational Trust Group of Institutions Faculty of Pharmacy Ram Ganga Vihar Phase-2, Moradabad, Uttar Pradesh, India-244001.

Article Received on 07/02/2018

Article Revised on 26/02/2018

Article Accepted on 18/03/2018

ABSTRACT

A nutraceutical is a food or a part of a food substance that provides medical or health benefits, including the prevention and treatment of diseases. Now a days people are deeply concerned about their health due to life style diseases like diabetes, hypertension, obesity etc. are very common. Besides that hectic working schedule, stressed conditions at work place, competitive environment among students, unhealthy food habits, disturbed biological clock of sleeping due to night shift in many Industries and lack of physical exercise leading society in a diseased state in very early age. Medicines are universally known for their severe side effects and nobody can ignore this. So in current environment nutraceutical can play a key role in the maintenance of health and in treatment of diseases without any side effects. In present scenario, by looking forward in Indian market, pharmaceutical companies have introduced a lot of health supplement and nutraceuticals. Due to lack of strict nutraceutical regulations, it is a challenge for the consumers to identify the suitable nutraceutical for their health and to get assurance of their safe use. Therefore, in this review, we have focused on detailed introduction of nutraceuticals, their sources and effects along with their rational use.

KEYWORDS: Nutraceuticals, Phytonutraceuticals, Functional food, Rational.

INTRODUCTION

The term 'nutraceuticals' was coined by combining the terms 'nutrition' and 'pharmaceutical' by Stephen Defelice MD, founder and chairman for innovation in Medicine, New Jersey, in 1989. According to him, 'nutraceuticals are food or part of a food that provides health benefits and are used for prevention or treatment of a disease'. [1] Hippocrates (460-377 BC), known as the father of modern medicine stated, 'Let food be thy medicine and medicine be thy food' to establish the relationship between appropriate foods for health and therapeutic benefits. [2] In human health, nutraceuticals play a major role in treating various diseases like obesity, cardiovascular diseases, cancer, osteoporosis, arthritis, diabetes, cholesterol etc. They help in maintaining our normal physiological functions. [3]

Categories of Nutraceuticals [4,5]

- **1. Nutrient**: A feed constituent should be available in the form and given at a level that will help support the life of an animal. Some of the feed nutrients are proteins, fats, carbohydrates, minerals and vitamins.
- **2. Dietary Supplement**: A product that contains one or more of the following dietary ingredients: vitamin, mineral, herb or other botanical, amino acid (protein) and

also includes concentrates, constituents, extracts or metabolites of these compounds.

- 3. Nutraceuticals: Any non-toxic food component that has scientifically proven health benefits, including prevention and treatment of disease.
- **4. Herbals**: Herbs or botanical products are used as concentrates and extracts that provide various remedies to treat acute and chronic diseases.

Advantages of Nutraceuticals^[6,7]

- 1. Reduce side effects.
- 2. Increases health benefits.
- 3. Provide dietary supplements naturally.
- 4. Easily available and cheap.
- 5. It provides food for populations with special needs (eg: nutrient-dense foods for the elderly).

Disadvantages of Nutraceuticals^[6,7]

- 1. Bioavailability: Nutraceuticals are being eliminated from the body and do not provide any medicinal benefit with poor bioavailability.
- 2. Impact of Placebo Effect: Consumers may not use nutraceuticals accurately for healing illness, when the body is often able to recover on its own.

- **3. Product Quality Issues:** Nutraceuticals from the international market may claim to use organic ingredients, but the lack of regulation may compromise the safety and effectiveness of products.
- **4. Safety and Interactions with Other Drugs:** The problem is that many of these products do not provide consumers with proper information about their safety and effectiveness, possible side effects, interaction with prescription medicines or the effect they have on existing medical conditions.

Classification of Nutraceuticals^[8] Nutraceuticals are considered in two ways

- · Potential nutraceuticals
- · Established nutraceuticals

A potential nutraceutical is one that gives an exact health or medical profit; potential nutraceuticals becomes established nutraceuticals only when it is having a enough clinical data. But the majority of the nutraceutical products are in the 'potential' group, waiting to become established.

The food products used as nutraceutical are grouped as

- ➤ Probiotic
- ➤ Prebiotic
- ➤ Dietary fibres
- ➤ Omega 3 fatty acids
- Antioxidant. [9,10]

Probiotics

According to WHO Probiotics are living Microorganisms which upon ingestion in certain numbers, exert health effects, beyond inherent basic nutrition.

Probiotics could be part of the natural microbiota of both animals and humans, they have been used since the beginning of history as starter cultures. Probiotics are present in almost all fermented foods-vegetables, meat and dairy products and they have a long history of consumption and safe use. Lactic acid bacteria and Bifidobacteria are the best candidates for use as Probiotic culture. Lactic acid bacteria have the "General Recognised as Safe" (GRAS) status and Assigned by Food and Drug Administration (FDA). Blfidobacteria have the "Qualified Presumption of Safety" (QPS) status and Assigned by the European Food Safety Agency (EFSA).

Example

Lactobacillus, Bifidobacterium, Yeast, Enterococcus faecium, Bacillus. [11]

Prebiotics

Prebiotics and synbiotics are dietary substances (mostly consisting of nonstarch polysaccharides and oligosaccharides poorly digested by human enzymes)

that nurture a selected group of microorganisms living in the gut. They favor the growth of beneficial bacteria over that of harmful ones. [12]

Unlike probiotics, most prebiotics are used as food ingredients—in biscuits, cereals, chocolate, spreads, and dairy products, for example.

Commonly known prebiotics are: • Oligofructose • Inulin • Galacto-oligosaccharides • Lactulose • Breast milk oligosaccharides. [12]

Lactulose is a synthetic disaccharide used as a drug for the treatment of constipation and hepatic encephalopathy.

The prebiotic oligofructose is found naturally in many foods, such as wheat, onions, bananas, honey, garlic, and leeks. Oligofructose can also be isolated from chicory root or synthesized enzymatically from sucrose. Fermentation of oligofructose in the colon results in a large number of physiologic effects, including.

- Increasing the numbers of bifidobacteria in the colon
- Increasing calcium absorption
- Increasing fecal weight
- Shortening gastrointestinal transit time
- Possibly, lowering blood lipid levels.

The increase in colonic bifidobacteria has been assumed to benefit human health by producing compounds to inhibit potential pathogens, by reducing blood ammonia levels, and by producing vitamins and digestive enzymes. [13,14]

Synbiotics are appropriate combinations of prebiotics and probiotics. A synbiotic product exerts both a prebiotic and probiotic effect. [15]

Dietary Fibres

Dietary fibre is a vital element of a healthy diet. It helps move food and waste efficiently through the digestive system. Fibre is the piece of plant foods that cannot be broken down by human digestive enzymes in the small intestine. Fibre is generally complex carbohydrates. The two types of fibre are soluble and insoluble. While they work differently, both are wanted for correct bowel function. Most fibre sources have both kinds of fibre in varying amounts.

Insoluble fibre cannot be dissolved in water. This type of fibre attracts water to the intestines, making stools bulky and soft. It also speeds the movement of food through the digestive tract. Therefore, insoluble fibre may help avoid diverticular disease, colon cancer, hemorrhoids, and constipation. Cellulose, hemi cellulose and lignin are insoluble fibres. They produce the tough, chewy texture of wheat bran, whole grains, corn bran, and some vegetables.

Soluble fibre, or fibre that can dissolve in water, slows the progress of food through the body but does not increase faecal bulk. Soluble fibre helps maintain a healthy cholesterol level, normalize blood sugar levels in diabetics and may even help diminish blood pressure. Pectins and gums are examples of soluble fibres, and they are found in beans, oat bran, psyllium husks, and some fruits and vegetables.

Examples

Fruits, vegetables, cereals, grains and pasta etc. [16]

Omega-3 Fatty acids (FAs)

Omega-3 FAs are a family of naturally occurring polyunsaturated fatty acids (PUFAs). Humans do not have the necessary metabolic pathways to synthesis the precursor FA (linolenic acid), which is essential for the production of the longer bioactive FAs. Therefore, these long-chain PUFAs must be obtained either from plant sources or by direct intake of EPA and DHA from marine or industrial products. [17]

Both omega-3 (ω -3) and omega-6 (ω -6) fatty acids are important components of cell membranes and are precursors to many other substances in the body such as those involved with regulating blood pressure and inflammatory responses. There is increasing support for omega-3 fatty acids in protecting against fatal heart disease and it is known that they have anti-inflammatory effects, which may be important in this and other diseases. There is also growing interest in the role of omega-3 fatty acids in the prevention of diabetes and certain types of cancer. [18]

The human body is capable of producing all the fatty acids it needs, except for two: linoleic acid (LA), an omega-6 fatty acid, and alpha-linolenic acid (ALA), an omega-3 fatty acid. These have to be consumed from the diet and are therefore termed "essential fatty acids". Both of these fatty acids are needed for growth and repair, but can also be used to make other fatty acids (e.g. arachidonic acid (AA) is formed from LA). However, as conversion to the omega-3 fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) is limited, it is recommended that sources of these are also included in the diet. ALA and LA are found in plant and seed oils. Although the levels of LA are usually much higher than those of ALA, rapeseed oil and walnut oil are very good sources of the latter. EPA and DHA are found in oily fish (e.g., salmon, mackerel, and herring). AA can be obtained from animal sources, such as meat and egg yolk.[19,20]

Antioxidants

Antioxidants are substances that may protect cells from the injury caused by unstable molecules known as free radicals. Antioxidants act together with and stabilize free radicals and may avoid some of the injure free radicals might otherwise cause. Free radical damage may lead to cancer. Examples of antioxidants include beta-carotene, lycopene, vitamins C, E, A and other substances. Antioxidants are essential and vital for plants and animals" sustenance. They are substances that protect cells from the injury caused by unstable molecules known as free radicals. The sources and origin of antioxidants which include fruits and vegetables, meats, poultry and fish were treated in this study. The types of antioxidants such as ascorbic acid, glutathione, melatonin, tocopherols and tocotrienols.

Examples

Meats, fish, Nuts, Grains and poultry. [21]

Dietary Supplement

The DSHEA formally defined "dietary supplement" using several criteria. A dietary Supplement.

➤ 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 vita-min, 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 labelled 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). [22]

Functional Foods: Functional foods are designed foods which provide enriched foods close to their natural state to consumer, rather than manufactured dietary supplements in liquid or capsule form. A process of making enriched food is called Nutrification. Functional foods provide required amount of vitamins, fat, carbohydrate, amino acid etc. to body. Established requirement that functional food should possess are.

- (1) Functional foods should be in their naturally-occurring form.
- (2) Functional foods should be an essential part of our daily diet.
- (3) Functional foods should regulate a biological process in hopes of preventing or controlling disease. [23]

Nutrients

Substances which have established Nutritional functions e.g. Vitamins, Minerals, Amino Acids, Fatty acids, etc.

• Most common Nutrients used/ supplemented as Nutraceutical are

Minerals and Vitamins or in combination or in combination with other antioxidants. [24]

Health Benefits of Nutraceuticals [25]

Health Benefits of different common nutraceuticals are as follows.

Vitamins

Fat Soluble Vitamins

- Vitamin A: Acts as antioxidant, essential for growth and development, maintains healthy vision, skin and mucous membranes, may aid in the prevention and treatment of certain cancers and in the treatment of certain skin disorders.
- Vitamin D: Essential for formation of bones and teeth, helps the body to absorb and use calcium

Vitamin E: Antioxidant, helps to form blood cells, boosts immune system

• Vitamin K: Essential for blood clotting

Water Soluble Vitamins

- Vitamin C: Antioxidant, necessary for healthy bones, gums, teeth and skin. Helps in wound healing, prevent from common cold.
- Vitamin B 1: Helps in carbohydrate metabolism, essential for neurological function.
- Vitamin B 2: Energy metabolism, maintain healthy eye, skin and nerve function.
- Vitamin B 3: Energy metabolism, brain function
- Vitamin B 6: Helps to produce essential proteins, convert proteins to energy
- Vitamin B 12: Help in producing genetic material, formation of RBC, maintenance of CNS, synthesis of amino acids, involved in metabolism of protein, fat and carbohydrate.
- Folic acid: Helps in RBC formation, formation of genetic material of cell, very much essential during pregnancy
- Pantothenic acid: Aids in synthesis of cholesterol, steroids, and fatty acids, crucial for intraneuronal synthesis of acetylcholine

Vitamins like Compounds

- L- Carnitine: Helps in oxidation of fatty acids, role in oxidative phosphorylation,
- Choline: Lipotropic agent, used to treat fatty liver and disturbed fat metabolism,
- Inositol: For amino acid transport and movement of Potassium and sodium.
- Taurine: Helps in retinal photoreceptor activity, bile acid conjugation, WBC antioxidant activity, CNS neuromodulation, platelet aggregation, cardiac contractibility, sperm motility, insuline activity,

Minerals

- Calcium: essential for bone and teeth, maintaining bone strength, nerve, muscle and glandular function, blood clotting,
- Iron: energy production, Hb, oxygen transport,
- Magnesium: for healthy nerve and muscle function, bone formation,

- Phosphorous: energy production, phosphorylation process, bone and teeth, for genetic material.
- Cobalt: component of Vit. B 12 and B 12 coenzymes,
- Copper: Hb and collagen production, function of heart, energy production, absorption of Iron.
- Iodine: proper function of Thyroid gland.
- Chromium: with insulin it helps in conversion of carbohydrate and fat into energy, treatment of diabetes.
- Selenium: Antioxidant, functioning of heart muscle, part of GPX enzyme.
- Zinc: Essential for cell reproduction, for development in Neonates, wound healing, production of sperm and testosterone hormone.

Herhals

- Herbals/ Phytochemicals: Herbs or Botanical products
- Aloe vera: Anti-inflammatory, emollient, wound healing.
- Evening Primrose oil: Dietary supplement of linoleic acid, treatment of atopic eczema,
- Garlic: Antibacterial, antifungal, antithrombotic, antiinflammatory.
- Ginger: carminative, antiemetic, treatment of dizziness
- Ginseng: Adaptogen.
- Green tea: Antioxidant, reduces risk of CVD, enhances humoral and cell mediated Immunity.
- Vegetables, fruits, whole grain, herbs, nuts and various seeds contain an abundance of phenolic compounds, terpenoids, sulphur compounds, pigments etc. that has been associated with protection / treatment of certain disease conditions.^[25]

Examples of Nutraceuticals Currently Available In $Market^{[25]}$

- **1.Fortified Cereals**-various cereals contain vitamins and minerals.
- **2. Vitamin and Mineral Supplements**-Vitamin A (Beta- Carotene), lycoten forte etc.
- **3. Additional Supplements**-supplements other than vitamin and minerals which have beneficial effect on health for example-cod liver oil, primrose oil, and flaxseed oil (omega pure) etc.
- **4. Energy Drinks and Tablets** Red Bull, Tropicana fruit Juice, Minute Maid Pulp, Frooti, Real Juice etc.
- **5. For Healthy Heart**-Abcor by Nutri-pharma, claimed to reduce cholesterol by 15-20% in 4 months, novomega, carnicare, coq10, lycotenforte.
- **6. Protein Powder** Nutral-P, Nutral-D, Nutral-G, Protein-X.
- **7. Pro-Biotics & Prebiotics** -Bacteria containing foods that believed to improved health. For example- coloncare capsules & Sachets, A blend of 6 probiotics, 2 prebiotics along with colostrum.
- **8. Sports Products** Glucon-D (Heinz), Glucose D (Dabur).

Nutraceutical and Health^[25,26,27]

List of Nutraceutical components along with their source & potential benefits

Class / components	Source	Potential benefit	
1. n-3 FA(DHA, EPA)	Fish oils, berseem & maize fodder,	Reduce CVD	
	mustard, linseed, rapeseed	improve mental, visual function	
2. Polyphenols			
Anthocyanidine	Fruits		
Catechins	Tea, babul pods, mustard cake, rape	Neutralises free radicals, reduce risk of cancer, Diabetes, CVD etc.	
Flavonone	Citrus		
Flavones	Fruits, vegetables, soya bean		
proanthocyanidine	Cocoa, chocolate, tea, rape seed	Reduce CVD	
3. Saponins	Soybeans, GNC, lucerne, chick pea	Lower cholesterol, anti-cancer	
4.Probiotics / Prebiotics /			
Synbiotics		Improve GI health	
Lactobacillus	Dahi, yogurt		
Fructo -oligosaccharides	Whole grains, onions, combination of Pro		
Fructo-ongosaccharides	& Prebiotics		
5.Phytoestrogen			
Daidzein , Zenistein	Soybean, flax, lentilseed, maize,	Reduce menopause symptoms,	
	berseem, lucerne, subabul fodder	bone health	
Lignans	Flax, rye, vegetables	Reduce cancer and heart diseases	
6.Caroteinoids			
β- caroteine	Berseem, lucerne, oat & maize fodder,	Nutralises free radicals	
	Carrots, vegetables, fruits		
Luteine	vegetables	Healthy vision	
Zeoxanthine	Eggs, citrus, corn		
Lycopene	Tomatoes	Reduce prostate cancer	
7.dietary fiber		Reduce breast, colon cancer	
Insoluble fiber	Wheat bran	Reduce CVD	
β-glucan	Oats		
Whole grain	Cereal grains		

Fortified food

Food fortification or enrichment is the process of adding micronutrients (essential trace elements and vitamins) to food. It may be a purely commercial choice to provide extra nutrients in a food, while other times it is a public health policy which aims to reduce the number of people with dietary deficiencies within a population. Staple foods of a region can lack particular nutrients due to the soil of the region or from inherent inadequacy of a normal diet. Addition of micronutrients to staples and condiments can prevent large-scale deficiency diseases in these cases.

As defined by the World Health Organization (WHO) and the Food and Agricultural Organization of the United Nations (FAO), fortification refers to "the practice of deliberately increasing the content of an

essential micronutrient, i.e. vitamins and minerals (including trace elements) in a food irrespective of whether the nutrients were originally in the food before processing or not, so as to improve the nutritional quality of the food supply and to provide a public health benefit with minimal risk to health", whereas enrichment is defined as "synonymous with fortification and refers to the addition of micronutrients to a food which are lost during processing". [28]

Phytochemicals^[29]

Among the phytochemicals/phytonutrients mentioned as potentially providing health benefits are polyphenols, flavonoids, isoflavonoids, anthocyanidins, phytoestrogens, terpenoids, carotenoids, limonoids, phytosterols, glucosinolates and fibers.

Polyphenols	Sources
Flavonoids (Anthocyanidins): Cyanidin 3-glycosides, Malvidin, Delphinidin,Pelargonidin	Blue berries, black berries, cranberry, raspberry, black currant, black grape, straw-berries, cherries, plums, pomegranate, juice, red wine
Flavonoid glycosides: Rutin, Hesperidin, Naringin	Orange, orange juice, lemon, grapefruit, tangerine juice
Flavones: Apigenin, Luteolin	Celery hearts, celery, olives, peppers, fresh parsley, dry parsley, oregano, rosemary, thyme.
Flavanones: Naringenin,	Grapes, citrus fruits and their juices, tangerine juice,
Eriodictyol, Hesperetin	peppermint

Flavanols: Morin, Procyanidins	Apricots, apples, grapes, peaches, pears, plums, raisins,
Prodelphinidins, Catechin, Epicatechin and their gallates	berries, cherries, red wine, tea, chocolate
Anthoxanthins (Flavonols): Myricetin, Fisetin, Quercetin, Kaempferol, Isorhamnetin	Cherry, tomatoes, spinach, celery, onions, peppers, sweet potato, lettuce, broccoli, kale, buckwheat, beans, apples, apricots, grapes, plums, berries, currants, cherries, juices, ginkgo biloba, red wine, tea, cocoa
Isoflavones: Genistein, Daidzein, Equol	Soybean, soy products, soy cheese and sauces, grape seeds/skin,
Phenolic acids: Caffeic acid, Chlorogenic acid, Ferulic acid, p-coumaric acid, Sinapic acid, Ellagic acid, Gallic acid	Lemon, peach, lettuce, coffee beans, tea, coffee, cider, Strawberry, raspberry grape juice, pomegranate juice bluberry, cranberry, pear, cherry, cherry juice, apple, apple juice, orange, grapefruit
Tannins: Catechin, Epicatechin polymers, Ellagitannins, Proanthocyanidins, Tannic acids	Pomegranate, walnuts, peach, olive, plum, chick pea, peas, grape seeds and skin, apple juice, strawberries, raspberries, blackberry, lentils, haricot bean, red wine, cocoa, chocolate, tea, coffee, immature fruits
Diferuloylmethane: Curcuminoids	Turmeric

Rational use of Nutraceuticals [30,31,32]

The explosive demand growth for bioactive ingredients for nutraceuticals and functional foods is being driven by frequently cited health concerns:

- Cardiovascular disease
- ❖Breast, skin, colorectal, and brain cancers
- ❖Female health concerns
- **♦**CNS disorders
- ❖ Metabolism management
- ❖Gastrointestinal disorders
- ❖Immuno modulation

Dietary factors play an important role in premature chronic disease appearance, disease progression, morbidity and mortality. Approximately 40-50% cardiovascular proportion in disorders. 35-50% proportion in cancers, and 20% proportion in osteoporosis is attributable to dietary factors. Use of food as medicine for treatment and prevention of various disorders is not a recent development. Fortification of table salt with iodine and wheat flour with iron/folic acid has been used with specific aims of prevention of iodine deficiency goiter and anemia for long. Similarly, food fortified with vitamin A has been found to be a feasible and cost-effective approach to reduce vitamin A deficiency. A growing interest in relationship between diet and health has added impetus to the demand for information on nutraceuticals. This increased interest has been aided by advances in science and technology, increasing health care costs, changes in food laws affecting label, and product claims and aging population in various countries. Along with offering treatment, use of nutraceuticals favours a preventive treatment model as well.

A significant problem with the use of nutraceuticals in treating diseases is the lack of serious studies published with clear clinical evidence. The development, production, packaging, marketing, and sales of nutraceuticals has come a long way and is evolving constantly. Nutraceuticals are the preferred choice of today's consumer for regular usage. The latest scientific

research and clinical trials continue to boost and add impetus to this industry.

Indian Regulatory aspects of Nutraceuticals^[33,34]

The regulatory framework of nutraceuticals in India needs attention from the relevant authorities. Globally, the regulatory authorities are aware of changing needs of consumers and proactively protect consumers by amending existing laws to accommodate changes but in India old laws such as Prevention of Food adulteration Act, 1954, which regulates packaged foods, still exist for manufacturers. In addition, they need to tolerate by many other cumbersome laws such as:

- ➤ Standards of Weights and Measures Act, 1976, and the Standards of Weights and Measures
- ➤ (Packaged Commodities) Rules, 1977 (SWMA)
- ➤ Infant Milk Substitutes, Feeding bottles and infant foods (regulation of production, Supply and Distribution) Act, 1992 with Rules, 1993 (IMS)
- ➤ Edible Oils Packaging (Regulations) Order,1998
- Fruit Products Order 1955 (FPO)
- ➤ Meat product Order 1973
- ➤ Milk and Milk Products Order 1992
- ➤ Vegetable Oils Products (Regulation) Order 1998 (VOP)
- Consumer Protection Act 1986 and the Consumer Protection (Amendment) Act, 2002 and Rules 1987
- Environment Protection Act, 1986 and Rules 1986
- ➤ Agricultural Produce (Grading and Marking) Act, 1937 (as amended up to 1986) and 49
- ➤ General Grading and Marking Rules 1986 and 1988 (AGMark)
- ➤ Bureau of Indian Standards (BIS) Act 1986

Food Safety and Standard Authority of India $(FSSAI)^{[35]}$

Food Safety and Standard Authority of India (FSSAI) was passed by the parliament in 2006 and in 2008, it came into existence. Food Safety and Standard Act 2006 consists of 12 chapters and chapter IV article 22 of the Act addresses nutraceutical, functional food, dietary supplements and need to regulate these products such

that anyone can manufacture, sell or distribute or import these products. These products include novel foods, genetically modified article of food, irradiated food, organic food, and food for special dietary uses, functional food, nutraceuticals and health supplements. Article 23 and 24 address the packaging and labelling of food and restriction of advertisement regarding foods.

Current status of nutraceuticals in India

India's nutraceutical industry is set to double in size to Rs 26,764 crore (approx USD 4 billion) by 2020 as rapid surge in the demand for dietary supplements from the upper and middle class will drive the growth for the industry over the next five years, noted the drug industry leaders.

Nutraceuticals are a rising branch in the pharmaceuticals industry and is estimated to clock a compounded annual growth rate of about 16 per cent in the next five years, the Drug Marketing and Manufacturing Association (DMMA) informed.

The country currently, is witness to a spate of changes in lifestyles and rise in lifestyle diseases like Diabetes, blood pressure, obesity, cardio-vascular problems among others, which has increased the demand for supplements to nutrition among the upper and middle class.

In spite of on a strong growth path, the industry in India lacks a dedicated law guiding the sector or rules that defines the composition of nutraceuticals.

Moreover, a recent Assocham-RNCOS joint study has revealed that 60 per cent to 70 per cent of dietary supplements sold across India are fake, counterfeit, unregistered and unapproved and are extremely difficult to identify, DMMA stated. "The new regulations will come into play only in 2018, so our efforts are directed towards making use of the time to throw light on new licensing norms, approvals that will be now necessary and mark the future paradigm of marketing among others.

REFERENCES

- 1. De Felice L Stephen. The nutraceutical revolution, its impact on food industry. Trends in Food Sci. and Tech, 1995; 6: 59-61.
- 2. Rajat S, Sharma M, Singh R, Kumar S. Nutraceuticals: a review. Int Res J Pharm. 2012; 3(4): 95-99.
- 3. Das L, Bhaumik E, Raychaudhari U, Chakraborthy R. Role of nutraceuticals in human health. J Food Sci Technol, 2012; 49(2): 173-83.
- Brower V. Nutraceuticals: poised for a healthy slice of them healthcare market? Nat Biotech, 1998; 16: 728-731
- 5. Zeisel SH. Regulation of "Nutraceuticals". Science, 1999; 285: 185-186.

- 6. Dharti ST, Gandhi S, Shah M. Nutraceuticals portmanteau of science and nature. Int J Pharm Sci Rev Res., 2010; 5(3): 33-38.
- 7. Sapkale AP, Thorat MS, Vir PR, Singh MC. Nutraceuticals global status and applications: a review. J Pharm Chem Sci., 2012; 1(3): 1166-1181.
- 8. Manisha Pandey. Nutraceuticals: new era of medicine and health, 2010; 3(1): 12-13.
- 9. Kokate CK, Purohit AP, Gokhale SB. Nutraceutical and Cosmaceutical. Pharmacognosy, 21st edition, Pune, India: Nirali Prakashan, 2002; 542-549.
- 10. S.C Ng et al., Mechanisms of Actions of Probiotics: Recent Advances Inflamm. Bowel Dis., 2009; 15: 300-310.
- 11. Gibson, G.R.; Roberfroid, M.B.Dietary Modulation of the Human Colonic Microbiota: Introducing the concept of Prebiotics. J. Nutr, 1995; 125: 1401-1412. www.uhs.berkeley.edu.
- 12. Prerna K. Ratnaparkhi, Nikita P. Karode, Kalpesh B. Patil, Shashiraj N.Gohel, Vipulkumar D. Prajapati and Girish K. Jani. Nutraceuticals-its Current Scenario and Challenges in Dietary Supplements, 2015; 4(7): 460-474.
- 13. De Preter, V.; Hamer, H.M.; Windey, K.; Verbeke, K. The impact of pre- and/or probiotics on human colonic metabolism: Does it affect human health? Mol. Nutr. Food Res., 2011; 55: 46–57.
- 14. Grajek, W.; Olejnik, A.; Sip, A. Probiotics, prebiotics and antioxidants as functional foods. Acta Biochim. Pol., 2005; 52: 665–671.
- 15. Schiffrin, E.J.; Kumar, V.B.; Brown, C.; Hager, C.; Van't Hof, M.A.; Morley, J.E.; Guigoz, Y. Systemic inflammatory markers in older persons: The effect of oral nutritional supplementation with prebiotics. J. Nutr. Health Aging, 2007; 11: 475–479.
- Irene gazi, evangelos N. Liberopoulos, vasilios G. Saougos, moses elisaf. Beneficial Effects of Omega-3 Fatty Acids: The Current Evidence, 2006; 47: 223-231.
- 17. 14. Seo T, Blaner WS, Deckelbaum RJ: Omega-3 fatty acids:molecular approaches to optimal biological outcomes. CurrOpin Lipidol, 2005; 16: 11-18.
- 18. 15. Holub BJ: Clinical Nutrition: 4. Omega-3 fatty acids in cardiovascular care. CMAJ., 2002; 166: 608-615
- 19. Harrison N, Abhyankar B: The mechanism of action of omega-3 fatty acids in secondary prevention post-myocardial infarction. Curr Med Res Opin, 2005; 21: 95-100.
- 20. A. A. Hamid, O. O. Aiyelaagbe, L. A. Usman, O. M. Ameen and A. Lawal. Antioxidants: Its medicinal and pharmacological applications Ira s. krull. Michael E. Swartz. Striving to validate nutraceuticals. 2011; 19: 1142-4.
- 21. BHMA Scientific Committee, British Herbal Pharmacopoeia (British Herbal Medicine Association, Dorset, United Kingdom, 1990; 1).
- 22. Kalra EK. Nutraceutical--definition and introduction. AAPS Pharm Sci., 2003; 5: 27-28.

- 23. Hardy G. Nutraceuticals and functional foods: introduction and meaning, Nutrition, 2000; 16: 688.
- 24. M. Blumenthal, W. Busse, A. Goldberg, J.Gruenwald, T. Hall, C. Riggins, and R. Rister, The Complete German Commission E Monographs (American Botanical Council, Austin, Texas, in cooperation with Integrative Medicine Communications, Boston, Massachusetts, 1998).
- Govind Shukla, Sangita Kumari, Anna Victoria Zamora Maguddayao, Shivani Prashar, C.J. Sampath Kumar, "Nutraceuticals: The Future Therapeutics 'International Journal of Pharmacology & Toxicology, 2014; 4(3): 146-150.
- 26. Hardy G. Nutraceuticals and functional foods: introduction and meaning, Nutrition, 2000; 16: 688.
- 27. Deal CL, Moskowitz RW. Nutraceuticals as therapeutic agent in asteoarthritis. Osteoarthritis, 1999; 25: 379.
- 28. Shubhangi Pant and Dipanshu Chinwan, "Food Fortification and Enrichment" International Journal of Basic and Applied Biology Print ISSN: 2394-5820, Online ISSN: 2349-2539, Volume 2, Number 3; October-December, 2014; 166-168.
- 29. Dhan Prakash, Charu Gupta, Girish Sharma, "Importance of Phytochemicals in Nutraceuticals" Journal of Chinese Medicine Research and Development Oct., 2012; 1(3): 70-78.
- 30. Whitman M. Understanding the perceived need for complementary and alternative nutraceuticals: lifestyle issues Clin J Oncol Nurs, 2001; 5: 190-194.
- Rissanen TH, Voutilainen S, Virtanen JK, Venho B, Vanharanta M, Mursu J and Salonen JT. Low Intake of Fruits, Berries and Vegetables Is Associated with Exces Mortality in Men: the Kuopio Ischaemic Heart Disease Risk Factor (KIHD) Study. J Nutr, 2003: 133: 199-204.
- 32. Temple WJ and Gladwin KK. Fruits, vegetables, and the Prevention of cancer: Research challenges. Nutrition, 2003; 19: 467-470.
- 33. Palthur MP, Palthur SSS, Chitta SK. Nutraceuticals: concept and regulatory scenario. Int. J Pharm Pharm Sci., 2010; 2(2): 14-20.
- Gupta S, Chauhan D, Mehla K, Sood P, Nair A. An overview of nutraceuticals: Current scenario. J Basic & Clin Pharm, 2010; 2: 55-62.
- Debjit Bhowmik, Harish Gopinath, B. Pragati Kumar, S. Duraivel, K. P. Sampath Kumar, "Nutraceutical –A Bright Scope and Opportunity of Indian Healthcare Market" The Pharma Innovation Journal, Jan 2013; 1(11).