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CLASSIFICATION, REGULATORY ACTS AND APPLICATIONS OF NUTRACEUTICALS FOR HEALTH

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ABSTRACT

Nutraceuticals are medicinal foods that enhance health, modulate immunity and thereby prevent and cure specific diseases. They may range from natural diets, herbal products to genetically engineered foods and processed products such as cereals, soups and beverages. Biofortified crops have been considered as a complementary strategy for delivering nutrition to malnourished populations. Dairy products that contain probiotic organisms such as Lactobacillus and Bifidobacterium species represent a new research area which improves gut health by modulating gut microbial composition. The ability of nutraceuticals to influence chronic diseases like diabetes, different types of cancers, etc. should be recognized as an enormous opportunity in their treatment. They will play important role in future therapeutic developments. In this review, an attempt has been made to discuss history, classification, commercial products and regulations of nutraceuticals.

KEYWORDS: *Nutraceuticals, Phytochemicals, Probiotic microorganisms, Fortified, Recombinant.*

INTRODUCTION

About 2500 years ago, Hippocrates (460–377 BC), the well recognized father of modern medicine, conceptualized the relationship between the use of appropriate foods for health and their therapeutic benefits [1]. Then Theophrastus (370-285 BC), Cato (234-149 BC), Pliny the Elder (23-79 AD) and Galen (131-201 AD) warned against adulteration of food products[2]. Since 2000 BC Schwan, in 1837 employed microbes (fungus or yeast) for product generation by the process of alcoholic fermentation. Funk (1884-1967), the 'father of vitamin therapy' began a new path of scientific research on vitamins and establishes them as constituents of food necessary for the maintenance of good health [www.paulingblog.wordpress.com].

The term 'nutraceutical' was coined from 'nutrition' and 'pharmaceutical' in 1989 by DeFelice and was originally defined as 'a food (or part of the food) that provides medical or health benefits, including the prevention and/or treatment of a disease' [3]. A nutraceutical may be a naturally nutrient- rich food such as spirulina, garlic, soy or a specific component of a food like omega-3 oil from salmon. They are also known as medical foods, nutritional supplements and dietary supplements. It ranges from isolated nutrients, dietary supplements, genetically engineered 'designer' foods, herbal products, and processed products such as cereals and soups. They have received considerable interest because of their presumed safety and potential nutritional and therapeutic effects [4]. People can improve their health by supplementation and by consuming foods that have been formulated or fortified. Another reason for the growing trend of nutraceuticals is public education, renewable source, cultivation and processing, environmental friendliness and local availability [5]. United Kingdom, Germany and France were the first who considered that diet is more important factor than exercise or hereditary factors in achieving a good health. Canada defined them as 'a product produced from foods but sold in pills, powders, (potions) and other medicinal forms not generally associated with food'. In India, nutraceutical are the food components made from herbal or botanical raw materials, which are used for preventing or treating different types of acute and chronic maladies [6].

CLASSIFICATION

Nutraceuticals are categorized on the basis of foods available in the market [www.aboutbioscience. org/]

1. **Traditional nutraceuticals**
2. **Non-traditional nutraceuticals**

1. **Traditional nutraceuticals** are simply natural with no changes to the food**.** Food contains several natural components that deliver benefits beyond basic nutrition, such as lycopene in tomatoes, omega-3 fatty acids in salmon or saponins in soy. Applications of traditional nutraceutical in chronic disease control are discussed in (**Table 1**). They are grouped on the basis of

I. **Chemical Constituents**
   a) Nutrients
   b) Herbals
   c) Phytochemicals
II. **Probiotic Microorganisms**

Table 1: Application of traditional nutraceutical in chronic disease control

Nutraceutical	Dose/ Duration	Effect	References
Allenic carotenoid fucoxanthin (brown seaweeds)	2.4 mg /day	Improves insulin resistance and decreases blood glucose levels through the regulation of cytokine secretions from WAT (white adipose tissues)	***7***
n-3 PUFAs (polyunsaturated fatty acids)	No data	Prevents several disorders affecting lungs and airways	***8***
ASU (unsaponifiable residues of avocado and soybean oils)	300mg / 3 years	Stimulates synthesis of aggrecan and extracellular matrix component as type II collagen and by reducing the production of catabolic (MMP-3) and pro-inflammatory (IL-8 and IL-6) mediators in OA (osteoarthritis)	***9***
CLA (Conjugated linoleic acids)	3 months	Significantly improves AHR (Airway hyper responsiveness) associated with a reduction in leptin/ adiponectin ratio in mild asthma	***10***
Siphonaxanthin, a marine carotenoid (green algae)	20µM / within 6h of treatment in HL-60 cells	Induces apoptosis in HL-60 cells by decreasing Bcl-2, and increases activation of caspase-3	***11***
FPP(Fermented papaya preparation)	6g/day / 6 months	Unregulated TNF-α and thioredoxin (Trx) in liver cirrhosis	***12***
MUFAs (monounsaturated fats)	No data	Lowers CVD (cardiovascular disease) risk and MS (metabolic syndrome)	***13***
$1,25(OH)_2D$, or calcitriol	200–600 IU/day	Regulates the levels of p21 and p27 and increases expression of BRCA-1 and -2 tumor suppressor genes contributing in the DNA repair mechanism	***14***
Resveratrol	No data	Chemosensitizes tumor by modulating drug transporters, cell survival proteins, cell proliferative proteins, and members of the NF-κB and STAT3 signaling pathways	***15***
Fortified wheat flour	100 to 150 µg/day	Reduces prevalence of *NTDs* (neural tube defect) at birth and increasing blood folate concentrations	***16***

III. Nutraceutical Enzymes

I. **Chemical Constituents**

a)Nutrients

Substances such as vitamins, minerals, amino acids and fatty acids with established nutritional functions. Most vegetables, wholegrain cereals, dairy products, fruits and animal products such as meat, poultry, contain vitamins and are helpful in curing heart diseases, stroke, cataracts, osteoporosis, diabetes and cancer [www.cdc.gov/]. Minerals found in plant, animal and dairy products are useful in osteoporosis, anemia and build strong bones, teeth, muscles, improve nerve impulses and heart rhythm [www.netdoctor.co.uk/]. Flax seed and salmon contain fatty acids omega-3 PUFAs, and are potent controllers of the inflammatory processes, maintenance of brain function and reduce cholesterol deposition [www.medicinenet.com/].

b) *Herbals*

Nutraceuticals holds a great promise to improve health and prevent chronic diseases with the help of herbals. Some examples are willow bark (*Salix nigra)*, having active component as salicin, which is anti-inflammatory, analgesic, antipyretic, astringent and antiarthritic [17]. Parsley *(Petroselinum cripsum*) contains flavnoids (apiol, psoralen) and is diuretic, carminative and anti-pyretic [www.indianetzone.com/]. Peppermint (*Mentha piperita)* contains menthol as an active component and cures cold and flu [18]. Lavender (*Lavandula angustifolia)* contains tannin which is helpful in curing depression, hypertension, stress, cold,cough and asthma [www.essentialoils.co.za/]. Cranberries *(Vaccinium erythrocarpum)* contain proanthocyanadin and are found to be useful in cancer, ulcers and urinary tract infections [www.hubpages.com/].

c) *Phytochemicals*

According to Best [www.benbest.com/] phytochemicals is one class of nutraceuticals. They are classified on the basis of chemical name given according to their phytochemical properties. For example, Carotenoids (Isoprenoids) found in various fruits, vegetables and egg yolk, are anti-carcinogenic, boost natural killer immune cells and protect cornea against UV light. Legumes (chickpeas and soybeans), grains, palm oil contain non-carotenoids, which remove cholesterol and are anti-carcinogenic. Flavonoid polyphenolics are found in berries, fruits, vegetables, and legumes, which are potent antioxidants, phytoestrogens, prevent breast cancer, prostate cancer and control diabetes. Non-flavonoid polyphenolics are present in dark grapes, raisins, berries, peanuts, turmeric roots are strong anti-inflammatory, anti-oxidants, and effective anti-clotting agents and reduce cholesterol. Phenolic acids, found in blueberries, tomatoes and bell peppers having antioxidant activity, reduce mutagenicity of polycyclic aromatic hydrocarbons. Seeds of *Barbarea verna*, broccoli contain isothiocyanates (glucosinolates) and have antitumorigenisis activity.

II. Probiotic Microorganisms

The scientific interest in probiotics boosted from the work of Metchinkoff to transform the toxic flora of the large intestine into a host-friendly colony of *Bacillus bulgaricus* was found by Hord [19]. 'Probiotics' mean 'for life' and are defined as live microorganisms, which when consumed in adequate amounts, confer a health effect on the host [20]. They are friendly bacteria that promote healthy digestion and absorption of some nutrients. They act to crowd out pathogens, such as yeasts, other bacteria and viruses that may otherwise cause disease and develop a mutually advantageous symbiosis with the human gastrointestinal tract [21]. They have an antimicrobial effect through modifying the microflora, preventing adhesion of pathogens to the intestinal epithelium, competing for nutrients necessary for pathogen survival, producing an antitoxin effect and reversing some of the consequences of infection on the intestinal epithelium, such as secretory changes and neutrophil migration. Probiotics can cure lactose intolerance by the production of the specific enzyme (*ß*-galactosidase) that can hydrolyze the offending lactose into its component sugars [22]. Sources of probiotic microorganisms are mentioned (**Table 2**).

III. Nutraceutical Enzymes

Enzymes are an essential part of life, without which our bodies would cease to function. Those people who are suffering from medical conditions such as hypoglycemia, blood sugar disorders, digestive problems and obesity, eliminate the symptoms by enzyme supplements to their diet. These enzymes are derived from microbial, plant and animal sources [www.specialtyenzymes.com/] (**Table 3**).

Table 2: Sources of probiotic microorganisms [21]

Milk	Yoghurt	Fermented products	Human breast milk	GI tract	vegetables/ grains/fruits
Lactobacillus acidophilus *L. lactis*	*L.delbrueckii subp bulgaricus*	*L. casei* *L. cellobiosus* *L. curvatus* *L. fermentum* *L. helviticus* *L. farciminis*	*L. reuteri* *L. salivarius*	*L. gasseri* *L. johnsonii*	*L. brevis* *L. plantarum*
	Bifido-bacterium adolescentis	*B. thermophilum* *B. animalis*	*B. infantis* *B. longum* *B. breve* *B. lactis*		
Propioni-bacterium freudenreichii	*Streptococcus thermophilus*	*Enterococcus faecium* *Pediococcus acidilactici*		*Escherichia coli Nissle 1917*	*Leuconstoc mesenteroides*
					S. cerevisiae *S. boulardii* Mushrooms

Table 3: List of nutaceutical enzymes from microbes, plants and animals

Microbial Enzymes/source	Plant Enzymes/source	Animal Enzymes/source
Hemicellulase (microorganisms and mushrooms)	Hemicellulase (plant walls)	OxBile (ox)
Catalase	Pectinase (cell wall)	Pancreolipase (pancreatic juice)
Amyloglucosidase (ascomycetes)	α- Galactosidase (beans, cabbage, Brussels sprouts, broccoli, asparagus, other vegetables, and whole grains)	Trypsin (pancreatic juice)
Glucoamylase (*A. niger, Saccharomycopsis fibuligera*)	β-Amylase (higher plants)	Chymotrypsin (all classes of vertebrates)
Cellulase (all living cells)	Bromelain (pineapple)	Pepsin (animals tracheal secretions)
Invertase – Sucrase (yeast)	Biodiastase (soybean)	Lysozyme (saliva, tears, egg white, and many animal fluids)
Lactase – β-Galactosidase (bacteria)	Glucoamylase (callus and suspension cultures of sugar beets (Beta vulgaris L.) as well as in mature roots)	α –Amylase (saliva)

2. **Non-traditional nutraceuticals** are artificial foods prepared with the help of biotechnology. Food samples contain bioactive components which are engineered to produce products for human- wellness. They are arranged into

a)Fortified nutraceuticals

b)Recombinant nutraceuticals

a) Fortified nutraceuticals

It constitutes fortified food from agricultural breeding or added nutrients and/or ingredients. e.g. orange juice fortified with calcium, cereals with added vitamins or minerals and flour with added folic acid. Some examples are milk fortified with cholecalciferol used in vitamin D deficiency [23].

Prebiotic and probiotic fortified milk with *Bifidobacterium lactis HN019* used in diarrhea, respiratory infections and severe illnesses, in children [24]. Banana fortified using soybean *ferritin* gene in iron deficiency was discovered by Kumar [25].

b) Recombinant nutraceuticals

Energy-providing foods, such as bread, alcohol, fermented starch, yogurt, cheese, vinegar, and others are produced with the help of biotechnology. The production of probiotics (**Table 4**) and the extraction of bioactive components by enzyme/fermentation technologies as well as genetic engineering technology are achieved through biotechnology.

Table 4: Product produced by recombinant microorganisms, plants and animals

A. Recombinant microorganisms			
Source	**Enzyme**	**Products**	**References**
Acetobacter xylinum	β-glucuronidase	Kombucha beverage	**26**
Escherichia coli K-12	Chymosin	Milk-coagulated products	**27**
Fusarium venenatum	Xylanase	Increased bran solubilization	**28**
Aspergillus oryzae	Esterase–lipase, Aspartic proteinase, Glucose oxidase, Laccase, Lipase, Pectin esterase,	Alcoholic beverages (Sake , koji)	**29**
Saccharomyces cerevisiae	Stilbene synthase and 4-coumaroyl-CoA	Resveratrol	**30**
Spirulina Pacifica	Indoleamine 2,3-dioxygenase (IDO)	Increased hemoglobin	**[www.nutraceuticalsworld.com/]**
B. Recombinant plant			
Recombinant	**Deficiency**	**Gene for recombination**	**References**
Gold kiwifruit	Iron	High level of Ascorbic acid, carotenoids lutein and zeaxanthin	**31**
Potatoes	Protein	Tuber-specific expression of a seed protein, *AmA1(Amaranth Albumin 1)*	**32**
Golden mustard	Vitamin A	Soybean *ferritin* gene	**33**
Multivitamin corn	Multivitamin	Vitamins β-carotene corn (*Zea mays*) phytoene synthase (*psy1*) cDNA), ascorbate (rice dehydroascorbate reductase *(dhar*) cDNA), and folate (*E. coli folE* gene encoding GTP cyclohydrolase *(GCH1*)	**34**
Maize	vitamin A (retinol)	Bacterial genes *crtB* and *crtI*	**35**
Tomato	Folate	Aminodeoxychorismate synthase (*AtADCS*)	**36**
Golden rice	vitamin A (retinol)	Two daffodil genes and one bacterial gene	**[www.rockfound.org]**
Iron rice	Iron deficiency	Soybean *ferritin* gene	**[www.biotech.nature.com]**
C. Recombinant animals			
Fermented soya milk	Calcium deficiency	*Lactobacillus acidophilus* American Type Culture Collection (ATCC) 4962	**37**
Cattle	human lysozyme	*rHLZ* expression vector *pBC2-HLY-NEOR*	**38**
Yogurt	probiotics microorganism	*Bifidobacterium lactis Bb-12* and *Lactobacillus acidophilus LA-5*	**39**
Cows	Lactoferrin deficiency	Recombinant human lactoferrin (rhLf)	**40**

COMMERCIAL NUTRACEUTICALS

New molecule is difficult to discover and more expensive and risky than ever before. Many pharmaceutical companies are now trying to manufacture nutraceutical because there is undoubtedly a very huge and growing market. Nutraceuticals cover most of the therapeutic areas, such as anti-arthritic, cold and cough, sleeping disorders, digestion and prevention of certain cancers, osteoporosis, blood pressure, cholesterol control, pain killers, depression and diabetes. Recognition of health benefits from consumption of omega-3 rich seafoods is one of the most promising developments in human nutrition and disease prevention research in the past three decades [41].

Table 5: List of commercial nutraceutical of USA [www.nutraceuticalsworld.com/]

Product	Source	Category	Company
Probiotic Wraps & Hummus	GanedenBC30 (*Bacillus coagulans*)	Support immune function and promote digestive health	Cedar's Mediterranean Foods
Vita Kids Bread	Fortified with MEG-3 (maternally expressed 3) brand omega-3	Omega-3 EPA/DHA, along with folic acid, vitamin C and D	Irish Pride Bakeries
Splenda Essentials	Wheat breads	Zero calorie sweetener products	McNeil Nutritionals
GREENSuperFood Antioxidant & Greens Powder	Rice, raspberry	Defend against free radicals ,supports brain function , immune system	Amazing Grass
Phenorex	Bitter orange	Burn fat	Gaspari Nutrition
Assure for Heart & Energy	Tangerine , kiwi strawberry, melon	Heart rhythm	Assure Food & Beverage Company
Vectomega	Salmon	Enhances absorption of omega- 3	Europharma
BrainShiner	*Ginkgo biloba*, ginseng	Increase memory retention	Multifunction Supplements
Fuze	Fruits	Source of antioxidant vitamins A, C and E	Whitestone
Collagen Enhance Chews	Red wine, from grapes	Age-defying properties	ResVitále
Forgiven Alcohol Burner	*Rhodiola rosea* extract	Breakdown alcohol by-products	Forgiven Bottling Group
Collagen Glucosamine Complex	Chicken cartilage	Slows down the secretion of joint-cartilage degrading enzymes	Jamieson Laboratories
Fish Oil Plus	Salmon	Perfect brain food	Pacific Health, Inc.
GoodBelly Probiotic Coconut Water, SuperGreen Live & StraightShot	Coconut water	Probiotics for vegan and allergy-prone consumers	NextFoods
Daytime Restore & Nighttime Repose	Ginseng, G*inkgo biloba*,	Restful sleep	Xigo Health
CogniSure	Proline-rich polypeptide complex	Support healthy aging of the brain, for Alzheimer's Disease.	Metagenics Inc.
Fat-Free Milk Plus DHA Omega 3	Vegetarian, algal oil	Support brain, heart and eyes at every stage of life	WhiteWave Foods Company
Rice Protein Concentrate	Brown rice	High-protein alternative	Jarrow Formulas
Rescue Water	Berry, Lemon, Orange	Support liver function and have necessary nutrients	AriZona Beverage Company
Calcium Plus Milk	Fortified milks	Lower risk of osteoporosis	Shamrock Farms
Trident Vitality	Mint and white tea	Maintain tooth	Cadbury North America
Bite-amins	Blend of B vitamins, garlic, *Echinacea*, vitamin C, quercetin, bromelain, curcumin and capsaicin.	Anti-mosquito pill	VitaPill LLC

Bio Serae Laboratories of France manufactures 'Serenzo certified Organic' which constitutes citrus extract and act as an anti-stress product, 'Resveravine' constitutes resveratrol and help in cardio-vascular protection and anti-ageing properties [www.bioserae.com/]. Shotz Health of UK prepares 'Big Shotz' from ginseng, prebiotics rich in MEG-3 brand omega-3 EPA/DHA [http://www.nutraceuticalsworld.com/].

Guangzhou Lohas Biological Technology Co. Ltd. of China produces 'Ginseng Kianpi Pil' using reishi extract, ginseng extracts, *Rhodiola rosea* extract as dietary supplement. [www.company.indiatradepage.com/].

An Indian company, for example La Casa Agrotech Private Ltd. manufactures 'Smrutihills' from Brahmi, Mandukparnee as nervine tonic for mind & memory. SAB Herbals & Nutraceuticals assembles 'Methoxsalen Xanthotoxin Calcium Sennoside' from phytochemicals used in treating psoriasis, eczema and vitiligo [www.hotfrog.in/Companies/].

Isha Agro Developers Pvt. Ltd. produces 'Imunohills' from amla, guduchi, gokshura, which promotes cellular & humoral immunity. Bio Bodyfuelz Ltd. prepares 'PWR Sports' from *Sida cordifolia* extract which helps to boost endurance and refreshes muscles and 'Fat Burner' from cocoa beans extract (6% Theobromine). Life Style Care produces 'Arctic Sea Super Omega' from olive oil, fish oil and is a rich source of omega-3 fatty acids and 'Forever Absorbent C' from bioflavonoids of oranges and papayas. Essential'z Energize Your Health manufactures 'Muscle Juice®™' from protein blend (whey protein isolate, whey potein concentrate, calcium caseinate and egg white albumin) which feeds and nourishes the muscles. Amrutam Life Care Private Ltd. prepares 'Obexi' from *Boerhaavia diffusa* and is an anti-obesity drug [www.trade.indiamart.com/]. USA manufactured products are mentioned below.

(**Table 5**).

Table 6: Regulatory Act(s) and issues of Asian countries

Country	Regulatory act	Regulatory issues	References
Japan	FOSHU(Food for specified health use),1991	Focuses on health claims for specific products	**43**
	Food with Health Claims (FHC),2001	Category of products expanded to include capsules and tablets	**44**
	Foods with Nutrient Function Claims" (FNFC),2005	Restricted to the specified nutrients having nutritional function claims in FHC	**44**
China	State Food and Drug Administration of China (SFDA), 2003	Oversees and coordinate the health, food, and drug agencies	**[www.gain.fas.usda.gov]**
	SFDA (State Food and Drug Administration,2005	Guideline of registration for functional foods was promulgated	**45**
	State Council Legislative Office (SCLO),2009	Regulates foods that have a functional or health claim associated with their use	**46**
India	The Food Safety and Standard Act (FSSA), 2006	Manufacture, sell or import of novel foods, GMF, irradiated food, organic food, and food for special dietary uses, functional food, nutraceuticals and health supplements	**47**
	The Food Safety and Standard Authority of India (FSSAI), 2008	Single reference point for all matters relating to food safety and standards	**47**
	Food Safety and Standards Rules and Regulations, 2009	More emphasis on science based and participatory decisions	**47**
	The Food Safety and Standard Authority of India (FSSAI), 2010	Implemented	**47**

Table 7: List of Regulatory Act(s) and issues in European countries

Country	Regulatory act	Regulatory issues	References
USA	Nutrition Labeling and Education Act (NLEA),1990	Nutrition labeling of most foods regulated by the Agency	**48**
	Dietary Supplement Health and Education Act (DSHEA),1994	Describe the role of a nutrient or a dietary ingredient in the normal structure or function of the human body	**[www.vm.cfsan .fda.gov/]**
	Food and Drug Administration Modernization Act (FDAMA),1997	Federal Food, Drug, and Cosmetic Act relating to the regulation of food, drugs, devices, and biological products	**49**
	Food Safety Modernization Act (FSMA),2011	Ensure safe US food supply by preventing contamination	**[www.fda.gov/]**
European union	Functional food science in Europe (FUFOSE),1996	Establish a science-based approach for concepts in functional food science	**50**
	Regulation EC no. 258/97,1997	Applies to GMP, foods and food ingredients	**51**
	Regulation (EC) No 1831/2003	For the authorizations of probiotics used as additives	**52**
	Directive 2004/24/EC	Medicinal claims are made based on its traditional use of herbs	**53**
	Regulation (EC) No 1924/2006	Establishes rules in labelling, presentation and the advertising of foods	**54**
	Regulation (EC) No 353/2008	Establishes implementing rules for health claims in Regulation (EC) No 1924/2006	**55**
	Regulation (EU) No 383/2010	Authorize food which reduces disease risk and children's health	**56**
Brazil	National Sanitary Surveillance Agency, ANVISA,2002	Check natural or synthetic substances having a demonstrated and physiologic activity	**57**
Canada	Canadian Food and Drugs Act and regulation,1953	Presented the definition of food	**58**
	Food Directorate of the Health Protection Branch of Health Canada,1996	Nutraceutical generally sold in medicinal forms not usually associated with food	**[www hc-sc.ca/]**
	Canadian Food and Drugs Act,2001	Describe foods with health benefits beyond basic nutrition	**[www hc-sc.ca/]**
	Natural Health Product Directorate (NHPD), 2003	Define nutraceutical	**[www.canadagazette.gc.ca/]**
Australia and New Zealand	Food Standards Australia New Zealand (FSANZ),1991	Develops food standards to cover the food industry in Australia and New Zealand	**[www.comlaw.gov.au/]**
	Australian Capital Territory- Food Regulations Act, 2002	Modification made in Food Act available in Parliamentary Counsel	**[www.legislation.qld.gov.au/]**
	Queensland - Food Act, 2006	Ensure food for sale is safe and suitable for human consumption	**59**
	New South Wales Government-Food Regulation, 2010	Regulation in food safety for food business	**59**

NUTRACEUTICAL REGULATIONS

Food regulation is aimed at protecting the consumer's health, increasing economic viability, harmonizing well-being and engendering fair trade on foods within and between nations. For nutraceutical industries, two challenges are apparent; regulatory uncertainty and credibility of

labeling claims [42]. The food sector in India has been governed by multiple laws enacted at different points of time to complement and supplement each other. 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. Following pressure from the industries 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 [6]. Regulatory acts and issues are divided into two groups: Governed by Asian countries (**Table 6**) [43-47] and European countries (**Table 7**) [48-59]

CONCLUSIONS

Nutraceuticals can provide substantial health benefits especially in the prevention and/or treatment of acute and chronic human diseases. But its development depends upon its quality, safety, long-term adverse effects, and toxicity as well as supplementation studies and clinical trials in humans. Attempts are made to avoid genetic disorders using nutraceuticals in form of enzymes, probiotics and fortified food. Commercial nutraceuticals have to pass through strict regulatory controls to provide a positive impact on an individual's health.

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