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NUTRACEUTICALS AND FUNCTIONAL FOODS

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1. Introduction

Hippocrates (father of modern medicine) has raised the statement "Let food be the medicine, the medicine shall be the food" has increased the consumers as well as food and nutrition scientist attention towards the health advantages of certain foods (El Sohaimy, 2012).Sometimes the terms nutraceutical and functional food are misinterpreted to be one and the same, however difference exists between the two terms. Nutraceuticals derived from biologically active substance that provides benefits to health, usually in supplement form, whereas functional foods deliver its benefits in food form only.

During 1980's of Japan, the term functional foods was came into existence for improving the nutritional quality and enhancing the life span of old age people in order to save or to control the healthcare costs. As per the norms of European Food Information council, biologically active substance should be present in the functional foods for the health well-being (Anonymous, 2006) which may be health food, fortified/enhanced/ enriched products, dietary supplements and altered products.

In 1989, Stefen De Felice introduced the term nutraceuticals from the two words, namely nutrition and pharmaceutical. He illustrated that nutraceuticals are the food/food ingredient that offers medical or salubrious advantages, which includes prohibition and/or provides treatment to cure disease (El Sohaimy, 2012). They can be taken as capsules, pills and tinctures. Nutraceutical includes different kinds of products such as dietary supplements, functional beverages, genetically engineered foods, herbal/protein/minerals/vitamins supplemented products and other processed products. Shahidi (2009) emphasized that food or a part of food used for derivation of nutraceuticals and functional food. These might be similar to the conventional food in appearance. While, nutraceuticals are usually considered to be purified or isolated form of foods which available as medicine in market (Health Canada, 1998).

For development of novel nutraceuticals products and functional foods, different kinds of natural plant sources (fruits and vegetables, herbs, cereals) (Johanningsmeier and Harris, 2011and Harbourne *et al.*, 2013), mal sources such as dairy products, meat, eggs, animal foods (Mestre Prates and Cristina Mateus, 2002), marine sources such as crustaceans, fish and fish waste, microalgae, fungi, algae/seaweed and cyanobacteria/ extremophiles (Freitas *et al.*, 2012) which have biologically active substance may be utilized to fight against cancer, chronic disease, neurodegenerative diseases and other health related diseases.

2. Difference between nutraceutical and functional foods

Basically, health and nutrition promoting foods are described by two terms as nutraceuticals and functional foods. Nutraceuticals are the isolated, purified and formulated healthful products which are taken in capsules, tinctures, or pills/tablets forms and available in market as medicinal forms and usually not integrated with foods. Whereas as, functional foods are taken as regular foods as a part of uncommon diet and not in the form of dose (Hasler, 1998) which provides physiological benefits beyond basic nutrition function (Peter, 2002). According to Otles and Cagindi (2012) nutraceuticals are related to medical claims which prevent as well as cure the disease which involves dietary supplements and other kinds of foods, however, functional foods are involved ordinary foods which only decline the disease not prevent and cure the disease.

Essential nutrient (vitamins, proteins, fats, carbohydrates, etc.) required by body for its healthy survival is called as functional foods. When functional food acts as means for prevention and/or curing of any disease/ disorders other than anemia, it is called a nutraceuticals (Kalra, 2003).

3. Functional foods and their bioactive components

Functional foods contain number of bioactive compounds found

in, or resulted from source of plant (fruits and vegetables), marine, animal that provides relevant health benefits. Table 1 preset the different functional food components extracted from different sources with its potential health benefits.

Functional food components	Food Source	Health benefits
Carotenoids		
β (Beta)-carotene	Carrots, cantaloupe, kale, papaya, pumpkin, sweet potatoes, spinach, tomatoes, mango	 May protect the body from free radicals which damage cells through oxidation May slow down cognitive decline May lower the risk of developing cancer or heart disease
Lutein, Zeaxanthin	Asparagus, broccoli, carrots, citrus fruits, corn, collards, eggs, green beans, green peas, leaf cabbage, romaine lettuce, spinach, turnip greens	• May decrease possibility of chronic eye diseases (age related macular degeneration and cataracts)
Lycopene	Tomatoes as well as its processed products, gac, watermelon, red/pink grape fruit, guava, papaya, red cabbage, mango, carrots	 May slow down breast and prostate cancer growth by disturbing signal pathways which usually helps in faster growth of tumors May protects eyes from oxidative stress May reduce neuropathic pain
Dietary (functional an	nd total) Fiber	
Soluble fiber	Apples, barley, beans, carrots, citrus fruits, oats, peas, psyllium seed husk	 May slow down the level of total blood cholesterol May helps to reduce the blood pressure as well as inflammation May provides healthy bowel movements
β (Beta) glucan	Barley, rye, Oat and its products such as bran, flour, meal	 May lower cholesterol and triglycerides May reduce possibility of developing diabetes (type 2) May stimulates immune system

Table 1. Functional components, source and its health benefits

Insoluble fiber	Flour (whole wheat), bran (corn, wheat), nuts, fruit skins, vegetable (Potatoes, cauliflower, green beans)	May helps in maintaining healthy digestive tractMay decrease possibility of breast or colon cancer
Whole grains	Buckwheat, bulgur, cereal grains, bread (whole wheat), rice (brown, wild), oatmeal, whole rye, triticale, millet, sorghum, quinoa	 May decrease chances of coronary heart disease (CHD) and gastrointestinal cancers as well as several hormone-dependent cancers May reduce the risk of diabetes and maintain the healthy blood glucose levels May contribute to maintain as well as to achieve a healthy weight
Fatty acids		
Monounsaturated fatty acids (MUFAs)	Red meat, whole milk products, olives and avocados. Olive oil, Tree nuts, canola oil, macadamia nut oil, grapeseed oil	• May reduce risk of CHD, healthier serum lipid profiles
Omega/w/n-3 fatty acid (α-Linolenic acid)	Walnuts, oil (flaxseed, canola, Echium, hemp)	 Anti-inflammatory and anti- clotting effects May improve eye as well as heart health May help to maintain mental function
Long chain Omega/ w/n-3 fatty acids (DHA/EPA)	Algal oil, fish oil, fatty fish (tuna, salmon and other)	 May reduce possibility of CHD, autoimmune diseases, such as rheumatoid arthritis May improve an infant's cognitive as well as visual development
Conjugated linoleic acid	Cheese, beef, meat items, some mushroom species (Agaricus bisporus, Agaricus subrufescens)	May acts as body building aidMay improve immune health as well as body composition
Flavanoids		
Anthocyanins (Cyanidin, Delphinidin, Malvidin, Pelargonidin)	Fruits, tomato, kidney beans, beetroot	 May improve cholesterol levels and blood sugar metabolism May helps to prevent high blood pressure and breast cancer

		• May protect the body from free radicals which damage cells through oxidation
Flavanols (Catechins, Epicatechins, Epigallocatechin)	Apples, blueberries, pears, tea	May provides protection to body against free radicalsMay promote strong blood vessel function
Procyanidins and Proanthocyanidins	Apples, cranberries and its products, cocoa, grapes, cinnamon, tea, strawberries, chocolate	• May helps in the improvement of urinary tract as well as heart well-being
Flavanones (Hesperetin, Naringenin)	Citrus	 May protect the body from free radicals which damage cells May decrease the possibilities of certain kinds of diseases (cancer as well as chronic) May prevent some cardiovascular disorder May prevent human platelet aggregation
Flavonols (Quercetin, Kaempferol, Isorhamnetin, Myricetin)	Apples, broccoli, buckwheat, kale, onions, tea	 May protect the body from free radicals which damage cells through oxidation May reduce the possibilities of certain disease (cardiovascular disease chronic disease and CHD)
Isothiocyanates		
Sulforaphane	Broccoli and its sprouts, cabbage, cauliflower	 May helps in the purification of unwanted compounds May boosts the antioxidant capacity of cells May protect against cardiovascular and neuro- degenerative diseases May prevents and combats cancer
Minerals		
Calcium	Leafy vegetables, low-fat dairy products, fish, foods and drinks enriched with calcium	 May strengthens bones as well as decrease the chances of osteoporosis May helps in maintaining the optimal body weight

		•	May decrease the chances of colon cancer and kidney stones
Magnesium	Spinach, prickly pear, salmon, pumpkin seeds, cereal (all bran), almonds, brazil nuts, beans	•	May improve bone health May boost the immune health May lowers the anxiety and stress
Potassium	Potatoes, sweet potatoes, banana, tomato sauce without addition of sugar and salt, tuna, low-fat dairy products, citrus juices, beans, leafy greens	•	May protect against cardiovascular disease May regulates blood pressure May boost brain function
Selenium	Seafood, red meat, whole grains, garlic, liver, eggs, legumes (beans and peas), nuts	•	May prevent new free radicals formation by participating in various cellular reactions May helps in the improvement of immune as well as prostate health
Phenolic acids			
Caffeic acid and Ferulic acid	Apples, citrus, pears, plums, kiwis, onions, some vegetables whole grains, coffee	•	May prevent cellular damage by free radical May improve health of eye as well as heart
Plant stanols/sterols			
Free Stanols/Sterols	Corn, fortified foods and beverages, soy, wheat, wood oils,	•	May decrease the level of cholesterol
Stanol esters/Sterol esters	Dietary supplements, enriched foods and beverages	•	May decrease the chances of CHD
Polyols			
Sugar alcohols (Sorbitol, Xylitol, Maltitol, Isomalt, Mannitol, Lactitol, Erythritol	Chewing gums, frozen desserts, baked goods, hard candies and other food applications	•	May prevent tooth decay May reduce calories which helps in weight management
Prebiotics			
Fructo oligosac charides (FOS), Inulin, Polydextrose	Asparagus, bananas, chicory roots, garlic, honey, whole grains, onions, leeks	•	May helps in the improvement of gastrointestinal health May increase the absorption of calcium and magnesium

Probiotics		
Yeast, <i>Lactobacilli</i> , <i>Bifidobacteria</i> and other specific strains of beneficial bacteria	Yogurts and cultured dairy products, sauerkraut, tempeh (fermented soybean product)	• May modify the immune response and improves its barrier function
Phytoestrogens		
Isoflavones–Daidzein, Genistein	Soya bean as well asits products	 May strengthens bones May reduce total and harmful cholesterol Maintain or may increase beneficial cholesterol May improve menopausal health for women
Lignans	Flaxseeds, rye, whole grain, sesame and sunflower seeds, cashews, kale, broccoli, cauliflower, carrot	May improve heart and immune healthMay lower the risk of cancer
Soy Protein		
Soy Protein	Soybean as well as its products (roasted nuts, milk, cheese, tofu, yogurt)	May improve heart healthMay prevent breast cancer
Sulfides/Thiols		
Diallyl sulfide, Allyl methyl trisulfide	Garlic, leeks, onions, scallions	 May helps in the detoxification/purification of unwanted compounds May reduce risk of blood clots as well as heart disease May reduce cholesterol
Dithiolethiones	Cruciferous vegetables	May acts as a potential cancer chemopreventive agentsMay improve immune function
Vitamins		
A	Organ meats, milk, eggs, carrots, sweet potato, spinach, liver, oranges, pears	May improve the health of eye, immune, bone and skinMay contributes to cell integrity
B1 (Thiamin)	Cereal grain, legumes, meat, pork	 May improve mental function May helps to regulate metabolism May keeps nervous system healthy

B2 (Riboflavin)	Fish, dairy products, meat and legumes	• May increase growth of cell growth
B3 (Niacin)	Dates, fish, egg, meat, peaches, nuts	 May promotes healthy nervous system and energy metabolism May increase growth of cell growth May helps in there gularization of metabolism
B5 (Pantothenic acid)	Yolks, liver, peanuts	• May supports to stabilize metabolism as well as hormone synthesis
B6 (Pyridoxine)	Chickpea, meat, beef liver, potatoes, nuts, banana, fish	 May improve immune health May helps to maintain healthy metabolism, liver and nerve function as well as boost the energy level
B9 (Folate or folic acid)	Citrus, asparagus, broccoli, beans, legumes, green leafy vegetables, okra, carrots, celery	 May helps in prevention of neural tube defects May helps against anemia, indigestion abnormal brain growth, skin disorders
B12 (Cyanocobalamin)	Eggs, meat, cheese, poultry, shellfish, milk	• May helps in the regularization of metabolism as well as increase the formation of blood cell
Biotin	Almonds, eggs, nuts, legumes, liver, salmon, dairy products, oysters	 May helps in treating skin disorders May helps to regulate metabolism and boost hair growth
С	Citrus, guava, kiwi, kale, sweet red/green pepper, papaya, broccoli, parsley, pineapple, brussels sprouts	 May helps to treat eye disorders, scurvy, diabetes. May helps in the neutralization of free radicals May enhanceresistive power of body
D	Fatty fish, egg yolks, sunlight, milk	May prevents osteoporosis, diabetes, arthritis, tooth decay.May boost immunity and lower down blood pressure

Е	Spinach, dandelion greens, avocado, hazelnuts, sunflower	•	May improve blood circulation, skin care
	seeds, almonds	•	May improve heart health May boost immunity

Ref: Anonymous, 2009

A. Antioxidants

Antioxidant is a substance which helps in inhibiting or delaying the oxidation of other bioactive substances. Chemical reaction cause oxidation which may sometimes generate reactive substances (free radicals) leading to oxidative stress or cell damage. They exist in foods in the forms of minerals, vitamins, carotenoids and polyphenols. Unique colour is a main identification mark of antioxidants. Cherries, tomato are usually identified by its deep red colour, carrots by its orange colour, mango, saffron, corn by its yellow colour, grapes and blueberries by its purple colour. Vitamins A, vitamin C, vitamin E, β -carotene, lycopene and mineral selenium are mostly known for its antioxidant activities in the foods. Lycopene is a carotenoid pigments which is responsible for red-orange colour of food and found abundant in tomato (1.21-6.43 mg/100g), watermelon (2.28-5.37 mg/100g), red grapefruit (2.81-4.22), papaya (2.27-3.54 mg.100g) and dried apricot (0.55-1.22 mg/100g) (Wawrzyniak, 2005). Also, concentrated tomato products (paste, ketchup, sauce) are also suggested as good source of lycopene for consumption (El Sohaimy, 2012). Furthermore, cooked tomato products contain more lycopene content than raw tomato products (El Sohaimy, 2012).

B. Dietary Fibre

Dietary fiber occurs in the form of insoluble or soluble fiber in the plant that resists human digestive enzymes. Dietary fiber mainly classifies in two forms: soluble fiber and insoluble fiber. Edible part of plant food is nothing but soluble fiber which is resistant to digestion and absorption in the small intestine. Due to the action of colonic bacteria, as passing through the large intestine (colon), fermentation process occurs. On the contrary, insoluble fiber is made up of the structural material of cell wall of plant foods. Dietary fibers include cellulose, hemicellulose, pectin substances, lignin, gums and non-digestible carbohydrates that are occurred in cereals (rice, wheat), millets (sorghum, pearl millet, finger millet), pulses and legumes (whole greengram and bengalgram, dhal of greengram, blackgram, redgram and bengalgram), nuts and oilseeds (groundnut, dry coconut), fruits and vegetables (banana, mangoes amaranth, spinach, ridge gourd, brinjal,

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snake gourd, pumpkin, bottle gourd), roots and tubers (potato and sweet potato). Intake of dietary fiber in healthy adults should be in the range of 35-40 g/day. It observed that women consumed less amount of dietary fiber (15-30g/day) and much smaller about 15-19 g/day in tribal population (Singh and Singh, 2015).

It is suggested that healthy adults should eat between 35-40 g/day dietary fiber in small amounts but at regular intervals. Also, the intake of dietary fiber is low in females (15-30 g/day) and much lesser in tribal population (15-19 g/day) (Singh and Singh, 2015). Dietary fiber content in the Indian raw foods is listed in Table 2.

Food items	CF	TDF	SF
Cereals			
Rice	0.2	4.11	0.92
Wheat	0.3	12.48	2.84
Millets			
Pearl millet	1.2	11.33	2.19
Maize	2.7	11.54	1.65
Jowar	1.6	9.67	1.64
Finger millet	3.6	11.85	0.89
Pulses and legumes			
Lentils	0.7	10.31	2.04
Bengalgram dhal	1.2	15.3	2.56
Pigeonpea (Cajanus cajan)	0.9	9.14	2.33
Mugbean dhal	0.8	8.23	1.69
Fruits			
Apple	1.0	3.2	0.9
Banana	0.4	1.8	0.7
Tomato	0.8	1.7	0.5
Orange	0.3	1.1	0.5
Vegetables			
Amaranth	1.0	4.0	0.9
Cabbage		2.8	0.8

Table 2. Content of dietary fiber in some Indian foods

Cauliflower	1.2	3.7	1.1	
Eggplant	1.3	6.3	1.7	
Guar	3.2	5.7	1.6	
Okra or okro	1.2	3.6	1.0	
Palak	0.6	2.5	0.7	
Roots and tubers				
Carrot	1.2	4.4	1.4	
Onion	0.6	2.5	0.8	
Potato	0.4	1.7	0.6	

Values are in g per 100g of food, CF: Crude fiber, TDF: Total dietary fiber, SF: Soluble fiber

Ref: Singh and Singh, 2015

C. Omega -3 fatty acids

Omega/ ω /n-3 fatty acids, mainly involved α -linolenic acid (ALA) observed in oil extracted from plant and eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) detected in oil extracted from fish, aquatic animals. They are able to protect heart disease by decreasing the occurrence of arrhythmias and reducing the serum triacylglycerols levels (Mishra *et al.*, 2013). Now-a-days, flaxseed becomes more popular for containing n-3 fatty acids specifically ALA, lignin and protein hydrolysates. Oil removed from flaxseed plant seeds known as polyunsaturated oil is contains large amount of ALA (around 54-57% of its weight of total fatty acids). Other useful oils such as gamma-linolenic acids beneficial for skin diseases, premenstrual pains and conjugated linoleic acid (CLA) is available in meat or dairy products. CLA reduces the development of adipose fat. For instant energy source, medium chain fatty acid containing oils and foods are used. Table 3 showed the recommended daily dose of ω -3 fatty acids.

Table 3. Guidelines for daily dose of omega-3 fatty acids

Hea	lth agencies/organisation	Recommended daily dose
•	World Health Organization	0.7 g/day
•	Indian Council of Medical Research	1.6 g ALA/day (male), 1.1g ALA/ day (female) and >250 mg EPA & DHA/ day
•	British Nutrition Foundation Task Force	1.0-1.5 g/day

•	U.K. Department of Health	0.2 g/day (common population)
•	European Academy of Nutritional Science	0.2 g/day (common population)
•	American Heart Association	0.5-1.0 g/day

Source: Garg et al., 2006; ISSFAL 2004; ICMR 2010

D. Phytosterols and phytostenols

Phytosterols are structurally and functionally similar to cholesterol but possess different side chain configuration (Fernandes and Cabral, 2007). Phytosterols exist in two forms such as free form (represents cellular wall which shows the structural functions) and esterified form (represent the storage products within the cell).Saturated plant sterol derivatives are termed as plant stanols or phytostanols and can be obtained by the hydrogenation of sterols. Availability of such sterols is not abundant in nature. Human body can't synthesize phytosterols and phytostanols and hence they are derived from dietary sources. The consumption of phytosterols and phytostanols reduces the cholesterol absorption in the body and improves the circulation of lipids. Daily intake of 2-3 g (approximately) of phytosterols/phytostanols showed maximum effects (Anonymous, 2018).

E. Probiotics and Prebiotics

Living microorganisms are known as probiotics which offer health benefits when taken in sufficient amount (Anonymous, 2002). Probiotics helps to resolve the problem related to digestion, respiration, immunological, transmittable disease in kids and high-risk group people. They can be found in both supplement form or as components of foods and beverages. To be used as food material, probiotic microorganisms should possess capability to survive, multiply in the gut as well as in the intestine containing bile, resistance power against gastric juices.

Prebiotics is non-digestible dietary components that goes via small intestine undigested and fermented while reaching the large colon improving digestive system. The most common example of prebiotic is fructooligosaccharides, whereas non-starch polysaccharides, plant wall polysaccharides, pectins are not necessarily prebiotic agents, but most are classified as dietary fiber. All fiber is not prebiotic and all prebiotic is not fiber, but the common things in the fiber and prebiotics is that neither is digestible by human enzymes (Floch, MH, 2014). The product which contains both prebiotic bacteria and probiotic bacteria is called as 'synbiotic' which act together in a synergistic way more effectively.

4. Nutraceuticals and functional foods market in India

The rapidly increasing consumer awareness towards salubrious foods have entered functional foods into the global markets with force in past decades and rapidly gained market share. Nutraceuticals market containing dietary supplements, sports and energy drinks/products, body building aids and weight loss products is growing extensively. About 93% of global nutraceuticals market is concentrated in United States, Europe and Japan with the valued at \$160.6 billion in 2013, raiseto \$171.8 billion in 2014. The market is expected to reach \$241.1 billion by 2019 with 7.0% compound annual growth rate (CAGR) from 2014 to 2019 (Anonymous, 2015).

The health and fitness consciousness of consumers, readiness of people to payfor health foods and additives are resulted in rapidly growing the popularity and growth of nutraceuticals and functional market in India. The Indian nutraceuticals market can be categorized broadly into dietary supplements (32%), functional food and beverage (68%) (Fig. 1) (Anonymous, 2015). Nowadays, the Indian market of functional foods and beverages is emerging, mainly due to the existing belief and dependence on Ayurveda and traditional knowledge by quantum of growing middle class people, which increases country's buying power. The market of nutraceutical is of worth around USD 2.2 billion. Nutraceutical market has its dominance in south part of country like Tamil Nadu and Andhra Pradesh followed by West Bengal and Eastern states.

In India, nutraceuticals market is predicted to expand at 20% to \$ 6.1 billion by 2019-2020. The market of fortified foods is also projected to expand swiftly with a CAGR of 21.7% by 2018 (Rajagopal, 2014). About 36% of neutraceutical market in India is dominated by vitamins and minerals, followed by a share of 9.0% by probiotic, while 5.0 per cent market share is dominated by ω -3 fatty acids.

DSM, BASF and Merckruled vitamins, minerals market. Also, DSM dominates the market related to w-3 fatty acids. In contrast, probiotic market is dominated by Danisco, Chr. Hansen, and Yakult.

5. Motivators of nutraceuticals and functional foods market

According to the reports of U.S. state department and United Nations department of economic and social affairs (2013), 8% fraction of the world population are over 65 years of age and this fraction will increase





to about 13% by 2030. Such population is more in developing countries rather than developed countries (Daliri and Lee, 2015). Apart from this, due to the ever increase in the price of health care, researchers, health professionals and food industry are eager to come out some sort of remedies so that the things can be managed effectively. The rising chances of obesity, diabetes, eye-health issues, increase in cardiovascular diseases, transforming food consumption patterns in developing markets, increasing liking for preventive medicine, enhancing popularity of nutraceuticals containing organic/natural components, demand for multivitamins and ingredients like omega 3s and astaxanthin are the key factors for uplifting of the market of nutraceutical and functional food (Zawistowski, 2014). Nutraceuticals enriched with conjugated linoleic acid (CLA) soy, whey and dietary fibers are helpful in weight management, cardiac care, immunity and digestive health and are hence popular. The awareness of products having ample bioavailability of health beneficial constituents is regularly increasing among the consumers. Liquid nutraceuticals like enhanced water, energy juice, sports drink as well as liquid dietary supplements, oral powder, liquid suspensions, oxygenated water, nutrient enhanced vitamin water, ready-to-drink (RTD) beverages, liquid shooters, liquid shots, antioxidant berry juice blends, omega 3 oils and essential oils present substantial growth prospects (Bourne Partners, 2013).

6. The future of nutraceuticals and functional foods

Currently more focus in terms of research has been initiated to increase our understanding and need of nutraceuticals and functional food. In this direction, government organization, food scientist, and private research institutes are working substantially. Basically, the efforts are concentrated towards identification of different functional foods and its mechanism which help or prevent chronic disease or optimize health and ultimately reduce the cost of healthcare, which indeed help in reduction of healthcare costs.

Emerging area of research namely 'nutrigenomics' has attracted the food nutritionists worldwide. Nutrigenomics establish a relationship between specific nutrients and specific nutrient diets based on an individual's genotype which have greater impact on future research and development in functional foods. It modifies the diet plant according to genetic profile of individual. Food biotechnology is another emerging field that will have a great impact on the future of nutraceutical and functional foods. With the help of modern techniques of biotechnology, composition of food can be altered e.g. golden rice enriched with β carotene and rice fortified with iron (Institute of Food Technologies, 2000). Consumption of fortified/enriched grains helps in preventing diseases such as ischemia caused by iron and blindness due to vitamin A deficiency. Addition of nutritious or non-nutritious ingredients in the food might benefit in inhibiting the diseases related to cancer, diabetes, bone or heart (Falk *et al.*, 2002).

There is a seven-step procedure that emphasized important things need to focus in development as well as marketing of functional foods is presented in Fig. 2 (Mishra *et al.*, 2013):

1	Identification of relationship between functional food components and its health benefits
2	Demonstration of bioactive components effectiveness and determination of intake level to achieve desired effect
3	Safety demonstration at efficacious levels consider prior GRAS and/or food additive use, assess safety if component is new to food use and address potential allergenicity, if necessary
4	Development of suitable food vehicle for the bioactive component such that it is appropriate for the intended consumer and delivers the bioactive ingredient at the desired level.
5	Demonstrate scientific sufficiency of the evidence for efficacy includes conduct independent peer review via GRAE panel, submit evidence to FDA for claim approval, if necessary.
6	Communicate benefits to consumers includes public understanding of foods, food components, and dietary supplements and its benefits, communicate with accuracy and balance, follow the guidelines of International Food Information Council with IFT and other association
7	Conduct in- market surveillance to confirm efficacy and safety includes monitor efficacy, monitor intake and safety.

Fig 2. Seven-step procedure for bringing or introducing nutraceuticals and functional foods to market

7. Safety concern in the development of nutraceuticals and functional food

Although, nutraceuticals and functional foods play prominent character in the inhibition of specific diseases as well as provides health benefits, but the necessary safety standards must be maintained for consumers under all conditions of use. Manufacturing companies prepare functional foods basically for particular people (e.g. suffering from high level of cholesterol) and in a precise quantity (quantity indicated in a health claim report) people can utilized the food in different means. Other members of the family (children, old age persons, pregnant or lactating women or persons who are under medications) may also be served. However, maintaining of safety level in a way that even if they consume more of such foods than normal amounts, the risk is minimal. It is misguided to add the ingredients into functional foods which are unsafe for all groups of people. Additional of herbal ingredients into functional foods is an illustration of this problem. The safety appraisal will change depending upon the levels (macronutrient or micronutrient) of added component. Also, the requirement is subjected to the active component effect as well as its lethal effects.

8. Health related claims

Health claims define a relationship among a food, its component, disease orhealth associated condition. Health claims are established on the basis of scientific report of high standard and important scientific agreement (Hasler, 2008). Currently, three types of health related used which includes health claims (define the relation between diet and disease), nutritional claims (define the level of a nutrient or dietary ingredients in food products by mentioning free, high and low or comparing the level of a nutrient in a food to that of another food, using terms such as more reduced etc.) and structural/functional claims (describe the health-promoting or nutritional benefits allowed on dietary supplement label).

The success of a nutraceuticals and functional foods can depend to a large extent on the regulatory framework in which it is allowed to be marketed. From country to country, the method of regulating the composition and labeling of food varies extremely. In India, nutraceuticals are generally labelled as food for special dietary use which includes extracts from plants and animals, minerals, vitamins and proteins. Food Safety and Standard Act (2006) controls nutraceuticals and functional foods manufacturing and marketing.

9. Challenges in development of nutraceuticals and functional foods

Developing nutraceuticals and functional food involves an expensive, lengthy and tedious procedure because it faces difficulty in getting country regulations and health claim proof, innovative food products from food companies. Traditionally, food companies have funded research regarding formulation of a new and novel product, but in the case of functional food, the risks are higher for food companies as well as consumers. Exclusive ingredients may be used in the preparation of functional and nutraceutical products whose rights can be documented in the form of patent, however, "free" ingredients are present in maximum products which copied effortlessly leads to the limited competitive benefits to the inventor company (Daliri and Lee, 2015). Moreover to get the scientific evidence to prove claim of health benefits is really difficult task. Also, difficulty in recognizing the biological markers forwell-being or risk reduction, longer time for clinical studies, difficulty in searching of powerful evidence of effective dose while antagonistic results often require additional studies, difficulty in health claim substantiation creates problem in the development of good new product. Hence, the food companies have dependency on physiological factors like bioavailability, molecular interactions that control biological functions, or age-related physiology and many other factors. Currently, only few products like the Nestle's LC1 or Benecol from Raisio, bifidogenic yogurt and phytosterol-based margarine are clearly stoodin market on health benefits with scientific proof. The maximum food companies are working only on development of "functionalize" conventional product by addition of some minerals, vitamins, or herbal extracts, in place of developing new food products which helps to give common health benefits. Despite all this difficulty, the functional foods and nutraceutical market is still growing.

10. Epilogue

Functional foods contain many physiologically active ingredients extracted from plant/animal sources and are beneficial for human wellbeing. Nutraceuticals and functional foods can collectively counter on the growing burden of the health care system by endorsing prevention rather than treatment. Moreover, it is a matter of challenge to recognize suitable bioactive substances and identify their role in prevention of many diseases. It is mandatory to demonstrate the potential health benefits of the foods for which the health-diet relationships are not appropriately validated in a scientific manner. Such foods adhere good potential to be included as an important component of a healthy lifestyle and hence to the food industry.

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