



NUTRACEUTICALS: VARIOUS FUNCTIONS & APPLICATIONS

Anjali Sharma†, Saxena Nidhi

Faculty of Pharmaceutical Science, Jayoti Vidyapeeth Women's University, Jaipur, Rajasthan, India.

ARTICLE INFO

Short Review Article History

Received: 11 August, 2015

Accepted: 12 October, 2015

Corresponding Author:

†Anjali Sharma

Faculty of Pharmaceutical Science,
Jayoti Vidyapeeth Women's
University, Jaipur, Rajasthan, India.

Mail ID: anjali18oct@gmail.com

ABSTRACT

Nutraceutical can be defined as, "a food (or part of a food) that provides medical or health benefits, including the prevention and/or treatment of a disease". However, the term nutraceutical as commonly used in marketing has no regulatory definition. Nutraceuticals must not only supplement the diet but should also aid in the prevention and/or treatment of disease and/or disorder. India is the world's second largest producers of fruits and vegetables but only a small amount of perishable agriculture products are processed approximately 2% in comparison of 80% in US. Barriers to growth on food sector include poor infrastructure and logistic and tight food regulation. The Food Safety and Standard Act 2006 aims to establish a single reference point for all matters relating to Food Safety and Standards, by moving from multi-level, multi-departmental control to a single line of command. There is currently no official harmonized definition or harmonization of the technical requirements and guidelines for functional food products in Asia. Academics and food companies generally understand functional foods to contain or to be fortified with nutrients or other bioactive compounds that help to maintain and promote health.

Keywords: Nutraceutical, Health, Foods, Protein, Act

© www.albertscience.com, All Right Reserved.

INTRODUCTION

The term "nutraceutical" was coined from "nutrition" and "pharmaceutical" in 1989 by Stephen DeFelice, MD, founder and chairman of the Foundation for Innovation in Medicine (FIM), Cranford, NJ. According to DeFelice, nutraceutical can be defined as, "a food (or part of a food) that provides medical or health benefits, including the prevention and/or treatment of a disease". However, the term nutraceutical as commonly used in marketing has no regulatory definition [1-2]

Main proposes is to redefine functional foods and nutraceuticals. When food is being cooked or prepared using "scientific intelligence" with or without knowledge of how or why it is being used, the food is called "functional food." Thus, functional food provides the body with the required amount of vitamins, fats, proteins, carbohydrates, etc, needed for its healthy survival. When functional food aids in the prevention and/or treatment of disease(s) and/or disorder(s) other than anemia, it is called a nutraceutical. (Since most of the functional foods act in some way or the other as anti-anemic, the exception to anemia is considered so as to have a clear distinction between the two terms, functional food and nutraceutical.) Thus, a functional food for one consumer can act as a nutraceutical for another consumer. Examples of nutraceuticals include fortified dairy products (e.g., milk) and citrus fruits (e.g., orange juice) [3-5].

The DSHEA formally defined "dietary supplement" using several criteria. A dietary supplement [3-6]:

- is a product (other than tobacco) that is intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients.
- is intended for ingestion in pill, capsule, tablet, or liquid form system.
- is not represented for use as a conventional food or as the sole item of a meal or diet.
- is labeled as a "dietary supplement."
- includes products such as an approved new drug, certified antibiotic, or licensed biologic that was marketed as a dietary supplement or food before approval, certification, or license (unless the Secretary of Health and Human Services waives this provision).

Thus, nutraceuticals (as per the proposed definition) differ from dietary supplements in the following aspects [3-6]:

- Nutraceuticals must not only supplement the diet but should also aid in the prevention and/or treatment of disease and/or disorder.

- Nutraceuticals are represented for use as a conventional food or as the sole item of meal or diet.

A ray of "cure preference" in the mind of common patients revolves around nutraceuticals because of their false perception that "all natural medicines are good." Also, the high cost of prescription pharmaceuticals and reluctance of some insurance companies to cover the costs of drugs helps nutraceuticals solidify their presence in the global market of therapies and therapeutic agents. The use of nutraceuticals, as an attempt to accomplish desirable therapeutic outcomes with reduced side effects, as compared with other therapeutic agents has met with great monetary success [4, 5]. The preference for the discovery and production of nutraceuticals over pharmaceuticals is well seen in pharmaceutical and biotechnology companies. Some of the pharmaceutical and biotechnology companies, which commit major resources to the discovery of nutraceuticals include Monsanto (St Louis, MO), American Home Products (Madison, NJ), DuPont (Wilmington, DE), Abbott Laboratories (Abbott Park, IL), Warner-Lambert (Morris Plains, NJ), Johnson & Johnson (New Brunswick, NJ), Novartis (Basel, Switzerland), Metabolex (Hayward, CA), Genzyme Transgenic, PPL Therapeutics, Interneuron (Lexington, KY) [4-7].

However, with all of the aforementioned positive points, nutraceuticals still need support of an extensive scientific study to prove "their effects with reduced side effects. This

can be achieved by the enactment of FIM proposed Nutraceutical Research and Education Act (NREA) [8]. The NREA includes the creation of a Nutraceutical Commission (NUCOM) specifically for the review and approval of nutraceuticals and the creation of a nutraceutical research grants program specifically for clinical research. As per FIM, the key elements of NREA should include a mechanism to create the exclusive rights to claims necessary for private investment in research and development, and the creation of appropriate channels for the review, approval, and regulation of new products and claims. We believe that in so doing the NREA should keep in check the cost of nutraceuticals and thereby assure access for everyone [4-7].

CLASSIFICATION

Another method of grouping nutraceuticals is based upon their chemical nature. This approach allows nutraceuticals to be categorized under molecular/elemental groups. This preliminary model includes several large groups, which then provide a basis for sub classification or subgroups, and so on. One way to group nutraceuticals (figure 1) grossly is as follows [6-8]:

- Isoprenoid derivatives
- Phenolic substances
- Fatty acids and structural lipids
- Carbohydrates and derivatives
- Amino acid-based substances
- Microbes
- Minerals

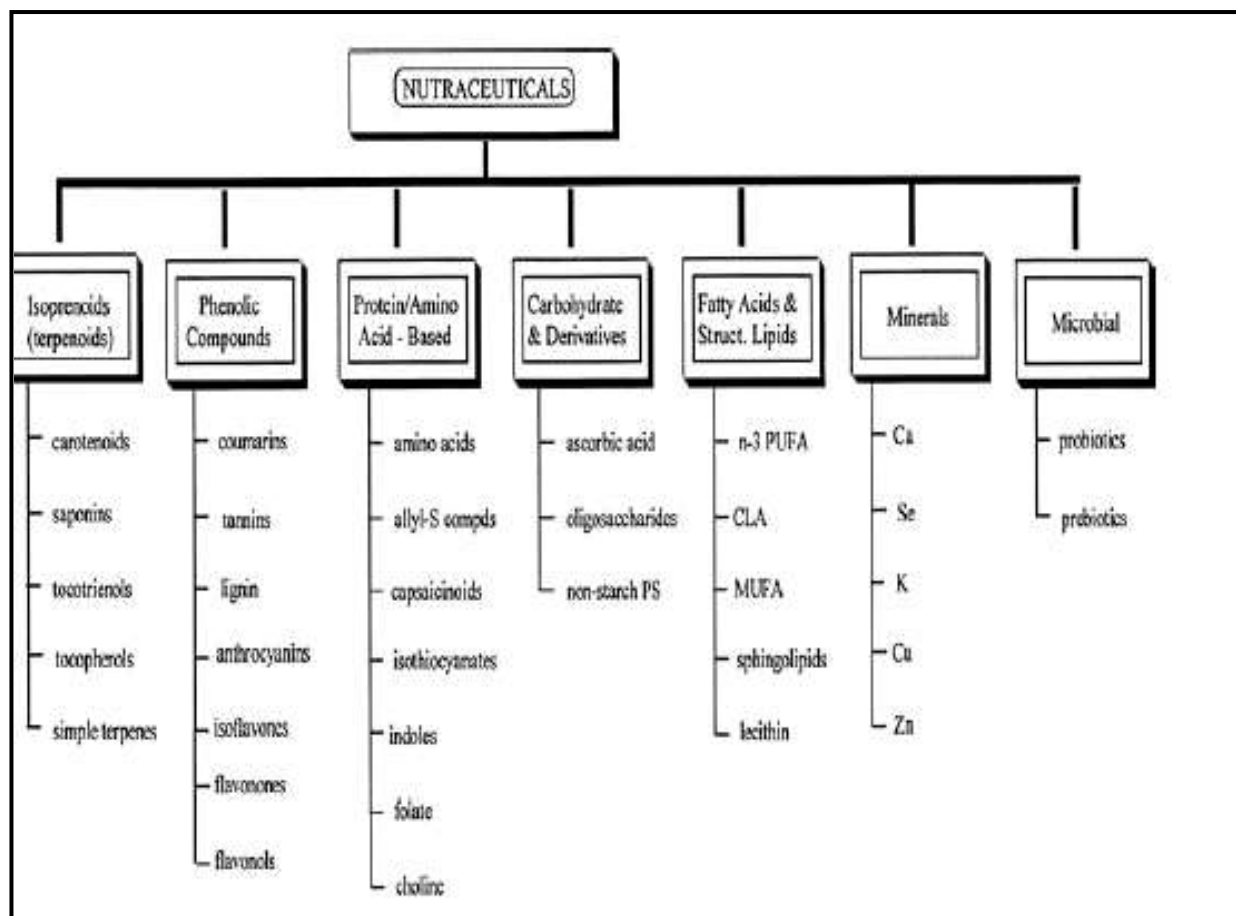


Figure 1: Organizational scheme for nutraceuticals

Law governing the nutraceuticals:

Functional Food is the generic term related for food that has been linked to health benefits. The Institute of Medicine's Food and Nutrition Board (U.S.) has defined functional food as "any food and food ingredients that may provide health benefit beyond the traditional nutrition that it contains". Functional food can be either from plant sources or animal sources. The term nutraceutical was coined in the USA and is used to describe foods or food components which have the potential to cure specific disease conditions [5-8]. Historically, in India multiple laws and regulation prescribed varied standards regarding food, food additives, contaminants, food colors, preservatives and labeling. India has recently passed food safety and standard act 2006 –a modern integrated food law to serve as a single reference point in relation to regulation of food products including nutraceutical, dietary supplements and functional food. The food safety and standard act has needed to still make considerably substantive with infrastructure and appropriate stewardship for it to match with international standards of U.S. and Europe. A significant augmentation is necessary for act to have magnitude of impact on India functional food and nutraceutical industry like the dietary supplements health education act (DSHEA) 1994 has had on dietary supplement industry in U.S. The passing of this Indian act is a significant first step; a lot more has to happen to eliminate the confusing overlap with old laws and regulations. Yet, in India functional foods/nutraceuticals are not categorized separately as in U.S, Europe, and Japan. And also, the concept of functional food is somewhat different connotations in different countries. In Japan, for example functional foods are defined based on their use of natural ingredients. In the United States however; functional food concept can include ingredients that are product of biotechnology. And in India these functional foods can include herbal extracts, spices, fruits, and nutritionally improved foods or food products with added functional ingredients. The present article deals with the history and present regulatory status of functional foods/nutraceuticals in India [5-9].

History of Food Regulation in India

India is the world's second largest producers of fruits and vegetables but only a small amount of perishable agriculture products are processed approximately 2% in comparison of 80% in US. Barriers to growth on food sector include poor infrastructure and logistic and tight food regulation. The multiplicity of food regulation policy makers and enforcement agencies prevailing in different sectors of food industry contributed to considerable confusion among the consumers, producers, and retailers and business and such a detrimental to growth of functional food and nutraceutical industry [7-10].

By the mid 1990s the food processing sectors laws framed in a veritable grid of regulation including a multitude of states law as well as following national laws [7-10]:-

- Export (Quality Control and Inspection) Act 1963

- Solvent Extracted Oil Control (SEO) Order 1967
- The Insecticide Act 1968
- Meat Food Products Order MFPO 1973
- Prevention of Food Adulteration Act (PFA) 1954 rules (ministry of health and family welfare & family welfare) with last amendments in 1986
- Bureau of Indian Standards Act 1986
- Environmental Protection Act 1986
- Pollution Control Act 1986
- Milk and Milk Products Order 1992
- The Infant Milk substitutes feeding bottles & infants food (regulation of production, supply) Act 1992 & Rules 1993
- Food Product Order FPO 1995
- Agriculture Produce Act
- Essential Commodities Act 1995 (Ministry of Food & Consumers Affairs)
- Industrial license
- Vegetable Oil Product Control (VOP) order 1998

In 1998 Prime Minister's council on trade and industry appointed a subjective group on food and agriculture industries which recommends a unified legislation under a single food regulatory authority. Public experts, member of standing committee of parliament encouraged the convergence of current food laws with single regulatory authorities accountable for public health and food safety in India. Special emphasis was given on nutraceutical and functional food- a poorly defined segment with growing potential and implications on health of consumers. In 2002, a National non profit Association had been constituted with main objectives that every food manufacturing company should provide scientific based support to their products in order to protect the consumers and to promote & defend a regulatory environment conducive to industry in general as well as consumers' protection. In 2003, a Ministry of Health expert group report indicated to need under food laws, to create new categories for regulating functional food and dietary supplements. It is recommended that there should be mandatory safety testing for these products. In India voluntary standards are developed by Bureau of Indian Standards and National standards body, which comprise representatives from various food sectors stakeholder groups. These standards basically deal with product certification, quality, system certification and testing and consumers affairs. Efforts are made to match Indian standards with international ones. In 2005, a number of committee, including the standing committees of parliament on agriculture submitted its 12th report in which the need for a single regulatory body and integrated law has emphasized. Finally Indian food safety standard bill 2005 signed into law, promising a major impact on Indian food processing industry [7-10].

The Indian Food Safety and Standard Act came into enforcement in 2006 with the two main objectives [7-10]:

- To introduce a single statute relating to food, and
- To provide for scientific development of the food processing industry.

Food Safety and Standard Act 2006

The Food Safety and Standard Act 2006 aims to establish a single reference point for all matters relating to Food Safety and Standards, by moving from multi-level, multi-departmental control to a single line of command. It incorporates the salient provisions of the Prevention of Food Adulteration Act 1954 and is based on international legislations, Instrumentalities and Codex Alimentarius Commission. The salient features of this Act are as follows [7-10]:

- The Food Safety and Standards Act, 2006 consolidates the eight laws governing the food sector and establishes the Food Safety and Standards Authority (FSSAI) to regulate the sector and other allied committees. FSSAI will be aided by several scientific panels and a Central Advisory Committee to lay down standards for food safety. These standards will include specifications for ingredients, contaminants, pesticide residue, Biological hazards, labels and others.
- Everyone in the food sector is required to get a license or a registration that would be issued by local authorities.
- The law will be enforced through State Commissioners of Food Safety and local level officials.
- The Act provides for a graded penalty structure where the punishment depends on the severity of the violation.
- The responsibility of framing and regulating standards for nutraceuticals is to rest with the Food Safety and Standards Authority of India (FSSAI) as outlined in the Food Safety Act, 2006. The authority will be in charge of categories like functional foods, nutraceuticals, dietetic products and other similar products.
- Food Safety and Standard Act 2006 consists of 12 chapters, IV chapter article 22 of the Act addresses nutraceutical, functional food, dietary supplements and need to regulate these products such that anyone can manufacture, sell or distributes 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.

According to these Act Foods for special dietary uses, functional food or nutraceutical or dietary supplements are [6-10]:-

(a) foods which are specially processed or formulated in order to satisfy particular dietary requirements which exist because of particular physiological or physical condition and which are processed as such wherein the composition of these foodstuffs must differ significantly from the ordinary food of comparable nature, if such ordinary food exists one or more of the following ingredients namely:

- (i) Plants or botanicals in the form of powder, concentrates or extracts in water, ethyl alcohol, single or in combinations
- (ii) Minerals, vitamins or proteins (amounts not exceeding recommended daily allowance for Indians) or enzymes

- (iii) Substances from animal origin
 - (iv) A dietary substance being used by human beings to supplement the diet by increasing the total dietary intake.
- (b)(i) a product that is labeled as "food for special dietary uses" functional food or nutraceuticals dietary supplements which is not represented for use as conventional food and whereby such products may be formulated in the form of powders, granules, tablets, capsules, liquids, jelly and other dosage forms but not parenterals, and are meant for oral administration;
- (ii) such product does not include a drug as defined in clause (b) and ayurvedic, sidha and unani drugs as defined in clauses (a) and (h) of section 3 of the Drugs and Cosmetics Act, 1940 and rules made there under
 - (iii) does not claim to cure or mitigate any specific disease, disorder or condition (except for certain health benefit or such promotion claims) as may be permitted by the regulations made under this Act;
 - (iv) does not include a narcotic drug or a psychotropic substance as defined in the Schedule of the Narcotic Drugs and Psychotropic Substances Act, 1985 and rules made thereunder and substances listed in Schedules E and EI of the Drugs and Cosmetics Rules, 1945;
- (2)"genetically engineered or modified food" means food and food ingredients composed of or containing genetically modified or engineered organisms obtained through modern biotechnology, or food and food ingredients produced from but not containing genetically modified or engineered organisms obtained through modern biotechnology;
- (3)"organic food" means food products that have been produced in accordance with specified organic production standards;
- (4)"proprietary and novel food" means an article of food for which standards have not been specified but is not unsafe:
- Provided that such food does not contain any of the foods and ingredients prohibited under this Act and the regulations made there under.

Benefits of Implementation of Act

- Unification of eight laws i.e. steps to Harmonization.
- Alignment of international regulations.
- Science based Standards.
- Clarity and uniformity on novel food areas.
- Help curb corruptions.

Problems of Implementation of Act

- Regulation broadly defines the intervention of Government in industry.
- Regulation primarily controls the product quality in case of food.

Every system of regulation has its own pros and cons. But the benefits from the implementation of Food Safety and Standards Act overwhelmed the problems that rise due to implementation of this Act. Unlike the US, where the DSHEA is in place to regulate these products, in India the Government is in the process of drafting a law to regulate manufacturing, importing and marketing of health foods, dietary supplements and other nutraceuticals [7-9].

Emerging Opportunities

The United States Pharmacopoeia Convention (USP) decided to have a separate advisory panel on nutraceuticals and will be joining hands with Indian scientific community for developing safety standards for the entire range of dietary supplements and nutraceuticals that are currently not under the strict regulatory classification of either drugs or foods.

Domestic and multinational companies are vying for position in the US\$500m Indian nutraceuticals market, which is growing at 40% annually. Central Food Technological Research Institute (CFTRI), Mysore, is to be the major agency to associate with USP in this regard.

The US and Europe are going to be emerging markets for nutraceutical exports from India because an existing large market base is already in place and consumers are looking for better and healthier options to prevent lifestyle-related diseases.

The market potential for the US and European markets alone for nutraceutical exports from India by 2013 will be to the tune of \$75 billion. Companies like Amway India and Herbalife are utilizing direct multi-level marketing, to reach new consumers with about their products delivered by someone known and trusted. However, most of the large companies have not ventured into nutraceuticals or dietary supplements due to regulatory confusion, lack of adequate awareness and understanding, and poor vision of the market [7-10].

Claim Regulation

There is currently no official harmonized definition or harmonization of the technical requirements and guidelines for functional food products in Asia. Academics and food companies generally understand functional foods to contain or to be fortified with nutrients or other bioactive compounds that help to maintain and promote health [10-12].

Functional foods in Asia tend to be regulated under the conventional food category. Claims permitted in Asian country are:-

- Nutrient content claims – which state the level of certain nutrients on the product label.
- Nutrient comparative claims – which describe the nutrient content or energy value relative to other similar foods.

Disease risk reduction claim established by international standard setting body the codex alimentarius (references used by Asian food authority for the national food legislation) are generally not permitted in Asia. However these claims are used in northern Asian countries that have established regulation for functional food [9, 12-17].

Applications of Nutraceuticals:

Numerous nutraceuticals currently are on the market. The following table 1 represents a sample of available nutraceuticals, their components and their potential human health benefits [10-17].

Table 1: List of various applications of Nutraceuticals

CLASS/COMPONENTS	SOURCE	POTENTIAL BENEFIT
<u>Carotenoids</u>		
1. Beta-carotene	Carrots, various fruits	Neutralizes free radicals, which may damage cells; bolsters cellular antioxidant defenses
2. Lycopene	Tomatoes and processed tomato products	May contribute to maintenance of prostate health
<u>Dietary Fiber</u>		
Insoluble fiber	Wheat bran	May contribute to maintenance of a healthy digestive tract
<u>Fatty Acids</u>		
Monosaturated fatty acids	Tree nuts	May reduce risk of coronary heart disease
<u>Flavonoids</u>		
Flavonols	Onions, apples, tea, broccoli	Neutralize free radicals, which may damage cells; bolster cellular antioxidant defenses
<u>Isothiocyanates</u>		
Sulforaphane	Cauliflower, broccoli, cabbage, kale, horseradish	May enhance detoxification of undesirable compounds and bolster cellular antioxidant defenses
<u>Phenols</u>		
Caffeic acid, ferulic acid	Apples, pears, citrus fruits, some vegetables	May bolster cellular antioxidant defenses; may contribute to maintenance of vision and heart health
<u>Plant Stanols/Sterols</u>		
Stanol/sterol esters	Fortified table spreads, stanol ester dietary supplements	May reduce risk of coronary heart disease
<u>Polysols</u>		
Sugar alcohols (xylitol, sorbitol, mannitol, lactitol)	Some chewing gums and other food applications	May reduce risk of dental caries (cavities)
<u>Prebiotics/Probiotics</u>		
Lactobacilli, bifidobacteria	Yogurt, other dairy and nondairy applications	May improve gastrointestinal health and systemic immunity
<u>Phytoestrogens</u>		
Isoflavones (daidzein, genistein)	Soybeans and soy-based foods	May contribute to maintenance of bone health, healthy brain and immune functions; for women, maintenance of menopausal health
<u>Soy Protein</u>		
Soy protein	Soybeans and soy-based foods	May reduce risk of coronary heart disease
<u>Sulfides/Thiols</u>		
Dithiolthiones	Cruciferous vegetables	May contribute to maintenance of healthy immune function

CONCLUSION

Nutraceuticals must not only supplement the diet but should also aid in the prevention and/or treatment of disease and/or disorder. The United States Pharmacopoeia Convention (USP) decided to have a separate advisory panel on nutraceuticals and will be joining hands with Indian scientific community for developing safety standards for the entire range of dietary supplements and nutraceuticals that are currently not under the strict regulatory classification of either drugs or foods.

Domestic and multinational companies are vying for position in the US\$500m Indian nutraceuticals market, which is growing at 40% annually. India is the world's second largest producers of fruits and vegetables but only a small amount of perishable agriculture products are processed approximately 2% in comparison of 80% in US. Barriers to growth on food sector include poor infrastructure and logistic and tight food regulation.

The Food Safety and Standard Act 2006 aims to establish a single reference point for all matters relating to Food Safety and Standards, by moving from multi-level, multi-departmental control to a single line of command. There is currently no official harmonized definition or harmonization of the technical requirements and guidelines for functional food products in Asia. Academics and food companies generally understand functional foods to contain or to be fortified with nutrients or other bioactive compounds that help to maintain and promote health.

REFERENCES

1. Brower V. Nutraceuticals: poised for a healthy slice of the healthcare market?, *Nat Biotechnol*, 1998, 16:728-731.
2. Zeisel SH. Regulation of Nutraceuticals, *Science*, 1999, 285:185-186.
3. FDA/CFSAN resources page, Food and Drug Administration Web site. Dietary Supplement Health and Education Act of 1994. Available at: <http://vm.cfsan.fda.gov/dms/dietsupp.html>.
4. Kalra EK. Nutraceutical: Definition & Introduction, *AAPS Pharmsci*, 2003, 5(2), Article 25.
5. Gil H. Nutraceutical and Functional Food: Introduction and Meaning, *Nutrition*, 2000, 16: 688-689.
6. Brower V. Nutraceuticals: poised for healthy slice of healthcare market? *Nat Biotechnol.*, 1998, 16: 728-731.
7. <http://www.ift.org/cms>
8. J.E., Evolving supply chains in the nutraceuticals and functional food industry, *Can J Agri Econ*, 2004, 50(4): 559-568.
9. Available online at: <http://www.asnapp.org/country-progs/rwanda.html> [Accessed March 2, 2007]. Institute of Food Technologists Expert Panel on Food Safety and Nutrition, Medical Foods (Scientific status summary), *Food Technol*, 1992, 46: 87-96.
10. Kleter GA, WM van der EJ, Krieken Kok D Bosch, W Jordi and Gillissen LJWJ, Regulation and exploitation of the genetically modified crops, *Nature Biotechnol*, 2001, 19: 1105-1110.
11. Stramba-Badiale M, Fox KM, Priori SG, Collins P, Daly C, Graham I, Jonsson B, Schenck-Gustafsson K, Tendera M. Cardiovascular diseases in women: a statement from the policy conference of the European Society of Cardiology, *Eur. Heart. J.*, 2006, 27, 994-1005.
12. Wang CZ, Mehendale SR, Yuan CS. Commonly used antioxidant botanicals: active constituents and their potential role in cardiovascular illness, *Am. J. Chin. Med.*, 2007, 35, 543-558.
13. Riccioni G, Mancini B, Di Ilio E, Bucciarelli T, D'Orazio N. Protective effect of lycopene in cardiovascular disease, *Eur. Rev. Med. Pharmacol. Sci.*, 2008, 12, 183-190.
14. Laparra JM, Sanz Y. Interactions of gut microbiota with functional food components and nutraceuticals, *Pharmacol. Res.*, 2010, 61, 219-225.
15. Guarner F, Schaafsma GJ. Probiotics, *Int. J. Food Microbiol*, 1998, 39, 237-238.
16. De Vrese, Schrezenmeir MJ. Probiotics, prebiotics, and synbiotics, *Adv. Biochem. Eng. Biotechnol.*, 2008, 111, 1-66.
17. Pan MH, Ghai G, Ho CT. Food bioactives, apoptosis, and cancer, *Mol. Nutr. Food. Res.*, 2008, 52, 43-52.