

Nutraceuticals and functional foods: II. Current international regulatory status

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Introduction

Our ancestors consumed plant materials and animal products to live. As civilization progressed there were realizations that for sustenance of life and good health food should be composed of proper amounts of carbohydrate, protein, lipids and minerals. Carbohydrates provide the needed calories, while protein supplies the essential amino acids the body needs but cannot produce. Similarly, human body is also in need of certain mineral nutrients for body structure as well survival; for example calcium is needed for maintaining a healthy bone density especially in elderly women. Vitamins, on the other hand, are essential and for protection from common diseases such as scurvy, anemia, and ricket.

Over the years, studies have established the minimum requirements for different components of foods for sustenance and good health. The start of the twentieth century saw concerted efforts by developed countries to provide wholesome and nutritious foods for their citizens as well as global consumers through advances in the agricultural production and processing. Advances in pharmaceutical discipline were responsible for treatment and prevention of diseases. To the consumers of developed countries requirements for sustenance and good health needs were met at reasonable costs through advances in agricultural and health sciences. This freed them for travel outside their hemisphere in large numbers and observing about the eating habits of other cultures and their impact on health. It also became clear during this period of growth that the population in developed countries had higher proportions of certain chronic diseases than those who do not have easy access to such abundant supply of processed foods. There has been strong realization by consumers and the policy makers that nutrition has direct link to maintenance of good health, and diet needs to be improved for healthy lifestyle and prevention of some chronic diseases.

Although foods were available at affordable costs, the abundance and their easy access created health problems and consequently increasing health care costs. The five major diet-related diseases in the developed world include cardiovascular diseases, cancers, obesity, diabetes and strokes. Studies have associated dietary factors or secondary lifestyle with between one-fifth and one-third of cardiovascular deaths, 20-60% of fatal cancers, 50-80% of diabetes mellitus cases and 30% diabetes deaths ¹.

A product, regardless of its origin, which claims to provide health benefits (prevention, treatment included) is currently

classified as drugs (medicines) in many developed countries. However, in last two decades large epidemiological studies have correlated the health benefits of certain minor constituents in our daily diets, even though they are non-essential for survival. It is a fact that globally the health care cost is increasing and people are living longer. Longevity mandates prevention of chronic diseases and maintenance of healthier lifestyle. There are many products that have been derived from natural sources and are being marketed as health promoter. Consumers, based on their own research and knowledge, are using these supplements as complementary medicine and for therapy. Regulatory agencies are caught between the lack of explicit guidelines and consumers demand for availability of such compounds with full approval for safety of such products.

Regulatory agencies worldwide have taken notice of such demands for two reasons - to reduce health care costs as well to protect consumers from unsafe products. For example, health care cost in the US in 1999 was about 1.2 trillion dollars ². Countries have realized that status quo is not an option and have initiated reviews of their existing laws. Smith et al. ³ carried out a comparative analysis of regulatory framework for functional food development and commercialization in Japan, the European Union and Canada. Their conclusion was that Japan was the leader in developing regulations for commercialization of functional food with health claims. One of the major problems in developing regulations is the lack of a clear definition for functional foods. Most countries use a working definition, which differs considerably from country to country.

Claims

Approval of a claim depends on the type of claims being sought. There are three major types of claims based on a) nutrient content, b) structure function and c) health benefit.

a) The nutrient content claim, which makes claim on the content of a particular nutrient of a value, is the least controversial. There is a well-established guideline by the international Union of Nutritional Sciences Committee on Food Standards and Terminology. Details and are available at <http://www.iunsc.org/>

b) The structure-function claim promotes the role of a nutrient for a specific biological and physiological process. For example, daily consumption of 6.5 g of soy protein for maintaining and reducing cholesterol level, calcium prevents bone density losses etc. Several countries have legislation in place to grant such claims.

c) The health claim specifies the role of a nutrient, food products,

etc. in preventing, treatment and curing a disease and is highly controversial. Such a claim falls into the category of a drug.

Regulatory Situation in Various Countries

Japan: It was the first to introduce the term “functional foods” in early 1980s. Japanese Ministry of Health and Welfare consulted various government agencies, academics, food processors and advisory committees to define a category of foods, ingredients, with health promoting properties. One of the main reasons for establishing such a category was to reduce the escalating health care costs through regular diet. After lengthy consultation the legislation “*tokutei hokenyo shokuhin*”, which in English was translated as “foods for specified health use” (FOSHU), was introduced in 1991. The process of getting an FOSHU status is complex and involves 3-steps-development of a product using approved ingredients, conduct clinical trial and submit documentation to the Ministry of Health and Welfare for evaluation and approval.

United States of America: There is no legislative definition for Functional Foods in the US. In the USA the US Federal Food, Drug and Cosmetics (FD&C) and US Federal Trade Commission (FTC) have jurisdiction over foods. Under a memorandum of understanding (MOU), FD&C is responsible for labelling of product, whereas FTC is responsible for food advertising. However, none has the exclusive authority. Sales, development and health claims of foods fall under three major acts. They are: Nutrition labelling and Education Act (NLEA) of 1990; Dietary Supplementary Health and Education Act (DSHEA) of 1994 and Food and Drug Administration of Modernization of 1997. <http://www.functionalfoods.nu/file/dyn/0000m/381i/dyn381.asp>.

NLEA is most suited for nutrient claims, which allows generic diet-disease health claims. However, the claim is strictly monitored for wording. Over the years the legislation has undergone several revisions. The FDA adopted The Keystone National Policy Dialogue recommendation “significant scientific agreement” and “totality of evidence” as the essential elements for gaining acceptance under the NLEA, and granted health claim for oats in 1997 (Federal Register, 1997). Over the years, health claims has been modified several times to be ingredient specific and not product specific as was the case with the original claim for oats. The 1998 version of claim is for “soluble fibre from certain foods and coronary heart disease. In 1998 FDA also allowed Kellogg to make health claim for psyllium seed husks (Federal Register, 1998). <http://www.gpoaccess.gov/fr/index.html>.

DSHEA. One of the most important impacts of this legislation is that it established a formal definition of dietary supplements using several criteria and included herbs and other similar substances. Under this legislation substance such as ginseng, garlic, fish oil, psyllium, enzymes and mixture of these can now be marketed as dietary supplement. Also, there is no requirement for premarket safety evaluation for new food ingredient or the new uses for the existing ingredients, but meets the regular safety provisions. The burden of proof (unsafe) rests with FDA. Further this provision also allows extensive use of published materials in support of claim for other than diagnosis, prevention, treatment or cure of specific disease. For example, isoflavone “cures breast cancer” cannot be permitted. But, labelling calcium

to reduce the risk of osteoporosis is permissible. <http://www.cfsan.fda.gov/~dms/ds-oview.html>.

FDAMA affects all products regulated by the FDA. One provision in the act can speed up the process of marketing dietary supplement. The law allows companies to inform the FDA of their intent to use a new health claim based on an authoritative statement of one or more federal scientific bodies. It gives FDA 120 days to respond. If there is no negative response from the agency, the label claim can be made. The criteria of “authoritative” statement is defined as i) come from a federal scientific body (e.g. National Institutes of Health, National Centres for Disease Control and Prevention, US Department of Agriculture or National Academy of Science, ii) be published by the scientific body, iii) not be a statement by an employee of a federal scientific body but rather reflect a consensus within the scientific body, iv) be based on the scientific body’s deliberative review of the scientific evidence and v) state a relationship between a nutrient and disease or health-related condition. Some examples of authorized claims are: calcium and osteoporosis; sodium and hypertension; dietary fibre and cancer; dietary saturated fat and cholesterol and risk of coronary heart disease; fruits, vegetable and cancers. <http://www.fda.gov/opacom/7modact.html>.

Health Claims

In the US, the FDA has approved the following 13 health claims for use in the labeling of food: 1. calcium – osteoporosis, 2. sodium - high blood pressure, 3. saturated fat – cancer, 4. saturated and cholesterol – cardiovascular disease, 5. fruits, vegetables and cereals with dietary fibre – cancer, 6. fruits, vegetables and cereals with dietary fibre - heart diseases, 7. fruits and vegetables with antioxidants, vitamin A or C and fibre - cancer, 8. folic acid - neural tube injury, 9. sugar free sugar-alcohols – caries, 10. soluble fibre from oats and psyllium - reduced risk for coronary heart disease, 11. soya protein - reduced risk for heart disease, 12. plant sterol/stanol esters and risk of coronary heart disease, 13. whole grain - reduced risk for heart disease and certain cancer forms. <http://www.cfsan.fda.gov/~dms/flg-6c.html>.

Canada: As per current Canadian Food and Drug Acts any food that claims to have health benefits would fall into drug category. This limits the development of functional food and nutraceutical products for sale in Canada due to the very restrictive regulatory environment. Health Canada, the regulatory body, has taken steps to modify the acts to address the growing consumer demands for the availability of supplements with health claims. In the *Policy Paper on Nutraceuticals/Functional Foods and Health Claims on Food*, Health Canada made the policy decision that the structure/function and risk reduction claims for foods should be permitted while all others claiming to cure, treat, mitigate or prevent illness should be regulated as drugs. A consultative discussion paper “*US generic health claims in Canada*” sought input from stake holders, public and experts in the field. The process included review of the science supporting the ten generic health claims. A broad scientific agreement for five of the claims namely i) sodium and hypertension; ii) calcium and osteoporosis iii) saturated and *trans*-fat and cholesterol and coronary heart disease, iv) fruits and vegetable and cancer and v) sugar alcohols and dental caries was apparent. Claims such as folate and neural tube defects; fibre-containing grain products and vegetables and

cancer; and fruits, vegetables and grain products that contain fibre, particularly soluble fibre and risk of coronary heart disease are being reviewed further. However, claims pertaining to dietary fit and cancer are not being considered at this time due to lack of supporting scientific evidence. Similarly the claim of soluble fibre and risk of coronary disease needs more supporting data before such a claim can be allowed. Necessary legislative actions are underway to allow the first five as part of the process to develop health claim for NFF. In 2000, Health Canada started a consultation process on *A Proposed Regulatory Framework for Product-Specific Authorization for Health Claims for Foods*. The framework proposes “a food that is manufactured, sold or represented to have direct, measurable effect on a body function or structure beyond normal growth and development or maintenance of good health be required to submit detailed information to support such an effect before being advertised or offered for sale.”

On June 18, 2003 the new Natural Health Products Regulations (NHP Regulations) were passed and will come into force on January 1, 2004, with a transition period ranging from two years (for site licensing) to six years (for product licensing, for products already issued a Drug Identification number). For further details on the NHP Regulations please visit: <http://www.healthcanada.ca/nhpd>.

The European Union: Until recently the regulating the dietary supplement has been left with each member country. This created an unbalanced and highly fragmented situation. In order to harmonize the regulation on dietary supplement throughout its member states, applicants for membership and trading partners, the EU initiated a consultative process. After a lengthy, highly divisive consultative process, the Food Supplement Directive (Directive 2002/46/EC) was signed into law on July 12, 2002. This legislation harmonises vitamin and mineral regulations in all member countries, the 13 countries that have applied for admission. It is expected that the legislation will be adopted by Norway, Iceland, Switzerland and Liechtenstein, members of the European Free Trade Association.

This legislation establishes a list of minerals and vitamins that can be marketed in all member states, but will prohibit sale of a large number of nutrients currently sold in the United Kingdom and other European countries, because they are not in the list. In certain circle this legislation has been termed as draconian approach to regulate vitamins and minerals. Strangely enough the list does not include boron, vanadium, sulphur and amino acid chelates. Submission of dossier is required to put unlisted products on the positive list. This directive will also create a maximum safe upper limit for vitamins and minerals.

Austria, one of the EC members, wishes to adhere to its law, which defines food supplements as substances intended to be consumed without serving principally as food or relaxation and without being medicinal products. This allows Austria to place ban on the sale of food supplements sold at a distance in other member countries, and is in violation of rule of the EC treaty (Articles 28 to 30).

The next step would be to address the issues of fortified foods and health claims. The commission issued the draft regulations, which was subject to public consultation. It will now be passed on to inter-service consultation within the European Commission. No final decision is expected for another

2 or 3 years. The information on food supplements is available at: <http://europe.eu.int/scadplus/leg/en/lvb/121102.htm>.

Sweden: Since 1990, in consultation with the Swedish Nutrition Foundation (SNF), Sweden has allowed the use of health-related claims in the labelling and manufacturing of foods. In 2001, Sweden extended this generic claim to include product-specific physiological claims under PARNUT. This involves developing a Code with a consensus between industry, consumer groups, researchers and regulators. The Code involves two-step process. First the scientific evaluation with input from SNF and external experts and an evaluation report. The second step is the input from the assessment board for diet-health information. Further information is available at: http://www.snf.ideon.se/snf/en/rh/Health_claims_FF.htm.

Israel: The Food and Nutrition Service of Israeli's Health Ministry is proposing amendments to its existing food regulations which would allow manufacturers of certain food and supplement products to make claims about health benefits of their products. The amendments are an extension of the rules of the US Food and Drug as listed in DSHEA and FDAMA.

Conclusions

Japan is well advanced in regulating functional foods with health claim. United States, Israel and Sweden also have considerable legislation in place to monitor and regulate the new health promoting foods and ingredients. Canada has cautious approach to diet and health claims. Even though the European Commission has enacted law to harmonize the minerals and vitamins regulations between EU nations, it would be long time before all rules regulating the food supplements will be harmonized. This in turn would put the nationals, who would like to manage their own health, at a disadvantage because some proven health promoting products would not be available to them. Similarly, a number of manufacturers of food supplements and ingredients may not survive.

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