



## **REPORT ON FUNCTIONAL FOODS**

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## **I INTRODUCTION**

The role of dietary active compounds in human nutrition is one of the most important areas of concern and investigation in the field of nutritional science. The findings of investigations on this subject have wide-ranging implications for consumers, health-care providers and nutrition educators as well as food producers, processors and distributors. New evidence concerning the benefits and risks associated with particular aspects of dietary compounds is constantly emerging in both the scientific literature and the popular media. At times, controversies about these findings emerge. Sifting through all the claims and counterclaims, incomplete and incompatible studies, and biases and competing interests for the elements of truth and a prudent course of action is a challenge. However, such discrimination is essential because changing views about the effects of dietary compounds can profoundly influence the consumption of various foods and, ultimately, health and nutritional status, agricultural production, food processing technologies, food marketing practices and nutrition education.

The present report has the following principal objectives:

- To present current functional food situation;
- To examine the latest global and regional regulatory developments for health, nutrients or other functional claims relating to foods;
- To review and analyze scientific and technical literature related to functional foods and their role in improving nutrition;
- To establish key criteria for elaborating guidelines for the assessment of functional foods;
- To propose some recommendations on functional foods.

## **II CURRENT FUNCTIONAL FOOD SITUATION**

### **2.1 TERMINOLOGY AND DEFINITIONS**

The term “*Functional Foods*” was first introduced in Japan in the mid-1980s and refers to processed foods containing ingredients that aid specific body functions, in addition to being nutritious. Currently, there is no universally accepted term for functional foods. A variety of terms have appeared world-wide such as *nutraceuticals*, *medifoods*, *vitafoods* and the more traditional *dietary supplements* and *fortified foods*. However, the term *Functional foods* has become the predominant one even though several organizations have attempted to differentiate this emerging food category. Health Canada, for instance, defines a *functional food* as “similar in appearance to a conventional food, consumed as part of the usual diet, with demonstrated physiological benefits, and/or to reduce the risk of chronic disease beyond basic nutritional functions” and a *nutraceutical* as “a product isolated or purified from foods that is generally sold in medicinal forms not usually associated with foods (*Health Canada website: <http://hc-sc.gc.ca>*). In Korea, functional foods are defined as dietary supplement whose purpose is to supplement the normal diet and have to be marketed in measured doses, such as in pill, tablets (Kim et al, 2006).

However, functional foods are generally considered as those foods which are intended to be consumed as part of the normal diet and that contain biologically active components which offer the potential of enhanced health or reduced risk of disease. Examples of functional foods include foods that contain specific minerals, vitamins, fatty acids or dietary fibre, foods with added biologically active substances such as phytochemicals or other antioxidants and probiotics that have live beneficial. According to this definition, unmodified whole foods such as fruits and vegetables represent the simplest form of a functional food. For example, broccoli, carrots, or tomatoes would be considered functional foods because they are rich in such physiologically active components as sulforaphane, beta carotene, and lycopene, respectively.

➤ **Point 1: Functional foods should be clearly defined**

## 2.2 MARKET

There is clearly a difference between the Western perspective on functional foods and the Eastern perspective. In the West, functional foods are viewed as a revolution and represent a fast growing segment of the food industry. In the Orient, in contrast, functional foods have been a part of the culture for centuries. In Traditional Chinese Medicine, foods that have medicinal effects have been documented since at least 1000 BC. From ancient times, the Chinese have believed that foods have both preventive and therapeutic effects and are an integral part of health, a view that is now being increasingly recognized around the world (Shi, 2005).

The world market for functional foods and beverages is highly dynamic. According to an Euromitor survey, Japan is the world's largest market at US\$11.7 billion, then US is the second one market with around US\$10.5 billion while the European market is less developed with an estimated market of US\$7.5, the "big four" European markets being UK (US\$2.6 billion), Germany (US\$2.4 billion), France (US\$1.4 billion), and Italy (US\$1.2 billion) (Bech-Larsen & Scholderer, 2007).

As a result, developing countries - such as Brazil, Peru, Kenya- have started to emerge as active ingredients exporters to cater to the increasing demand in the developed countries (Williams *et al.*, 2006). Moreover, demand for functional foods within the developing countries is growing, presenting a lucrative opportunity to develop domestic markets. For instance, India, with its strong tradition of eating healthy foods, ranks among the top ten nations in buying functional foods and the market size is expected to nearly double in the next five years (Ismail, 2006). In Brazil, the sector is relatively young, but grows rapidly, sales value is projected to reach US\$1.9 billion by 2009. In China, the total functional foods market is approximately US\$6 billion per year, which is expected to double by 2010.

Even though detailed information on the size of functional food market is relatively sparse depending on how the category is defined, one thing that all studies seem to agree on is that functional markets grow steadily each year, with annual growth rate estimates varying between 8% and 14%. This trend is likely to continue as changing population demographics (e.g. an ageing population) and the effects of lifestyle diseases create greater demand for food products targeting health and wellness.

## 2.3 MARKET DRIVERS

Countries are currently faced with a number of major health challenges arising from an ageing population and an increase in lifestyle diseases. Current research suggests that functional foods can make a positive contribution to addressing those challenges. Behind functional food research and development, the key drivers are the food industry, consumers and governments.

- **Scientific investigations**

According to the traditional concept of nutrition, the primary role of the diet is to provide adequate quantities of nutrients to meet metabolic requirements and maintain optimal health. However epidemiological, experimental and clinical studies have shown that certain types of food and specific food components can affect a variety of body functions and provide health benefits (*Takachi et al. 2007; Nöthlings et al. 2007; Kuriyama et al. 2006, Arnoldi et coll., 2004; Remacle et al, 2004; Wildman et coll, 2006, Watson et al. and others*). Based on scientific data it is now accepted that diet can have beneficial physiological effects, beyond well-known nutritional effects, by modulating specific target function in the body. Therefore, diet not only helps to achieve optimal development and health, but it may promote better health and play an important role in disease prevention by reducing the risk of certain chronic diseases.

- **Socio-economics trends**

Many countries around the world have an ageing population due to reduced birth rates and greater life expectancy. As people are living longer, the older population is growing exponentially throughout the world. For instance, the Canada's National Statistical Agency reports that the proportion of the Canadian population aged over 60 is today 13 % and will increase over the next 20 years to reach around 25% of the total population in 2030. With lengthened years comes increased threat of chronic diseases and from a socio-economical viewpoint, countries are facing financial difficulties in medical care costs due to the increase in chronic diseases and the expansion of life spans. As an example, health expenditures in Canada are approximately \$100 billion annually, increasing yearly by 7%. Health expenditures of seniors represent 42% of total health costs. These expenditures will increase with life expectancy. A recent report estimates a saving of 20% per year to health care expenditures through functional foods (*Holub, 2002*). Thus, governments are aware of the economic potential of these products as part of public health prevention strategies. Moreover, a vast majority of people has a positive image of healthy food and agrees that food and nutrition have a positive impact on long-term and current health (*Landstrom et al. 2007*). The observed growth in this market is driven largely by consumers' aim for a healthier lifestyle through a dietary approach.

The growth of the functional foods sector not only represents significant benefits to the health sector but also offers opportunities for processing and manufacturing companies. Manufacturers and their search for added-value, higher margin products provided key impetus for the growth of functional products. However, the potential for financial gain resulted in many unsupported claims for functional ingredients by commercial enterprises whose interests lie more in profit rather than sound science (*Jones & Jew, 2007*). As a result, the functional foods field has been tarnished and suffers a credibility gap.

### **III REVIEW EXISTING NATIONAL, REGIONAL AND INTERNATIONAL REGULATORY SYSTEMS GOVERNING THE PRODUCTION AND DISTRIBUTION OF FUNCTIONAL FOODS**

A growing number of foods now carry nutrition and health claims and companies have been using health-related claims for years. The proliferation of claims on a variety of food products

and dietary supplements has created an environment of confusion and distrust among health professionals and consumers. Thus to harmonize the provision of this type of information, many countries worldwide have recently introduced a regulation on the use of nutrition and health claims for foods. This section presents an overview of the functional foods regulatory systems of Europe, USA, Canada, Australia, Japan and other asian countries as well as codex alimentarius.

All of the information for this analysis was obtained from publicly available sources provided by the respective regulatory authorities in each country. Moreover, very useful information on worldwide health claims regulatory systems have been obtained from the Australian National Centre of Excellence in Functional Foods<sup>1</sup>.

### III.1 EUROPE

Historically, companies attempting to launch a functional food in Europe have faced a variety of legislative frameworks regulating the approval of products, the kinds of nutrition information required on labels, and the types of functional and health claims that were allowed in connection with a product, often in a way that was highly inconsistent between EU member states (*Bech-Larsen & Scholderer, 2007; Butris, 2007; Kuhn, 2007; Madsen, 2007*). After a first attempt at harmonization, which technically prohibits all product-related communications from attributing properties for prevention, treatment or cure of human diseases to food (*European Parliament & Council of Europe, 2001*), the situation changed. On July 2003, the European Commission proposed a harmonized regulation COM/2003/0424 on nutrition and health claims made on foods, including dietary supplements (*Commission of the European Communities, 2003*). In December 2006, the regulation on the use of nutrition and health claims for foods was adopted by the Council and Parliament of Europe (*European Parliament & Council of Europe, 2006*<sup>2</sup>).

For the purposes of this regulation, the following definitions have been proposed:

- “*claim*”: any message or representation, which is not mandatory under Community or national Legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics;
- “*nutrition claim*”: means any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to: a) the energy (calorific value) it (i) provides; (ii) provides at a reduced or increased rate; or (iii) does not provide; and/or b) the nutrients or other substances it (i) contains; (ii) contains in reduced or increased proportions; or (iii) does not contain;
- “*health claim*”: means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health;
- “*reduction of disease risk claim*”: means any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease

It can be noted that medicinal claims for foods – *i.e.* claim, which states or implies that a product has the property of treating, preventing or curing human disease- are prohibited under National and European Labelling Rules. In order to be permitted to make a medicinal claim, a product must be classed as a medicine in accordance with the definition in the Directive

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<sup>1</sup> National Centre of Excellence in Functional Foods: <http://www.nceff.com.au/resources/regulations.html>

<sup>2</sup> Regulation (EC) on nutrition and health claims made on foods No 1924/2006 published in the Official Journal of the European Union 18.1.2007. Available at [http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l\\_012/l\\_01220070118en00030018.pdf](http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_012/l_01220070118en00030018.pdf);

2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

The European Food Safety Authority (EFSA) is involved in implementing the new regulation and has published a guidance to help companies who want to submit health claims for authorization (EFSA, 2007). The assessment of a health claim by EFSA is the first step in the authorization process. Only those claims which are scientifically substantiated will finally be authorized for use. The EU PASSCLAIM project<sup>3</sup> (Process for the Assessment of Scientific Support for Claims on Foods) provides industry, academics, consumer groups and regulators with the means to evaluate the scientific basis for health claims (Aggett et al. 2005). The final approval of a health claim is the responsibility of the European Commission and Member States, based on the scientific assessment expressed in the opinion of EFSA's Panel. It is the first time that a harmonized approach for authorizing health claims has been established across EU Member States.

- European Agencies:
  - European Commission: <http://ec.europa.eu>. The European Commission represents and upholds the interests of Europe as a whole. It is independent of national governments. It drafts proposals for new European laws, which it presents to the European Parliament and the Council. It manages the day-to-day business of implementing EU policies and spending EU funds. The Commission also keeps an eye out to see that everyone abides by the European treaties and laws. It can act against rule-breakers, taking them to the Court of Justice if necessary
  - European Food Safety Authority (EFSA): <http://www.efsa.europa.eu>. The European Food Safety Authority (EFSA) is an independent European agency funded by the EU budget that operates separately from the European Commission, European Parliament and EU Member States. A European Food Safety Authority ("the Authority") will provide scientific advice and scientific and technical support in all areas impacting on food safety. It constitutes an independent source of information on all matters in this field and ensures that the general public is kept informed.
  - European Food Information Council (EUFIC): [www.eufic.org](http://www.eufic.org). The European Food Information Council (EUFIC) is a non-profit organization which provides science-based information on food safety & quality and health & nutrition to the media, health and nutrition professionals, educators and opinion leaders.
  - International Life Sciences Institute (ILSI): [www.ilsa.org](http://www.ilsa.org). The international Life Sciences Institute (ILSI) is a non-profit, worldwide foundation that seeks to improve the well-being of the general public through the advancement of science. Its goal is to further the understanding of scientific issues relating to nutrition, food safety, toxicology, risk assessment, and the environment by bringing together scientists from academia, government, and industry.

### **III.2 USA**

Currently, Food and Drug Administration (FDA) has neither a definition nor a specific regulatory rubric for foods being marked as "functional foods", they are regulated under the same regulatory framework as other conventional foods under the authority of the Federal Food Drug and Cosmetic Act<sup>4</sup>. There are three categories of claims that can be used on food:

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<sup>3</sup> PASSCLAIM Consensus on criteria. Available at <http://europe.ilsa.org/NR/rdonlyres/693AF260-444C-4ABE-B314-7176FBE78857/0/PASSCLAIMConsensusonCriteria.pdf>

<sup>4</sup> Claims that can be made on foods in USA are available at: <http://www.cfsan.fda.gov/~dms/hclaims.html>;

- **Health Claims** - Health claims describe a relationship between a food substance and a disease or health-related conditions. There are three sets of legislation by which FDA exercises its oversight in determining which health claims may be used on a label or in labeling for a food or dietary supplement:
  - **NLEA Authorized Health Claims** – Under the provisions of the Nutrition Labeling and Education Act (NLEA) of 1990, the Dietary Supplement Act of 1992, and the Dietary Supplement Health and Education Act of 1994 (DSHEA), FDA may authorize a health claim for a food or dietary supplement based on an extensive review of the scientific literature, generally as a result of the submission of a health claim petition, using the significant agreement standard to determine the nutrient/disease relationship is well established (*Link to the significant scientific agreement standard: <http://www.cfsan.fda.gov/~dms/ssaguide.html>*); Example of NLEA Authorized Health Claims: "diets high in calcium may reduce the risk of osteoporosis";
  - **Health Claims Based on Authoritative Statements** – Under the 1997 Food and Drug Administration Modernization Act (FDAMA), a health claim may be authorised for a food based on an authoritative statement of a scientific body of the U.S. government or the National Academy of Sciences. FDA has prepared a guide on how a firm can make use of authoritative statement-based health claims on food (not currently available for dietary supplements) (*link: <http://www.cfsan.fda.gov/~dms/hclmguid.html>*). Companies wishing to make such a claim must submit a notification to the FDA which reviews whether the notification includes the information necessary for the claim and notifies the submitter by letter within 120 days if notification does not comply. Examples of health claims based on authoritative statements may also be found at: <http://www.cfsan.fda.gov/~dms/flg-6c.html>.
  - **Qualified Health Claims** – FDA's 2003 *Consumer Health Information for Better Nutrition Initiative* provides for the use of qualified health claims when there is emerging evidence for a relationship between a food, food component, or dietary supplement and reduced risk of a disease or health-related condition. In this case, the evidence is not well enough established to meet the significant scientific agreement standard required for FDA to issue an authorizing regulation. Both conventional foods and dietary supplements may use qualified health claims. FDA uses its enforcement discretion for qualified health claims after evaluating and ranking the quality and strength of the totality of the scientific evidence. FDA has prepared a guide on interim procedures for qualified health claims and on the ranking of the strength of evidence supporting a qualified claim, available at: <http://www.cfsan.fda.gov/~dms/hclmgui3.html>. FDA information on qualified health claims may be found at: <http://www.cfsan.fda.gov/~dms/lab-qhc.html>. A summary of the qualified health claims authorized by FDA are available at: <http://www.cfsan.fda.gov/~dms/qhc-sum.html>.

A new guidance for industry on the process for evaluating the scientific evidence for a health claim is under evaluation (*Food and Drug Administration, Draft guidance: Evidence-Based Review System for the Scientific Evaluation of Health Claims: July 2007 CFSAN/Office of Nutrition, Labeling and Dietary Supplements. available at <http://www.cfsan.fda.gov/~dms/hclmgui5.html#fn1>*)

- **Nutrient Content Claims** - The Nutrition Labelling and Education Act of 1990 (NLEA) permits the use of label claims that characterize the level of a nutrient in a food (i.e., nutrient content claims) made in accordance with FDA's authorizing regulations. Conditions for nutrient content claims are described in the FDA food labelling guide (*available at <http://www.cfsan.fda.gov/~dms/flg-toc.html>*). Most nutrient content claim regulations apply only to those nutrients or dietary substances that have an established daily value (*available at <http://www.cfsan.fda.gov/~dms/flg-7a.html>*). A summary of the rules for use of nutrient content claims can be found in Chapter VI of The Food Labelling Guide: *<http://www.cfsan.fda.gov/~dms/flg-toc.html>*. Examples of nutrient content claims can be found in Appendices A and B of The Food Labelling Guide: *<http://www.cfsan.fda.gov/~dms/flg-6a.html>* and *<http://www.cfsan.fda.gov/~dms/flg-6b.html>*.
  
- **Structure/Function Claims** - Structure/function claims have historically appeared on the labels of conventional foods and dietary supplements as well as drugs. However, the Dietary Supplement Health and Education Act of 1994 (DSHEA) established some special regulatory procedures for such claims for dietary supplement labels. Structure/function claims describe the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans, for example, "calcium builds strong bones." In addition, they may characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function, for example, "fiber maintains bowel regularity," or "antioxidants maintain cell integrity," or they may describe general well-being from consumption of a nutrient or dietary ingredient. Structure/function claims may also describe a benefit related to a nutrient deficiency disease (like vitamin C and scurvy), as long as the statement also tells how widespread such a disease is in the United States. The manufacturer is responsible for ensuring the accuracy and truthfulness of these claims; they are not pre-approved by FDA but must be truthful and not misleading. If a dietary supplement label includes such a claim, it must state in a "disclaimer" that FDA has not evaluated the claim. The disclaimer must also state that the dietary supplement product is not intended to "diagnose, treat, cure or prevent any disease," because only a drug can legally make such a claim. Further information regarding structure/function claims can be found in FDA's January 9, 2002 *Structure/Function Claims Small Entity Compliance Guide: <http://www.cfsan.fda.gov/~dms/sclmguid.html>*. Manufacturers of dietary supplements that make structure/function claims on labels or in labelling must submit a notification to FDA no later than 30 days after marketing the dietary supplement that includes the text of the structure/function claim.
  
- **Agencies:**
  - **The Food and Drug Administration (FDA)** (<http://www.fda.gov>) - The Food and Drug Administration (FDA) is responsible for ensuring that all foods in the American food supply (other than meat products, poultry products, and egg products that are regulated by the U.S. Department of Agriculture) are safe, secure, sanitary, wholesome, and properly labelled;
  - **The American Heart Association (AHA)** – a national, voluntary health agency in the USA whose mission is to reduce disability and death from cardiovascular diseases and stroke;
  - **The Institute of Medicine (IOM)** – an independent, private, scientific advisor serving Canada and the USA, providing unbiased, evidence-based, and authoritative information and advice concerning health and science policy.

### III.3 CANADA

In Canada, Health Canada<sup>5</sup> regulates the functional foods and nutraceutical industry and the Canadian Food Inspection Agency<sup>6</sup> enforces these regulations. Within Health Canada's Health Products and Food Branch, the Food Directorates regulates functional foods, while the Natural Health Products Directorate regulates other natural health products including vitamins, minerals; herbal remedies; homeopathic medicines; traditional medicines such as traditional Chinese medicines; probiotics, and other products like amino acids and essential fatty acids. A recent paper<sup>7</sup> focussed on the different types of nutrition claims currently available for use in Canada and their associated requirements. Briefly, the term "health claim" is not defined in Canada but currently, there are 3 types of nutrition claims allowed:

- **Nutrient Content Claims-** Nutrient content claims are the simplest label statement as they identify/quantify the amount of a nutrient contained in a food. In addition, comparative nutrient content claims (e.g. reduced, less, light) are allowed based on the standardized reference amount. Detailed information on Nutrients content claims are available on the Canadian Food Inspection Agency 2003 *Guide to Food Labelling and Advertising* at <http://www.inspection.gc.ca/english/fssa/labeti/guide/ch7e.pdf>.
- **Biological Role/ Structure Function Claims** – The second category of nutrition claims are referred to as biological role or structure/function claims. Biological role claims are for nutrients, not a food containing the nutrient. These statements identify the generally recognized function of a nutrient as an aid in maintaining the functions of the body necessary for the maintenance of good health, or for normal growth and development. A biological role claim may not refer directly or indirectly to the treatment, mitigation or prevention of any disease, disorder or abnormal physical state, or symptoms of same, nor may it refer directly or indirectly to correcting, restoring or modifying organic functions. Example of biological role claims for nutrient: protein helps build and repair body tissues. Other examples of approved nutrients and their recognized biological role/function can be found in the 2003 *The Canadian Food Inspection Agency Guide to Food Labelling and Advertising* at <http://www.inspection.gc.ca/english/fssa/labeti/guide/ch8e.shtml#8.5>.
- **Risk Reduction Health Claims** – Health Canada began to consider the possibility of risk reduction claims for foods in 1999, by reviewing the ten U.S. approved health claims. Based on an extensive review of the scientific evidence, Health Canada approved five of the claims (<http://www.inspection.gc.ca/english/fssa/labeti/guide/ch8e.shtml>). In 2002, an Interim Guidance Document ([http://www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/abstract\\_guidance-orientation\\_resume\\_e.html](http://www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/abstract_guidance-orientation_resume_e.html)) was published that outlined standards of evidence for evaluating foods with health claims. In 2003, the Food and Drug Regulations were amended to introduce the first series of authorized health claims in Canada. In the meantime Health Canada developed a proposed regulatory framework for product-specific authorization of health claims (*available at: http://www.hc-sc.gc.ca/fn-an/label-etiquet/nutrition/claims-reclam/final\_proposal-*

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<sup>5</sup> Health Canada's website: <http://www.hc-sc.gc.ca/>

<sup>6</sup> Canadian Food Inspection Agency's website: [www.inspection.gc.ca/](http://www.inspection.gc.ca/)

<sup>7</sup> Available at [http://www4.agr.gc.ca/resources/prod/doc/agr/pdf/Health-Claim\\_Primer-rev.pdf](http://www4.agr.gc.ca/resources/prod/doc/agr/pdf/Health-Claim_Primer-rev.pdf)

*proposition\_final01\_e.html*). The framework for the authorization of health claims for foods in Canada distinguishes between generic claims and product-specific claims. Generic claims are associated with nutrients, other food components, foods or food groups which contribute to a dietary pattern of eating associated with a reduction in risk for a disease. Product-specific claims are associated with a specific food which has demonstrated a measurable health benefit beyond normal body function, growth, development or maintenance of good health. The five authorized health claims are considered generic claims. Health Canada continues to review the scientific evidence supporting three additional generic health claims: vegetables, fruit and whole grain and a reduced risk of coronary heart disease; folic acid and a reduced risk of neural tube effects; and soluble fibre grains and a reduced risk of coronary heart disease. Health Canada has clearly indicated that it is now the responsibility of the food industry to gather the supporting scientific evidence and prepare the necessary submission to Health Canada requiring approval of additional health claims. To facilitate the development of a submission for foods with claims, Health Canada has provided an *Interim Guidance Document, Preparing a submission for foods with health claims: incorporating standards of evidence for evaluating foods with health claims* (available at: [http://www.hc-sc.gc.ca/fn-an/label-etiquet/nutrition/claims-reclam/abstract\\_guidance-orientation\\_resume\\_e.html](http://www.hc-sc.gc.ca/fn-an/label-etiquet/nutrition/claims-reclam/abstract_guidance-orientation_resume_e.html) Accessed: October 23, 2007)

In Canada, the most of nutraceuticals fall under the *Natural Health Products Regulations* of the *Food and Drugs Act* which came into effect on January 1, 2004. Several guidance documents have been created to provide industry with clear guidelines on how to comply with the Regulations (available at: [http://hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/index\\_e.html](http://hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/index_e.html)). In addition, a compliance policy is in place to ensure the safety of Canadians until all natural health products have undergone Health Canada's approval process ([http://hc-sc.gc.ca/dhp-mps/prodnatur/legislation/pol/complian-conform/complian-conform\\_pol\\_e.html](http://hc-sc.gc.ca/dhp-mps/prodnatur/legislation/pol/complian-conform/complian-conform_pol_e.html)). NHPs must be safe for consideration as over-the-counter products, be available for self-care and self-selection and not require a prescription to be sold. Products requiring a prescription will continue to be regulated under the Food and Drug Regulations (Canada Gazette: Regulations Amending the Food and Drug Regulations (1416 — Nutrition Labelling, Nutrient Content Claims and Health Claims) Vol. 139, No. 19 - May 7, 2005 at <http://canadagazette.gc.ca/part1/2005/20050507/html/regle4-e.html>).

- **Agencies:**
  - **Health Canada** (<http://www.hc-sc.gc.ca/>) is the Federal department responsible for establishing policies, setting standards and providing advice and information on the safety and nutritional value of food. Health Canada administers many pieces of legislation and develops and enforces regulations under this legislation that have a direct impact on the health and safety of Canadians. The Department consults with the Canadian public, industry, non-governmental organizations (NGOs) and other interested parties in the development of these laws. Health Canada also prepares guidelines in order to help interpret and clarify legislation and regulations. Through the *Food and Drugs Act*, Health Canada regulates the labelling of food products in Canada.
  - **The Canadian Food Inspection Agency** provides all federal inspection services related to food and enforces the food safety and nutritional quality standards established by Health Canada.

### III. 4 **Japon**

Japan is by far and away the most developed market for functional foods, although the Asia-Pacific region generally is an important market for these products. Consumers have a long-held awareness of the role of food in health and functional foods have been regarded as an integral part of the culture for many years (*Shi et al. 2005*). The Japanese scientific academic community defined 'functional food' early in the 1980s. That is, functional foods are those that have three functions. The primary function is nutrition. The secondary function is a sensory function or sensory satisfaction. The third is the tertiary function, which is physiological. The Japanese Ministry of Health, Labour, and Welfare (MHLW) set up 'Foods for Specified Health Use' (FOSHU) in 1991 as a regulatory system to approve the statements made on food labels concerning the effect of the food on the human body. FOSHU refers to foods containing ingredient with functions for health and officially approved to claim its physiological effects on the human body. FOSHU is intended to be consumed for the maintenance / promotion of health or special health uses by people who wish to control health conditions, including blood pressure or blood cholesterol. Food products applying for approval by FOSHU are scientifically evaluated in terms of their effectiveness and safety by the Council of Pharmaceutical Affairs and Food Hygiene under the MHLW. In order to sell a food as FOSHU, the assessment for the safety of the food and effectiveness of the functions for health is required, and the claim must be approved by the MHLW (*available at: <http://www.mhlw.go.jp/english/topics/foodsafety/fhc/index.html>*). The regulatory range of FOSHU was broadened in 2001 to accept the forms of capsules and tablets in addition to those of conventional foods. FOSHU increased the total to about 330 items in January 2003. Examples of approved Foshu products are: Foods to modify gastrointestinal conditions: Oligosaccharides, lactose, bifidobacteria, lactic acid bacteria; Foods related to blood cholesterol level: Chitosan, soybean protein, degraded sodium alginate. In addition to regular FOSHU, qualified FOSHU and standardized FOSHU were introduced to facilitate applicants for FOSHU approvals. Examples of approved reduction of disease risk claims regarding these substances are : Calcium and Osteoporosis: *"Intake of proper amount of calcium contained in healthy meals with appropriate exercise may support healthy bones of young women and reduce the risk of osteoporosis when aged."*

In April 2001, the MHLW enacted a new regulatory system, 'Foods with Health Claims', which consists of the existing FOSHU system and the newly established 'Foods with Nutrient Function Claims' (FNFC) (Shimizu, 2003). FNFC refers to all food that is labeled with the nutrient function claims specified by the MHLW. Under the FNFC, twelve vitamins (vitamins A, B<sub>1</sub>, B<sub>2</sub>, B<sub>6</sub>, B<sub>12</sub>, C, E, D, biotin, pantothenic acid, folic acid, and niacin) and two minerals (Ca and Fe) are standardized. Examples of claims regarding these substances are as follows: 'Calcium is a nutrient which is necessary to form bones and teeth'; 'Vitamin D is a nutrient which promotes calcium absorption in the gut intestine and aids in the formation of bones.' The upper and lower levels of the daily consumption of these nutrients are also determined. The labelling of functional foods should always be based on scientific evidence and be in harmony with international standards. The nutrient–function claim was adopted in the guidelines for nutrition claims by the Codex Alimentarius in 1997. The claims of the Japanese FNFC are equivalent to the nutrient function claims standardized by the Codex Alimentarius. The enhanced function claim and the disease risk-reduction claims were proposed by both the Codex Alimentarius and an Economic Union project in 1999. The structure function claim, which is similar to the enhanced function claim, was enacted by the Dietary Supplement Health and Education Act in the USA in 1994. Most of the statements of the Japanese FOSHU system are close to the category of structure/function claims in the USA or the enhanced function claims of the Codex Alimentarius.

- Agencies

- Ministry of Health, Labour and Welfare  
<http://www.mhlw.go.jp/english/index.html>

### **III. 5 Other asian countries**

Recently, the Asian-Pacific Network for Food and Nutrition (ANFN) of the FAO regional office for Asia and the Pacific held its regional expert consultation on functional foods and their implications in the daily diet and published a report on the development and status of Functional foods in different asian countries including China, India, Bangladesh, Indonesia, Nepal, Malaysia, Philippines, Thailand, Sri Lanka, and Vietnam (FAO, 2004). In Korea, the term “health/functional food” (HFF) refers to food supplements containing nutrients or other substances (in a concentrated form) that have a nutritional or physiological effect whose purpose is to supplement the normal diet. The Korean Health/Functional Food Act that came into effect in 2004 requires these products to be marketed in measured doses, such as in pills, tablets, capsules, and liquids. HFFs are of two types: generic and product-specific. There are 37 ingredients listed in the act for generic HFFs, and if an HFF contains a new active ingredient that is not included in the generic 37 products, it is considered a product-specific HFF. The standardization, safety, and efficacy of a new active ingredient are reviewed by the Korean Food and Drug Administration in order to receive approval as a product-specific HFF. Conforming with international standards and protecting public health requires constant upgrading of the Health/Functional Food Act (Kim et al. 2006).

### **III. 6 Codex Alimentarius**

The Codex Alimentarius has defined two types of nutrition claims- Nutrition content claim and Nutrient comparative claim- and three types of health claims- nutrient function claims; enhanced function claims and reduction of disease risk (Codex Alimentarius Commission, 2004)<sup>8</sup>.

- **Nutrition Claims** -Guidelines for the use of nutrition claims by the Codex Committee on Food Labeling proposed that *‘nutrient claim means any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrate, as well as the content of vitamins and minerals’*. Nutrition Claims include two types: (i) Nutrient content claim that is a nutrition claim that describes the level of a nutrient contained in a food and (ii) Nutrient comparative claim is a claim that compares the nutrient levels and/or energy value of two or more foods.
- **Health Claims** - Guidelines for the use of nutrition claims by the Codex Committee in Food Labelling proposed that *“health claim means any representation which states, suggests or implies that a relationship exists between a food or a constituent of that food and health”*. Health claims include three types: (i) Nutrient Function Claim that is the claim that describes the physiological role of the nutrient in growth, development, and the normal function of the body’; (ii) Enhanced Function Claim concerns specific beneficial effects of the consumption of foods and their constituents in the context of the total diet and relate to a positive contribution to health or to improvement of a function or to modifying or preserving health and (iii) Disease Risk Reduction Claim relates to the consumption of a food or food constituent, in the content of the total diet, to the reduced risk of developing a disease or a health-related condition. Risk

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<sup>8</sup> *Guidelines for Use of Nutrition Claims and health claims.* available at [www.codexalimentarius.net/download/standards/351/CXG\\_023e.pdf](http://www.codexalimentarius.net/download/standards/351/CXG_023e.pdf)

reduction means significantly altering a major risk factor(s) for a disease or a health-related condition. Diseases have multiple factors and altering one of these risk factors may or may not have a beneficial effect. The presentation of Risk Reduction Claims must ensure, for example, by use of appropriate language and reference to other risk factors, that consumers do not interpret them as prevention claims.'

**Conclusion/Recommendations** - Several approaches to the use of health claims on foods have been made around the world, and the common theme is that any health claim will require scientific validation and substantiation. There is also broad consensus that any regulatory framework should protect the consumer, promote fair trade and encourage innovation in the food industry. However, there is a clear need to have uniform understanding, terminology and description of types of nutrition and health claims.

➤ **Point 2 : Health claims vs structure/function claims vs nutrition claims should be clearly defined**

#### **IV – SCIENTIFIC DEVELOPMENTS**

The emergence of dietary compounds with health benefits offers an excellent opportunity to improve public health and thus, this category of compounds has received much attention in recent years from the scientific community, consumers and food manufacturers. The list of dietary active compounds (vitamins, probiotics, bioactive peptides, antioxidants . . .) is endless, and scientific evidence to support the concept of health promoting food ingredients is growing steadily (Wildman, 2006). This section is aimed at illustrating the concepts of functional foods by focusing on major target functions and on the science base required for providing evidence that specific nutrients positively affect function.

##### **IV.1 Diseases/ target functions:**

- **Gastrointestinal functions** - The GI target functions which are associated with a balanced microflora together with an optimal gut associated lymphoid tissue are relevant to the state of well-being and health and to the reduction of the risk of diseases. Probiotics (e.g. lactobacilli or bifidobacteria) and prebiotic (like inulin and its hydrolysate oligofructose) are recent concepts in nutrition that have already and will in the future be used to support the development of functional foods targeted towards gut function. However, colonic functional foods will not be treated in this report since they have been the object of a recent report of a joint FAO/Who expert committee (FAO, 2006).
- **Defence against reactive oxidative species** - Oxidation of DNA, proteins and lipids by reactive oxygen species (ROS) plays an important role in aging and in a wide range of common diseases, including cancer and cardiovascular, inflammatory and neurodegenerative diseases, such as Alzheimer's disease and other age-related degenerative conditions and. But it is becoming more and more evident that ROS also play an essential role in regulating gene expression and in participating in cell signalling. Maintaining a balance between production and destruction of ROS is thus a key element in well-being and health and it is likely to play a role in reducing the risk of disease. Different target functions in relation to the maintenance of such a balance have been identified: i) Preservation of

structural and functional activity of DNA that can be evaluated by measuring DNA integrity, damaged DNA based or specific gene expressions; ii) Preservation of structural and functional integrity of circulating lipoproteins by measuring either lipid hydroperoxides or their derivatives or oxidised low-density-lipoproteins in plasma; iii) Preservation of structural and functional integrity of protein. Different studies evidenced that plant-based diets, in particular those rich in vegetables and fruits, provide a great amount of antioxidant phytochemicals, such as vitamins C and E, glutathione, phenolic compounds (flavonoids) and vegetable pigments, which offer protection against cellular damage (Dimitrios 2006; Kuriyama et al. 2006; Seifried et al. 2007, Zhang 2007).

- **Cardiovascular Disease (CVD)** – Cardiovascular disease remains the principle cause of death in both developed and developing countries, accounting for roughly 20% of all worldwide deaths per year. Lifestyle factors including a diet high in saturated fat, in energy and in cholesterol- have an important role in the CVD risk. Epidemiological studies examining CVD risks in different populations have observed a positive correlation between elevated levels of low density lipoprotein (LDL) cholesterol and development of CVD as well as low levels of high density lipoprotein (HDL) cholesterol and CVD. Consuming a diet rich in natural antioxidants has been associated with prevention from and/or treatment of CVD. Bioactive components of food, which are of special interest, include the Vitamins E and C, polyphenols, carotenoids mainly lycopene and  $\beta$ -carotene, and coenzyme Q10, featured by antioxidant properties. (Kaliora et al. 2006 & 2007; Lovegrove & Jackson, 2000).
- **Cancer** – Dietary factors are thought to account for about 30% of cancers in western countries and thus, diet is second only to tobacco as a potentially preventable cause of cancer. The contribution of diet to risk of cancer in developing countries is lower around 20 %. The interactions between diet and the biological processes leading to the development of cancer are extremely complex. However, over the past decades a large body of epidemiological evidence in favour of a protective effect of biologically active food components has appeared and become generally accepted by nutritionists and regulatory bodies. Dietary antimutagens which may provide a means of slowing progression toward cancer have been identified such as certain types of dietary fibres, certain probiotics or small molecule dietary antioxidants including ascorbic acid, vitamin E, glutathione, various polyphenols, carotenoids and selenium have been suggested to be important antimutagen agents. These last ones possibly through their ability to scavenge free radicals, and prevent their interactions with cellular DNA. Many fruits and vegetables contain compounds that will protect against mutation and cancer by several mechanisms. For example, kiwifruit has antioxidant effects and may also affect DNA repair enzymes. Dietary folate may be a key factor in maintenance of methylation status, while enhanced overall levels of vitamins and minerals may retard the development of genomic instability. The combination of each of these factors could provide a sustainable intervention that might usefully delay the development of cancer. Although there are a range of potentially antimutagenic fruits, vegetables and cereals available, current intake is generally below the level necessary to protect from dietary or endogenous mutagens. Functional foods development could be provide an alternative approach.

- **Osteoporosis** – Osteoporosis is a growing concern of the aging population. Quality of life is the credo. Governments develop health campaigns related to the prevention of osteoporosis in order to reduce its impact on public health costs. One of the problems consumers and governments are faced with is that the most important period to influence bone mass is the age between adolescence and 30 years, long before signs of osteoporosis become apparent. In this respect it has been hypothesized that dietary measures to maximize bone mass early in life and reduce the loss of bone mass later in life are accepted best and are therefore most promising. Once food components are discovered which may help to prevent the risks of osteoporosis it is required that solid evidence is obtained on the efficacy of these components when taken daily. Promising in this respect are vitamin K, phyto-estrogens and non-digestible carbohydrates, in addition to the well established key-nutrients calcium and vitamin D (Pérez-López, 2007).

**IV.2 Scientific controversies** - Inconsistent data have resulted in overt inconsistencies regarding the impact of certain food ingredients on health indices or dietary active compounds have shown some effects in a number of studies, but the data obtained seem contradictory when looked at in totality (*Jones and Jew, 2007*). And, dietary active compounds which have shown some effects in a number of studies, but the data obtained seem contradictory when looked at in totality. Examples of inconsistencies include the controversy for vitamin E and  $\beta$ -carotene. Indeed, randomized, controlled clinical trials have shown that  $\beta$ -carotene and vitamin E, which were widely believed to be safe, increase mortality and morbidity (*Bjelakovic, et al. 2007, Miller et al. 2005*). More recently, a study demonstrated that a long-term selenium intake appears to increase the risk for type 2 diabetes even though the daily supplementation was 200  $\mu\text{g/d}$  a dose equal to the half of the Tolerate Upper Intake Level (UL) (400 $\mu\text{g/d}$ ) determined by the Institute of Medicine (*Stranges et al., 2007*). In the same spirit, even though a number of epidemiologic studies significantly associate an increased consumption of fish and omega-3 fatty acids with a reduced risk of developing cognitive impairment, dementia or AD, some research does not report this linkage (*Arendash et al., 2007*). A recent study published in this month's issue of *Nutrition Reviews* call for a careful reconsideration of fortification programs, since adding folic acid to the diet may benefit some consumers but cause damage to others (*Kim, 2007*). The absence of unequivocal evidence supporting diet-disease relationships poses a challenge for the public to place their faith in nutritional messages.

In conclusion, a series of epidemiological studies indicated that consumption of specific foods (including beverages) may be inversely associated to the risk of diseases and substantial progress has been made concerning the impact of dietary active on target function. However, controversies or inconsistent data regarding the impact of certain foods ingredients on health indices increase and poses a challenge for the public to place their faith in nutritional messages.

➤ **Point 3 : Health claims should require scientific validation and substantiation to avoid controversies**

## **V - SOME CRITERIA FOR THE DEVELOPMENT OF GUIDELINES FOR THE ASSESSMENT OF FUNCTIONAL FOODS**

There is a wide variety of claims currently used in the labelling and advertising of foods relating to substances that have not been shown to be beneficial or for which there is not sufficient scientific agreement. Thus, it is necessary to ensure that the substances for which a claim is made have been shown to have a beneficial nutritional or physiological effect. However, there is debate regarding the information required to document beneficial effects and how to communicate such benefits through claims. Two reports, which deliver criteria to assess the scientific support for claims in food, have recently been published from experts groups from USA and Europe. The European report – “*PASSCLAIM: Process for the assessment of scientific support for claims on foods*” - is a consensus document that has been born of wide and intensive consultation among diverse stakeholders including academic experts, representatives of public interest groups, regulators, and the food industry which provides scientific assessment framework that can be used throughout Europe (*Passclaim, 2005 available at Available at <http://europe.ilsa.org/NR/rdonlyres/693AF260-444C-4ABE-B314-7176FBE78857/0/PASSCLAIMConsensusonCriteria.pdf>*) (Agget *et al.*, 2005). The american experts report -“*Functional Foods: Opportunities and Challenges*” - provides a comprehensive review of functional foods that emphasizes their importance, summarizes the applicable U.S. laws and regulations, and presents scientifically based guidance for demonstrating both safety and efficacy (*IFT Expert Reports, 2005 available at [http://members.ift.org/IFT/Research/IFTExpertReports/functionalfoods\\_report.htm](http://members.ift.org/IFT/Research/IFTExpertReports/functionalfoods_report.htm)*).

This section is aimed at developing guidelines for the assessment of functional foods. It summarises the conclusions of expert groups taking in consideration the two consensus documents (*Passclaim Report* and *IFT report*) and other pertinent papers that have critically assessed the science base required for providing evidence that specific nutrients positively affect target functions.

### **Criterion 1 – The food or food component to which the claimed effect is attributed should be characterized**

Functional ingredients are a diverse class of compounds and may be represented by single component ingredients, or complex herbal extracts or products derived from novel sources or processes; the compositional analysis for each of these types of products is a critical determinant of the approach to the determination of safety for the ingredient.

- **History of the product** - To avoid variability, product standardisation is necessary and for that, different information concerning the product source, the growth conditions, the raw material, process applied to starting material. This point is particularly important in the case of botanical preparation for which the chemical properties should be reproducible from batch to batch (*Shilter et al., 2003*).
- **Chemical analysis** - Compositional analysis of food products is crucial for guaranteeing food quality and safety. Each category presents its own challenges for adequate chemical characterization. The simplest type of product consists of a single chemical component that may be identified and quantified by a single analytical method. However, a product that consists of a complex mixture, e.g. an extract of a plant, may require a suite of several analytical methods to identify and quantify the myriad components that may be members of different classes of chemicals including contaminants, impurities. For example, some

plants contain aristolochic acid, a naturally occurring toxin that has been reported in the medical literature to cause cancer and kidney failure in humans. While some techniques, such as HPLC can yield profiles of characteristic components, such techniques are unlikely to be sufficient alone to characterize: (i) the ensemble of substances that are known to be or suspected of being the active ingredient, (ii) the ensemble of substances that are associated with the active ingredient (i.e. “related substances”) and, (iii) any unintended constituents of the ingredient, i.e. unavoidable impurities. While the measurement of the traditional macronutrients such as protein, fat and minerals, relies on basic chemical techniques, the identification of more specific components, such as individual polyphenols is a complex process since more than 8000 phenolic structures are currently known. A chemical fingerprint of the material would be required with limits on the range of variability. Due to the complex nature of many of the products, a perceived need was recognised for a careful investigation into of standardized analytical methods to verify compliance with labelling at least of the composition. In Europe, the Institute for Reference Materials and Measurements has compiled a database on standardised analytical methods that could be considered for the analysis of active compounds in functional foods (*Buchgraber & Karaali, 2005*) and in the USA numerous organizations have undertaken programs to develop both general frameworks for the analytical characterisation of products as well as methods for specific products (*Kruger & Mann, 2003*).

- **Safety-** Since the functional ingredient will be added to food, it must first be approved for use in food either via a food additive petition or obtaining GRAS (Generally Recognized As Safe) status. However, functional ingredients are biologically active and may therefore produce a range of outcomes in the body, at various levels of intake, from suboptimal physiologic action to therapeutic effect to frank toxicity. Understanding the mechanisms for pharmacologic activity as well as for toxicological potential is important to predict the consequences of exposure at different dose levels. The intended use and potential exposure to a functional ingredient must be compared to its determined safe level of ingestion; depending upon the compound, historical exposure and/or scientific studies (animal toxicology, absorption, distribution, metabolism and excretion (ADME), clinical trials) may be used to determine that safe level. This point is important since the margin of safety between the intended level of ingestion and a potentially toxic level may be very small.

**Criterion 2 – The efficacy of food or food component to which the claimed effect is attributed should be demonstrated without ambiguities**

Building a strong scientific basis for functional food claims relies on the ability to demonstrate the efficacy of functional food components. It is complex and costly task, but it is essential to acceptance of functional food. Because of the number of bioactive compounds and the diversity of likely biological effects, numerous and diverse experimental approaches must be taken to increase the understanding of the biology of bioactive compounds. At the end, substantiation of a claim should be based on human data. Different criteria have to be considered:

- **Biological Endpoints and biomarkers** - One key, but difficult, approach to the development of functional foods is the identifications and validation

of relevant markers that can predict potential benefits or risks relating to a target function in the body. Researchers face challenges in identifying appropriate biomarkers. Different expert working groups evaluated the categories of scientific evidence needed to support claims in relation to target functions evidencing possible biomarkers for bone health and osteoporosis (*Prentice et al., 2003*), cancer (*Rafter et al., 2004*), gut health and immunity (*Cummings et al., 2004*), mental state and performance (*Westenhofer et al., 2004*), diabetes (*Riccardi et al., 2004*) or cardiovascular disease (*Mensink et al., 2003*). **Although many possible biomarkers have been identified, few have been validated, and it is well recognised that many more are needed.**

- **Evidence from human studies** - Substantiation of a claim should be based on human data. However, linking specific benefits to the consumption of individual foods or specific food components is difficult and requires rigorous scientific protocols. The design of studies should include different considerations: (i) Study groups that are representative of the target group; (ii) appropriate controls; (iii) an adequate duration of exposure and follow up to demonstrate the intended effect; (iv) characterisation of the study groups background diet and other relevant aspects of lifestyle; (v) an amount of the food or food component consistent with its intended pattern consumption (*Agget, 2005*). These studies must be able to answer to different questions: **What are functions to promote? When a function is targeted, what are the impacts on the other functions? What are organ sites? What is target population? When a group is targeted, what are the impacts on the all population? What are side effects? What dose/level?**

**Criterion 3 – The safety of food or food component should be demonstrated at efficacious levels**

Although a functional ingredient is intended to produce a positive health benefit through physiologic or pharmacologic activity in the body, similar to a drug, there is a risk for a lifetime exposure and unsupervised consumption, as is the case for nutrients and food additives. Once food components are identified which may help to prevent the risk of disease, it is required that solid evidence is obtained on the safety and efficacy of these compounds when taken daily and on a long period.

Safe levels of intake must be considered when evaluating functional foods in the context of a healthy diet. For the majority of research studies, the optimal levels of nutrients and other physiologically active components in functional foods have yet to be determined in humans. The safety evaluation of dietary active compounds must take into account potential adverse effects of low intake (clinical deficiency) as well as effects from intakes that are too high (clinical toxicity). The dose-effect relationship might lead to considerations of physiological/nutritional disturbances that are irrelevant to standard safety assessment.

For functional foods, destined solely for special target population groups it is necessary to ensure safety to health for all groups likely to be potential consumers, particularly sensitive groups e.g. infants, pregnant women, breast-feeding mothers, and elderly and chronically sick people.

**Criterion 4 - The impact of food matrices on the activity and bioavailability of food component should be addressed**

The functional effect of a food or food component depends on the active component gaining access to the functional target site. However, foods are mostly complex mixtures of macro- and micro- components that can trap active compound, modulate its release or inhibit its activity (*Chen, Subirade et al. 2006 and 2007*). Moreover, most of dietary active compounds are sensitive to conditions encountered during food processing such as temperature (vitamin), oxygen (antioxydant compound), light or in the gut such as acidic pH of stomach (probiotic), digestives enzymes (active peptides/proteins), presence of other nutrients. Thus, the food matrix both in its raw state, after storage or culinary preparation can have a significant influence on the activity or release on the key components. Selection and development of a appropriate food vehicles that 1) maintain the active molecular form until the time of consumption, and 2) deliver this form to the physiological target within the organism, is an important step to the success of a functional food. As an example, it has been demonstrated that plant sterol efficacy differs across various matrices, the milk matrix being almost three times more effective than in bread or cereal (*Jones, 2007*).

**VI- SOME PRELIMINARY RECOMMENDATIONS** (some recommendations have previously been made by FAO (FAO, 2004) and have been identified by \*).

- **Point 1 . Functional foods should be clearly defined**
  - An international definition for functional foods should be adopted:
    - Functional foods should be “a food similar in appearance to a conventional food (beverage, food matrix), consumed as part of the usual diet which contains biologically active components with demonstrated physiological benefits and offers the potential of reducing the risk of chronic disease beyond basic nutritional functions”\*;
    - Biologically active components should be dietary (nutrient or not) compound present in unmodified whole food or added to a food vehicle.
  - An international database from dietary active compounds should be encouraged:
    - Biologically active components could originate from different origins - animal, plants, micro-organisms- and should be fully characterised, standardised and exempt of toxic compounds;
    - The establishment of an international database of dietary active compounds to be used in functional food development should be encouraged. Such a list should be regularly updated taking into account new scientific and technological developments and data on safety, bioavailability, stability and other relevant data. Limit levels (minimum and maximum) for the addition of dietary active compounds should be set, in international recommended standards, according to the purpose of the addition;

- Standardised analytical methods for the analysis of dietary active compounds should be inventoried in an international database.
  - The basic principles for the addition of dietary active compounds in foods could be based on the principles for the addition of essential nutrients to foods as stated by the Codex Alimentarius Commission:
    - The active compound should be present at a level which will not result in either an excessive or an insignificant intake of the added compounds considering amounts from other source in the diet; but the level should be sufficient to exerce its beneficial effects;
    - The addition of an active compound to a food should not result in an adverse effect on the metabolism of any other nutrient;
    - The active compound should be stable in the food under customary conditions of packaging, storage, distribution and use;
    - The active compound should be biologically available from the food;
    - Methods of measuring, controlling and/renforcing the levels of added active compounds in the foods should be available.
- **Point 2 . Health claims vs structure/functions claims vs nutrition claims should be clearly defined**

There is a need to have a clear distinction between functional and health claims and to harmonize these definitions. The two broad categories, already adopted in some countries (EU), could be defined as follow:

- Nutrition Claims could be referred to what the product contains;
- Health Claims: could be related to what the food or food components does or do.

The Codex Alimentarius guidelines for use of nutrition and health claims in food labelling (see p. 13) should be encouraged.

- **Point 3 . Health claims should require scientific validation and substantiation**
  - Substantiation of a claim should be based on human data using rigorous scientific protocols:
    - There is a need to identify and validate relevant markers that can predict potential benefits or risks relating to a target function in the body;
    - Scientific substantiation of functional properties should follow standard protocols and would include *in vitro*, epidemiological and *in vivo* studies according to Codex guidelines\*.
    - It is necessary to ensure that the substances for which a claim is made, have been shown to have a beneficial physiological effect;
    - Functional foods should be efficient i.e. demonstrate their effects in amounts that can normally be expected to be consumed in the diet;

- There is a need to define guidelines for safety and efficacy assessment of functional foods;
  - Safety and efficacy should be analyzed taking in consideration long-term consequences and interactions between components;
  - Safe levels of intake must be considered when evaluating functional foods in the context of a healthy diet;
  - For the majority of research studies, the optimal levels of nutrients and other physiologically active components in functional foods should be determined in humans;
  - Unwanted effects should be determined on all population including targeted population, if there is, and population groups outside the intended target group. The population targeted by the product should be clearly identified\*;
  
- **At the end, even though a functional food is considered to have specific health benefits, excessive consumption should not be encouraged as this may displace other foods in the diet. The emphasis should be on variety, moderation, balance and a combination of foods to promote health and nutrition wellbeing.\***

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