

FUNCTIONAL FOODS AND NATURAL HEALTH PRODUCTS
REGULATIONS IN CANADA AND AROUND THE WORLD:
NUTRITION LABELS AND HEALTH CLAIMS

By

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EXECUTIVE SUMMARY

The functional food and natural health products industry has become an important part of the global food industry. Consumer awareness of, attitudes toward and acceptance of these products is increasing and the global market size exhibits an upward trajectory. Depending on the definition of functional food, the global market size is estimated to be approximately US\$30 to US\$60 billion, representing 1-3 percent of the total food market (Kotilainen et al 2006). In Canada, the number of firms involved in the production of these products was approximately 8.1% of the total food industry in 2007 (Cinnamon 2007). The importance of functional food and natural health products is reflected in the interest in regulation of health claims and standards from industry stakeholders and policymakers.

The scientific evidence and awareness of the correlation between diet and health, increasingly sedentary lifestyles, aging population, and the ever increasing health care costs in Canada and other countries with publicly funded health care systems have increased the interest in healthier food products (functional foods and natural health products). Several factors are known to contribute to the general health of the population; however there is increasing recognition among health professionals, policymakers and consumers of the link between diet and health. The World Health Organization identifies nutrition as a significant and manageable determinant of chronic disease, stressing the need for a shift in nutrient intake towards 'healthier' foods. The incidence and severity of many major diseases such as diabetes, coronary heart disease, and cancer are affected by diet. It is estimated that these four dietary-related diseases accounted for \$29.4 billion of direct and indirect health care costs in 1993 (2004 dollars) or 19% of Canadian health care costs. Recent innovations in the agricultural and food sector have produced functional foods with the potential to reduce the risk of some of these major diseases. The growing burden of health care costs remains a key policy issue in Canada. Hence, the potential implications for public health care costs of increasing the consumption of healthier foods in diets is of major policy relevance.

Recent policy responses have included measures to better inform consumers about the nutrient content of foods to facilitate healthier eating choices which could result in a healthier population and a reduction in the rising health care costs. One example of this in Canada in 2005 was the introduction of mandatory nutrition labelling on pre-packaged foods and the requirement to label the presence of trans-fats in these foods. Enhancing the information to consumers is an important policy response to improving health. Attempting to solve this market failure (based on

information asymmetry by permitting health claims for functional food and natural health products) has led, in some cases, to the proliferation of many health claims. Currently, there are many and varied health claims permitted on these products around the globe. Furthermore, there are many policy implications with respect to the regulatory environment for approval of new functional/healthier foods and natural health products, as well as the current labelling regulations for health claims on food and natural health products.

In this project, we examine the functional foods and natural health product regulations and policies in Canada and around the world, including a number of countries: the United States, European Union, United Kingdom, Sweden, Russia, Australia and New Zealand, Japan, Brazil, Korea, China, Taiwan, Singapore, Malaysia, Hong Kong, India, Thailand, and The Philippines. Differences in regulations, policies and health claims, as well as challenges facing the industry, are explored. We examine specifically disease risk reduction claims, structure/functional claims, nutrient content claims, and nutrient labelling regulations, as well as novel food registration. To broaden our understanding of this important sector, we compare and contrast different policies and regulations around the world and make policy recommendations that could improve Canadians' well-being and increase social welfare. If successful policies from other countries can be adopted, this could accelerate and foster innovation in the sector. Growth in the sector could lead to great social and private benefits¹.

There is no unique global definition for the term “health claim”. In Canada, the generally accepted definition for a health claim on food is “any representation in labelling and advertising that states, suggests, or implies that a relation exists between the consumption of foods or food constituents and health” (Health Canada 2010). Health claims can be distinguished (divided) into generic and product-specific claims. Generic claims specify a relationship between a food constituent and a health effect and can be used on any food so long as the food meets the conditions for using the claim. Product-specific claims, on the other hand, can only be used by products that undergo a registration process for a claim that specifies a relationship between the food or food constituent and a health benefit.

In addition to these distinctions, health claims are usually divided into two different categories (Subirade 2007). One kind of health claim is a disease risk reduction claim specifying the relationship between the consumption of a nutrient and its effects on disease risk. For

¹ In a companion report to this analysis, Malla et al. (2013) provide an overview of industry and market trends in the functional food and natural health products sector, as well as a comprehensive review of literature examining consumer awareness and product developments.

example, several countries (Canada, USA, Australia and New Zealand, The Philippines and Japan) permit claims linking the presence of calcium and/or Vitamin D and the reduced risk of osteoporosis. Structure/function claims, on the other hand, link the presence of a nutrient to normal growth, development, or functioning of the human body. For example, several countries (Canada, Australia and New Zealand, Sweden, Singapore, Malaysia and Japan) permit claims linking the presence of calcium and/or Vitamin D and proper bone structure.

Nutrition content claims or nutrition claims can also often be made on food and sometimes on nutraceuticals. Nutrition claims describe the presence or absence of a nutrient. Claims that are permitted are usually those that have positive implications for health. In a way, nutrient content claims are implied health claims. For example, in some countries, (Canada, USA, European Union, Taiwan, Hong Kong, Japan, among others) firms can claim a food to be “high in potassium and low in sodium”, both of which contribute to reduced risk of high blood pressure and cardiovascular disease.

Nutrition labelling regulations on food vary from country to country. Specifically of interest here are nutrition facts tables which display information about levels of nutrients per serving. In some countries (Canada, USA, Brazil, Taiwan, Singapore, Russia, India), nutrition labelling is mandatory, while in other countries (UK, Sweden, EU), labelling is voluntary unless a claim is made. As such, labelling is seen as a key part of informing the consumer about the foods they eat and allowing them to see that the claims that firms make on their foods are not misleading. Labelling on nutraceuticals vary from country to country, with some countries using labelling that treats the products more like drugs than food (e.g. Canada, Australia).

There are broad regulatory differences across countries when it comes to functional food regulations. Some countries have a body that regulates the use of health claims (for example, Health Canada in Canada, the Food and Drug Administration in the USA, The Ministry of Health, Labour, and Welfare in Japan, the Korean Food and Drug Administration (KFDA), the State Food and Drug Administration (SFDA) in China, and the Food Control Department in Singapore). Historically, some governments permitted health claims but left it up to private interests to regulate their use (United Kingdom and Sweden). Other countries have decided to cooperatively develop regulations together on health and nutrition claims (e.g. European Union, Australia and New Zealand). All of the countries examined in this study no longer permit self-regulation. Future directions thus appear to be towards cooperation between countries (which

would be important for countries with close trade ties) or direct domestic government regulations on health and nutrition claims.

Currently, in Canada there are nine approved generic disease risk reduction health claims permitted on food which can also be used on natural health products (NHPs). Canada requires a premarket approval for all health claims and has a relatively lengthy and stringent process of new claim approval. The nine claims are:

- 1) Low Sodium and High Potassium linked to reduced risk of high blood pressure;
- 2) Adequate vitamin D and Calcium intake linked to reduced risk of osteoporosis;
- 3) A diet low in saturated and trans fatty acids linked to reduced risk of heart disease;
- 4) Consumption of fruit and vegetables linked to reduced risk of some kinds of cancer;
- 5) Maxima fermentable carbohydrates in gum linked to reduced risk of dental caries or cavities;
- 6) Phytosterols linked to lowering cholesterol;
- 7) Oat fibre linked to reduced risk of heart disease.
- 8) Barley products and blood cholesterol lowering.
- 9) Unsaturated fat and blood cholesterol lowering.

There are 26 approved structure/function claims and no claims approved yet under therapeutic claims². In addition to these claims, nutrition content claims can also be made. There is also mandatory food labelling and in most cases labelling must be in both French and English.

Natural health products (NHPs) in Canada are regulated differently than functional food. The regulatory systems for NHPs are essentially product-specific. The National Health Products Directorate evaluates and approves the NHP if and only if its efficacy and safety can be proven. The level of evidence required is also dependent on the claim (disease risk reduction claims require stronger evidence, including clinical studies). Natural health products are more tightly regulated than functional foods as they fall under NHP regulations.

Novel foods in Canada are required to undergo a novel food application. Novel food refers to foods resulting from a process not previously used for food and food that has been modified by genetic manipulation known as genetically modified foods. The approval process is administered through the Bureau of Chemical Safety, the Bureau of Nutritional Sciences, and the Bureau of Microbial Hazards. The evaluators from these bureaus assess the novelty of the food

² Therapeutic claims on food are technically permitted in Canada, although none have been approved for use on functional foods. A therapeutic claim suggests that the consumption of a nutrient, vitamin, or mineral would treat or mitigate disease conditions or restore normal bodily functions.

and must reach a unanimous agreement about the safety of the food before it receives the approval from the novel food section of Health Canada.

On the global scene, most countries regulate the use of health claims on functional food and natural health products. However, the extent of the regulations differs among countries, which is evident in the scope of permitted health claims globally (Table A).

In Canada, qualified health claims are not permitted, in contrast to countries like the United States and Japan. Qualified health claims are claims that contain credible but inconclusive evidence. The authorization of these claims requires lower standards of evidence. They also usually require the provision of a disclosure statement or a less authoritative wording than full strength claims. This would encourage research by reducing the level of evidence required for claims. Some countries, however, reject the use of lower standards for disease risk reduction claims (e.g. South Korea, Australia and New Zealand) because of the importance of not misleading consumers about the nature of these relationships. Currently the United States has approved twenty two qualified health claims and Japan has the qualified FOSHU. This distinction between Canada and the rest of the world is reflected in the small number of approved health claims.

In addition, Canada does not permit product specific claims on food. Product specific claims are used only by products that undergo a registration process for a claim that specifies a relationship between the food or food constituent and a health benefit. Countries like Japan, China, South Korea, Malaysia, and Sweden historically, however, do permit product specific claims. Generic claims unlike product specific claims create a free rider problem: many firms can benefit but only one firm has to go through the application process to get approval for a new claim. However, the advantage of the generic system is that more products can use approved health claims, with the potential for health benefits to consumers who recognize the relationship between diet and health. Allowing product-specific claims reduces spillover benefits that would otherwise accrue to other firms producing similar food products. This imperative must be balanced with the objective to provide consumers with accurate information. Hence, product specific claims have proven to induce investment and also research & development expenditures due to the elimination of free ridership. Consequently, a potential step towards encouraging research and development by firms would be to allow product-specific claims. Finally, unique among the countries under study here, Canada also permits therapeutic claims on food, although no therapeutic claims have been approved at this time.

Comparing Canada to other countries, there are additional noticeable differences. Most structure/function claims in Canada have been approved as disease risk reduction claims in other countries. Some examples include: folate and fetal neural development; soluble fibre and heart disease; selenium and antioxidants/cancer (Table A). These claims are approved as disease risk reduction claims in the United States but are structure/function claims in Canada. In addition, Canada, like the United States, has strict requirements for nutrition labelling compared to the EU. In the EU, labelling is optional unless a claim is made. Labels in the EU only need a very short list of nutrients compared to Canada and the USA. Nutritional regulations in Canada require labels to be in both English and French.

Regulations on nutraceuticals/natural health products vary from country to country. Some countries treat natural health products in a similar manner to food. Japan and China are the examples par excellence of this, making little or no legal or regulatory distinction between food and pill forms. The United States does distinguish between food and natural health products (dietary supplements) but does not impose significantly different regulations (the same generic claims are available to food and to dietary supplements). New Zealand treats natural health products (dietary supplements) like food but does not permit certain claims (including disease risk reduction claims) on supplements. However, the regulatory requirements for dietary supplements are somewhat lax. The EU treats food supplements as a food but significantly limits food supplements to only approved vitamins and minerals. Then there are countries that place natural health products in a grey zone between food and drugs. Brazil, Canada, and Australia all regulate natural health products differently than food, using a product-specific system with a more substantial level of evidence required. South Korea is the example best example of this category, restricting functional foods to natural health products and requiring licenses even for venders of the products, not just the producers.

To sum up, it is suggested that Canada lags behind the rest of the world in regards to health claims for these products. Canada has a fairly stringent regulatory procedure in the areas of functional food and natural health products compared to other countries like the United States, Japan, and the EU. While this remains important in terms of consumer protection, a balance is required and the bureaucracy surrounding the approval process and the stringent requirements are such that it is often very difficult for a new claim to get approval. The relatively few disease risk reduction health claims approved in Canada, absence of qualified health claims and the

prohibition of product specific claims on food are all indicators of a relatively more restrictive regulatory environment.

Nevertheless, there is evidence of robust socio-economic potential in the sector. Studies have shown that health claims on food can lead to improved health, health care cost reductions and increased export market opportunities. The adoption of policies such as the use of qualified health claims and product specific claims similar to that used in the US, Japan and China could facilitate greater innovation in the sector. Efforts to harmonize or establish equivalence with health claims in other countries (particularly the United States) could facilitate trade. Targeted public policies (e.g. period of exclusivity with respect to health claims, patents incentives, tax incentives and subsidies) can also be used to stimulate R&D on healthier food products.

Health claims on foods have become an increasingly important policy issue. The growing burden of health care costs remains a concern in Canada and other countries with public funded health care systems. The potential effects on public health care costs of increasing the consumption of functional/healthier foods is of major policy relevance. As the Canadian regulatory system for health claims and functional foods continues to evolve insights from other regulatory jurisdictions can provide useful lessons. The relatively small size of the Canadian domestic market means that substantial differences between Canadian regulations and those of major export markets are likely to further inhibit investment in functional food development in the Canadian market. As ever the challenge remains balancing consumer protection from fraudulent or misleading health claims with a regulatory environment that encourages investment in R&D into products with positive health benefits for consumers.

TABLE A: GLOBAL HEALTH CLAIMS³

COUNTRIES	Disease Risk Reduction Claims	Structure/Function Claims
Canada	Sodium & Potassium → high blood pressure; Calcium & Vitamin D → Osteoporosis; Saturated & trans fat → heart disease; Vegetable & fruits → cancer; Maximal fermentable carbohydrates → dental caries; Phytosterols → Cholesterol lowering; Oat fibre → reduced risk of heart disease. Barley products → Cholesterol lowering; Unsaturated fats → Cholesterol lowering.	Coarse wheat bran, Psyllium → Regularity; Green tea, Selenium, Phosphorous, Vitamin C, E → Antioxidant effect on blood; Protein → Body tissues or antibodies; Fat, Carbohydrates → Energy; ARA, DHA → Development of brain, eyes and nerves; Calcium, Phosphorous, Vitamins A, C, D → Bones, Teeth; Thiamine, Niacin, Riboflavin, Pantothenic and Magnesium acid → Normal growth, metabolism and tissue formation; Folate → Fetal neural development; Vitamin B12, Iron → Red blood formation; Iodine → Thyroid gland formation
United States	SSA Claims⁴: Soy protein, fruits, vegetables, soluble fibre → Coronary heart disease (CHD); Fat, fibre containing grain products → Cancer; Folate → Neural tube defects. Qualified Claims⁵: Tomatoes, Calcium, Green tea, Selenium, Antioxidants vitamins → Cancer; Nuts, Walnuts, omega-3 fatty acids, B-vitamins, corn oil, unsaturated fats from canola oil, monosaturated fatty acids from olive oil → Heart disease; Calcium → Hypertension; Chromium → Picolinate Diabetes; Phosphatidylserine → Cognitive dysfunction.	Permitted but the Food and Drug Administration (FDA) does not keep a list of the claims.
European Union	Plant sterols & stanols → Heart disease; Chewing gum sweetened with 100% Xylitol → Dental plaque. -Health claims are permitted on food products intended for children under 2 years. -Over 4000 claims (structure/function and disease risk reduction) under evaluation by the European Food Safety Authority (EFSA).	A list of acceptable claims was to be created by January 31 2010 as per EU1924/2006, but is yet to be finalized and approved by the Commission. <u>Children’s Growth and Development (Article 14(1)(b)) Claims</u> α-Linoleic acid (ALA) & Linoleic acid (LA) → normal growth/development if children; Calcium, Vitamin D, Phosphorus, and Protein → growth and development of bone in children <u>Emerging Scientific Evidence/Request for Proprietary Information (Article 13(5)) Claims</u> Water-soluble tomato concentrate → blood flow
Sweden	Energy → Obesity; Hard Fat, Dietary fat (oats), Omega-3 fatty acids, Whole grains, Salt → Heart disease; Dietary → fibre constipation; Salt → High blood pressure; Calcium and/or vitamin D → Osteoporosis; Sugar → Caries; Iron → Iron deficiency	Vitamin C, E, Beta-carotene → antioxidants; Vitamin C → Iron absorption; Calcium, Vitamin D → bone development; Zinc → Enzyme systems; Iron → blood & hemoglobin production; Dietary fibre → normal bowel function; Carbohydrates → blood sugar

³ For more information and distinction between functional food and NHP claims, see report and Tables 1 & 2 in Appendix 1

⁴ Claim must meet the significant scientific agreement (SSA) standards which are strong standards that provide a high level of confidence in the validity of the substance/disease relationship.

⁵ These claims go through the same evaluation procedure as SSA claims, but do not require the same level of qualified expert consensus. There is some credible evidence for these claims, but the evidence is inconclusive.

China	-Disease risk reduction health claims can be made between the approved food or food constituents and the following 4 health effects: Weight loss; Cholesterol (blood lipids) reduction; Blood pressure; and Blood sugar.	23 health effects approved. Eg. Improves skin's oil content; Regulates gastrointestinal tract flora; Facilitates feces excretion; Assists in protecting against gastric mucosa damage.
Australia and New Zealand	-Sodium(with or without potassium), Fruits, vegetable , Saturated and /or trans fat →Heart disease; Calcium → Osteoporosis; Folic Acid → Neural tube defects.	24 approved claims. E.g. Vitamin D → Calcium & phosphorus utilization and absorption; Selenium, Vitamin E → Antioxidant; Vitamin K → Proper coagulation; Thiamine → Normal metabolism of carbohydrates; Riboflavin, Niacin → Metabolism.
Japan	-Disease risk reduction claims are referred to as FOSHU claims. -There are 3 categories of FOSHU [regular(specific); qualified; and standardized] -Regular/Specific claims: Calcium →Osteoporosis; Folic acid →Neural tube defects. -Standardized and Qualified claims: No list available. Well over 600 products have approval	-Structure/function claims are known as food with nutrient function claims (FNFC). -There are 12 listed FNFC for vitamins, 5 for minerals and over 600 unlisted for other food products.
Brazil	Omega-3 fatty acids → Heart health, Dietary fibre, Fat, Quitosane, Phytosterols, Soy protein → Cholesterol; Mannitol, Xylitol, or Sorbitol →Dental carries.	Lycopene → Antioxidant; Dietary fibres, Lactulose → Normal intestinal function; Inulin, Probiotics, Fructo-oligosaccharides → Gut flora
Republic of Korea	35 ingredients approved to have claims	Permitted but no list available Qualified Claims on the following: Reduction of blood pressure; Reduction of cholesterol; Reduction of body fat; Maintenance of good health; Modulation of blood glucose level; Modulation of postprandial glucose level; Maintaining health gastrointestinal conditions; Antioxidants effects; Improvement of memory functions; Improvement of cognitive functions
Philippines	Calcium →Osteoporosis; Low fat food → cancer	Permitted but no list available
Malaysia	Permitted but no list of claims available	Folic acid → Growth and cell division; Iron, Vitamin B12 → Red blood cell formation; Niacin, Vitamin B2, B1 → Energy; Magnesium, Vitamin D → Calcium absorption and retention; Calcium → Bone health; Vitamin C → Iron absorption; Inulin, Oligofructose → Intestinal health
Taiwan	Not Permitted	Approved health effects: Regulate blood lipids; Improve gastrointestinal functions; Alleviate osteoporosis; Maintain dental health; Regulate immune system; Regulate blood sugar level; and protect liver.
India	Not Permitted	No list available
Singapore	Not Permitted	Protein → Body tissues; Low lactose content → Lactose intolerant; Calcium, Vitamin D3 → Bone strength; Iron →Energy; Folate → Fetus growth, development and red blood cells formation.

Russia	Not Permitted	Examples of approved health effects: Optimization carbohydrates, fat, vitamins and other metabolism in various functional conditions; Improvement of the function of the human organ/system; Decrease morbidity; Improvement of the gastrointestinal tract formation.
Hong Kong	Not Permitted	Permitted but no list available
Thailand	Not Permitted	No complete list available; include: folate→red blood cell formation; calcium→bones and teeth

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***FUNCTIONAL FOODS AND NATURAL HEALTH PRODUCTS
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NUTRITION LABELS AND HEALTH CLAIMS***

1. Introduction

Around the world, governments are seeking effective ways of minimizing healthcare costs and maximizing citizens' health. This is exacerbated by the rise of lifestyle and diet related diseases. At the same time, firms are seeing opportunities in burgeoning "health food" and related goods markets (see, for example, Ohama et al. 2008; Williams and Ghosh 2008; Toledo and Lajolo 2008). The relationship between diet and health is becoming increasingly important in the context of ageing populations in the developed world. Healthier diets today may lead to fewer diseases tomorrow. The consumption of functional foods and/or nutraceuticals/natural health products provides an avenue for improving citizens' welfare.

Definitions of functional food vary from country to country. For the purposes of this analysis we use Canada's definition of functional food. Canada defines **functional food** as a food similar in appearance or substance to conventional food consumed as a normal and regular part of the diet with demonstrable health benefits. We also use Canada's definition of nutraceuticals. **Nutraceuticals** are concentrated forms of food or food constituents that can be taken in pills, powder, or other medicinal forms that have specific health benefits (Health Canada 1998). In Canada, **natural health products** (including most nutraceuticals but also homeopathic and traditional medicines) are considered an intermediate substance between food and drugs, and are regulated differently than food (Walji and Boon 2008). Moreover, these benefits may align with the profit-maximizing motive of firms. Consumers desiring to be healthier will likely see food with health benefits as superior to food without health benefits and may be enticed into substituting food with health benefits for food without health

benefits. However, in order for consumers to choose functional foods and nutraceuticals/natural health products over conventional foods, they must be provided with information. Many countries have thus moved to regulate health and nutrient content claims. These claims are usually permitted on labelling and in advertisements and to inform consumers about the health benefits of the consumption of the food or the food constituent.

Health claims can be either generic or product-specific. Generic claims tend to specify relationships between a food constituent and a health effect, and can be used on any food so long as the food meets the conditions for using the claims. Product-specific claims, on the other hand, can only be used by products that undergo a registration process for a claim that specifies a relationship between the food or food constituent and a health benefit (Subirade 2007).

In addition to these distinctions, claims are usually divided into two different categories: disease risk reduction claims and structure/function claims (Subirade 2007). A **disease risk reduction** claim usually specifies the relationship between the consumption of a nutrient and its effects on disease risk. For example, several countries (Canada, USA, Australia and New Zealand, Philippines and Japan) permit claims linking the presence of calcium and/or Vitamin D and the reduced risk of osteoporosis. **Structure/function claims**, on the other hand, link the presence of a nutrient to normal growth, development, or functioning of the human body. For example, several countries (Canada, Australia and New Zealand, Sweden, Singapore, Malaysia and Japan) permit claims linking the presence of calcium and/or Vitamin D and proper bone structure.

Nutrition content claims or nutrition claims can also often be made on food (Malla 2004) and sometimes on nutraceuticals/natural health products. Nutrition claims simply

describe the presence or absence of a nutrient. Claims that are permitted are usually ones that have positive implications for health. In a way, nutrient content claims are implied health claims. For example, in some countries (Canada, USA, European Union, Taiwan, Hong Kong, Japan, among others), firms can claim a food to be “high in potassium and low in sodium”, both of which contribute to reduced risk of high blood pressure and cardiovascular disease.

An additional regulatory hurdle to functional foods may be novel food approval (Malla 2004). If a food meets certain conditions (e.g., it has no history as safe use of a food), then it may be subject to novel food registration before entering the market. This generally requires a safety assessment. Details of novel food registration procedures in many of the countries are provided below.

Nutrition labelling regulations vary from country to country. Specifically of interest here are nutrition facts tables, which display information about levels of nutrients per serving. In some countries (Canada, USA, Brazil, Taiwan, Singapore, Russia, India), nutrition labelling is mandatory, while in other countries (Sweden, the EU, including the UK), labelling is voluntary unless a claim is made. As such, labelling is seen as a key part of informing the consumer about the foods they eat and confirming that the claims that firms make on their foods are not misleading. Labelling on nutraceuticals/natural health products vary from country to country, with some countries using labelling that treats these products more like drugs than food (e.g. Canada, Australia), but others the reverse.

There are broad regulatory differences across countries when it comes to functional food regulations. Some countries have a body that regulates the use of health claims (for example, Health Canada in Canada, the Food and Drug Administration in the USA, The Ministry of Health, Labour, and Welfare in Japan, the Korean Food and Drug Administration

(KFDA), the State Food and Drug Administration (SFDA) in China, and the Food Control Department in Singapore). Historically, some governments permitted health claims but left it up to private interests to regulate their use (United Kingdom and Sweden). Other countries have decided to cooperatively develop regulations together on health and nutrition claims (European Union, Australia and New Zealand). All of the countries under study here no longer permit self-regulation. Future directions thus appear to be towards cooperation between countries (which would be important in countries with close trade ties) or direct domestic government regulations on health and nutrition claims.⁶

The objective of this document is to provide a review of functional food and nutraceutical regulations around the world, especially those examples with regulatory relevance for Canada⁷. This document examines the varying regulations on food and nutraceuticals/natural health products in terms of registration (if necessary) and permitted claims. This document also examines labelling of functional foods and nutraceuticals/natural health products and novel food registration procedures as these affect incentives for firms to innovate. This document begins with Canada before examining the United States, the European Union, historical regulation in the United Kingdom and Sweden, Russia, Australia and New Zealand's joint regulation, Japan, Brazil, Korea, China, Taiwan, Singapore, Malaysia, Hong Kong, India, Thailand and The Philippines. This document concludes with a brief comparison and analysis section to provide insights into potential regulatory lessons for Canada.

⁶ See Appendix 2 for the Codex Alimentarius recommendations on health and nutrition claims.

⁷ In a sister analysis to this report, Malla et al. (2013) provide an overview of industry and market trends in the functional food and NHP sector, as well as a comprehensive review of literature examining consumer awareness and product developments. These issues are not addressed here and interested readers are referred to Malla et al. (2013) for further details.

2. Functional Foods, Nutraceuticals, Health Claims, and Related Regulations

Canada

Canada permits both generic health claims and nutrient content claims on food. Permitted health claims include both disease risk reduction claims and structure claims and are regulated by the *Food and Drug Regulations* Act. Unique in the countries under study here, Canada also permits therapeutic claims on food, although no therapeutic claims have been approved at this time. Therapeutic claims suggest that the consumption of a certain nutrient will treat or mitigate a disease or condition or restore or otherwise modify an existing function (Canadian Food Inspection Agency 2009). This is in stark contrast to many other countries that explicitly prohibit the use of therapeutic claims on food. On the one hand, this provides an opportunity for firms to innovate. On the other hand, this may be seen as elevating food to the status of a drug and the standards of evidence for proving therapeutic effects of food may simply be too high for food realistically to be able to meet them. Nutrition content claims can also be made and Canada has a relatively heavily regulated nutrition claim system compared to other countries. Nutrition labelling requirements in Canada are more stringent than other countries, with mandatory labelling for all pre-packaged food with labelling usually required in both French and English. Food that is novel must undergo a novel food application. The novel food registration process is more stringent in Canada than in some countries, especially the USA, but is not as stringent as elsewhere, particularly the European Union. Product specific claims regulation covers nutraceuticals as Natural Health Products (NHP).⁸

⁸ There is also a voluntary industry regulated Health Check program, whereby products with certain nutritional profiles are permitted to use the Health Check logo. See Appendix 4 for details on this program.

In Canada, health claims and nutrient content claims are permitted under the *Food and Drug Regulations* (FDR) Act. A health claim is any claim that relates the consumption of a food or ingredient and health. Disease risk reduction claims relate the consumption of food (or a food component) and the risk of developing a diet-related disease (Canadian Food Inspection Agency and Health Canada 2009). There are nine disease risk reduction claims currently permitted in Canada (DOJ, n.d.; Canada 2010; Health Canada, 2012a; Health Canada 2012b):

- Low sodium and high potassium and reduced risk of high blood pressure;
- Adequate Vitamin D and calcium intake and reduced risk of osteoporosis;
- A diet low in saturated and trans fatty acids and reduced risk of heart disease;
- Consumption of fruit and vegetables and reduced risk of some kinds of cancer;
- Maximal fermentable carbohydrates in gum and reduced risk of dental caries or cavities;
- Phytosterols and lowering of cholesterol;
- Oat fibre and reduced risk of heart disease.
- Barley products and blood cholesterol lowering.
- Unsaturated fat and blood cholesterol lowering.

There are several regulations and conditions that accompany the use of disease risk reduction claims⁹. Disease risk reduction claims must not be misleading. As such, they must be based on adequate scientific evidence and it should be reasonable and feasible for an individual to consume an effective amount of the food in the context of a healthy diet. Except for a few exempt foods (“local,” “test market,” or “specialty” foods), claims must appear in both English and French. When the disease risk reduction claim is made, the food must also declare a Nutrition Facts table, including the amount of nutrient, mineral, or vitamin that has the disease risk reducing effect. The claims themselves must be written as regulated, and

⁹ When health claims are generic, manufacturers are not required to prove that their product(s) contain the required amount of ingredient(s) associated with the claim or the truthfulness and efficacy of the health claim (no pre-market approval/notification required), though they should be able to provide the information when requested.

cannot be modified to contain intervening information. These claims are not allowed on food intended for children under two years old or for food intended for very low energy diets (Canadian Food Inspection Agency and Health Canada and Health Canada 2009).

Therapeutic claims on food are technically permitted in Canada, although none have been approved for use on functional foods. A therapeutic claim suggests that the consumption of a nutrient, vitamin, or mineral would treat or mitigate disease conditions or restore normal bodily functions. Therapeutic claims must undergo the same evaluation procedure as disease risk reduction claims (see below). The approval of the claims for use would require an amendment to the FDR (Canadian Food Inspection Agency and Health Canada 2009).

Structure/function claims (called “nutrient function claims” and formerly “biological role claims”) are also considered health claims. Unlike disease risk reduction claims, nutrient function claims must not refer to disease risk mitigation or prevention. Instead, they describe the nutrient’s importance in promoting normal and healthy growth and functioning. It is not mandatory (but it is recommended) that nutrient function claims be in both English and French. There are three function claims based on food or food constituents (coarse wheat bran and regularity, green tea and antioxidant effect on blood; and psyllium and regularity). There are sixteen established nutrient function relationships involving nutrients, vitamins, and minerals that can be used:

- Protein and body tissues or antibodies;
- Fat and energy or fat-soluble vitamins;
- ARA and development of brain, eyes, and nerves;
- DHA and development of brain, eyes, and nerves;
- Carbohydrates and energy or utilization of fat;
- Vitamin A and bones and teeth or night vision or skin and membranes;
- Vitamin D and bones and teeth or calcium and phosphorus utilization;
- Vitamin E as antioxidant or oxidation of fatty tissues;
- Vitamin C as antioxidant or bones and cartilage or teeth and gums;
- Thiamine and carbohydrates or normal growth;

- Riboflavin and metabolism or tissue formation;
- Niacin and growth and development or metabolism or tissue formation;
- Vitamin B₆ and metabolism or tissue formation;
- Folate and fetal neural development;
- Vitamin B₁₂ and red blood cell formation;
- Pantothenic acid and metabolism and tissue formation;
- Calcium and bones and teeth;
- Phosphorus and bones and teeth;
- Magnesium and metabolism and tissue formation and bone development;
- Iron and red blood cell formation;
- Zinc and metabolism and tissue formation;
- Iodine and thyroid gland function;
- Selenium as antioxidant.

New nutrient function claims are subject to approval. Approval is granted based on the petitioner demonstrating that the Institute of Medicine of the US National Academies has established a Recommended Dietary Allowance (RDA), Adequate Intake (AI), or Acceptable Macronutrient Distribution Ranges (AMDR) for the nutrient. There must also be broad consensus in the scientific community on the nutrient's functions. Approval is also contingent upon a scientific authority (either the Institute of Medicine of the US National Academies or the European Food Safety Authority) having evaluated the nutrient and its function within the last fifteen years (Canada Food Inspection Agency and Health Canada 2009).

Regulatory amendments to include new health claims can be made but the claims must first undergo a claim evaluation process before being adopted by the government of Canada. Firms or individuals interested in receiving approval for a new health claim must apply to Health Canada. There are three main criteria involved in assessing a health claim: causality, generalization, and quality assurance. Applicants must clearly establish a causal link between a food and healthiness by providing a comprehensive list of studies that involve original research in humans on the effects of the food on the health effect. The claimed effect must be

meaningfully generalizable to the wider population or a subgroup thereof. The food must conform to quality assurance standards (Health Canada 2009b).

If the food results from a process not traditionally used for food, or does not have a history of safe consumption as a food, or is genetically modified and deemed novel, then the food must undergo novel food registration either before or in conjunction with a health claim application (Health Canada 2009a; 2009b). To get novel food approval, manufacturers apply to the Novel Foods Section. The Novel Foods Section then forwards the application to the following bureau: the Bureau of Chemical Safety, the Bureau of Nutritional Sciences, and the Bureau of Microbial Hazards. First, evaluators in this bureau assess whether or not the food is “novel” based on the three categories noted above. Then, evaluators must unanimously agree that consumption of the novel food poses no health risks. If so, then the Novel Food Section prepares a proposal for the Food Rulings Committee. Upon the approval of the proposal, the manufacturer is then permitted to sell the food as human food in Canada (Health Canada 2006).

The FDR also regulates permissible nutrient content claims although these are not considered health claims. These claims describe the level of a nutrient or nutrients, vitamin or vitamins, and mineral or minerals in food. Usually, the nutrient must be present per stated serving size of the food and per reference amount of the food. Claims must be in both English and French, unless the food is a “local food,” a “test market food,” or a “specialty food.” Claims must also be accompanied by a Nutrition Facts table unless the food is non-prepackaged, the claim is advertised in a generic ad that names no brands, the food is a one-bite confection, the food is certain bottled dairy products, or certain individually portioned foods (Canada Food Inspection Agency and Health Canada 2009; Canada 2010). A wide

variety of claims are permitted on numerous nutrients (see Table 3 in Appendix 1) corresponding to minimum or maximum levels of those nutrients in a food per stated serving size and reference amount. The stated serving size is declared on each food's nutrition labelling (in the Nutrition Facts table). The reference amount is a regulated and standardized (by Health Canada) serving of food a person consumes at a sitting (Canada Food Inspection Agency and Health Canada 2009).

Some of the claims are similar across nutrients. For example, many claims involving the term "reduced" mean that the food has been modified or processed to contain at least twenty five percent less of the nutrient than the reference food. Claims involving "lower" are similar except that the food has not been modified or processed to achieve the twenty five percent reductions. Different kinds of foods can be used as reference foods in different claims. Some claims require that the reference food be of the same food group, while others require a "similar reference food." However, reference foods are only needed for comparative claims (Canada Food Inspection Agency and Health Canada 2009). Other common claims include "low" and "free." Low can be used to describe the nutrient content levels of energy, fat, protein, saturated fat, and trans fat (among others). Free can be used in describing the same nutrients, except protein. Light can only be used in energy and fat nutrient content claims and can only be used in place of "reduced." Saturated and trans fat claims are highly interrelated (to be "low in saturated fat" the food has to have less than 2g combined of saturated and trans fat per serving size and reference amount and have less than 15 percent of total energy coming from fat). Nutrient content claims can be used for vitamins and minerals as well, provided that there is a recommended daily intake (RDI) for that vitamin or mineral and there are some

claims that apply to vitamins and minerals solely (e.g. “added/fortified”) (Canada Food Inspection Agency and Health Canada 2009).

In Canada, food must be labelled with a nutrition facts table unless the food is exempt. There are a variety of exemptions for food, most notably when there is zero for all nutrients required to be listed in a nutrition facts table, when the food is a fresh vegetable or fruit with no added ingredients, or when the food is sold by individuals at a farmers’ market (see Appendix 3 for a full list of exemptions). Some food never loses its exemption (for example, one bite confections). Otherwise, food automatically loses its labelling exemption:

- When a vitamin, mineral, or nutrient is added to the food;
- When aspartame or other artificial sweeteners are added;
- When the food is ground meat, or when the label or advertisement contains a nutrient content claim, a health claim, health-related statement, or the phrase “nutrition facts.”

Nutrition facts tables must be in both English and French, either in the same table or in two separate tables¹⁰. The nutrients, vitamins, and minerals that must be contained in the table are: calories, total fat, saturated fat, trans fat, cholesterol, sodium, carbohydrates, sugars, fibre, protein, vitamins A and C, calcium, and iron. There is also a long list of optional nutrients, vitamins, and minerals that can be declared in a nutrition facts table including: polyunsaturated and monounsaturated fat, soluble fibre, vitamin D, niacin, or zinc. Optional information must be declared when any reference is made to them on their label or in advertisements (including nutrient content, structure/function, and health claims). Additionally, potassium content must be displayed when it has been added or there are claims about salt content (Canada Food Inspection Agency and Health Canada 2009).

Natural health products are now under the Natural Health Product Directorate and are governed by the natural health product regulations (under the Canada Food and Drug Act) that

¹⁰ Similar to the case of generic health claims, manufacturers are responsible to comply with regulations concerning nutrient fact table. However, they may be subject to audit through a compliance test.

came into effect in 2004¹¹. Previously, the status quo practice was that natural health products were not defined by the Canada Food and Drug Act (nutraceuticals were only defined). Health Canada (1998) clearly distinguishes between functional food and nutraceuticals. Nutraceuticals are isolated or purified nutrients sold in medicinal form (e.g. pill form, or more broadly, in doses); nutraceuticals must have a health effect (Health Canada 1998). Regulations place different requirements on nutraceuticals than on food. Functional food (or, in some cases, conventional food with a functional aspect) are regulated differently than Natural Health Products (NHPs), a group of products which include most nutraceuticals but also homeopathic and traditional medicines (Walji and Boon 2008).

Health Canada in 2001 created the Natural Health Product Directorate (NHPD) to resolve the inconsistencies in the system. The directorate introduced a drafted regulation that addressed issues relating to product licensing, site licensing, good manufacturing practices, labelling and packaging, clinical trials, and adverse reaction reporting (Jepson 2002, Government of Saskatchewan 2008). The NHP regulation in Canada came into effect in 2004 (Health Canada 2004). The new regulation defined NHPs to include vitamins and minerals which were restricted under the previous regulatory system. Health Canada (2004) ensured that the NHP regulation is based on five fundamental systems. The five fundamentals of the new regulation are: 1) product licensing that requires all NHPs to display a product identification number with the prefix NPN and in the case of homeopathic medicine the prefix DIN-HM; 2) site licensing which requires all manufacturers, packagers, labellers and importers to be licensed to ensure that facilities for production are appropriate; 3) good manufacturing practices to ensure product safety and quality; 4) labelling/packaging standards

¹¹ In Canada, food is under the governance of the Food Directorate branch of Health Canada and all health claims applications are assessed using the Food and Drug Regulations under the Canada Food and Drug Act.

to enable consumers to make informed choices; and finally 5) an adverse reaction system to monitor all adverse reactions associated with the product.

NHPs are essentially a product-specific regulatory system. The same types (therapeutic, disease risk reduction, structure/function) of health claims are permitted on NHPs as on foods, but the National Health Products Directorate (NPHD) evaluates each NHP and its associated health claim separately (Health Canada 2006a; 2006b).

The NPHD evaluates product licence applications for manufacturing NHPs and their associated claims. The NPHD approves the NHP if and only if it can be proven it is both effective and safe (Walji and Boon 2008). Specifically, benefits must outweigh the risks. The level of risk is dependent on several factors, including the seriousness of the condition it is meant to address and whether it is meant for sole use or in conjunction with other factors. The level of evidence required is also dependent on the claim (therapeutic claims require stronger evidence, including clinical studies than structure/function claims) (Health Canada 2006a).

Applicants can choose between two different kinds of claims: traditional use or non-traditional use claims. Traditional use claims require the applicant prove that the product, made according to tradition, has been used for at least 50 consecutive years. These claims are worded as “Traditionally used...” (Health Canada 2006a). Non-traditional use claims require the use of scientific substantiation in order to be approved. This may include clinical trials, observational studies, and expert opinions. The strength of evidence required to substantiate the claim is dependent on both the severity and symptoms of the condition and whether it is a therapeutic, disease-risk reduction, or structure/function claim (Health Canada 2006a).

Labelling requirements differ for NHPs compared to food. The dosage form (e.g. tablets) must be stated. The brand name and product number (assigned after product licence

approval) must also appear on the label. Medicinal and non-medicinal ingredients must be listed separately. The quantity of medicinal ingredients per dose must also be stated. Unlike food, NHPs must have a health claim. Recommended dosing should also be provided. Risk information, if determined necessary by the NHPD, must be displayed. Nutritional labelling is strictly prohibited (so as not to confuse people by implying that NHPs are food) (Health Canada 2006b).

In conclusion, Canada has a fairly stringent regulatory procedure as evidenced by the few disease risk reduction claims that are approved (although their number has been increasing), as well as the novel foods application requirement. Strict nutrient content claims rules and nutrition labelling rules also indicate a strongly regulated market. Nutraceuticals are more tightly regulated than functional foods as they fall under NHP regulations. However, nutraceuticals are also subject to product specific regulation which reduces spillover benefits and increases incentives for firms to apply to use claims. This is because, unlike general claims, only the firm that applies for the claim can use it on that particular product. With generic claims, anyone can use the claim after it is approved. Potential improvements will be considered after examining all other countries under study.

United States

The U.S. possesses a laxer regulatory structure that is still somewhat similar to Canada. However, this situation may change with the passing of the U.S. Food Safety Modernization Act 2011.¹² Claims are regulated by a federal agency, as in Canada. However, the regulatory environment is friendlier to the approval of new claims and novel foods.

¹² The new Food Safety Modernization Act signed into law on January 4th 2011 affects the functional food and beverage sector in the U.S. The \$1.4 billion bill is specifically aimed at ensuring the safety of all food produced in the U.S. or imported from overseas. (see appendix 6, for more information on the Act).

Qualified claims that have lower standards of scientific evidence for approval are permitted as a result of legal action on First Amendment rights for both food and nutraceuticals (dietary supplements). Structure/function claims on food and dietary supplements¹³ do not require pre-market approval by the Food and Drug Administration. Novel foods are essentially viewed as extensions of conventional foods and as such only encourage firms to informally consult with the Food and Drug Administration to ensure the safety of the food. Nutrition content claims are regulated to about the same extent as in Canada. Nutrition labelling is mandatory and covers a similar number of nutrients.

There were important amendments to the US Federal Food, Drug, and Cosmetic Act (FFD&C Act) in the 1990s. The National Labeling and Education Act (NLEA) in 1990 first established the Food and Drug Administration's (FDA) ability to regulate nutrient content claims and health claims. In general, nutrition labelling must not be misleading, and the NLEA provides guidelines for regulatory control over health claims and nutrient content claims. The claim must meet the significant scientific agreement standard (SSA) to be an SSA health claim. More specifically, the FDA has an evidence-based system for evaluating the quality of scientific studies on the substance/disease relationship and whether the studies show a causal substance/disease relationship. To achieve SSA, the FDA must judge that:

Qualified experts would likely agree that the scientific evidence supports the substance/disease relationship that is the subject of a proposed health claim. The SSA standard is intended to be a strong standard that provides a high level of confidence in the validity of the substance/disease relationship... SSA occurs well after the stage of emerging science, where data and information permit an inference, but before the point of unanimous agreement within the relevant scientific community that the inference is valid (Food and Drug Administration 2009a).

¹³ There are other important categories of food in the US. Firms can manufacture medical foods or foods for special dietary uses. Appendix 5 provides the details on these categories.

The Food and Drug Administration Modernization Act in 1997 (FDAMA) provides an alternative process to obtain SSA health claim authorization. An FDA review of scientific evidence would not be necessary if any US federal scientific agency (with responsibility for public health) or the National Academy of Sciences could provide an authoritative statement about potential disease risk reduction claims (Hoadley and Rowlands, 2008). The FDA has sixteen approved SSA claims (Food and Drug Administration 2009b):

Health Claims (Approved Under FDA Scientific Evidence Review)

- Calcium, Vitamin D and Osteoporosis;
- Dietary Lipids(Fats) and Cancer
- Dietary Saturated Fat and Cholesterol and Risk of Coronary Heart disease;
- Dietary Noncariogenic Carbohydrate Sweeteners and Dental Caries;
- Fiber Containing Grain Products, Fruits, and Vegetables and Cancer;
- Folate and Neural tube defects (in infants);
- Fruits and Vegetables and Cancer;
- Fruits, Vegetables, and Grain Products High in Fiber, particularly Soluble Fiber, and Risk of Coronary Heart disease;
- Sodium and Hypertension;
- Soluble Fiber from certain foods and Risk of Coronary Heart disease;
- Soy Protein and Risk of Coronary Heart disease;
- Plant Sterol/Stanol esters and Risk of Coronary Heart disease.

Health Claims (Approved Based on Authoritative Statements by Federal Scientific Bodies - FDAMA)

- Potassium and the Risk of high blood pressure and strokes;
- Whole Grain Foods and Risk of Heart disease and Certain Cancers;
- Fluoridated Water and Reduced Risk of Dental Caries;
- Saturated Fat, Cholesterol, and Trans fat and Reduced Risk of Heart Disease.
- Substitution of Saturated Fat with Unsaturated Fatty Acids and Heart Disease.

The FDA has also decided to permit qualified health claims. These claims go through the same evaluation procedure as SSA claims, but do not require the same level of qualified expert consensus. There is some credible evidence for these claims but the evidence is inconclusive. This is because the FDA was forced on appeal in *Pearson v. Shalala* to facilitate the use of health claims that do not meet the SSA standard as long as a disclosure statement is

also made. The court ruled that to only permit claims that met the SSA standard would infringe upon First Amendment rights, specifically freedom of speech (Food and Drug Administration 2009a). The FDA has approved twenty two qualified health claims (Food and Drug Administration 2009d): The SSA claims are identified in Food and Drug Administration (2009b) as:

- Tomatoes and/or tomato sauce and prostate cancer;
- Tomato sauce and ovarian cancer;
- Tomatoes and gastric cancer;
- Tomatoes and pancreatic cancer;
- Calcium and colon/rectal cancer;
- Calcium and recurrent colon polyps;
- Green tea and cancer;
- Selenium and cancer;
- Antioxidant vitamins and cancer;
- Nuts and heart disease;
- Walnuts and heart disease;
- Omega-3 fatty acids and Coronary Heart Disease;
- B vitamins and vascular disease;
- Monounsaturated fatty acids from olive oil and heart disease;
- Unsaturated fats from canola oil and heart diseases;
- Corn oil and heart disease;
- Phosphatidylserine and dementia;
- Phosphatidylserine and cognitive dysfunction;
- Chromium picolinate and diabetes;
- Folic acid and neural tube defects (claim recommends twice the intake of approved SSA claim);
- Calcium and Hypertension
- Calcium and Pregnancy-Induced Hypertension or Pre-eclampsia

The FDA does permit structure/function claims on food, but does not evaluate the structure/function claims on food and does not need to be advised of the use of the claim. The claim must not be misleading or untrue, similar to any information on the label and must be substantiated, but that substantiation does not need to be provided to the FDA in the case of food. As a result, the FDA does not approve or keep a list of structure/function claims in use on food (Food and Drug Administration 2009c). As an example, the relationships between

Vitamin A and night vision or calcium and bone and teeth development or vitamin E as an antioxidant are substantiated enough for use as structure/function claims. The firm must conduct research, namely, collect scientific literature so as to substantiate the claim before using it. The food must also contain sufficient quantities of the nutrient and enough of the nutrient can be consumed in a day to have the claimed effect for the claim to not be misleading. The firm does not need pre-market approval from the FDA to use the claim on food.

Nutrient content claims, on the other hand, are regulated in the US. These claims are specifically detailed in the Code of Federal regulations (21 CFR 101.13). Nutrient content claims other than those provided for by the FDA are prohibited. Claims can only be made using the wording or synonyms provided. Claims must be accompanied by additional information, which varies from claim to claim, and usually requires nutrition labelling. “Free,” “low,” “reduced” and “less” have all been defined for use with calories, fat, saturated fat, and sodium (see Table 4) (Food and Drug Administration 2008). Vitamins and minerals can also have a variety of nutrient content claims if they have a recommended daily intake established. “Comparative claims” are also permitted, but unlike in Canada, there is no difference between using “reduced” and “less”; in either case the food has been modified to achieve the reduction in the level of a given nutrient to make it eligible for the claim. The claims need not be explicit, and there is a list of implied claims provided in the Code of Federal Regulations (CFR) or firms can petition the FDA for the use of new implied claims. The claim “healthy” is treated as an implied nutrient content claim. Food labelled “healthy” must meet requirements for levels of total fat, saturated fat, sodium, cholesterol, and beneficial nutrients. Additionally, products that make nutrient content claims are forced to

include a disclosure statement if the total fat, saturated fat, cholesterol, and sodium levels exceed certain standards. For example, if the food exceeds 13g total fat per reference amount customarily consumed (RACC); then “See nutrition information for total fat content” must also be provided. The disclosure statement is to be placed immediately adjacent to the claim (Food and Drug Administration 2008). Of particular importance for functional foods are the definitions for “high potency,” which has a higher standard for the use of the claim on foods than on dietary supplements (nutraceuticals) (Hoadley and Rowlands, 2008).

Compared to Canada, the US has relatively lax regulations concerning “novel foods”. Essentially, the position of the FDA is that “novel foods” [including genetically-modified (GM) food] are extensions of conventional foods (Blakeney 2009). The FDA issued a statement interpreting its role in regulating foods resulting from new processes in the policy statement “Foods Derived from New Plant Varieties.” The statement notes that under the Public Health Service Act, the FDA is responsible for ensuring that food is safe and in compliance with regulations. The FDA recommends that firms informally consult with the FDA “to ensure that the safety and regulatory of a new food is properly resolved” (Food and Drug Administration 1992). The FDA has also proposed a 120 day pre-market notification rule for bioengineered food from plants so that the FDA can ensure that the food being marketed is safe and complies with all regulations (Food and Drug Administration 2001). However, this pre-market notification rule is only proposed and has not been adopted. This is in contrast to Canada, where firms must achieve pre-market registration before a novel food can enter the market (see above).

The FDA also regulates and monitors nutrition facts tables. The FDA exempts certain food from this labelling requirement, including food: produced by a small business, food

served in restaurants and take-out or delivery food intended for immediate consumption, donated food that is given free to the consumer, and fresh produce and seafood (see Appendix 3 for a complete list). Minimally, the tables must include: calories, calories from fat, total fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrates, dietary fibre, sugar, protein, vitamins A and C, calcium and iron. If any of the following are added to the food, then they must also be declared in the facts table: vitamins D, E, or K, thiamin, riboflavin, niacin, vitamin B₆, B₁₂, folate, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, and chloride. Optional nutrients and minerals (e.g. mono- and poly-unsaturated fat, soluble fibre, potassium) must be declared in the table if they are featured in a nutrient content claim (Food and Drug Administration 2008).

The term “nutraceutical” is not defined in the US. However, most nutraceuticals fall into the “dietary supplement” regulatory category. Dietary supplements contain an amino acid, a vitamin, a mineral, an herb, or any combination or extract of these nutrients. Dietary supplements come in a measured dose form (pill, capsule, tablet, powder, and or liquid) (United States 1994).

Generic SSA and qualified health claims (disease risk reduction claims) can be used on dietary supplements, providing they meet the same requirements. The approval process for new SSA and qualified health claims is thus the same whether the firm decides to make a dietary supplement (nutraceutical) or a functional food. Structure/function claims are also permitted on dietary supplements, but the regulatory procedure is slightly different. The FDA requires pre-market notification of at least thirty days before the firm can use the claim on a product (United States 1994). The firm must have scientific substantiation for the claim in

case the FDA wants to investigate the truthfulness of the claim and in order for the labelling not to be misleading. Nutrient content claims are also permitted on dietary supplements.

Regulations on dietary supplement approval are also relatively lax. Dietary supplements do not require FDA approval or registration before being sold on the open market. Even when the key ingredient is novel, or some scientific evidence suggests that the ingredient may be harmful, the burden of proof is on the FDA to demonstrate that the dietary supplement is unfit for sale (Food and Drug Administration 2009e; United States 1994). This creates a very friendly environment for innovation in dietary supplements, although arguably at the expense of greater consumer protection.

Like nutrition labelling on food, labelling on dietary supplements must be truthful and not misleading. In “Supplement Facts” tables, firms must list (if they are present in measureable amounts): total calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fibre, sugars, protein, vitamin A, vitamin C, calcium, and iron. Nutrients must be listed if they are added to the supplement for the purposes of supplementation or if a health or structure/function claim is made about the nutrient. “Serving Size” and “Servings per Container” must also be provided (Food and Drug Administration 2005).

In conclusion, the large number of generic disease risk reduction claims approved likely equates to lower costs and thus greater incentives for research and development. The fact that firms do not need pre-market approval from the FDA to use structure/function claims also increases the appeal of food research and development, as does the relative size of the US market compared to Canada. The ease of novel food introduction into the market also makes research and development in functional foods more likely than in more stringent regulatory

environments (e.g. Canada, and especially the European Union). While there are distinctions between food and nutraceuticals (dietary supplements) in the United States, regulations on nutraceuticals are not significantly more stringent than on food and remain generic.

European Union

Prior to 2006, the European Union (EU) left health claims to the jurisdiction of member states. Since then, the EU has been engaged in assessing generic health claims in four separate categories -- the most specialized system of all generic claims systems under study here. The costs associated with regulation in this system are high. Many more claims have been rejected¹⁴ than accepted and the approval of general structure/function claims has slipped past its deadline in the original directive. Moreover, the EU's strict novel and genetically modified food regulations impose significant additional risks and costs to firms looking to innovate. Nutrition labelling, contrary to the other regulations, is quite minimal. Labelling is optional unless a claim is made. Labels only need a very short list of nutrients compared to Canada and the USA. Despite all the regulatory difficulties, the EU market may be an attractive outlet for firms seeking to sell functional food (large market with an ageing population). Moreover, there may be benefits to harmonizing legislation across countries (firms do not have to follow different regulations to sell the same product in both the United Kingdom and Italy, for example).

EC regulation 1924/2006 addresses health claims and nutrient content claims for the first time in an attempt to harmonize member state law on these issues. (Note: EC Regulation 1169/2011 amends EC1924/2006 and EC1925/2006; no changes to articles 13 or 14 changes

¹⁴ See for list of rejected health claims.
http://ec.europa.eu/food/food/labellingnutrition/claims/community_register/rejected_health_claims_en.htm

to article 7). The goals of the regulation include avoiding misleading or untrue claims, avoiding the perception by consumers that the benefits from nutrients cannot be achieved through a balanced diet or that some food is unsafe or nutritionally inadequate, and avoiding condoning excess consumption of food. There are several conditions for making nutrient content claims (nutrition claims in the regulation) and health claims: the claim must have some established positive nutritional or physiological effect, nutrients in the food must be either high or low enough to achieve the desired effect, and the consumer need only consume a reasonable amount of the product to achieve the desired nutritive or physiological effect. This is similar to the requirement in both the United States and Canada that it be feasible for the consumer to ingest the product as part of a regular diet to obtain the effect in the claim. For all health claims, a disclosure statement must be made if consuming too much of a product may be hazardous to one's health, despite some of the positive physiological benefits (EC Regulation 1924/2006).

There are four different kinds of health claims permitted in the EU: Article 13 (1) health claims, Article 13 (5) health claims, Article 14 (1) (a) health claims, Article 14 (1) (b) health claims. Article 13 (1) health claims are primarily structure/function claims, but also include claims on psychological or behavioural functions and claims about weight control through reducing hunger or increasing satiety (health claims regarding weight slimming products are banned in general) (EC Regulation 1924/2006). These claims were to be collected by member states and provided to the European Food Safety Authority (EFSA) for evaluation by January 31 2008. The Commission of the EU was to provide a list of acceptable claims by January 31 2010 in consultation with the EFSA, but the process was considerably delayed (initially, over 40,000 health claims were submitted to the Commission, which the

Commission consolidated to 4,185 claims to be evaluated by EFSA (European Food Safety Authority n.d.). New health claims legislation eventually came into full effect in December 2012.

Three disease risk reduction claims under Article 14(1) (a) have been approved. Food can be labelled with claims showing a relationship between: **plant sterols and heart disease, plant stanols and heart disease, and gum sweetened with 100 percent xylitol and dental plaque (and dental caries or cavities)** (European Union 2009). To be able to use health claims, applicants provide information to a national authority in a member state, which then forwards the application to the EFSA. The EFSA issues an opinion based on whether or not the health claim is substantiated by scientific evidence and whether or not the health claim is in compliance with EU 1924/2006. EFSA approved health claims are then forwarded to the Commission, which decides whether or not to permit the health claim, based on consideration of EFSA's opinion, other EU law, and other relevant factors. This method is used to approve health claims on children's development and health (Article 14(1)(b)) and claims based on newly developed scientific evidence or a proprietary information request (Article 13(5) (EC Regulation 1924/2006).

In contrast to other countries like Canada, which prohibits the use of claims on products intended for children under the age of two, the EU has provisions for claims for the health and development of children and has adopted six health claims pertaining to the normal health and development of children. These claims show a relationship between: essential fatty acids and growth and development, calcium and Vitamin D and bone growth and development, calcium and bone growth and development, Vitamin D and bone growth and

development, phosphorus and bone growth and development, and protein and normal growth and development (European Union 2009).

One Article 13(5) claim (claims on emerging scientific evidence or a request for proprietary information) about a tomato compound and blood flow has also been adopted (see Table 2 in Appendix 1) (European Union 2009). The procedure for approval of these claims is not different from the other claims, other than the fact that the firm needs to provide reasons as to why the information is proprietary (EC Regulation 1924/2006).

The European Commission delayed a proposal regarding new health claims allowed, initially until the end of 2011. This was necessitated by the concerns raised by stakeholders in the industry about the rewording of the health claims submitted to the European Food Safety Agency. The huge volume of submitted health claims and the required examination of the scientific backing of the claims also contributed to the delay. (EurActiv 2010). New health claims legislation eventually came into full effect in December 2012. The European Health Claim Regulation lists 222 approved health claims and applies to all foodstuffs on the market; new products can only carry these generic health claims if they meet the conditions of use. Companies will still be able to apply for individual health claims subject to individual scientific evaluation and pre-market approvals (Gruenwald, 2013).

EC regulation 1924/2006 also provides for some explicitly listed nutrient content claims. These claims include claims on energy, fat, saturated fat, unsaturated fat, sugars, fibre, protein, and sodium, as well as claims on vitamins and minerals (see Table 5, Appendix 1). It also allows for comparative claims on nutrients (e.g. fat, protein) but not on vitamins or minerals. The use of the term light/lite means the same as “reduced.” The use of “reduced” is more stringent than in Canada. Food must have at least thirty percent less of a nutrient than a

comparable food to qualify for the term (unless it is a micronutrient, in which case a ten percent reduction is all that is needed). The use of the term “natural” is conditional upon the nutrients in the nutrient content claim being there without modification to the food (EC Regulation 1924/2006).

Novel food regulation in the EU is significant. A wide range of food is considered novel, including: genetically modified food, food produced from genetically modified organisms, food produced by algae, fungi, or microorganisms, food isolated from plants and animals without a history of safe use as food, or food that has been processed and the process has dramatically changed the food (EC Regulation 258/97). To achieve novel food registration, the food must achieve three criteria. The food must not pose a hazard to the consumer, mislead the consumer, or differ significantly from other products on the market that it is intended to replace to the extent that it would have a nutritionally disadvantageous impact on the consumer. The applicant must apply to a member state for permission to sell the good in that market. The member state will then assess the food based on the three aforementioned criteria and then permit the sale of the food if it passes the assessment in that member state’s market, and finally the report is given to the Commission and other member states where they have 60 days to file comments or objections. If there is an objection or if it is determined that the food requires additional assessment, an additional assessment will then be carried out (EC Regulation 258/97). Scientific requirements for the novel foods application are given in Commission Recommendation 97/618/EC.

Food that is genetically modified, contains genetically modified organisms, or food that is produced from ingredients produced by genetically modified organisms must also receive pre-market approval obtained through a separate process. The EFSA issues an opinion

on whether or not the genetically modified food meets the same three criteria for novel food applications. After issuing the opinion, the Commission makes a draft decision based on the EFSA's opinion. A final decision is later reached to authorize or reject the food (EC Regulation 1829/2003). Foods that have come into incidental contact with genetically modified foods are permitted in the EU, but the food must be 0.9 percent or less genetically modified (European Union n.d.).

European Union nutrition table regulations are given in the European Council Directive 90/496/EEC. Originally, nutrition labelling was optional, unless a nutrient content claim is made on the label or in advertisements. As a result of EU regulation 1924/2006, nutrition labelling is also mandatory when health claims are made. Labelling is meant for products destined for "ultimate consumers" and these regulations are not intended to apply to water products or dietary supplements. The tables must be in a language that the consumer can easily understand. Minimally, the labels must be in tabular form (unless space dictates otherwise) and include values of energy, protein, carbohydrates, and fat. If there are nutrition content claims on sugar, saturated fat, fibre, or sodium, those nutrients must be included in the table. Optionally, the tables can include a wide variety of nutrients, vitamins, and minerals, including but not limited to: starch, polyols, monounsaturated fat, polyunsaturated fat, cholesterol, Vitamin A, Vitamin D, calcium, or iron (European Council Directive 90/496/EEC). Regulation 1169/2011 repeals 90/496/EEC and amends 1924/2006 to include the addition of vitamins and minerals and of certain other substances to food as referenced in 90/496/EEC.

Four years before the EU harmonized health claims regulations, the EU developed harmonized regulations for nutraceuticals. In Directive 2002/46/EC, the EU began regulating

“food supplements.” Food supplements are concentrated doses (e.g. tablets, pills, capsules, powders, etc.) of vitamins and minerals with the intention of achieving nutritive or physiological effects. Food supplements themselves are legally considered food (not drugs or an intermediate category) (European Parliament and Council Directive 2002), thus, all health and nutrition claims that can be used on other foodstuffs can also be used on food supplements. However, the list of nutrients eligible for food supplement status is short. Only vitamins and minerals are eligible, and only those provided for in the original directive or subsequently approved by the Commission in additional directives are permitted. Nutrients added to the list of acceptable food supplements must undergo a safety evaluation. This safety evaluation is separate and distinct from novel food registration if novel food registration is deemed necessary. A technical dossier and application must be made to the EFSA, and the EFSA will prepare an opinion and the Commission will use that opinion to determine whether or not to permit the nutrient as a food supplement (Health and Consumers Directorate-General, 2009).

The 2002 Directive also provides the requirements for labelling food supplements.

Labels must include:

- the nature of the nutrients;
- the daily recommended serving;
- a warning not to exceed daily recommended serving;
- a statement that the food supplement is not a substitute for a varied diet;
- a statement that the food supplement should be kept out of reach of children;

The numerical amount of nutrient(s) intended as the supplement is declared (European Parliament and Council Directive 2002).

The EU regulates functional food tightly as indicated by the paucity of claims approved and extensive list of claims denied. The novel food registration procedure is the most stringent of any country or group of countries under study here, imposing additional costs on novel functional food producers. Nutraceuticals (food supplements) are considered

food and can use approved claims. However, food supplements are limited to vitamins and minerals only, a significantly narrower band of products than elsewhere. Despite this tight regulatory regime, there may be benefits to negotiating harmonization or recognition of equivalence of legislation on functional foods between trading partners, thereby opening up a wider market to firms and removing the need to adhere to different regulations in different countries in order to be able to market the same products. Realistically, however, given the considerable legislative differences that exist between the EU and other countries this would be a significant challenge.

United Kingdom

The new EU health and nutrition claims (excluding general structure/function claims governed by Article 13(1) of EC Regulation 1924/2006), supersede the United Kingdom's (UK) domestic health claims regulation. Nevertheless, a review of the prior regulatory environment in the UK is instructive. Previously the UK government did not explicitly regulate health claims. The Food Labelling Regulations Act (1996) set out some guidelines for claims in the UK, but left much room for interpretation and application. Only claims that promised a medicinal or therapeutic effect were made illegal (United Kingdom 1996). The government left room for firms to self-regulate, providing an alternative to many other countries' approaches to regulation. Generic disease risk reduction claims, structure/function claims, nutrition claims, and innovative claims (qualified claims) were all permitted. Novel food regulations and nutrition labelling regulations were largely governed by EU regulations during the time that the UK had health claims.

The Joint Health Claims Initiative (JHCI) was formed as a self-regulatory agency for trade associations, along with consumer organizations and enforcement authorities to regulate

the use of health claims in the UK. The JHCI stopped operating in 2007 after the EU adopted a health and nutrition claims regulation. The JHCI defines health claim as a claim (expressed or implied in labelling or in advertising) that a food has a specific health benefit or reduces the risk of a specific disease or illness or other negative health impact. The JHCI regulated two kinds of health claims: generic and innovative. Generic health claims were based on established and widely accepted scientific knowledge on a relationship between a food/nutrient and a health effect. Innovative health claims were to be applied to new foods or in cases where the science was still emerging and scientific agreement was not near consensus (Joint Health Claims Initiative n.d.). The claims were evaluated by JHCI and they approved five generic health claims, all of which were disease risk reduction claims: reduced saturated fat and cholesterol, wholegrain foods and heart health, soya protein and blood cholesterol, oats and blood cholesterol, omega-3 fatty acids and heart health (see Table 1, Appendix 1) (Joint Health Claims Initiative 2007). As one can see, only disease risk reduction claims were approved. The JHCI was working on a list of structure/function claims that never came to fruition. A list of “well-established” structure/function claims was provided to the UK Food Standards Agency (FSA), but these claims were not to be used at the time and were not approved for use before the EU began regulating health claims (Joint Health Claims Initiative 2003).

Health claims were partially regulated by UK legislation and also by the JHCI code of practice. These documents ensured first and foremost that health claims could not be misleading. Misleading claims are considered a criminal offence (United Kingdom 1996). Claims could not denigrate other foods or imply that a balanced diet did not have a positive health effect. Claims had to be contextualized as part of the overall diet. They had also to be

on foods with serving sizes reasonable enough to be consumed in one day to achieve the health benefit. It was recommended that firms provide the following information, in addition to the statutory labelling requirements:

- full nutrition declaration;
- quantified serving size;
- target population and any sectors that should avoid consuming the food;
- safe maximum intake if eating too much could prove harmful;
- quantity of food and pattern of consumption required to achieve the desired effect;
- declare how much of the nutrient required for the health benefit per 100g or serving size (Joint Health Claims Initiative n.d.).

There were several key requirements for firms desiring health claim approval. Firms had to demonstrate that:

- food or its components contribute to a positive health effect in target population (as part of normal consumption and diet);
- the effect is long-term and not short-term;
- the effect can be obtained by eating a reasonable amount of the food;
- group that can benefit from this effect (whole population, sub-group, or at-risk group of elderly or lactating or pregnant women);
- how the effect occurs (although the precise mechanism is not needed) (Joint Health Claims Initiative n.d.).

Claims approval was granted by the JHCI on the basis of the totality of scientific evidence. Claims were evaluated based on human studies (which were necessary), but also animal studies or cellular studies (Joint Health Claims Initiative n.d.).

Nutrient content claims were also permissible under UK law, and were regulated more than health claims (now UK nutrient content claims are determined by EU regulation—see above). The regulation provided a list of nutrition content claims which were restricted to use, but there was nothing in the legislation to prohibit the use of claims on other nutrients as firms saw fit. The restricted claims were on: energy, protein, vitamins, minerals, and cholesterol. Otherwise, foods that had nutrition claims based on other nutrients had simply to be capable

of fulfilling the claim and have nutrition labelling (United Kingdom 1996). Detailed requirements for the claims can be found in Table 7, Appendix 1.

Nutrition labelling involving tables was entirely voluntary, unless the firm makes a nutrition claim (under the Code of Practice of the JHCI, nutrition labelling was only recommended when health claims were used). Nutrition claims did not trigger compulsory labelling as long as they were in generic advertisements (i.e., no particular brands mentioned). Energy, protein, carbohydrate, fat, and the nutrient subject to the nutrition claim declarations were compulsory when a nutrition claim was made. The government recommended including sugars, saturated fat, fibre, and sodium as well.¹⁵ Other declarable nutrients included: polyols, starch, mono-unsaturates, poly-unsaturates, cholesterol, vitamins, and minerals (Food Standards Agency 1999).¹⁶

Compared to the other countries under study, the UK provided the most latitude to firms using health claims. The government relied heavily upon self-regulation by firms with only a few restrictions (e.g., no therapeutic claims, restrictions on some nutrition claims). Surprisingly, in this relatively lax environment, the JHCI apparently did not authorize misleading or erroneous claims.¹⁷

Sweden

Sweden, like the UK, used a self-regulatory scheme to regulate the use of health claims. Now, Sweden, like all other member states, must comply with EC Regulation 1924/2006 (see above). The government directly regulated nutrient content claims (nutrition

¹⁵ If the food was labelled with one of these optional nutrients, then all had to be declared. For example, if fibre was labelled on the food, then the label had to also include sugar, saturated fat, and sodium declarations (Food Standards Agency 1999).

¹⁶ Novel foods were regulated at the EU level before regulations on health claims were adopted. See EU section for more detail.

¹⁷ No information on dietary supplements in the UK was available. Since 2002, food supplement regulation matches the EU.

claims in Sweden), but firms were responsible for regulating the use of health claims on products. Three different kinds of health claims were permitted: structure/function claims (nutrient function claims), generic disease risk reduction claims, and product-specific health claims (product-specific physiological claims). Sweden is one of only two countries to have allowed both generic and specific health claims (the other is Japan).

Nutrition claims were simple statements of nutrition content without reference to any particular health effects. Health claims were any representation that implicitly or explicitly made a connection between consumption of a food or nutrient and health. Nutrient function claims referred to a nutrient's role in proper functioning, growth, or development of the body. Disease risk reduction claims, on the other hand, specified a relationship between some nutrient or nutrients and reduced risk of disease in the context of the overall diet. Product-specific health claims (PFP claims) dealt with representations that a product—as opposed to its nutrients—had a specific health effect (Livsmedelsföretagen et al. 2004). Swedish List Product Specific Claims 2008 lists 19 products that are allowed to make product specific claims. Firms apply to use PFP claims on their products and their products alone. In comparison, any firm whose product meets the nutritional requirements can use generic claims (Livsmedelsföretagen et al. 2004).

Generally, claims were to be used to inform consumers of the importance of diet for health, and not to instill confidence in the food or food industry. The claims had to put in the context of other activities important for health (e.g. diet, exercise). More specifically, disease risk reduction claims had to be concordant with Swedish Nutrition Recommendations and relate to well-documented and scientific relationships between nutrients and disease risk reduction in Sweden (Livsmedelsföretagen et al. 2004).

Disease risk reduction claims were generic, so they could not be worded so as to imply the product had a product-specific effect. The food had to be consumed in a reasonable amount in the context of a balanced diet and it had to meet certain nutritional criteria. Ten generic disease risk reduction claims were approved (Livsmedelsföretagen et al. 2004):

- Energy and Obesity
- Hard Fat (Saturated and trans Fat) and Heart disease/Atherosclerosis
- Dietary Fibre and Heart disease/Atherosclerosis
- Salt and Heart Disease/Atherosclerosis/High Blood Pressure
- Omega-3 Fatty Acids and Heart Health
- Dietary Fibre and Constipation
- Calcium and/or Vitamin D and Osteoporosis
- Sugar and Caries
- Iron and Iron Deficiency
- Whole Grains and Heart Disease

Nutrient function claims were only permitted if they were generally acknowledged (e.g. in the current version of the Nordic Nutrition Recommendations (NNR), and in the current *Kost, Motion, och Hälsa*, the National Food Administration book on diet and exercise and health). The functions had to be relevant to consumers in Sweden. Because nutrient function claims were generic health claims, they could not be worded to imply or explicitly state that the product itself has the specific effect. Function claims could be combined with nutrition claims. Generally, foods making nutrient function claims needed to have at least 15% RDI of the nutrient per 100g or serving. Claims regarding iron required 10% RDI of iron per 100g or serving. Claims regarding dietary fibre required at least 2.5g per 100g or serving and at least 3.75g per amount reasonably expected to be consumed in a day. Some, but not all, nutrient function claims that could be used involved: Vitamin C/Vitamin E/Beta-carotene as antioxidants protecting the body, Vitamin C and iron absorption, Vitamin D and bone building, calcium and bone building, zinc and enzyme systems, iron and blood or hemoglobin,

dietary fibre and normal bowel function, and carbohydrates in pasta and blood sugar (see Table 2, Appendix 1).

It is important to note that nutrient functions had to be relevant for the Swedish population, so some claims that may be approved elsewhere might not be approved for use in Sweden, even if there was a scientifically substantiated claim. For example, the use of a claim for Vitamin A and enhanced night vision was not permitted because it was deemed irrelevant (Livsmedelsföretagen et al 2004).¹⁸

The voluntary code did not apply to food supplements (“nutraceuticals”). Instead, claims on food supplements were prohibited (Mejborn 2007). Consequently, food supplements regulation in Sweden prior to the 2002 EU Directive on food supplements are not considered here because our primary concern is with health claims, not food and supplement regulations in general.

Similarly to the JHCI in the UK, Sweden’s self-regulation did not result in a proliferation of health claims. Firms responsibly exercised health claims, establishing product-specific health claims in addition to generic disease risk reduction and structure/function claims. The UK and Sweden used similar regulatory systems, but their regulatory systems differ from that of the EU’s. The EU did not leave firms in control of health claims, and further differentiated between different kinds of health claims, although the EU does not permit qualified claims. The status of the UK regulations on dietary supplements (nutraceuticals) could not be determined. Sweden forbade the use of health claims on food supplements. The EU does permit the use of health claims on food supplements, but limits the definition of food supplement to vitamins and minerals (although that list could be expanded).

¹⁸ Information on nutrient content claims and nutrition labelling in Sweden could not be obtained.

Russia

In Russia, food products with health benefits are known as Biologically Active Food Supplements (BAFS). The Russian Federation defines BAFS as nutritive substances and minor food components used to ameliorate deficiencies, decrease risk of debilitating diseases, and improve quality of life (Tutelyan and Sukhanov 2008). There are two different categories of BAFS. They are nutraceuticals and Parapharmaceuticals. Nutraceuticals refers to biologically active substances, which are basic components of organisms, vitamins or their predecessors, macro and microelements (iron, calcium, selenium, zinc, etc.), dietary fibres and indispensable amino acids used for correction of chemical composition of food. Parapharmaceuticals are biologically active substances with a certain pharmacological activity which are used for auxiliary therapy and maintaining organs and systems within their normal physiological limits. The compositions of these two categories are different for adults and children under 14 years.

Nutrient content claims and structural/functional health claims are permitted on BAFS. However, disease risk reduction health claims are prohibited and nutrition labelling is mandatory. Nutrient content claims are generic and they include claims such as (Tutelyan and Sukhanov 2008)

- Additional source of a particular vitamin or mineral substance;
- If the product is made of only herbal components, then claims like “source of arbutin”.

Structure/function claims are product specific and must be scientifically proven. This claim is made to describe the expected effect of the product on the physiological function of the human body. Examples of the structure/function claims are (Tutelyan and Sukhanov 2008):

- Optimization of carbohydrates, fat, vitamin and other metabolism in various functional conditions;
- Normalization and/or improvement of the function state of the human organ/system;
- Decreased morbidity risk;
- Improvement of the gastrointestinal tract microflora.

Products carrying structure/function claims require pre-market approval and a product licence before they can be marketed. The claims cannot use words that will relate the product to a disease in any way.

Nutritional labelling is mandatory for BAFS in Russia. All labels must meet the required standards before they are allowed into the market. Labelling standards are set out in regulation GOST P51074-2003 (2005) and amended in 2009 which will be superseded by TR TS 022/2011 “Food Products Labelling” on July 1 2013 as regulations in Russia come more in line with those of the EU (Gain Report 2011). It is an offence to make a false claim on the label. Labelling standards include the following (Tutelyan and Sukhanov 2008):

- The name of the product;
- Complete composition of the product (the ingredients in the product should be listed and their respective quantity);
- All other substances in the product and their quantity should also be listed;
- Recommendations for the use of the product including the dosage and route;
- All contradictions or side effects;
- Notice to indicate that the product is not a drug;
- A “consult your doctor before use” notice;
- Storage conditions, expiry date, registration number, date of registration and the manufacturer information.

The label should not contain information that cannot be scientifically substantiated. Terms and phrases like ecologically clean product cannot be used on the labels of BAFS.

Russia is one of the countries with well-established regulations for nutraceuticals. The Health Ministry is responsible for regulation of these products. The regulations in Russia appear to be stricter than some other countries. The distinction between Biologically Active Food Substances (BAFS) and Parapharmaceuticals in Russia is not very clear, and disease risk

reduction and therapeutic claims are prohibited. These factors could serve as disincentives to firms and investors.

Australia and New Zealand

Australia and New Zealand saw the benefits of coordinating policy in the area of health claims and the Australia and New Zealand Food Regulation Ministerial Council agreed to the development of a joint policy on nutrition content and health claims (Veeman 2002). Disease-risk reduction claims and structure/function claims are permitted. Qualified claims, however, are not. Structure/function claims regulation is modelled after the USA FDA's stance. No pre-market approval is required, although firms need substantiation of structure function claims. Novel food registration is required for novel functional foods. Nutrition content claims are permitted, but are not currently exhaustively listed or regulated. Nutrition labelling is mandatory and is similar to requirements in Canada and the USA.

Australia and New Zealand have placed a unique mark on novel food registration. Unlike other countries under study, foods that successfully attain novel food status are eligible for exclusive market access to Australia and New Zealand for fifteen months to the exclusion of other brands. This unique feature increases the incentive firms to research novel functional foods, and reduces the spillover benefits that accrue to other firms when one firm applies for novel food registration in another country. In other countries, once a food receives novel food approval, other firms with the same nutrient or nutrients can all enter the market at the same time. Only one firm has to apply for and bear the costs of novel food approval and registration. Therefore, there are significant spillover benefits that accrue to firms that do not bear the novel food registration costs. Australia and New Zealand reduce the spillover benefits and increase the benefits for the applicant through the 15 months of exclusive market access.

Health claims are split into two groups: general level claims and high level claims. General level claims are equivalent to structure/function claims, in that they describe the relationship between a nutrient and a health function. High level health claims are disease risk reduction claims. They elucidate a relationship between the consumption of a nutrient and the risk of a disease (Food Standards Australia New Zealand 2008a).

Food Standards Australia New Zealand (FSANZ) has evaluated seven high level health claims and approved five of those seven. The proposed approved health claims are (Food Standards Australia New Zealand 2010a):

- Sodium (with or without Potassium) and Heart Disease
- Fruits and Vegetables and Heart Disease
- Saturated and /or trans Fat and Cholesterol or Heart Disease
- Calcium (with or without Vitamin D) and Osteoporosis
- Folic Acid and Neural tube defects

Rejected health claims sought to establish a relationship between **whole grains and heart disease** and between **omega-3 fatty acids and heart disease** (Food Standards Australia New Zealand 2010a).

While these claims have been approved, the transition to the new standard is not yet complete. As such, currently, only a claim basing folic acid on neural tube defects is permitted as Australia and New Zealand transition to a new standard outlining high level health claims (Food Standards Australia and New Zealand 2010c).

Before using a new high level health claim that is not currently approved, the firm must obtain pre-market approval from FSANZ who will evaluate whether or not there is “convincing” scientific evidence for the claim. If the evidence is less convincing, (for example, “probable” or “insufficient”) then the claim will not be approved. These claims are generic insofar as a successful application means that any firm can use the claims, as long as

they meet the conditions prescribed in the standard (including certain nutritional scoring requirements, so that foods that use high level claims do not contain excessive levels of unhealthy nutrients) (Food Standards Australia New Zealand 2008b).

General level health claims do not require pre-market approval but they do require scientific substantiation (similar to the US situation). FSANZ has a list of approved general level claims that count as scientific substantiation for firms wishing to use those claims (Food Standards Australia New Zealand 2013). The claims are:

- Vitamin D and calcium for phosphorus utilization and absorption;
- Vitamin E as antioxidant;
- Vitamin K for proper coagulation;
- Thiamine and normal metabolism of carbohydrates;
- Riboflavin and metabolism;
- Niacin and metabolism;
- Pantothenic acid and metabolism of fat;
- Vitamin B₆ and metabolism of protein;
- Folate and blood formation;
- Vitamin B₁₂ and blood formation;
- Biotin and fat metabolism or energy production;
- Vitamin C and connective tissue;
- Calcium and bones and teeth;
- Magnesium and metabolism;
- Iron and blood formation;
- Copper and immune system;
- Iodine and thyroid hormones;
- Zinc and wound healing;
- Manganese and bone function;
- Phosphorus and bones and teeth;
- Selenium as antioxidant;
- Protein and building and repairing body tissues;
- DHA and brain, eyes, and neural development;
- Dietary fibre and normal laxation
- Potassium
- Chromium and macronutrient metabolism
- Fluoride and tooth mineralization
- Molybdenum and sulphur amino acid metabolism
- Choline and homocystine metabolism
- Vitamin A and vision
- Folic Acid and neural tube development

- Beta-glucan and reduced blood cholesterol
 - Carbohydrate and normal metabolism
 - Energy and normal metabolism
- (Food Standards Australia and New Zealand 2013).

In addition to this list, firms can use approved high level health claims as the basis for a general level claim. A third means of substantiation is based on a declaration made by an “authoritative source” (FSANZ determines what constitutes an “authoritative source”). A systematic review of the scientific literature indicating significant support for the general level claim can also be used as substantiation (Food Standards Australia and New Zealand 2008c).

Nutrient content claims are also permitted. New nutrient content claims have come into force with the implementation of the new standard 1.2.7 in January of 2013. These nutrient content claims are provided in Table 8 (Appendix 1). Australia and New Zealand use a similar approach to the transitional content claims that the UK used for the nutrient content claims. No specific wordings were provided for claims about omega fatty acids (any), however, “goodsources” and “increased” are used for Omega-3, while “increased” is used for Omega-6, Omega-9 and polyunsaturated fatty acids. There is a minimum quantity required to make a claim on omega fatty acids. Australia and New Zealand are the only countries to regulate and authorize the use of gluten content claims. The “free” claims in Australia and New Zealand are also much stricter than other countries, requiring no detectable levels of nutrients for those claims (Food Standards Australia New Zealand 2010b).

There are also regulations for nutrition labelling. The *Australia New Zealand Food Standards Code* sets out regulations for “nutrition information panels” in Standard 1.2.8, similar to the nutrition facts tables in Canada. Nutrition information panels must contain the following information: the number of servings of food in the package, the average quantity of food in a serving, the average energy in a serving, the average amounts of protein, fat,

saturated fat, carbohydrate, and sugar in a serving, the average quantity of sodium in a serving, and the amount of a nutrient or biologically active substance that is in a nutrition claim made on the food in a serving. These must be expressed both in per serving and in per 100g or 100ml amounts. The panel must include trans, mono-, and poly-unsaturated fats when a nutrition claim is made on cholesterol or on unsaturated, trans or saturated fat. Similarly, dietary fibre must be declared when a claim is made about dietary fibre, sugar, or other carbohydrates. Percentage daily intake of the nutrients may also be listed, but it is unnecessary (Food Standards Australia and New Zealand 2010b).

Like other countries, Australia and New Zealand provides a list of exemptions for nutrition information panels. Almost all of the exemptions are based on the type of food sold (e.g. tea, coffee, kava, herbs, and spices are all exempt from nutrition information table labelling). Other countries tend to have more exemptions based on who is selling or buying the good (e.g. farmers' markets in Canada and small businesses in the United States). Australia and New Zealand only exempt food sold at fund-raisers from nutrition information tables. However, all exempt food loses its exemption if a nutrition claim is made on the food, and the food must either be labelled accordingly, or the information must be given to the purchaser on request (Food Standards Australia and New Zealand 2010b).

Novel foods must also undergo a registration process. Novel foods are foods without a history of safe use. These foods undergo a safety assessment to determine if they are safe to eat. A unique factor in the Australia and New Zealand case is that the firm applying for permission for a novel food can receive exclusive access to the Australia and New Zealand markets for that food for fifteen months (Food Standards Australia and New Zealand 2010d).

The draft standard for health and nutrient content claims applies to food only. This is because of the decision to regulate nutraceuticals as dietary supplements under a separate regulatory body as of 2003. In 2003, Australia and New Zealand signed a treaty with the intention of establishing the Australia New Zealand Therapeutic Products Authority (ANZTPA), which includes authority over complementary and alternative medicines, including dietary supplements (nutraceuticals). In June of 2011 Australia and New Zealand signed an agreement for the joint regulation of therapeutic products. A discussion paper has been released with submissions in response due February 21 2013 (TGA and Medsafe 2013). Therefore, there is currently no joint regulatory procedure covering dietary supplements in New Zealand and Australia, however, a proposal has been put forward. Regulations on these matters thus remain at the national level, discussed in detail below.

In Australia, the Australian Regulatory Guidelines for Complementary Medicines (ARGCM) set out the regulations for registering and selling complementary medicines. Complementary medicines include, but are not limited to products that have approved vitamins, minerals, and amino acids but also homeopathic medicines (Therapeutic Goods Administration 2006).¹⁹

Approval is granted on a product-by-product basis. This approval is contingent upon evidence of both safety and efficacy of the claim because complementary medicines must possess claims. Claims are split into two types with different levels of evidence for the two types. One type is traditional use evidence. Among other forms of evidence, written histories of use in traditional or classical medical literature and other countries' acceptance of the claim constitute evidence of traditional use (Williams and Ghosh 2008). The applicants that go

¹⁹ See Williams and Ghosh (2008) for a complete listing.

through traditional use regulation can use either “general” or “medium” level claims. General traditional use claims can be made in relation to: health maintenance, vitamin/mineral supplementation, or symptom relief (without mention of disease causing the symptom) (Williams and Ghosh 2008). Medium level traditional use claims pertain to: health improvement, disease-risk reduction, symptom relief of specific disease or condition, or helping manage specific symptom or disease or condition (Williams and Ghosh 2008).

Scientific evidence can also be used to substantiate the same general and medium level claims. However, “high” level claims are restricted to complementary medicines with the highest quality of scientific evidence. High level claims include treatment or curing, illness prevention, or treatment of specific vitamin/mineral deficiencies (Williams and Ghosh 2008).

To make a high level claim, a complementary medicine must be “registered” as opposed to “listed.” Listed complementary medicines are considered lower risk than registered medicines. As a result, most complementary medicines are “listed” rather than “registered” (and only possess general or medium level claims) (Williams and Ghosh 2008).

Therapeutic Goods Order 69 (TGO 69) sets out labelling requirements for therapeutic goods, including complementary medicines (which include nutraceuticals). Labels must be in English and use metric units to list the amounts of the active ingredients. All active ingredients must be named and listed with quantities or proportions, but only certain inactive ingredients are required to be listed (see TGO 69 for information on required inactive ingredients). The name of the dosage form is also required, as is the quantity of goods in the package and any applicable warning statements deemed necessary. Finally, directions on how to use the goods must also be provided (Australia 2001).

In New Zealand, recent amendments to the 1985 Dietary Supplements Act clarified the definition of dietary supplement. A dietary supplement is any amino acid, edible substance, herb, mineral, nutrient or vitamin normally available in food that is put into a controlled dosage form and is intended to be taken orally (New Zealand 2010).

Besides clearly defining dietary supplements, the 1985 Dietary Supplements Act remains relatively unchanged by the 2010 amendments. The act permits claims but they cannot be misleading and cannot be therapeutic. Therapeutic claims are ones that claim: disease prevention or treatment, disease or disorder or condition diagnosis, body weight or shape or size altering, or physiological function modification (New Zealand 2010).

New Zealand has a very laissez-faire regulatory system for dietary supplements. Nowhere in the 1985 Dietary Supplements Act and its amendments is pre-market approval provided for. The firm still holds responsibility for ensuring the product is safe. The firm must also ensure that if it uses claims, that they not be misleading or therapeutic. Violations of these and other regulations in the Act are met with a fine (New Zealand 2010).

Dietary supplement labelling in New Zealand includes a consumer information panel. The consumer information panel must declare all active ingredients and their quantities or proportions per dosage unit. Inactive ingredients (but not their quantities or proportions) must also be listed, with either their specific or class names. The permitted class names are: antioxidants, artificial sweeteners, colouring or colour, encapsulating aids, flavouring or flavour, minerals, preservatives, tablet aids, and vitamins. The consumer information panel must also include any storage instructions where appropriate. Other general labelling requirements include information on daily doses for adults and children, warning statement in case of overdose, and expiry date (New Zealand 2010).

The new standards for the regulation of health and nutrition claims which begins in January 2013 (Standard 1.2.7 – Nutrition, Health and Related Claims) consolidates several current standards. The system involves generic disease risk reduction claims that must be approved prior to use and structure function claims modelled after the US (no pre-market approval required, but substantiation must be kept). The prospects of a joint standard on complementary medicines (including nutraceuticals) are less likely. In Australia, nutraceuticals are regulated like a drug and involve product-specific claims. In New Zealand, nutraceuticals are called dietary supplements and are treated more or less like food. Moreover, there is no pre-market approval necessary for dietary supplements in New Zealand. Novel food regulation is innovative, with a potential fifteen-month exclusive access to the Australia and New Zealand market if a firm makes a successful application

Health Effect is defined as an effect on one or more of the following (Standard 1.2.7)

- a biochemical process or outcome;
- a physiological process or outcome;
- a functional process or outcome;
- growth and development;
- physical performance;
- mental performance;
- a disease, disorder or condition.

Nutrition content claim (Standard 1.2.7) pertains to the the presence or absence of:

- a biologically active substance; or
- dietary fibre; or
- energy; or
- minerals; or
- potassium; or
- protein; or
- carbohydrate; or
- fat; or
- the components of any one of protein, carbohydrate or fat; or
- salt; or
- sodium; or
- vitamins; or glycaemic index or glycaemic load;.

Japan

Japan was one of the first countries to move toward regulating functional foods. Facing an ageing population and rising health care costs, regulation began in earnest in the 1980s. Japan uses a largely product-specific system for health claims, with a relatively new category for generic claims. Disease risk reduction and structure/function claims are both permitted. Qualified claims are also permitted, while some generic structure/function claims are permitted. Japan has a relatively uncomplicated nutrition claim system, with only four categories: “rich in,” “source,” “low,” and “does not contain” with specific minimal or maximal levels of nutrients in question. Like other countries, nutrition labelling in Japan is voluntary unless a claim is made. The list of required nutrients is relatively short. A new food labelling law mandating nutritional labelling is expected to come into effect in 2013, with a five year grace period (Gain Report 2013a).

Health claims in Japan are divided into two main categories (as well as some sub-categories): Foods with Nutrient Function Claims (FNFC) and Foods for Specified Health Uses (FOSHU). FOSHU is a product-specific health claim system. Functional foods for which a firm wants to make a health claim need FOSHU approval. Well over 600 different products have been authorized to make regular FOSHU claims (Hayashi 2007). Regular FOSHU stands in contrast to qualified and standardized FOSHU (if a health claim is not qualified or standardized then it is a regular FOSHU claim). Regular FOSHU also includes disease risk reduction claims (sometimes called Specific FOSHU) (Hayashi 2007). The only disease risk reduction FOSHU claims approved are for **calcium and osteoporosis** and **follic acid and neural tube defects in infants** (see Table 1, Appendix 1) (Ministry of Health, Labour, and Welfare n.d.).

There are four main criteria for regular FOSHU approval. First, the effect of the functional food on the human body must be clearly proven. Second, there must be no safety issues with the food. Third, the food must not contain an excess of unhealthy ingredients (e.g. salt). Fourth, the food must have established quality assurance and control methods. The Ministry of Health, Labour, and Welfare makes the decision whether or not to grant FOSHU approval after consulting with the Council on Pharmaceutical Affairs and Sanitation to determine the effectiveness of the food. The Ministry also consults with the Safety Commission to ensure the food is safe for consumption (Ministry of Health, Labour, and Welfare n.d.).

In addition to regular FOSHU, there are two other types of FOSHU: qualified FOSHU and standardized FOSHU. Qualified FOSHU are for foods that have a function for which there is not conclusive scientific evidence. The wording of qualified FOSHU claims usually includes the statement that the “grounds for this effectiveness have not necessarily been established”. Standardized FOSHU is for food processing ingredients that are well established in FOSHU claims. When many products that have these ingredients achieve a certain number of FOSHU claims, then new products seeking to make claims based on those ingredients have a shorter process to achieve approval (Ministry of Health, Labour, and Welfare n.d.). For example, products that fall under standardized FOSHU claims regarding maintaining gastrointestinal functioning and health (specifically, these products can claim that they “maintain a healthy gut”) contain:

- 3-8g/day of indigestible dextrin;
- 7-8g/day of polydextrose;
- 1-3g/day of xylo-ooligoacharide;
- 3-8g/day of fructo-oligosaccharide;
- 2-6g/day of soybean oligosaccharide;
- 10g/day of isomalto oligosaccharide;

- 2-8g/day of lacto-fructo-oligosaccharide;
- 2-5g/day of galacto-oligosaccharide;
- 5-12g/day of partially hydrolyzed guar gum (Omaha et al. 2008; Hayashi 2007).

Foods with Nutrient Function Claims (FNFC) are structure/function claims. These claims can be made on food without prior approval of that specific food (generic claim), unlike any FOSHU claims. FNFC claims evidence of a relationship between a vitamin or mineral and a health function or structure. Food must fall within a certain range of values and must bear a disclosure statement depending on the vitamin or mineral. Twelve vitamin claims have been approved for claims (see Table 2, Appendix 1) (Ministry of Health, Labour, and Welfare n.d.):

- Niacin and skin or mucous membranes
- Pantothenic acid and skin or mucous membranes
- Biotin and skin or mucous membranes
- Vitamin A and night vision or skin or mucous membranes
- Vitamin B₁ and skin or mucous membranes
- Vitamin B₂ and skin or mucous membranes
- Vitamin B₆ and energy from protein or skin or mucous membranes
- Vitamin B₁₂ and red blood cell formation
- Vitamin C and skin or mucous membranes or antioxidant
- Vitamin D and absorption of calcium or bone growth
- Vitamin E and prevention of fat oxidation or cell health
- Folic acid and red blood cell formation or normal fetus development

Five minerals have been approved for claims (see Table 2) (Ministry of Health, Labour, and Welfare n.d.):

- Zinc and normal taste or skin or mucous membranes or protein and nucleic acid metabolism
- Calcium and bone and teeth development
- Iron and red blood cell formation
- Copper and red blood cell formation or enzymes function or bone formation
- Magnesium and bone and teeth development or enzymes function or energy generation

Nutrition content claims are permitted in Japan. There are four different kinds of statements (ranked in order from highest to lowest concentration of the nutrient): “high”

statements, “contains” statements, “low” statements, and “does not contain” statements. “High” and “contains” statements apply to nutrients that are useful for healthy living. The amount needed to make these claims varies for solid and liquid food and must also meet a minimum per 100kcal energy requirement. Generally, the minimum amount required for solid food is twice that of liquid food. Similarly, “high” statements generally required twice the level of the nutrient as “contains” statements (see Table 9, Appendix 1). “Low” and “not contained” statements apply to nutrients that need to be consumed in limited amounts. There is no per 100kcal requirement here. For “low” statements, food in liquid form is held to a higher standard (must have less of a nutrient to qualify for the “low” statement) (see Table 2) (Ministry of Health, Labour, and Welfare n.d.).

Nutrition information labelling is optional unless a claim is made. When nutrition information is provided, it must be done so in the following order: serving size, energy, protein, fat, carbohydrates, and sodium. Any other nutrients should be declared after sodium. Vitamins that can be declared in nutrition labelling are: niacin, pantothenic acid, biotin, Vitamin A, Vitamin B₁, Vitamin B₂, Vitamin B₆, Vitamin B₁₂, Vitamin C, Vitamin D, Vitamin E, Vitamin K, and folic acid. Minerals that can be declared in nutrition labelling are: zinc, potassium, calcium, chromium, selenium, iron, copper, sodium, magnesium, manganese, iodine, and phosphorus (Ministry of Health, Labour, and Welfare n.d.).

In Japan, novel foods and food additives are products that have been produced through the use of recombinant DNA techniques (genetically modified). The products must undergo examination for safety assessment and their methods of manufacturing should also undergo confirmation of compliance standards for manufacturing established by the Minister for Health and Welfare. Nutrition labelling is mandatory for all novel foods and food additives in

Japan. The applicable claims are similar to that of FOSHU products. As of May 12 2010, there were 116 foods and 14 food additives evaluated and approved individually by the Ministry. Currently, there are about 13 food and 2 food additives being evaluated²⁰ (Ministry of Health, Labour and Welfare – Japan 2006).

Originally, FOSHU claims were only permitted on “conventional food” and not nutraceuticals. However, as of 2001, FOSHU approval was extended to products in alternative forms, including tablets and capsules. Some dosage methods are still restricted to drugs only, including ampoules and oral sprays. Most importantly, there is no legal or regulatory distinction in Japan between “supplements” or “nutraceuticals” and “conventional food.” As such, all FOSHU regulations are the same whether or not the product comes in a conventional food format or a nutraceutical format. Regardless, the vast majority of products (over 700) with FOSHU approval are in conventional food form. Indeed, the fact that Japan does not distinguish between conventional food and nutraceuticals may make it challenging for foreign firms used to dealing with differing regulations for food format Vs. nutraceuticals (Ohama et al. 2008).

Japan currently provides an interesting mix between a purely generic system and a purely product-specific one. Although the system is decidedly more product-specific, standardized FOSHU lowers the costs to individual firms seeking claims on ingredients with well-established ingredient-health effect relationships. At the same time, there are potentially significant returns to investment for firms wishing to market a new product with health benefits.

²⁰ <http://www.mhlw.go.jp/english/topics/food/3-5.html#top>

Brazil

Brazil was a leading regulator of functional foods in Latin America, being the first country in the region to adopt functional food and health claim regulations in 1999. Brazil permits both generic disease risk reduction claims and structure/function claims, but specifically prohibits the use of therapeutic claims. Nutrient content claims are also permitted and nutrition labelling is mandatory. Novel food registration is necessary for novel functional foods.

The disease risk reduction claims permitted are (Toledo and Lajolo 2008):

- Omega-3 fatty acids and triglycerides (heart health)
- Beta-glucan (dietary fibre) and cholesterol
- Psyllium (dietary fibre) and fat absorption
- Quitosane and fat and cholesterol absorption
- Phytosterols and cholesterol
- Mannitol, xylitol, or sorbitol and dental caries
- Soy protein and cholesterol

The structure/function claims permitted are (Toledo and Lajolo 2008; Stringuta et al 2012):

- Lycopene as antioxidant
- Dietary fibres and normal intestine function
- Powered resistant dextrin (dietary fibre) and normal intestine function
- Partially hydrolyzed guar gum (dietary fibre) and normal intestine function
- Polydextrose (dietary fibre) and normal intestine function
- Fructooligosaccharides and gut flora
- Inulin and gut flora
- Lactulose and normal intestine function
- Probiotics and gut flora
- Luetin as antioxidant
- Zeaxan as antioxidant

All firms seeking to use a claim must achieve premarket approval (all functional food must achieve pre-market approval before using a new or existing claim). The food must be both safe and effective before a claim can be used. The extent of documentation required is

contingent upon the kind of claim; sometimes a single scientific study may be seen as good enough for the food to qualify for using the claim while in other cases a single scientific study may result in the rejection of the claim. There are really no specific criteria for how many scientific studies are needed, but data from well-designed and implemented human studies are key (Toledo and Lajolo 2008).

There is a novel food registration procedure in place in Brazil. The procedure applies to foods that have not been historically consumed in Brazil and foods with substances already consumed but those substances have been augmented to be at levels significantly greater than used in other foods. The National Health Surveillance Agency (ANVISA) oversees the registration procedure. ANVISA evaluates whether or not the food is safe for consumption on the basis of scientific studies (in animals and humans, as well as clinical and epidemiological studies). ANVISA also makes the decision to approve or reject the novel food by looking at the food's regulatory status in other countries (Toledo and Lajolo 2008).

Nutrient content claims are also permitted in Brazil. Values for “low” and “free” claims have been established for solid and liquid food and for energy, fat, saturated fat, cholesterol, sugars, and sodium. Generally, the maximum level for “free” claims is half the level of “low” claims. Cholesterol claims are contingent upon also meeting a certain level of saturated fat (see Table 9, Appendix 1). A “free” claim is permitted with respect to trans fat and is conditioned upon the levels of saturated fat in the food. “Source” and “rich” claims are permitted on protein and vitamins and minerals with established daily recommended values. “Rich” claims require twice the minimum levels of protein, vitamins, or minerals in “source” claims. Only one comparative claim is permitted, and that is a “reduced” energy claim, where the food must have been reduced in energy by at least 30 percent (Hong Kong 2008).

Nutrition labelling is mandatory in Brazil for all prepackaged foods. Nutrition labels must include: protein, calories, carbohydrates, cholesterol, total fats, saturated fats, trans fat, calcium, iron, sodium, and dietary fibre. If a health or nutrient content claim is made on a nutrient, then that nutrient must be declared (Coitinho et al. 2002; Food and Environmental Hygiene Department 2005).

For Brazil, functional food regulation came at the end of the 1990s. At that time, nutraceuticals were seen as occupying a fuzzy and grey area between food and drugs. ANVISA felt that more time was needed to develop regulations on nutraceuticals. A regulatory framework for nutraceuticals was established in 2002. Nutraceuticals in Brazil are called “bioactive substances”. These are substances that have a particular physiological or metabolic function and must be extracted and isolated from their original source (Toledo and Lajolo 2008).

Unlike health claims on conventional food, health claims on nutraceuticals are product-specific. This is primarily due to concerns over safety because of the concentrated nature of the products. Unlike conventional food, bioactive substances must carry an approved health or function claim. Moreover, the list of bioactive substances is quite restrictive. The list of eligible substances is currently limited to:

- Carotenids;
- Phytosterols;
- Flavonids
- Phospholipids
- Organosulfur compounds;
- Polyphenols;
- Probiotics (Toledo and Lajolo 2008).

Brazil’s regulatory system is most like Canada. Generic claims are permitted, pre-market approval is necessary for all claims, nutrition labelling is mandatory, novel functional

foods must undergo a registration procedure, and qualified claims are not permitted. Even when it comes to nutraceuticals, Brazil and Canada are similar. Brazil sees nutraceuticals (bioactive substance) as occupying a similar position in a grey area between medicine and food just as Canada sees NHPs. Brazil also uses a product-specific regulatory system for nutraceuticals.

Republic of Korea

The Republic of Korea (South Korea) is unique among the countries studied. It defines functional food significantly differently than other countries, restricting functional food to nutraceuticals. Some generic claims are permitted (and were permitted before South Korea began regulating functional foods in earnest), but it is primarily a product-specific system. Three types of claims are permitted: disease risk reduction, structure/function, and “other function” claims. Other function claims have three different levels of scientific evidence. Functional foods in South Korea must bear nutrition labelling, and have significantly more stringent labelling requirements than in other countries.

South Korea permits the use of health claims, but defines functional food differently than many other jurisdictions. In South Korea, health/functional food is defined as ingredients manufactured and processed into the form of a tablet, pill, powder, or liquid so they can be consumed in measured doses. These ingredients must have some functional importance for the human body (e.g. disease risk reduction or normal growth and development) (Korea 2006; Kim et al. 2008). Conventional food or food supplemented with vitamins, minerals, or nutrients are thus ineligible for the health claims. Instead, for a firm to be able to use claims, the food must come in some sort of medicine-like form, making all functional foods essentially nutraceuticals in South Korea. This can be contrasted drastically with the

regulatory stances of Canada, US, and EU, which all allow the use of health claims on food that does not come in pill form (Zawistowski 2008). In order to be able to sell health/functional food in South Korea, the businesses must obtain government permission, a more invasive regulatory approach than is present in other countries (Korea 2006). In other countries, only the manufacturers themselves need to get approval. South Korea requires that anyone selling the product have government approval to do so, treating retailers of the products much more like pharmacies than is the case elsewhere.

Disease risk reduction health claims on nutraceuticals are divided into two broad groups. In one group there are generic claims that products (supplements and ginseng) that were allowed under the Food Hygiene Act and can still be used. Generic health claims can be made on the following ingredients:

- Ginseng products;
- Red ginseng products;
- Eel oil products;
- EPA/DHA-containing products;
- Royal jelly products;
- Yeast products;
- Pollen products;
- Squalene-containing products;
- Yeast-containing products;
- Chlorella products;
- Spirulina products;
- Gamma-linolenic-acid containing products;
- Embryo bud oil products;
- Embryo bud products;
- Lecithin products;
- Octacosanol-containing products;
- Alkoxy-glycerol-containing products;
- Grape seed oil products;
- Fermented vegetable-extract products;
- Mucopolysaccharide products;
- Chlorophyll-containing products;
- Mushrooms products;
- Aloe products;

- Japanese apricot-extract products;
- Soft-shelled-turtle products;
- Beta-carotene products;
- Chitosan-containing products;
- Chiti-oligosaccharide-containing products
- Glucosamine-containing products
- Propolis-extract products
- Green-tea-extract products
- Soy-protein-containing products
- Phytosterol-containing products
- Fructooligosaccharide-containing products
- Red yeast rice products (Kim et al. 2008).

Any ingredients not graced with a generic claim must go through a product specific approval process. To be eligible for a claim, the product's manufacturing process must be sufficiently standardized. Additionally, the product needs to pass both a safety evaluation and an efficacy evaluation (Kim et al. 2008).

The Korean Food and Drug Administration (KFDA) evaluates all three of these criteria. Firms rely on toxicity tests and human studies, as well as historical evidence of safe use by humans to demonstrate to the KFDA that the product is safe. The efficacy of the product is demonstrated through the use of scientific studies. No precise formula is used by the KFDA to evaluate the efficacy of health claims, but two major areas are examined when looking at efficacy. The quality of the individual studies supporting the claim must be high. The KFDA looks very favorably upon "randomized, double-blind, parallel group, placebo controlled intervention study [ies]" (Kim et al. 2008). Additionally, the studies themselves need to be placed into the context of the entire domain of scientific evidence on the subject: a large number of independently conducted high quality studies bode well for efficacy approval (Kim et al. 2008)

The KFDA has different standards for different health claims. Disease risk reduction claims require the highest level of scientific agreement (many high quality studies showing a

functional relationship between the nutrient and the risk of a disease). Only one disease risk reduction claim was approved for use in 2005 involving the reduced risk of dental caries (see Table 1). Claims that go one step further than disease risk reduction claims (disease prevention or therapeutic claims) are prohibited (Kim et al. 2008).

South Korea also permits nutrient function claims that show a relationship between a nutrient and normal human growth, development, or functioning. Tertiary nutrition textbooks can provide evidence for these claims, so long as the nutrients have an established recommended daily allowance (Kim et al. 2008).

Finally “other function” claims are also permitted. These claims capture residual claims that are not prohibited and do not fall into either of the other two categories. These claims describe a nutrient’s specific beneficial effect on human health (improving it or preserving it). As of 2005, the following claims were permitted on some products:

- Reduction of blood pressure;
- Reduction of cholesterol;
- Reduction of body fat;
- Maintenance of good health;
- Modulation of blood glucose level;
- Modulation of postprandial glucose level;
- Maintaining health gastrointestinal conditions;
- Antioxidant effects;
- Improvement of memory functions;
- Improvement of cognitive functions (Kim et al. 2008).

“Other claims” can have differing levels of scientific evidence. The highest level of evidence would garner a “convincing” claim with the wording “Can have a beneficial effect on (function)” (Kim et al. 2008). Lower levels of evidence—for example, the use of in vitro or animal studies as opposed to human studies—may qualify the claim for “probable” claims or “insufficient” claims. Insufficient claims carry a disclaimer that the claimed effect is not fully verified. Probable claims use the word “may” instead of the word “can” used by convincing

claims. Insufficient claims are also accompanied by disclaimers that the effect “requires verification” or that “scientific evidence is insufficient” (Kim et al. 2008).

Health/functional foods in South Korea must bear nutrition labelling. Labels must contain the following information:

- Representation (text or symbol) that the supplement is a health/functional food;
- Health claim;
- List of functional nutrient(s) and amounts as a percentage of recommended daily allowance;
- Directions for consumption and warnings of excess consumption;
- Sell by date and method of storage;
- Disclaimer that health/functional food does not prevent or cure any diseases;
- All requirements for general food labelling (Korea 2006; Zawistowski 2008).

South Korea’s product-specific claims have likely encouraged significant innovation.

The use of qualified claims (“other claims” with lower level of evidence) also reduces the risks of rejection for firms and encourages them to innovate. However, the restriction of functional food to nutraceuticals must be seen as limiting choice for both consumers and firms. Permitting functional food would allow consumers another way of improving their diet and health. Additionally, the government’s strict control of who can sell nutraceuticals may evidence a proclivity to treat nutraceuticals more like drugs than food. Therefore, while the product-specific regulatory system encourages innovation, research is limited both by government regulations over who can sell functional food (nutraceuticals) and by the limited definition of functional foods (only permitting nutraceuticals).

People’s Republic of China

The People’s Republic of China (China) is another example of an Asian country that permits functional food. In China functional foods are usually called health foods. Like Japan and South Korea, it is a product specific system of registration. Both disease risk reduction

claims and structure/function claims are permitted. The regulatory process in China for achieving approval of health claims is stricter than elsewhere, requiring the applicant to conduct studies through an approved agency in addition to the regular scientific literature review. Novel food registration requires similar testing. Only recently has China moved to instituting mandatory nutrition labelling and regulating nutrient content claims after abuses by firms.

The State Food and Drug Administration (SFDA) have a list of permissible health claims (disease risk reduction claim) that firms can apply to use. Claims can be made between the approved food and/or food constituent and the following four health effects (see Table 1):

- weight loss;
- cholesterol (blood lipids) reduction;
- assists in blood sugar reduction;
- assists in blood pressure reduction (Yang 2008).

China also permits the use of structure/function claims. The structure/function claims are also product specific. Firms apply to the SFDA to use claims that specify a relationship between the food and or food constituent and the following twenty three health effects (see Table 2):

- enhances immunity;
- antioxidative;
- assists in memory improvement;
- alleviates eye fatigue;
- facilitates lead excretion;
- moistens and cleans throat;
- improves sleep;
- facilitates milk secretion;
- alleviates physical fatigue;
- enhances anoxia endurance;
- assists in irradiation hazard protection;
- improves child growth and development;
- increases bone density;
- improves nutritional anemia;

- assists in protecting against chemical injury to the liver;
- eliminates acne;
- eliminates skin chloasma;
- improves skin's water content;
- improves skin's oil content;
- regulates gastrointestinal tract flora;
- facilitates digestion;
- facilitates feces excretion;
- assists in protecting against gastric mucosa damage (Yang 2008).

The approval process for health food claims is very similar for domestic and foreign applicants. The SFDA requires samples of the food as well as a scientific evidence literature review and an approved testing agency for evaluation. The testing involves safety and efficacy assessments. If the firm wishes to use a claim not in the approved list of twenty seven claims, the firm must arrange for testing (human and animal trials) to demonstrate efficacy. The SFDA may also commission an inspection of the manufacturer's facilities to evaluate safety. If the application is approved, then a Domestic Health Food Registration Certificate or an Imported Health Food Approval Certificate is issued. Imported Health Food Approval Certificates are only valid for five years (Roberts and Rogerson 2008).

Health foods that are considered novel are also subject to novel foods registration. Novel foods are defined as raw foods or food materials with no history of safe use as a food in China (genetically modified organisms are regulated by laws and a different ministry than novel foods). The Ministry of Health evaluates the safety of novel foods (or the demonstration that the novel food is substantially similar to other registered novel foods). Similarly to the health food approval process, the Ministry of Health in this case requires samples of the food be sent to an approved testing facility to determine the food's safety. This testing is conducted at a cost to the applicant. On-site examinations may also be conducted before the Ministry of Health makes its final decision on whether to approve the novel food. If the food is evaluated

as safe or substantially similar to other novel foods, then it will be permitted as a novel food in the Chinese market (Roberts and Rogerson 2008).

Lagging behind functional food and health regulations, China only recently began significantly regulating nutrition labelling and nutrition claims. Labelling remains voluntary. However, labelling is now guided by mandatory requirements when claims are made. Labels must include levels of protein, fat, carbohydrate, and sodium. Labels may voluntarily declare cholesterol, sugar, and fat content. Nutrition content claims can be made on calcium, iron, and fat and require that the food meet certain criteria for these foods. Labels must not be misleading or make claims regarding the curing of illness (Reuters 2008).

Similar to Japan, current Chinese regulations do not make a distinction between nutraceuticals and conventional food. Instead, firms face the same (stringent) regulatory procedure regardless of whether they choose to format the product in nutraceutical or food form (Roberts and Rogerson 2008).

In conclusion, product-specific claims regulations emerge as a regional preference of several Asian nations: South Korea, Japan, and China all have product-specific systems. China permits a wide list of claims, but has an extra step of safety assessment, requiring testing by approved agencies (scientific literature review is not enough for approval). Novel food registration is a similar process. The challenges China encountered with labelling suggest the importance of labelling regulations coexisting with health claims. New labelling requirements for pre-packaged food products was implemented in January 2013 by The Ministry of Health in China. Nutritional information on protein, fat, carbohydrate and sodium is required along with other nutrients when a nutrient content or nutrient comparative claim is made (GAIN Report 2013b).

Taiwan

Taiwan is one of the countries in the Pacific Rim with well-established functional food and nutraceutical regulation. In Taiwan, these products are known as health foods²¹. In 1999 the Health Department in Taiwan enacted the Health Food Control Act (HFCA) to define and regulate the production and health claims of health foods. The HFCA defines health food as food with specific nutrient or health maintenance effects which is especially labelled or advertised, and does not aim at treating or remedying human diseases (HFCA 2006). Taiwan's HFCA permits health maintenance claims, which are claims that the product promotes health by reducing the risk of serious illness (structure/function claims). The health maintenance claims are product specific and each product is assessed and evaluated before claims can be made. Therapeutic claims are not permitted under the HFCA. Nutrient content claims are permitted and nutrition labelling is also regulated. All health foods, both locally produced and imported, must undergo a registration process in Taiwan.

The health maintenance claims permitted include (Liu and Lee 2000):

- Regulate blood-lipid;
- Improve gastrointestinal functions;
- Alleviate osteoporosis;
- Maintain dental health;
- Regulate immune system;
- Regulate blood sugar level;
- Protect the liver.

Health maintenance claims must be scientifically substantiated. Where there is not enough evidence to do so the ingredients must be identified and supported with literature and submitted to the Department of Health for assessment and approval. Taiwan is very strict with the registration of health foods. Failure to comply with the registration process is an indictable

²¹ In Taiwan the definition used for natural health products and functional foods also applies to novel foods.

offence and comes with a jail sentence punishment and a fine. An initial permit to manufacture or import a health product is valid for a 5 year period which can be extended for another 5 years provided the renewal was applied 3 months before the old one expired. The permit can be revoked at any time if there is a doubt about the safety of the product or its ingredients (Liu and Lee 2000).

Nutrient content claims are permitted in Taiwan. However, the regulations concerning the nutrient content claims are very relaxed. Nutrient content claims are generic. Nutrient requirements to qualify as a health product and make nutrient content claims are not specifically stated. The level of nutrients such as cholesterol, sugar, salt, fat and saturated fat are not stipulated in the HFCA. Firms are at liberty to make any content claims about these nutrients in their products. There have been calls to amend the HFCA to restrict the amount of these nutrients that can be used in a health product when related claims are made but changes have not yet occurred. This aspect of the Act serves as an opportunity for manufacturers, both local and foreign, to enter the Taiwanese health food market (Zawistowski 2008).

Nutrition labelling is required on all foods in Taiwan. Conventional food labelling is regulated by the Food Administration Act (2007) and health food labelling is regulated by both the Food Administration Act and the Health Food Control Act. Taiwan's labelling standard is reminiscent of international standards stipulated in the Codex Alimentarius of the FAO/WHO. All labelling should be in Chinese and should be easily noticeable on the product.

Information required on the product should include the following (Gain 2012b):

- Product name
- Name, weight or volume of the contents; separate labelling is required if there is a mixture of two or more ingredients in the food composition
- Names of food additives
- Expiry date, methods and conditions of preservation

- Manufacturer's information and if imported, name and address of the local business operator
- All approved health claims
- Permit number and standard logo of the health food
- Nutrient composition and their contents
- Other material facts designated by the Health Department by way of public notice
- Intake amount and important messages and other necessary warnings
- Country of origin
- Country of origin of beef and/or beef cattle offal

The regulatory system regarding nutrient content claims in Taiwan is more relaxed compared to the Canadian system. Firms are at liberty to make any content claims about some nutrients (cholesterol, sugar, salt, fat and saturated fat) that are not stipulated in the HFCA. This flexibility may encourage more investment in the sector. Furthermore, the alignment of some Taiwanese regulations with international standards makes it easier for foreign manufacturers to enter the market.

Singapore

Singapore, unlike many other countries, does not have a legal definition for functional food and nutraceuticals. As with most Asian countries, the working definitions for functional food and nutraceuticals are aligned to international standards. In Singapore, the working definition for functional food is a food that delivers a health benefit beyond that of basic nutrition and a claim is made about its benefits. Nutraceuticals are known in Singapore as health supplements and the working definition refers to substances derived from natural sources, including botanical materials in the form of extracts, isolates and concentrates (EAS Asia 2009). The Food Control Department regulates claims on these products in Singapore.

Disease risk reduction health claims are not allowed on functional foods in Singapore. Structure/function health claims are permitted. Nutrition content claims are permitted and

nutrition labelling is mandatory. Functional foods in Singapore are regulated by the Sale of Food Act and the Food regulations. They are administered by the Agri-food and Veterinary Authority (AVA).

There are two categories of the *nutrient content claims* in Singapore: **Nutrient claims** and **Nutrient function claims**. A nutrient claim implies that a food has a nutritive property. The claim can be general or specific and can be stated positively or negatively. Nutrient function claims, which are like the structure/function claim in Canada, describe the physiological role of the nutrient in the growth, development and normal functions of the body. The nutrient function claim can also be positive or negatively stated.

The **nutrition claim** may refer to the following nutrients: energy, protein, total fat, saturated fat, cholesterol, carbohydrates (excluding dietary fibre), sodium and dietary fibre. An example of a nutrient claim would be: “this food has high energy content”. Other nutrients can be added to those listed above with the following exceptions:

- Starch, sugar and lactose may be inserted after carbohydrate;
- Polyunsaturated fat and monounsaturated fat may be inserted after saturated fat;
- Omega fatty acids may be inserted after polyunsaturated fat.

All the nutrients must be stated in the appropriate units. The units for energy must be in kilocalories and kilojoules. However, one unit can be stated provided the conversion factor is also stated.

Nutrient function claims allowed in Singapore are as follows (AVA 2011)

- Protein provides the essential amino acids needed to aid in the building and maintenance of body tissues;
- Protein helps in tissue building and growth;
- Low lactose content allows easier digestion for people who are lactose intolerant;
- Low lactose content eases digestion for people who are lactose intolerant;
- Vitamin D3 helps support calcium absorption and improves bone strength;
- Enriched with vitamin D3 for calcium absorption;

- Calcium helps build strong bones and teeth;
- Iron is an important component of red blood cells which carries oxygen to all parts of the body to help the body's production of energy;
- Iron is one of the essential minerals vital for life;
- Folate helps support fetus growth and overall development;
- Folate plays a role in the formation of red blood cells;
- Folate taken before and during early pregnancy helps in the mental/normal and overall development of fetus.
- Dietary fibre aids in digestion system.
- Vitamin C absorption of iron from non meat products
- Zinc growth
- Magnesium absorption and retention of calcium
- Vitamin A for eye development
- Vitamin B1, B2, B3 help to release energy from proteins, fats and carbohydrates
- Vitamin B6 is important for the production of energy.
- Vitamin B12 is necessary for fat, carbohydrate and protein metabolism and is needed for/helps in the formation of red blood cells.
- Vitamin E as an antioxydent.
- Vitamin K for bone strength.
- Iodine for synthesis of thyroid hormone.

The **nutrition function claims** must be scientifically proven before they can be allowed.

The criteria for a nutrient function claim to be allowed include (AVA 2011):

- The claim is about essential nutrients that have established recommendations about its intakes and nutritive importance;
- The claim enables the public to understand the information provided and its significance to their overall daily diet;
- There is at least 1/6 of the daily allowance of a nutrient present in the case of a positive claim of the presence of vitamins or minerals;
- The amount of nutrient should be low or less in the nutrient mentioned in a negative claim;
- The claim does not say or imply that the nutrient is a cure/treatment for a disease or gives protection from a disease;
- Claim of enrichment or fortification of the food with minerals or vitamins should contain at least 50% of the recommended daily allowance of the vitamin or mineral.

All functional foods must undergo premarket approval and it is the responsibility of the manufacturer to ensure that the product meets the required standard. The initial registration period is one year, which can be renewed for a five-year period. The Nutrition Programme

Management reserves the right to request a manufacturer to submit the method of analysis of the claim, the recipe for the product and a sample of the product itself.

Nutrition labelling is mandatory in Singapore. All labelling should be in English. The nutrition panel of the label should display the core list of nutrients (energy, protein, total fat, saturated fat, cholesterol, carbohydrate, dietary fibre and sodium). The nutrient values should be stated in per 100g/100ml and per serving. It must also include the number of servings per package and the serving size. The label should not contain any misleading information and should not be interpreted as medical advice from any person or institution. No words in the label should imply that the food will prevent or treat a disease or condition affecting the body (Health Promotion Board 2002).

Health supplements in Singapore refer to products meant to supplement diet and with benefits beyond those of normal nutrients. They can be in the form of capsules, softgels, tablets, syrups and any other form that is approved by the licensing authority. It should not be the sole item of a diet or meal and should not include any injectable and sterile preparation. Currently, health supplements are not subject to premarket approval and the safety and quality is the responsibility of the manufacturers (Health Sciences Authority 2010).

Health claims and **Nutritional claims** on health supplements (nutraceuticals) are permitted in Singapore. Nutritional labelling is also mandatory. The health supplements in Singapore are regulated by the Medicines Act 1975. False, misleading and deceptive claims are prohibited. Claims should not make any reference, direct or indirect to certain types of diseases. Currently, there are 19 diseases that cannot be referenced in a claim (Health Sciences Authority 2010, p.12):

1. Blindness
2. Cataract
11. Cancer
12. Conception and Pregnancy

- | | |
|-----------------------------|------------------------|
| 3. Dangerous drug addiction | 13. Deafness |
| 4. Diabetes | 14. Epilepsy or Fits |
| 5. Infertility | 15. Hypertension |
| 6. Frigidity | 16. Insanity |
| 7. Impotency | 17. Kidney disease |
| 8. Leprosy | 18. Menstrual disorder |
| 9. Paralysis | 19. Sexual function |
| 10. Tuberculosis | |

There are two categories of health claims on health supplements in Singapore.

Functional health claims and permissible health claims. **Functional health claims** are claims meant to support the natural physiological processes. Functional claims are generic and must be substantiated through ingredient-based evidence. Manufacturers can be called upon to provide this evidence by the health authority. Functional claims are not permitted to refer to any disease and may include claims like:

- General enhancement/maintenance of healthy functions;
- Supports healthy function of the human body such as maintaining healthy joints, supports natural physiological processes e.g. immune system, circulation and digestion.

Permissible health claims, which are similar to disease risk reduction claims in Canada, are product specific claims that are allowed by the health authority in Singapore. They are claims that indicate the reduction of symptoms associated with mild diseases and disorders. They are also permitted on treatment of vitamin and mineral deficiency diseases. Permissible health claims should be supported with ingredient-based and product-based evidence that are well documented in authorized referenced literature. Examples of permissible health claims include (Health Sciences Authority 2010, p.13):

- Relieves the discomfort associated with cold or flu symptoms;
- Relief of mild cough;
- Soothes sore throat;
- Relieves menopausal discomfort;
- Assists in maintaining joint mobility.

Manufacturers making health claims on their products must have evidence to support their claims and be prepared to provide them to the health authority when required to do so.

Nutritional structure/function health claims are generic claims that are made to indicate that the product provides nutritional supplementation beyond the normal nutritional value of food. They should be ingredient-based with each ingredient well documented in standard reference literature. For vitamins and minerals, nutritional claims are permitted when their contents in the product is greater than 30% of the RDA value. Examples of nutritional structure/function health claims include (Health Sciences Authority 2010, p.12):

- Nourishes the body;
- Enhances good health and growth;
- Strengthens the body (no reference to body organs);
- Supplements nutrition.

Manufacturers must have evidence to support the claims and be prepared to provide them to the health authority when required.

Nutrition labelling is mandatory in Singapore. Labelling on health supplements follows the same process as functional foods. They should be in English and must be openly displayed on the product. The name of the product, the recommended dosage, batch reference, expiry date and any necessary precautionary statements must be displayed on the final product. Ingredients used in the products must be listed on the label and they can be in their scientific, Latin or botanical names. All information on the label must be truthful and printed in a clear and legible manner (Health Promotion Board 2002).

Singapore has a well-established market for both functional foods and natural health products. In as much as there is no legal definition for functional foods, there is a clear distinction between functional foods and natural health products. Singapore has a well-developed regulatory system for these products. A manufacturer's ability to make legitimate

health claims on health supplements is a great incentive for investors to enter the Singapore market for natural health products. However, firm and consumer choices are limited by the prohibition of some health claims on food. Unique for countries under study here, Singapore regulates food more strictly than nutraceuticals. This is in stark contrast to Canada and Australia, who regulate nutraceuticals more strictly than food.

Malaysia

Malaysia does not have a specific definition for functional food. Functional foods are generally understood as foods that contain substances other than nutrients that may have beneficial effects on health beyond their nutritional properties. The great influx of these products into the Malaysian market has led to proposals for international regulation to better control them. Health claims, nutritional claims and labelling are permitted on functional foods in Malaysia. The claims all follow the guidelines of Codex Alimentarius. (FAO 2004)

Health claims are made to link a diet to a certain disease condition. The health claims in Malaysia are product specific and must always link the benefit from the product to the particular disease. It could either be a disease risk reduction claim or a disease prevention claim. Malaysia regulation does not strictly regulate these claims however certain claims are prohibited. Claims that involve words like medicated, compounded, and health cannot be used. Health claims that cannot be substantiated with scientific evidence are also prohibited.

There are three groups of nutrition claims permitted in Malaysia (Tee 2007a):

- Nutrient function claims;
- Nutrient content claims;
- Nutrition comparative claims.

Nutrient function claim promotes how the nutrient in the product can affect the physiological function of the body in terms of growth and development. Permitted nutrient function claims in Malaysia include the following (GAINS 2012c):

- Folic acid is essential for growth and division of cells;
- Iron is a factor in red blood cell formation;
- Niacin is needed for the release of energy from proteins, fats and carbohydrates;
- Magnesium promotes calcium absorption and retention;
- Calcium helps in the development of strong bones and teeth;
- Protein aids in building and repairing of body tissue;
- Vitamin C enhances absorption of iron from non-meat sources;
- Vitamin B12 is needed for red blood cell production;
- Vitamin B2 is needed for the release of energy from proteins;
- Vitamin B1 is needed for the release of energy from carbohydrates;
- Vitamin D helps the body utilize calcium and phosphorus.
- Sialic acid component of brain tissue
- Iodine for thyroid hormone
- Vitamin A for eye function
- Vitamin E protects the fat from oxidation
- Zinc essential for growth

Nutrient function claims are permitted on bioactive substances like probiotics and prebiotics in Malaysia. Nutrient function claims are not permitted to relate to the curing and treatment of a disease to the product. Claims that cannot be proved scientifically and those that imply that ordinary food cannot provide the needed nutrients of the body are also prohibited.

Nutrient content claims indicate the level of a nutrient in a food. There are two types of nutrient content claims in Malaysia. They can either be negative or positive. Negative claims imply that the food is free or less of a particular food component. Positive claims on the other hand, imply that the food is a source of, or high in, a stated food component or nutrient. A food with a positive claim like “source of” should have at least 15% more than the

nutrition reference values (NRV) of the stated nutrient and 30% more when it has a “high” or “enriched” claim (Zawistowski 2008)

Nutrition comparative claims are made when another product of similar type is compared to the one carrying the claim. Malaysian regulations require that both the food with the claim, and the one being compared to, be clearly identified. The stated claim should be on the product with the claim. An example of a nutrient comparative claim would be “reduced trans fat” when the product with the claim contains less trans fat compared to a previous type (Zawistowski 2008).

Natural health products are known in Malaysia as dietary supplements. They refer to products that are formulated to supplement diet in the form of pills, capsules and liquids. Dietary supplements should not be in the form of conventional food. Components of dietary supplements include vitamins, amino acids and natural substances which can be either animal or plant-based. All claims allowed for functional foods are also allowed for dietary supplements. However, all claims are product specific and are subject to a pre-market approval of the National Pharmaceutical Control Bureau (NPCB). The manufacturing process should also conform to the Good Manufacturing Practices requirements. Dietary supplements have to undergo a registration process. Each product can be registered for a five-year period after which new and updated information about the safeness of the product must be recorded before it can be renewed by the NPCB (Sie 2004).

Malaysia has a well-developed regulatory system for functional foods and natural health products. The alignment of their claims to the guidelines of the Codex Alimentarius is a step that facilitates access to the Malaysian market by investors. Firms may regard the ability

to make nutrient function claims on bioactive substances like probiotics and prebiotics in Malaysia as a valuable opportunity.

Hong Kong

Hong Kong does not have a legal definition for functional foods and nutraceuticals. The terms dietary supplement, nutraceuticals, designed foods, functional foods and natural health products are used interchangeably to refer to the same type of products. Health products in Hong Kong are currently divided into three categories: nutraceuticals, herbal-based products and vitamins. Outlets used in selling these products include pharmacies, health product stores, supermarkets and personal care stores (New Zealand Trade and Enterprise 2009).

In 2008, the Hong Kong legislative council enacted a legislative amendment to regulate food claims and labelling. The proposed amendments came into effect on 1 July 2010. Before this amendment, there were no regulations on health claims and nutrition labelling. The only prohibited claim before the amendment was disease prevention and cure claims (Centre for Food Safety-Government of Hong Kong 2008).

Under the proposed amendment, nutrient content claims, nutrient comparative claims and nutrient function claims will be permitted. Nutrition labelling will also be regulated. However, disease risk reduction and therapeutic claims are prohibited. The new amendments follow the guidelines of the Codex Alimentarius with a few additions. **Nutrition function claims** are allowed if there are local nutrient reference values (NRV) for that nutrient or the required level has been prescribed by the amendment. **Nutrient comparative claims** can only be made if there is at least a 25% difference in the nutrient levels between the two products being compared. **Nutrient content claims** are permitted when there is an objective standard

on what is meant by high or low in the context of a balanced diet. This is to prevent consumers from being misled about the actual nutrient content in a product.

Nutrition labelling under the new amendment requires listing of the energy and seven core nutrients, namely protein, carbohydrates, total fat, saturated fat, trans fat, sodium and sugars. In addition, any claimed nutrient in the product should also be listed on the label. Manufacturers can also voluntarily list nutrients which are not required by law. The labelling unit of energy can either be in kilocalorie or kilojoules and the nutrition labels in either per 100 g/ml or per serving format. The product labelling can either be in English, Chinese or both. In addition to the listing of the nutrients, the regulation requires that the name of the product, durability period, special condition for storage or instruction for use, weight or volume and the name of the manufacturer or packer to be on the label (Centre for Food Safety-Government of Hong Kong 2008).

Hong Kong, under the new amendment to regulate claims and labelling of functional foods, will be one of the jurisdictions with a friendly environment for these products. The Centre for Food Safety has the responsibility of regulating functional foods and natural health products. The regulations after the amendment will be in line with the Codex Alimentarius guidelines which should facilitate market access and investment in the sector.

India

Functional food, health supplements, nutraceuticals and food for special dietary use are used interchangeably in India. They are all referred to as foods which are specially processed or formulated to satisfy particular dietary requirements that exist because of a particular physical or physiological condition. They should differ from the composition of ordinary foods of comparable nature. Disease risk reduction health claims are prohibited.

However, nutrition structure/function health claims are permitted and labelling is mandatory for all functional foods in India (Food and Safety Standards Act 2006). Regulations are enforced by the Ministry of Health and Family Welfare. The act was updated in 2011 with the Food Safety and Standards (packaging and labelling) Regulations act. New regulations have come into effect in January of 2013 requiring the labelling of products containing biotechnology ingredients. Also, India has embarked on a process to harmonize India food standards with the Codex standards and other international best practices. This process was initiated in January 2013 with scheduled completion and implementation by December 2014 (FSSAI 2013).

Any claims that imply medicinal and therapeutic functions are not permitted by law. However, nutrition structure/function claims that are not misleading can generally be used on these products. There has to be enough scientific evidence to support the claim. While there is no pre-market approval for these products, the responsibility lies with the manufacturer to ensure that all claims satisfy the stipulated regulations (Food and Safety Standards Act 2006).

Labelling of these products is mandatory and it is an offence to sell a product without a proper label. All information on the label should be truthful and must not mislead the consumer. Information about ingredients, nutrients and quantity of the product on the label must not be different from the actual product in the package. Labels that falsely represent the product to promote its sale and give the public any guarantee of effectiveness that is not scientifically justified are not permitted..

India's health claims and labelling regulations are less restrictive compared to Canadian standards. Health claims are not permitted but nutrition claims are allowed and labelling is mandatory. If disease risk reduction health claims are permitted in the future, with

India's status as one of the new emerging economies in the world, it is likely to become an attractive market for further development of the functional food sector (Food and Safety Standards Act 2006)

Thailand

Functional foods in Thailand are defined as foods which are similar in appearance to conventional food, consumed as part of a normal diet, provide physiological benefits and reduce the risk of disease. There is often confusion on whether to classify a product as functional food or as a drug in Thailand. The ingredients used in its production supplies the identification used to classify these products. Health claims are prohibited in Thailand. However, nutrition claims are permitted and labelling is mandatory for all products that make claims (FAO 2004). The Thai Food and Drug Administration is the agency responsible for the regulation of functional foods.

Nutrient claims are generic and of three types: nutrient content claims, comparative claims and nutrient function claims. Thai nutrient claims are similar to Codex Alimentarius guidelines. Examples of nutrient content claims include 'low in fat', 'high in fibre' and 'source of calcium'. When a product is naturally free or low in a nutrient, it is prohibited to make a claim that implies the manufactured product is free or low in that same nutrient. Nutrient function claims that are permitted include 'folate is an important component of red cell formation' and also, 'calcium is an important component of bones and teeth' (Zawistowski 2008).

Nutrition labelling must be expressed in the Thai language. However, foreign languages can be included. The label should display the daily intake for ages of 6 years and up. All nutrients in the product should be listed and the recommended daily intake of that

nutrient must also be displayed on the label. The nutrition quantity per each serving should be displayed and for products that cannot display this information the “Nutrition value per 100 g.”, or “Nutrition value per 100 ml.” should be on the label (Ministry of Public Health 1998).

Thailand’s regulations of these products are not well-developed. The definitions are not well established and the lack of a clear distinction between functional foods, nutraceuticals and drugs may be a disincentive for investors. Nutritional claims [nutrient content claim, comparative claim and nutrient function claims (structural/functional claims)] are permitted, disease reduction health claims are prohibited, and nutrition labelling is mandatory. The nutrition claims and labelling standards follow the guidelines of Codex Alimentarius. Health claims are currently prohibited.

The Philippines

The Philippines, like some other countries, does not have a legal definition for functional foods. The working definition used is the Codex definition of functional food. They are known as foods that have nutritional benefit that can improve the state of health and well-being or reduce the risk of disease beyond the nutritive effects of conventional foods. These products may include vitamins and minerals. Some health claims are permitted. Nutrition claims are also permitted and nutrient labelling is mandatory (FAO 2004). The Bureau of Foods and Drugs of the Health Department in The Philippines is responsible for the regulation of these products.

Health claims that imply that a specific food is capable of preventing or curing a disease or its symptoms (therapeutic claims) are prohibited. However, there are two health claims that are currently allowed for functional food. The first is the claim ‘linking calcium to reduction of osteoporosis risk’. The other claim is ‘low fat food reduces the risk of cancer’.

The nutritive claims permitted are generic types like ‘low in a claimed nutrient’, ‘rich in a claimed nutrient’ or ‘a good source of it’ (Zawistowski 2008).

Nutrition labelling in The Philippines is mandatory and applies to all products. Labeling regulations require that all nutrition information must be on the product label in a tabulated form. The nutrients that remain after cooking the food should also be stated on the label and expressed in specified weight or volume of the food. The labelling should also indicate the minimum amount of nutrients that are present at all times (Department of Health Philippines 1984).

The Philippines does not have a legal definition for these products. There is no clear distinction between functional foods and nutraceuticals in The Philippines. The adoption of the Codex Alimentarius definition of functional foods may lead to the development of health claims regulations as well as labelling guidelines but at the present time mandatory nutrition labelling represents the primary type of health-related labelling in The Philippines.

3. Analysis and Conclusions

Several steps could likely be taken if the goal is to improve information available to consumers to make better choices and to provide consumers with healthier food options. Canada could permit some form of qualified health claims (as permitted in the USA, Japan, South Korea, and elsewhere). The authorization of these claims requires lower standards of evidence. They also usually require the provision of a disclosure statement or less authoritative wording than full strength claims. This would encourage research by reducing the level of evidence required for claims. Some countries, however, reject the use of lower standards for disease risk reduction claims (e.g. South Korea, Australia and New Zealand)

because of the importance of not misleading consumers about the nature of these relationships. At a minimum, however, qualified structure/function claims could be used in Canada.

Another potential step to encourage private sector research and development would be to allow product-specific claims. Generic claims create a free rider problem: many firms can benefit but only one firm has to go through the application process to get approval for a new claim. Allowing product-specific claims, as in Sweden historically, Japan, South Korea, and China, reduces spillover benefits that would otherwise accrue to other firms producing similar food products. This imperative must be balanced, however, with the desire to better inform consumers and encourage healthier food consumption choices. The advantage of the generic system is that more products can use approved health claims with the potential to facilitate improved consumer knowledge on the relationship between diet and health. A middle ground can likely be found to ameliorate the situation. Allowing both generic and product-specific claims as in Sweden, or standardized FOSHU as in Japan are definite possibilities. A more experimental possibility would be to adapt the Australia and New Zealand novel food approval process to functional foods allowing say a fifteen-month period of a new claim being product-specific, with claims becoming generic after that period.

One of the most interesting themes that emerges is that some countries permit disease-risk reduction claims while others prohibit them. Nine of the 18 countries examined currently permit disease-risk reduction claims, while Singapore (on food), Russia, Taiwan, Thailand, and Hong Kong all prohibit disease-risk reduction claims. This is a disincentive for firms wishing to market functional foods and nutraceuticals.

Novel food registration must balance the requirements of food safety while at the same time avoid discouraging research. The US system for food registration is the most favourable to encouraging research, but has the least favourable oversight of novel foods. On the other hand, the EU imposes extremely strict requirements on novel food safety and the avoidance of genetically modified organisms. The joint Australia and New Zealand policy holds promise, offering a potential middle ground. In Australia and New Zealand, food must undergo a safety evaluation process, but approved novel foods can receive a fifteen month brand-specific exemption. This system balances well the dual imperatives of research and safety because the fifteen month exemption provides incentives to research novel foods by reducing spillover benefits and increasing benefits to the applicant firm (as noted above).

There is broad consensus among the countries examined on nutrition labelling. Labels are required when claims are made. Several countries have mandatory nutrition labelling requirements, as is the case with Canada. There is some disagreement, however, on which nutrients must be included on labelling. The US and Canada both require more nutrients on labels than many of the other countries under study.

There are three broad regulatory types under study here: national, international, and self-regulatory. National systems are regulated by one government and apply domestically. International systems are usually regulated by a supranational authority (the Commission and EFSA in the EU and ANZFSANZ in Australia and New Zealand), although regulations could also be negotiated directly between states. Self-regulatory systems entrust health claim approval and regulation to firms and organizations of firms and sometimes consumer associations. The self-regulatory regime has lost favour (the EU did not adopt it, despite the recommendations of the UK). Australia and New Zealand explicitly rejected self-regulation,

with the perception that self-regulation in those countries had led to an uneven playing field in the market (Food Standards Australia New Zealand 2008b). National regulation was by far the most popular, but there may be untapped benefits in international regulation and harmonizing regulations across borders. It would make it easier for firms to export and import goods and provide firms with access to larger markets. It will be difficult, however, to change entrenched regulatory systems, especially in situations where one country has relatively stringent regulations (e.g. Canada) and the other one has relatively lax regulations (e.g. the US).

Regulations on nutraceuticals/natural health products vary from country to country. Some countries treat natural health products in a similar manner to food. Japan and China are prime examples of this, making little or no legal or regulatory distinction between food and pill form. The United States does distinguish between food and natural health products (dietary supplements), but does not impose significantly different regulations (the same generic claims are available to food and to dietary supplements). New Zealand treats natural health products (dietary supplements) like food, but does not permit certain claims (including disease risk reduction claims) on supplements. However, the regulatory requirements for dietary supplements are somewhat lax. The EU treats food supplements as a food, but significantly limits food supplements to only approved vitamins and minerals. Then there are countries that treat natural health products in a grey zone between food and drugs. Brazil, Canada, and Australia all regulate natural health products differently than food, using a product-specific system with a more substantial level of evidence required. South Korea is the primary example of this category, restricting functional foods to natural health products, and requiring licenses even for venders of the products, not just the producers.

The advantage of treating natural health products like food is that regulation does not factor into a firm's decision about which format to pursue. Regulation does not distort the costs or benefits of using food relative to using natural health products. The Canadian system, being of the latter variety, does recognize a potentially important difference between foods and natural health products, but differing regulations complicate decision making for firms. If firms choose the food route, then the regulation is less stringent but the claim does not belong to that firm on that product alone. If the firm chooses to register as an NHP, then the product gets the product specific claim but must meet more stringent regulations for approval. As a result, a firm's choice to manufacture food or natural health products is likely dependent on how firms view the trade-offs between the two differing systems.

As the Canadian regulatory system for health claims and functional foods continues to evolve insights from other regulatory jurisdictions can provide useful lessons. The relatively small size of the Canadian domestic market means that substantial differences between Canadian regulations and those of major export markets are likely to further inhibit investment in functional food development in the Canadian market. As ever the challenge remains balancing consumer protection from fraudulent or misleading health claims with a regulatory environment that encourages investment in R&D into products with positive health benefits for consumers.

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Appendix 1: Tables

Table 1. Disease risk reduction claims permitted in various countries

Canada

Food (generic claims)

- Sodium and potassium and high blood pressure
- Calcium and vitamin D and osteoporosis
- Saturated fat and trans fat and heart disease
- Vegetables and fruit and some types of cancer
- Maximal fermentable carbohydrates and dental caries
- Oat fibre and heart disease
- Phytosterols and cholesterol lowering
- Barley products and blood cholesterol lowering.
- Unsaturated fat and blood cholesterol lowering.

Nutraceuticals

Called Natural Health Products (NHPs) and product specific registration. While some claims that are used on food could be used on nutraceuticals, each firm desiring to make a product with the claim must receive approval individually. No list of claims available.

United States

Food & Nutraceuticals (dietary supplements) (generic claims)

Claims Meeting Significant Scientific Agreement (SSA)

- Calcium, Vitamin D and Osteoporosis
- Dietary Lipids(Fats) and Cancer
- Dietary Saturated Fat and Cholesterol and Risk of Coronary Heart disease
- Dietary Noncariogenic Carbohydrate Sweeteners and Dental Caries
- Fiber Containing Grain Products and Cancer
- Folate and Neural tube defects (in infants)
- Fruits and Vegetables and Cancer
- Fruits, Vegetables, and Grain Products High in Fiber, particularly Soluble Fiber, and Risk of Coronary Heart disease
- Sodium and Hypertension
- Soluble Fiber from certain foods and Risk of Coronary Heart disease
- Soy Protein and Risk of Coronary Heart disease
- Plant Sterol/Stanol esters and Risk of Coronary Heart disease
- Potassium and the Risk of high blood pressure and strokes
- Whole Grain Foods and Risk of Heart disease and Certain Cancers
- Fluoridated Water and Reduced Risk of Dental Caries
- Saturated Fat, Cholesterol, and Trans fat and Reduced Risk of Heart Disease

Qualified Health Claims

- Tomatoes and/or tomato sauce and prostate cancer
- Tomato sauce and ovarian cancer
- Tomatoes and gastric cancer
- Tomatoes and pancreatic cancer
- Calcium and colon/rectal cancer
- Calcium and recurrent colon polyps
- Green tea and cancer
- Selenium and cancer
- Antioxidant vitamins and cancer
- Nuts and heart disease
- Walnuts and heart disease
- Omega-3 fatty acids and Coronary Heart Disease
- B vitamins and vascular disease
- Monounsaturated fatty acids from olive oil and heart disease
- Unsaturated fats from canola oil and heart diseases
- Corn oil and heart disease
- Phosphatidylserine and dementia
- Phosphatidylserine and cognitive dysfunction
- Chromium picolinate and diabetes
- Folic acid and neural tube defects (claim recommends twice the intake of approved SSA claim)
- Calcium and Hypertension
- Calcium and Pregnancy-Induced Hypertension or Pre-eclampsia

European Union

Food and Nutraceuticals (generic claims)

Nutraceuticals are called food supplements and are eligible to bear same claims as food.

- Plant sterols and heart disease
- Plant stanols and heart disease
- Chewing gum sweetened with 100% xylitol and dental plaque

In EU regulation 1924/2006, these three diseases risk reduction health claims were initially permitted.

Member states and other stakeholders have provided the European Food Safety Authority (EFSA) and the EU Commission with thousands of health claims. A list of acceptable claims was to be created by the deadline of January 31 2010 as per 1924/2006, but has yet to be finalized and approved by the Commission.

United Kingdom***

Food (generic claims)

- Diet with reduced saturated fat and cholesterol
- Wholegrain foods and heart health
- Soya protein and cholesterol
- Oats and cholesterol
- Omega-3 fatty acids and heart health

Nutraceuticals

No information on nutraceuticals could be found in UK.

Sweden***

<p><i>Food (generic claims)</i></p> <ul style="list-style-type: none"> • Energy and obesity • Hard fat (saturated and trans fat) and heart disease/atherosclerosis • Dietary fibre (oats) and heart disease/atherosclerosis • Salt and heart disease/atherosclerosis/high blood pressure • Omega-3 fatty acids and heart disease/atherosclerosis • Dietary fibre and constipation • Calcium and/or vitamin D and osteoporosis • Sugar and caries • Iron and iron deficiency • Whole grains and heart disease <p>Product specific claims (PFP) allowed. No list found.</p> <p><i>Nutraceuticals</i></p> <p>Claims on food supplements were prohibited in Sweden.</p>
<p><i>Russia</i></p> <p><i>Nutraceuticals (Biologically Active Food Supplements or BAFS)</i></p> <p><u>Claims not permitted.</u></p>
<p><i>Australia and New Zealand</i></p> <p><i>Food (generic claims)</i></p> <ul style="list-style-type: none"> • Folate and neural tube defects in infants* ** • Sodium and hypertension** • Fruits and vegetables and coronary heart disease** • Saturated fat and/or trans fat and elevated cholesterol and heart disease** • Calcium (with or without vitamin D) and osteoporosis** <p><i>Nutraceuticals</i></p> <p>In Australia, regulated as complementary medicines (claims are product-specific). In New Zealand, regulated as dietary supplements, no pre-market approval required for claims (generic claims).</p>
<p><i>Japan</i></p> <p><u>Food and Nutraceuticals</u></p> <ul style="list-style-type: none"> • <u>Regular/Specific FOSHU (product specific)</u> Calcium and osteoporosis • Folic acid and neural tube defects <p><u>Standardized and Qualified FOSHU (product specific)</u></p> <p>No list of standardized and qualified FOSHU claims and products available. Well over 600 products have FOSHU approval.</p> <p><u>Standardized FOSHU example:</u> claims about maintaining gastrointestinal functioning and health</p>
<p><i>Brazil</i></p> <p><i>Food (generic claims)</i></p> <ul style="list-style-type: none"> • Omega-3 fatty acids and triglycerides (heart health) • Beta-glucan (dietary fibre) and cholesterol • Psyllium (dietary fibre) and fat absorption • Quitosane and fat and cholesterol absorption • Phytosterols and cholesterol • Mannitol, xylitol, or sorbitol and dental caries

<ul style="list-style-type: none"> • Soy protein and cholesterol <p><i>Nutraceuticals</i> Called bioactive substances and subject to product specific regulations and approval.</p>
<p>Republic of Korea <i>Nutraceuticals (product-specific)</i></p> <ul style="list-style-type: none"> • Reduction of dental caries <p>There are specified products (supplements and ginseng) and ingredients on which generic claims can be made</p>
<p>China <i>Food and Nutraceuticals are called health foods (product specific)</i> Approved functions:</p> <ul style="list-style-type: none"> • Weight loss • Cholesterol (blood lipids) reduction • Assists in blood sugar reduction • Assists in blood pressure reduction
<p>Taiwan <i>Food and Nutraceuticals called health foods</i> <i>Health Food Control Act health claims must be proven for health and or disease risk</i></p>
<p>Singapore <i>Food (generic claims)</i> <i>Five nutrient specific health claims can be made</i> <i>Nutraceuticals are known as health supplements (product specific claims)</i></p> <ul style="list-style-type: none"> • Relieves the discomfort associated with cold or flu symptoms • Relief of mild cough • Soothes sore throat • Relieves menopausal discomfort • Assists in maintaining joint mobility
<p>Hong Kong <i>Food and Nutraceuticals</i> <i>Claims not permitted</i></p>
<p>India <i>Food and Nutraceuticals</i> <i>Claims not permitted</i></p>
<p>Thailand <i>Food and Nutraceuticals known as Functional foods</i> <i>Claims not permitted however new regulations are pending</i></p>
<p>Malaysia <i>Food (generic & Nutraceuticals (dietary supplements) (product specific claims)</i> <i>52 nutrient and other functional claims are permitted</i> <i>Disease risk reduction claims are not permitted</i></p>
<p>Philippines <i>Food and Nutraceuticals known as Functional foods (generic)</i></p> <ul style="list-style-type: none"> • calcium to reduction of osteoporosis risk • low fat food reduces the risk of cancer

Sources: Compiled from information in Canada Food Inspection Agency and Health Canada (2009), Canada (2010), Food and Drug Administration (2009a; 2009d), European Union (2009), Food Standards Australia and New Zealand (2010), Livsmedelsföretagen et al. (2004), Joint Health Claims Initiative (n.d.) Ministry of Health, Labour, and Welfare (n.d.), Toledo and Lajolo (2008), Kim et al. (2008), Yang (2008), Liu and Lee (2000), (Zawistowski 2008), EAS Asia (2009), Singapore Health Promotion Board (2002), Singapore Health Sciences Authority (2010), New Zealand Trade and Enterprise (2009), Centre for Food Safety-Government of Hong Kong (2008), FAO (2004), India Food and Safety Standards Act (2006), Sie (2004), Tee (2007a), Thailand Ministry of Public Health (1998) and GAINS (2006).

*Only transitional health claim currently permitted.

**Claims that have met substantiation standards but have not been incorporated into regulations.

***As EU regulations have come into force to harmonize European health claims regulations, health claims not approved by EFSA and the Commission will no longer be allowed to be used in these countries.

Table 2. Structure/function claims in various countries

Canada

Food (generic claims)

Food or Food Constituent

- Coarse wheat bran and regularity
- Green tea and antioxidant effect on blood
- Psyllium and regularity

Nutrients, Vitamins, and Minerals

- Protein and body tissues or antibodies
- Fat and energy or fat-soluble vitamins
- ARA and development of brain, eyes, and nerves
- DHA and development of brain, eyes, and nerves
- Carbohydrates and energy or utilization of fat
- Vitamin A and bones and teeth or night vision or skin and membranes
- Vitamin D and bones and teeth or calcium and phosphorus utilization
- Vitamin E as antioxidant or oxidation of fatty tissues
- Vitamin C as antioxidant or bones and cartilage or teeth and gums
- Thiamine and carbohydrates or normal growth
- Riboflavin and metabolism or tissue formation
- Niacin and growth and development or metabolism or tissue formation
- Vitamin B₆ and metabolism or tissue formation
- Folate and fetal neural development
- Vitamin B₁₂ and red blood cell formation
- Pantothenic acid and metabolism and tissue formation
- Calcium and bones and teeth
- Phosphorus and bones and teeth
- Magnesium and metabolism and tissue formation and bone development
- Iron and red blood cell formation
- Zinc and metabolism and tissue formation
- Iodine and thyroid gland function
- Selenium as antioxidant

Nutraceuticals

Called Natural Health Products (NHPs) and product specific registration. While same claims that are used on food could be used on nutraceuticals, each firm desiring to make a product with the claim must receive approval individually. No list of claims available.

United States

FDA does not evaluate or regulate structure/function claims for food. FDA does have minimal regulation for dietary supplement (nutraceutical) structure/function claims, but does not evaluate the claims.

<p>European Union</p> <p><u>General Structure/Function (Article 13(1)(a)) Claims</u> <i>Food and Food Supplements</i> (nutraceuticals) (generic claims) In EU regulation 1924/2006, no structure/function claims were initially provided for. Member states and other stakeholders have provided the European Food Safety Authority (EFSA) and the EU Commission with thousands of structure/function (“general function” health) claims. A list of acceptable claims was to be created by the deadline of January 31 2010 as per 1924/2006, but has yet to be finalized and approved by the Commission.</p> <p><u>Children’s Growth and Development (Article 14(1)(b)) Claims</u></p> <ul style="list-style-type: none"> • α-linolenic acid (ALA) & linoleic acid (LA) and normal growth/development of children • Calcium and vitamin D and growth and development of bone in children • Phosphorus and growth and development of bone in children • Protein and growth and development of bone in children <p><u>Emerging Scientific Evidence/Request for Proprietary Information (Article 13(5)) Claims</u></p> <ul style="list-style-type: none"> • Water-soluble tomato concentrate and blood flow
<p>United Kingdom*</p> <p>None approved.</p>
<p>Sweden*</p> <p><i>Food</i> (generic claims) Vitamin C/Vitamin E/Beta-carotene are antioxidants Vitamin C and iron absorption Vitamin D and bone development Calcium and bone development Zinc and enzyme systems Iron and blood and hemoglobin production Dietary fibre and normal bowel function Carbohydrates and blood sugar Product specific claims (PFP) allowed. No list found.</p> <p><i>Nutraceuticals</i> Claims on food supplements were prohibited in Sweden.</p>
<p>Russia</p> <p><u><i>Nutraceuticals (Biologically Active Food Supplements or BAFS) (product specific), examples are:</i></u></p> <ul style="list-style-type: none"> • Optimization of carbohydrates, fat, vitamins and other metabolism in various functional conditions. • Normalization and/or improvement of the function state of the human organ/system • Decrease morbidity risk • Improvement of the gastrointestinal tract microflora
<p>Australia and New Zealand**</p> <p><i>Food</i> (generic claims) <u>FSANZ List of Pre-approved General Level Claims (not exhaustive)</u></p> <ul style="list-style-type: none"> • Vitamin D and calcium and phosphorus utilization and absorption • Vitamin E as antioxidant

- Vitamin K for proper coagulation
- Thiamine and normal metabolism of carbohydrates
- Riboflavin and metabolism
- Niacin and metabolism
- Pantothenic acid and metabolism of fat
- Vitamin B₆ and metabolism of protein
- Folate and blood formation
- Vitamin B₁₂ and blood formation
- Biotin and fat metabolism or energy production
- Vitamin C and connective tissue
- Calcium and bones and teeth
- Magnesium and metabolism
- Iron and blood formation
- Copper and immune system
- Iodine and thyroid hormones
- Zinc and wound healing
- Manganese and bone function
- Phosphorus and bones and teeth
- Selenium as antioxidant
- Protein and building and repairing body tissues
- DHA and brain, eyes, and neural development
- Dietary fibre and normal laxation

Nutraceuticals

In Australia, regulated as complementary medicines (claims are product-specific). In New Zealand, regulated as dietary supplements, no pre-market approval required for claims.

Japan

Food and Nutraceuticals (generic claims)

Vitamin Claims

- Niacin and skin or mucous membranes
- Pantothenic acid and skin or mucous membranes
- Biotin and skin or mucous membranes
- Vitamin A and night vision or skin or mucous membranes
- Vitamin B₁ and skin or mucous membranes
- Vitamin B₂ and skin or mucous membranes
- Vitamin B₆ and energy from protein or skin or mucous membranes
- Vitamin B₁₂ and red blood cell formation
- Vitamin C and skin or mucous membranes or antioxidant
- Vitamin D and absorption of calcium or bone growth
- Vitamin E and prevention of fat oxidation or cell health
- Folic acid and red blood cell formation or normal fetus development

Mineral Claims

- Zinc and normal taste or skin or mucous membranes or protein and nucleic acid metabolism

- Calcium and bone and teeth development
- Iron and red blood cell formation
- Copper and red blood cell formation or enzymes function or bone formation
- Magnesium and bone and teeth development or enzymes function or energy generation

Regular/Specific, Standardized, and Qualified FOSHU (product specific)

No list of FOSHU products and effects are available. Well over 600 products possess FOSHU registration.

Brazil

Food (generic claims)

- Lycopene as antioxidant
- Dietary fibres and normal intestine function
- Powdered resistant dextrin (dietary fibre) and normal intestine function
- Partially hydrolyzed guar gum (dietary fibre) and normal intestine function
- Polydextrose (dietary fibre) and normal intestine function
- Fructooligosaccharides and gut flora
- Inulin and gut flora
- Lactulose and normal intestine function
- Probiotics and gut flora

Nutraceuticals

Called bioactive substances and subject to product specific regulations and approval.

Republic of Korea

- Nutraceuticals (generic)

No list of claims available (No pre-market approval of new claims as long as the nutrients have an established recommended daily allowance)

*There are qualified claims (“other function” claims with lower level of evidence) that do not fall into either of the two categories of claims

- Reduction of blood pressure;
- Reduction of cholesterol;
- Reduction of body fat;
- Maintenance of good health;
- Modulation of blood glucose level;
- Modulation of postprandial glucose level;
- Maintaining health gastrointestinal conditions;
- Antioxidant effects;
- Improvement of memory functions;
- Improvement of cognitive functions

China

Food and Nutraceuticals are called health foods (product specific claims)

- Enhances immunity
- Antioxidative
- Assists in memory improvement
- Alleviates eye fatigue
- Facilitates lead excretion

- Moistens and cleans throat
- Improves sleep
- Facilitates milk secretion
- Alleviates physical fatigue
- Enhances anoxia endurance
- Assists in irradiation hazard protection
- Improves child growth and development
- Increases bone density
- Improves nutritional anemia
- Assists in protecting against chemical injury to the liver
- Eliminates acne
- Eliminates skin chloasma
- Improves skin's water content
- Improves skin's oil content
- Regulates gastrointestinal tract flora
- Facilitates digestion
- Facilitates feces excretion
- Assists in protecting against gastric mucosa damage

Taiwan

Food and Nutraceuticals called health foods(product specific claims)

- Regulates blood-lipid
- Improves gastrointestinal functions
- Alleviates osteoporosis
- Maintains dental health
- Regulates immune system
- Regulates blood sugar level
- Protects liver

Singapore

Food (generic claims)

- Protein provides the essential amino acids needed to aid in the building and maintenance of body tissues
- Protein helps in tissue building and growth
- Low lactose content allows easier digestion for people who are lactose intolerant
- Low lactose content eases digestion for people who are lactose intolerant
- Vitamin D3 helps support calcium absorption and improves bone strength
- Enriched with vitamin D3 for calcium absorption
- Calcium helps build strong bones and teeth
- Iron is an important component of red blood cells which carries oxygen to all parts of the body to help the body's production of energy
- Iron is one of the essential minerals vital for life
- Folate helps support fetus growth and overall development
- Folate plays a role in the formation of red blood cells

<ul style="list-style-type: none"> • Folate taken before and during early pregnancy helps in the mental/normal and overall development of fetus <p><u>Nutraceuticals are known as health supplements (generic claims)</u></p> <ul style="list-style-type: none"> • General enhancement/maintenance of healthy functions • Supports healthy function of the human body such as maintaining healthy joints, support natural physiological processes e.g. immune system, circulation and digestion.
<p>Hong Kong</p> <p><u>Food and nutraceuticals (generic)</u></p> <p>No list of claims available.</p>
<p>Malaysia</p> <p><u>Food (generic claims) and nutraceuticals (dietary supplements) (product specific claims)</u></p> <ul style="list-style-type: none"> • Folic acid is essential for growth and division of cells • Iron is a factor in red blood cell formation • Niacin is needed for the release of energy from proteins, fats and carbohydrates • Magnesium promotes calcium absorption and retention • Calcium helps in the development of strong bones and teeth • Protein aids in building and repairing of body tissue • Vitamin C enhances absorption of iron from non-meat sources • Vitamin B12 is needed for red blood cell production • Vitamin B2 is needed for the release of energy from proteins • Vitamin B1 is needed for the release of energy from carbohydrates • Vitamin D helps the body utilize calcium and phosphorus <p><u>Bioactive substances like probiotics and prebiotics</u></p> <ul style="list-style-type: none"> • Inulin helps increase intestinal bifidobacteria and helps maintain good intestinal environment • Oligofructose helps increase intestinal bifidobacteria and helps maintain good intestinal environment • Oat soluble fiber helps lower cholesterol • Plant sterol or plant stanol reduces cholesterol • Soy protein helps to lower cholesterol
<p>India</p> <p><u>Food and Nutraceuticals (generic)</u></p> <p>No list of claims available</p>
<p>Thailand</p> <p><u>Food and Nutraceuticals (generic).</u></p> <p>No complete list of claims available; include:</p> <ul style="list-style-type: none"> • folate is an important component of red cell formation • calcium is an important component of bones and teeth
<p>The Philippines</p> <p><u>Food and Nutraceuticals known as Functional foods (generic)</u></p> <p>No list of claims available</p>

Sources: Compiled from Canada Food Inspection Agency and Health Canada (2009), Food and Drug Administration (2009c), European Union (2009), Livsmedelsföretagen et al. (2004),

Food Standards Australia New Zealand (2008b), Ministry of Health, Labour, and Welfare (n.d.), Toledo and Lajolo (2008), and Yang (2008) Liu and Lee (2000), Zawistowski (2008), EAS Asia (2009), Singapore Health Promotion Board (2002), Singapore Health Sciences Authority (2010), New Zealand Trade and Enterprise (2009), Centre for Food Safety-Government of Hong Kong (2008), FAO (2004), India Food and Safety Standards Act (2006), Sie (2004), Tee (2007a), Thailand Ministry of Public Health (1998) and GAINS (2006).

*As EU regulations come into force to harmonize European health claims regulations, health claims not approved by EFSA and the Commission will no longer be allowed to be used in these countries.

Table 3. Nutrient content claims in Canada.

<u>Energy</u> Free Low Reduced/Light Lower Source More Representation that food is for use in “reduced energy” diet Representation that food is for “special dietary use” vis-à-vis energy value “Diet” food	<u>Protein</u> Low Source Excellent source More	<u>Fat</u> Free/100 percent fat-free Low Reduced Lower (percentage) fat-free No added fat Light Lean Extra lean	<u>Saturated Fat</u> Free Low Reduced Lower
<u>Trans Fat</u> Free Reduced Lower	<u>Polyunsaturated Fat</u> Source of omega-3 Source of omega-6	<u>Cholesterol</u> Free Low Reduced Lower	<u>Sodium/Salt</u> Free Low Reduced Lower No added sodium/salt Lightly salted Representation that food is for use in “sodium-restricted diets” Representation that food is “for special dietary use” with respect to sodium content
<u>Potassium</u> Source Good source Excellent source	<u>Sugars</u> Free Reduced Lower No added sugars	<u>Fibre</u> Source High source Very high source More	<u>Vitamin/Mineral</u> Contains Good source/high Excellent source/very rich/rich Added/fortified Higher

Source: Compiled from Canada Food Inspection Agency and Health Canada (2009).

Note: Not permitted on nutraceuticals. Nutraceuticals, as natural health products, are to have labelling that is distinctly different from food (see text for more information).

Table 4. Nutrient content claims in the United States.

Free	Low	Reduced/Less	Special
Calories	Calories	Calories	<u>Comparative Claims</u>
Fat	Fat	Fat	Light
Saturated fat	Saturated fat	Saturated fat	Reduced or added
Sodium	Sodium	Sodium	More or less
Sugars		Sugars	<u>Nutrients With</u>
			<u>Daily</u>
			<u>Recommended</u>
			<u>Values</u>
			High
			Good source
			Fortified*
			High potency**
			<u>Seafood and Game</u>
			<u>Meat Fat Content</u>
			Lean
			Extra lean
			<u>Other</u>
			Healthy
			Antioxidant claims
			Fibre claims
			Modified

Source: Compiled from Food and Drug Administration (2008).

* For use regarding protein, minerals, vitamins, fibre, and potassium only.

** For use regarding vitamins and minerals only.

Note: A different kind of nutrient content claim is allowed to be made on dietary supplements (percentage of nutrient per capsule) (Food and Drug Administration 2003).

Table 5. Nutrient content claims in the European Union.

<u>Energy</u> Low Reduced Free	<u>Fat</u> Low Free	<u>Saturated Fat</u> Low Free	<u>Sugars</u> Low Free None added
<u>Sodium/Salt</u> Low Very low Free	<u>Fibre</u> Source High	<u>Protein</u> Source High	<u>Vitamins/Minerals</u> Source High
<u>Generic**</u> Contains [name of nutrient] Increased [name of nutrient] Reduced [name of nutrient]	<u>Unsaturated fat*</u> Source of omega-3 fatty acids High in omega-3 fatty acids High monounsaturated fat High polyunsaturated fat High unsaturated fat	<u>Other</u> Light/lite Natural/naturally	

Sources: Compiled from EC Regulation 1924/2006 and European Union (2009).

* Claims added after EC 1924/2006 Annex of Regulation (EC) No. 1924/2006 lastly amended by Regulation (EC) No. 116/2010.

** Only valid for nutrients, not vitamins or minerals.

Note: Food supplements, as they are considered food, can use nutrition content claims. Since vitamins and minerals are the only acceptable food supplements, claims applicable to vitamins and minerals are the only acceptable claims.

Table 6. Nutrient content claims in the United Kingdom.

<u>Energy</u>	<u>Protein</u>	<u>Vitamin</u>	<u>Minerals</u>
<p>Reduced (at most $\frac{3}{4}$ the energy of a similar food)</p> <p>Low (at most 167kJ/100g)</p>	<p>Rich/Excellent Source (at least 20% of energy value provided by protein)</p> <p>All other claims (at least 12% of energy value provided by protein)</p>	<p>Rich/Excellent source (at least $\frac{1}{2}$ daily recommended value)</p> <p>All other claims (at least $\frac{1}{6}$ of daily recommended value)</p> <p>Applicable to:</p> <p>Vitamin A Vitamin D Vitamin E Vitamin C Thiamin Riboflavin Niacin Vitamin B₆ Folacin Vitamin B₁₂ Biotin Pantothenic Acid</p>	<p>Same as Vitamins</p> <p>Applicable to:</p> <p>Calcium Phosphorus Iron Magnesium Zinc Iodine</p>
<p><u>Cholesterol</u></p> <p>All food must have less than 0.005% cholesterol to bear claim</p> <p>If “reduced” claim is made without meeting 0.005% condition, the claim can only be made by meeting certain conditions</p>			

Source: Compiled from United Kingdom (1996).

Note: Dietary supplement regulations not found for United Kingdom, unclear as to whether dietary supplements could have used nutrient content claims.

Table 7. Nutrient content claims in Australia and New Zealand.

<u>Mono- and poly-unsaturated fatty acids</u> Increased	<u>Omega fatty acids</u>	<u>Low joule (energy)</u> Low Reduced or Light/Lite Diet	<u>Lactose</u> Low Free
<u>Sodium/salt</u> Low salt/sodium Reduced or Light/Lite No Added Unsalted	<u>Gluten</u> Free Low	<u>Omega-3</u> Good source Increased	<u>Omega-6</u> <u>Omega-9</u> Increased
<u>Carbohydrate</u> Reduced or Light/Lite Increased	<u>Cholesterol</u> Low Reduced or Light/Lite	<u>Dietary Fibre</u> Good source Excellent source Increased	<u>Fat</u> % Free Low Reduced or Light/Lite
<u>Glycaemic Index</u> Low Medium High	<u>Glycaemic Load</u>	<u>Potassium</u>	<u>Protein</u> Good source Increased
<u>Saturated & Trans Fatty Acids</u> Low Reduced or Light/Lite Low proportion	<u>Saturated fatty acids</u> Free Low Reduced or Light/Lite Low Proportion	<u>Sugar or sugars</u> % Free Low Reduced or Light/Lite No Added Unsweetened	<u>Trans Fatty Acids</u> Free Reduced or Light/Lite
<u>Vitamin or Mineral</u> Good source			

Source: Adapted from Standard 1.2.7.

Note: Nutraceuticals are regulated separately in Australia and New Zealand from joint regulation on food. As such, nutrient content claims as currently developed are only applicable to food.

Table 8. Nutrient content claims in Japan.

<u>"High" Claims</u>	<u>"Contains" Claims</u>
Protein (15g/100g solid food, or 7.5g/100ml liquid food, and 7.5/100kcal)	Protein (7.5g/100g solid food, or 7.5g/100ml liquid food, and 7.5/100kcal)
Dietary fibre (6g/100g, or 3g/100ml, and 3g/100kcal)	Dietary fibre (3g/100g, or 1.5g/100ml, and 1.5g/100kcal)
Zinc (2.10mg/100g, or 1.05mg/ml, and 0.70mg/100kcal)	Zinc (1.05mg/100g, or 0.53mg/100ml, and 0.35mg/100kcal)
Calcium (210mg/100g, or 105mg/ml, and 70mg/100kcal)	Calcium (105mg/100g, or 53mg/100ml, and 35mg/100kcal)
Iron (2.25mg/100g, or 1.13mg/100ml, and 0.75mg/100kcal)	Iron (1.13mg/100g, or 0.56/100ml, and 0.38/100kcal)
Copper (0.18mg/100g, or 0.09mg/100ml, and 0.06mg/100kcal)	Copper (0.09mg/100g, or 0.05mg/100ml, and 0.03mg/100kcal)
Magnesium (75mg/100g, or 38mg/100ml, and 25mg/100kcal)	Magnesium (38mg/100mg, or 19mg/100ml, and 13mg/100kcal)
Niacin (3.3mg/100g, or 1.7mg/100ml, and 1.1mg/100kcal)	Niacin (1.7mg/100g, or 0.8mg/100ml, and 0.6mg/100kcal)
Pantothenic acid (1.65mg/100g, or 0.83mg/100ml, and 0.55mg/100kcal)	Pantothenic acid (0.83mg/100g, or 0.41mg/100ml, and 0.28mg/100kcal))
Biotin (14micrograms/100g, or 6.8micrograms/100ml, and 4.5micrograms/100kcal)	Biotin (6.8micrograms/100g, or 3.4micrograms/100ml, and 2.3micrograms/100kcal)
Vitamin A (135micrograms/100g, or 68micrograms/100ml, and 45micrograms/100kcal)	Vitamin A (68micrograms/100g, or 34micrograms/100ml, and 23micrograms/100kcal)
Vitamin B ₁ (0.30mg/100g, or 0.15mg/100ml, and 0.10mg/100kcal)	Vitamin B ₁ (0.15mg/100g, or 0.08mg/100ml, and 0.05mg/100kcal)
Vitamin B ₂ (0.33mg/100g, or 0.17mg/100ml, and 0.11mg/100kcal)	Vitamin B ₂ (0.17mg/100g, or 0.08mg/100ml, and 0.06mg/100kcal)
Vitamin B ₆ (0.30mg/100g, or 0.15mg/100ml, and 0.10mg/100kcal)	Vitamin B ₆ (0.15mg/100g, or 0.08mg/100ml, and 0.05mg/100kcal)
Vitamin B ₁₂ (0.60micrograms/100g, or 0.30micrograms/100ml, and 0.20micrograms/100kcal)	Vitamin B ₁₂ (0.30micrograms/100g, or 0.15micrograms/100ml, and 0.10micrograms/100kcal)
Vitamin C (24mg/100g, or 12mg/100ml, and 8mg/100kcal)	Vitamin C (12mg/100g, or 6mg/100ml, and 4mg/100kcal)
Vitamin D (1.50micrograms/100g, or 0.75micrograms/100ml, and 0.50micrograms/100kcal)	Vitamin D (0.75micrograms/100g, or 0.38micrograms/100ml, and 0.25micrograms/100ml)
Vitamin E (2.4/100g, or 1.2mg/100ml, and 0.8)	Vitamin E (1.2/100mg, or 0.6mg/100ml, and 0.4mg/100kcal)
Folic acid (60micrograms/100g, or 30micrograms/100ml, and 20micrograms/100kcal)	Folic acid (30micrograms/100g, or 15micrograms/100ml, and 20micrograms/100kcal)

“Not Contained” Claims	“Low” Claims
Calories (5kcal/100g of solid food, or 5kcal/100ml of liquid food) Fat (0.5g/100g, or 0.5g/100ml) Saturated fat (0.1g/100g, or 0.1g/100ml) Cholesterol (5mg/100ml, or 5g/100ml, with 1.5g/100g saturated fat, or 0.75g/100ml saturated fat, and the energy from saturated fat must be 10% of total energy or less)* Sugars (0.5g/100g, or 0.5g/100ml) Sodium (5mg/100g, or 5mg/100ml)	Calories (40kcal/100g of solid food, or 40kcal/100ml of liquid food) Fat (3g/100g, or 1.5g/100ml) Saturated fat (1.5g/100g, or 0.75g/100ml, and energy from saturated fat must be at most 10% of total energy) Cholesterol (20mg/100g, or 10mg/100ml, with 1.5g/100g saturated fat, or 0.75g/100ml saturated fat, and the energy from saturated fat must be 10% of total energy or less)* Sugars (5g/100g, or 2.5g/100ml) Sodium (120mg/100g, or 120mg/100ml)

Source: Ministry of Health, Labour, and Welfare (n.d.).

Note: Unclear from sources whether nutrient content claims can be used on nutraceuticals. Given the fact that there is no regulatory or legal difference between nutraceuticals and food in the Japanese system (see text), it is probable that nutrient content claims can be used on nutraceuticals in addition to food.

*Must not have serving size of 15g or less. Saturated fat content cannot exceed 15% of the fat content.

Table 9. Nutrient content claims in Brazil.

<p><u>Energy</u> Low (40kcal/100g for solid food or 20kcal/100ml for liquid food maximum) Free (4kcal/100g or 4kcal/100ml)</p>	<p><u>Fat</u> Low (3g/100g or 1.5g/100ml maximum) Free (0.5g/100g or 0.5g/100ml)</p>	<p><u>Saturated Fat</u> Low (1.5g/100g or 0.75g/100ml and 10% total energy from saturated fat maximum) Free (0.1g/100g or 0.1g/100ml maximum)</p>	<p><u>Trans Fat</u> Free (0.2g/portion trans fat and 2g/portion saturated fat maximum)</p>
<p><u>Cholesterol</u> Low (20mg/100g and 1.5g/100g saturated fat and 10% energy derived from saturated fat maximum for solid food or 10mg/100ml and 0.75g/100ml and 10% energy derived from saturated fat maximum for liquid food) Free (5mg/100g and 0.75g/100g saturated fat and 10% energy from saturated fat maximum, 5mg/100ml 0.75g/100ml and 10% maximum)</p>	<p><u>Sugars</u> Low (5g/100g maximum for solid food and meets criteria for low in energy or reduced in energy or 5g/100ml and same conditions for liquid food) Free (0.5g/100g and low energy or reduced energy or 0.5g/100mlg and same conditions)</p>	<p><u>Sodium</u> Low (120mg/100g solid food or 120mg/100ml liquid food maximum) Very low (40mg/100g or 40mg/100ml) Free (5mg/100g or 5mg/100ml)</p>	<p><u>Protein</u> Source (10%RDI/100g for solid food or 5%RDI/100ml liquid food) Rich (20%RDI/100g or 10%RDI/100ml)</p>
<p><u>Vitamins and Minerals</u> Source (15%RDI/100g solid food or 7.5%RDI/100ml liquid food) Rich (30%RDI/100g or 7.5%RDI/100ml)</p>			

Source: Adapted from Hong Kong (2008).

Note: Unclear from sources whether or not nutrient content claims can be used on nutraceuticals in Brazil. However, given Brazil's stricter regulatory regime for nutraceuticals than for food, it is unlikely that Brazil permits nutrient content claims on nutraceuticals.

Appendix 2: International Regulatory System – Codex Alimentarius

Codex Alimentarius is a set of international standards, guidelines and related texts for food products. It was developed by the Codex Alimentarius Commission. The Commission is a joint commission set by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). The two main objectives of the Codex are to ensure the protection of consumer health and to facilitate international food trade. The Codex standards are not binding on member states but they are referenced in all World Trade Organization (WTO) disputes. Codex Alimentarius develop food standards, regulatory guidelines and other codes of practice²². The specific areas of regulations covered by the Codex include nutrition labelling, nutrition claims and health claims.

Health Claims

Codex defines health claim as “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” (FAO 2007, page 13). There are three different types of health claims. **Nutrient function claim**, this claim describes the physiological role of the nutrient in growth, development and normal function of the human body. **Enhanced function claim** refers to specific beneficial effects of the consumption of food and their constituents in the context of the total diet. **Disease Risk Reduction Claim** relates the consumption of a food or its constituents to the reduced risk of developing a disease or a health-related condition. The risk reduction claim should be presented in a way that will not make consumers presume them to be preventive claims. (FAO 2007)

²² http://www.codexalimentarius.net/web/index_en.jsp

Codex has some criteria for the substantiation of the health claims that apply to all types of health claims²³:

- i. Health claims should be based on evidence provided by human studies. These studies should not be only observational but also based on animal model studies that substantiate the relationship between the food and the health effect.
- ii. The totality of the evidence should be identified and reviewed. This must include unpublished data if applicable, evidence supporting the claim, evidence contradicting the claim and any unclear evidence.
- iii. Human- based evidence should demonstrate a consistent relation between the food and the claimed effect with little or no evidence to the contrary.
- iv. Nutrient function claims may be substantiated based on generally accepted authoritative statements by expert scientific bodies that have been verified over time.
- v. Observational evidence such as epidemiological studies can also be used to substantiate some health claims such as those that involve a food category and a health effect.

Nutrition Claims (Codex Alimentarius)

The guidelines for the use of nutrition claims proposed by Codex defines nutrition claim as “any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and the content of protein, fat and carbohydrate, as well as the content of vitamins and minerals”²⁴. The nutrition claims are divided into two categories. **Nutrient content claim** describes the level of a nutrient

²³ Nutrition and Health Claims CAC/GL 23-1997, p.3

²⁴ Nutrition and Health Claims CAC/GL 23-1997, p.1

contained in a food. **Nutrient comparative claim** is a claim that compares the nutrient levels and/or energy value of two or more foods.

Nutrient content claims (Codex Alimentarius)²⁵

- If a food by its nature is low in or free of the nutrient that is the subject of the claim, the term describing the level of the nutrient should not immediately precede the name of the food but should be in the form of “a low (nutrient name) food” or “a (nutrient name)-free food”.

Nutrient comparative claim (Codex Alimentarius)²⁶

- The foods being compared should be different versions of the same or similar foods. The foods should also be clearly identified.
- The amount of difference in the nutrient content should be stated and must appear in proximity to the comparative claim.
- Full details of the comparison should be given. They must be stated in the same quantity or unit of measurement.
- The comparison should be based on a relative difference of at least 25% in the nutrient content except for micronutrients where a 10% difference would be accepted.
- The use of the word “light” should follow the same criteria as for “reduced” and include an indication of what make the food “light”.

Nutrition Labeling (Codex Alimentarius 2010)

Codex Alimentarius provide guidelines on food labelling which is purported to provide consumers with information about a food facilitate informed consumption decisions. Food labelling according to Codex is a means of conveying information of the nutrient

²⁵ Nutrition and Health Claims CAC/GL 23-1997, p.2

²⁶ Nutrition and Health Claims CAC/GL 23-1997, p.2, 3

content of a food on the label. To ensure that nutrition labelling does not describe a product or present information which is misleading, deceptive or insignificant in any manner, the Codex prescribes principles about nutrient declaration, supplementary nutrition information and nutrition labelling (FAO 2007). These are reproduced below.

PRINCIPLES FOR NUTRITION LABELLING (Codex Alimentarius 1993, Page 30)

- ***Nutrient Declaration***

“Information supplied should be for the purpose of providing consumers with a suitable profile of nutrients contained in the food and considered to be of nutritional importance. The information should not lead consumers to believe that there is exact quantitative knowledge of what individuals should eat in order to maintain health, but rather to convey an understanding of the quantity of nutrients contained in the product. A more exact quantitative delineation for individuals is not valid because there is no meaningful way in which knowledge about individual requirements can be used in labelling.”

- ***Nutrition Labelling***

“Nutrition labelling should not deliberately imply that a food which carries such labelling has necessarily any nutritional advantage over a food which is not so labelled.”

- ***Supplementary Nutrition Information***

“The content of supplementary nutrition information will vary from one country to another and within any country from one target population group to another according to the educational policy of the country and the needs of the target groups.”

Currently, most countries are trying to synchronize their food regulations to be in accordance with the Codex standards. Though its application is voluntary, many Asian

countries in the Pacific Rim are trying to align their regulations for functional food and natural health products to the codex guidelines. Thailand, The Philippines, Malaysia, China, Korea are examples of countries who have adopted the Codex guidelines. Canada has not adopted the Codex guidelines. However, the government has set up various inter-departmental Codex committees with the responsibility of enhancing Canada's influence on Codex deliberations and decisions. The United States also participates fully in all Codex activities. Most of US regulations follow the guidelines of Codex. Countries without a legal definition for these products also use the Codex definition.

Appendix 3: Canadian and U.S. Labelling Exemptions

List of Exemptions for Canadian Nutrition Facts Table Labelling (Canadian Food Inspection Agency and Health Canada 2009):

- For spices and some bottled waters, when much nutritional information is by values of “0”;
- Beverages with an alcohol content of more than 0.5%;
- Fresh fruits and vegetables with no added ingredients (also fresh herbs);
- Raw, single ingredient meat and meat by-products (not ground meat);
- Raw single ingredient marine or freshwater animal products;
- Food is sold only by a retail establishment that prepares the food on-site;
- Food sold at a fair, farmers’ market, etc. by an individual who made the good;
- Individual servings of foods that are sold for immediate consumption (and have not been specially processed/packaged to prolong their shelf life);
- If the product has an available display surface of less than 200cm² and is sold at the same retail establishment as it is packaged;
- One-bite confections (never loses exemption);
- Prepackaged individual portions of food served by a restaurant with other food (e.g. creamers, crackers) (never loses exemption);
- Different kinds of goat and cow milk products vended in refillable containers (never loses exemption).

List of Exemptions for US Nutrition Facts Labels (Food and Drug Administration 2008):

- Food is manufactured by a small business;
- Food served in restaurants or delivered for immediate consumption;
- Delicatessen or bakery type foods prepared and sold at the same location;
- Foods with no significant nutrition (e.g. instant coffee, spices);
- Infant formula and food intended for consumption by children up to the ages of four (other labeling requirements for these foods);
- Dietary supplements;
- Medical foods;
- Bulk foods shipped for further processing or packaging before retail sale;
- Fresh produce and seafood;
- Custom processed fish or game meat (voluntary labeling on shelves in store);
- Certain egg cartons;
- Individual packages labelled “This unit not intended for retail sale” that make up a larger package that has a nutrition label;
- Self service bulk foods (voluntary labeling on shelves in store);
- Donated food given free to consumer.

Appendix 4: Health Check Program in Canada

Health Check is a not-for-profit program that is designed to evaluate food products in grocery stores and restaurant menus (Heart & Stroke Foundation, 2010). The Health Check logo is placed on all products that, having applied for the logo, meet the specified criteria and pay an annual fee. The program is built on the premise that diet and health are related. The Heart and Stroke Foundation, which is responsible for the Health Check program, maintains that a healthy and well-balanced diet can help achieve overall health. Under the program, food companies and restaurants voluntarily submit products or menu items to be evaluated by dietitians registered and endorsed by the foundation. The nutrient criteria used for evaluation are based on the recommendations of Canada's Food Guide to Healthy Eating. Currently, there are over 2000 Health Check products in grocery stores and they represent about 200 brands in almost 75 food categories. There are also over 700 restaurants with Health Check menus across the country.

Companies involved in the program earn the right to display the logo on their products by meeting the program's nutrient criteria and paying an annual fee. Depending on the food category, the participating products are evaluated on the basis of total fat, saturated fat, trans fat, fibre, sodium, calcium, sugar, vitamins, and minerals. Examples of the products evaluated and approved by the foundation include: Bunge Canada's Capri brand of 100% Pure Canola Oil (3L & 956mL); Parmalat's Beatrice Brand of 2% M. F. Omega 3 Milk Beverage 2L; and Unilever Canada's Becel brand of Buttery Taste Margarine 1.5lb.²⁷

²⁷ For complete list of all Health Check products see:
http://www.healthcheck.org/prodsearch?tid_2=All&tid=All&keys

The criteria to earn the Health Check logo are based on the Canadian food guide. The nutrient standards according to the Foundation will keep evolving with time as they are reviewed regularly. The foods are grouped into six different categories and the nutrients limits are defined. The categories (with a sample of some of the products and their nutrient criteria) are (Heart and Stroke Foundation 2010): **Grain Products** (e.g. bread - Fat: 3 g or less OR saturated fat: 2 g or less saturated and trans fat combined + 15% or less energy from the sum of saturated and trans fat; fibre: 2 g or more; Sodium: 360 mg or less and trans fat: 5% or less of total fat). **Vegetables & Fruit** (e.g. fruit Juices - 100% fruit juice (no added sugar)). **Milk & Alternatives** (e.g. yogurts - lower fat (2% M.F. or less); calcium: at least 15% of the Daily Value and sodium: 140 mg or less). **Meat & Alternatives** (e.g. sausages - lean: 10% or less fat; sodium: 360 mg or less and trans fat: 5% or less of total fat if the fat does not originate exclusively from ruminant meat). **Oils and Fats** (e.g. margarines – non-hydrogenated; sodium: 140 mg or less and trans fat: 2% or less of total fat). **Combination Foods** (e.g. soups - fat: 3 g or less; sodium: 480 mg or less; fibre: 2 g or more OR at least 5% of the Daily Value for vitamin A or vitamin C or iron or calcium or folate and trans fat: 5% or less of total fat).

The Health Check program has the potential to influence consumer choices. However, whether the checked products mean that they are the healthiest choice is an area that needs further research. The table below summarizes the Health Check criteria for selected products.

Selected Products and their Criteria (Heart and Stroke Foundation 2010)

GRAIN PRODUCTS

FOOD CATEGORY	CRITERIA FOR NEW SUBMITTED PRODUCTS	CRITERIA FOR PRODUCTS ALREADY IN THE PROGRAM *
Flour / Grains Products must fit the criteria per 30 g serving and per on-pack serving	- Fibre: 2 g or more - Sodium: 240 mg or less	- Fibre: 2 g or more - Sodium: 480 mg or less per 50g * All existing Health Check products must meet the new sodium criteria by November 1, 2010
Plain Popcorn Products must fit the criteria per 50 g serving and per on-pack serving	- No added salt	- No added salt
Breakfast Cereals (20 g to 42 g per 250 mL) Products must fit the criteria per 30 g serving and per on-pack serving	- Fat: 3 g or less OR No added fat - Fibre: 4 g or more - Sodium: 240 mg or less - Sugar 11 g or less (excluding sugars from pieces of fruit) except if 6 g or more fibre - Trans fat: 5% or less of total fat	- Fat: 3 g or less OR No added fat - Fibre: 4 g or more - Sodium: 480 mg or less - Sugar 11 g or less (excluding sugars from pieces of fruit) except if 6 g or more fibre - Trans fat: 5% or less of total fat * All existing Health Check products must meet the new sodium criteria by November 1, 2010.
Rice (except Instant Rice) / Grains (plain) Products must fit the criteria and per on-pack serving	- Sodium: 140 mg or less	- Sodium: 480 mg or less * All existing Health Check products must meet the new Sodium criteria by November 1, 2010.

VEGETABLES & FRUIT

<p>Fruit Juices Products must fit the criteria per 250 mL serving and per on-pack serving <i>*For single serving products: Only products with an individual format size of 360 mL or less are eligible.</i></p>	<p>- 100% fruit juice (no added sugar)</p>	<p>- 100% fruit juice (no added sugar)</p>
<p>Canned Vegetables (plain) Products must fit the criteria per 125 mL serving and per on-pack serving</p>	<p>- Sodium: 360 mg or less</p>	<p>- Sodium: 480 mg or less * All existing Health Check products must meet the new sodium criteria by November 1, 2010.</p>
<p>Tomato Paste Products must fit the criteria per 30 mL serving and per on-pack serving</p>	<p>- No added salt</p>	<p>- No added salt</p>
<p>Vegetables Juices and Blends products must fit the criteria per 250 mL serving and per on-pack serving</p>	<p>- Vitamin A and/or Folate: at least 15% of the daily value - Sodium: 480 mg or less</p>	<p>- Vitamin A and/or Folate: at least 15% of the daily value - Sodium: 650 mg or less * All existing Health Check products must meet the new sodium criteria by November 1, 2010.</p>

MILK & ALTERNATIVES

<p>Milk and Milk Based Drinks Products must fit the Criteria per 250 mL serving and per on-pack serving</p>	<p>- Lower fat (2% M.F. or less) - Calcium: At least 25% of the Daily Value - Sodium: 240 mg or less</p>	<p>- Lower fat (2% M.F. or less) - Calcium: At least 25% of the Daily Value - Sodium: 480 mg or less * All existing Health Check products must meet the new sodium criteria by November 1, 2010.</p>
<p>Cheese Products must fit the criteria per 30 g Serving and per on-pack serving</p>	<p>- Lower fat (20% M.F. or less) - Calcium: At least 15% of the Daily Value - Sodium: 240 mg or less</p>	<p>- Lower fat (20% M.F. or less) - Calcium: At least 15% of the Daily Value - Sodium: 480 mg or less per 50 g * All existing Health Check</p>

		products must meet the new sodium criteria by November 1, 2010.
Plant-based Beverages (e.g. soy beverages) Products must fit the criteria per 250 mL serving and per on-pack serving	- Fortified / Enriched - Fat: 3 g or less OR Saturated fat: 2 g or less saturated and trans fat combined + 15% or less energy from the sum of saturated and trans fat - Sodium: 240 mg or less	- Fortified / Enriched - Fat: 3 g or less OR Saturated fat: 2 g or less saturated and trans fat combined + 15% or less energy from the sum of saturated and trans fat - Sodium: 480 mg or less * All existing Health Check products must meet the new sodium criteria by November 1, 2010.

MEAT & ALTERNATIVES

Meats / Poultry (plain, seasoned, coated) Products must fit the criteria per 125 g (raw) or 100 g (cooked) serving and per on-pack serving	- Lean: 10% or less fat - Sodium: No salt or sodium ingredient added for plain meat. 360 mg or less for seasoned meats - Trans fat: 5% or less of total fat if the fat does not originate exclusively from ruminant meat	- Lean: 10% or less fat - Sodium: 480 mg or less - Trans fat: 5% or less of total fat if the fat does not originate exclusively from ruminant meat * All existing Health Check products must meet the new sodium criteria by November 1, 2010.
Ground Meats (plain, seasoned) Products must fit the criteria per 100 g (raw), 60 g (cooked) serving and per on-pack serving	- Lean: 17% or less fat - Sodium: No salt or sodium ingredient added for plain meat. 360 mg or less for seasoned meats - Trans fat: 5% or less of total fat if the fat does not originate exclusively from ruminant meat	- Lean: 17% or less fat - Sodium: 480 mg or less - Trans fat: 5% or less of total fat if the fat does not originate exclusively from ruminant meat * All existing Health Check products must meet the new sodium criteria by November 1, 2010.
Fish and Seafood (seasoned or coated) Products must fit the criteria per 125 g (raw), 100 g (cooked) serving and per on-pack serving	- Extra lean: 7.5% or less fat or No added fat - Sodium: 360 mg or less - Trans fat: 5% or less of total fat	- Extra lean: 7.5% or less fat or No added fat - Sodium: 480 mg or less - Trans fat: 5% or less of total fat * All existing Health Check products must meet the new sodium criteria by November 1, 2010.

OILS AND FATS

<p>Oils</p> <p>Products must fit the criteria per 10 mL serving and per on-pack serving</p>	<ul style="list-style-type: none"> - Saturated fat: 2 g or less saturated and trans fat combined + 15% or less energy from the sum of saturated and trans fat - Sodium: 140 mg or less - Trans fat: 2% or less of total fat 	<ul style="list-style-type: none"> - Saturated fat: 2 g or less saturated and trans fat combined + 15% or less energy from the sum of saturated and trans fat - Sodium: 480 mg or less per 50 g - Trans fat: 2% or less of total fat * All existing Health Check products must meet the new sodium criteria by November 1, 2010.
<p>Light Margarines</p> <p>Products must fit the criteria per 10 g serving and per on-pack serving</p>	<ul style="list-style-type: none"> - Non hydrogenated - Reduced fat (50% less fat than regular margarine) - Sodium: 140 mg or less - Trans fat: 2% or less of total fat 	<ul style="list-style-type: none"> - Non hydrogenated - Reduced fat (50% less fat than regular margarine) - Sodium: 480 mg or less per 50 g - Trans fat: 2% or less of total fat * All existing Health Check products must meet the new sodium criteria by November 1, 2010.
<p>Salad dressings</p> <p>Products must fit the criteria per 15 mL serving Serving on the label should be 15 mL except if total fat is less than 30% (10 g per 30 mL)</p>	<ul style="list-style-type: none"> - Saturated fat: 2 g or less saturated and trans fat combined + 15% or less energy from the sum of saturated and trans fat - Sodium: 140 mg or less - Trans fat: 5% or less of total fat 	<ul style="list-style-type: none"> - Saturated fat: 2 g or less saturated and trans fat combined + 15% or less energy from the sum of saturated and trans fat - Sodium: 480 mg or less per 50 g - Trans fat: 5% or less of total fat * All existing Health Check products must meet the new sodium criteria by November 1, 2010.

COMBINATION FOODS

<p>Pizza</p> <p>Products must fit the criteria per 140 g serving and per on-pack serving</p>	<p>Same as criteria for products already in the program</p>	<ul style="list-style-type: none"> - Fat: 10 g or less - Protein: 10 g or more - Sodium: 480 mg or less - Trans fat: 5% or less of total fat
<p>Potato and Pasta Salads</p> <p>Products must fit the criteria per 140 g serving and per on-pack serving</p>	<ul style="list-style-type: none"> - Saturated fat: 2 g or less saturated and trans fat combined + 15% or less energy from the sum of saturated and trans fat - Fat: 7.4 g or less - Sodium: 240 mg or less - Trans fat: 5% or less of total fat 	<ul style="list-style-type: none"> - Saturated fat: 2 g or less saturated and trans fat combined + 15% or less energy from the sum of saturated and trans fat - Fat: 7.4 g or less - Sodium: 480 mg or less - Trans fat: 5% or less of total fat <p>* All Health Check products must be reformulated by November 2010 for the new sodium criteria.</p>

For complete list of all health checked products see:

http://www.healthcheck.org/sites/default/files/editor/Nutrient%20Criteria_Retail_December2009_0.pdf

Appendix 5: Medical Foods and Food for Special Dietary Use in the US

There are four categories of food products recognized as having health benefits in the United States. They are **functional foods**, **dietary supplements**, **medical foods** and **food for special dietary use**. **Functional foods** are food products that move beyond necessity to provide additional health benefits that may reduce disease risk and/or promote optimal health. **Dietary supplements** are products that supplement diet and contain ingredients like vitamins, minerals, amino acid, etc. Dietary supplements cannot be presented in a conventional food form.

Medical foods are defined as a food which is manufactured to be consumed or administered under the supervision of a physician and is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation (Orphan Drug Act 1988).

Medical foods do not have to undergo premarket review or approval by FDA and individual medical food products are not permitted to make health claims and as such, do not have to be registered with the FDA. According to the FDA, ingredients used in medical foods must be approved food additives or a food additive that is the subject of an exemption for investigational use. Medical foods are exempted from the labelling requirements for health claims and nutrient content claims under the Nutrition Labeling and Education Act of 1990. They can be sold in food stores and pharmacies. However, they must follow the same labelling regulations as conventional food with exemptions such as.²⁸

²⁸ FDA 2010, 21 CFR 101.9(j) (8)

- “If it is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube;
- If it is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone;
- If it provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation;
- If it is intended to be used under medical supervision;
- If it is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.”

Foods For Special Dietary Use are defined as “a particular use for which a food purports or is represented to be used, including but not limited to the following: **1.** Supplying a special dietary need that exists by reason of a physical, physiological, pathological, or other condition . . . ; **2.** Supplying a vitamin, mineral, or other ingredient for use by humans to supplement the diet by increasing the total dietary intake. **3.** Supplying a special dietary need by reason of being a food for use as the sole item of the diet . . .”²⁹ Examples of such foods include infant foods, hypoallergenic foods such as gluten-free foods and lactose-free foods, and foods offered for reducing weight.

Food for special dietary use must also comply with the nutrient and health claims that are approved for conventional foods with health benefits (functional foods) or with those that are approved for specific products like diet and hypoallergenic foods (Kurpiewski 2008). Just like medical foods, food for special dietary use do not undergo FDA approval before they are

²⁹ Federal Food, Drug, and Cosmetic Act [Section 411(c)(3)]

marketed, with the exception of infant formula which falls under the category of food for special dietary use but must be pre-approved by the FDA. However, infant formulas are not required to be used under physician supervision. The infant formula ingredients must also be approved food additives or be Generally Recognized as Safe (GRAS) by the Food and Drug Administration.

Appendix 6: U.S. Food Safety Modernization Act – 2011

The \$1.4 billion bill which passed the U.S. Senate on December 22 2010 and was signed into law on January 4 2011 is aimed at enhancing the safety of food produced in the U.S. and imported from overseas, and to prevent food-borne illness.³⁰ Specifically, the Act is intended to improve the capacity of the Food and Drug Administration (FDA) to prevent food safety problems; improve the capacity to detect and respond to safety problems; and improve the safety of imported food (Food and Drug Administration 2011a). The Act expands the reach and regulatory powers of the FDA. Thus with the exception of meat, poultry and dairy, which technically falls under the jurisdiction of the U.S. Department of Agriculture, the FDA oversees the production of all food products (Huffington Post 2010).

The Food Safety Modernization Act 2011 is expected to bring major changes to food production and consumption in the U.S. A summary of key changes includes:

- “Food Recall Power – This provision empowers the FDA to directly issue a recall instead of the previous voluntary recall by companies.
- Fees for Re-inspection – This provision subjects companies that require recall or re-inspection to a fee designated by the FDA
- Update Performance Standards – The FDA is required to identify the most significant food threats every two years at minimum.
- Establish Foreign Offices – The FDA must establish offices in at least five foreign countries that export food to the United States to improve food oversight.
- Access to Records – FDA access to food production facility records will be expanded to aid in tracking purposes.

³⁰ This Act affects all food in the U.S. and as such also applies to functional food and beverages.

- Power to Suspend – If a possible health risk is suspected, the law gives the FDA the power to suspend a food production facility.
- Risk/Hazard Prevention – The law requires food production facilities to alert the FDA in writing of all identified hazardous practices currently in place and plans to implement preventive measures.
- Produce Safety Standards – The FDA is empowered to set nationwide standards for producing and harvesting fresh produce.
- Regulations on Food Unfit to Eat – The FDA, in conjunction with the Department of Homeland Security and Department of Agriculture, will issue regulations that prevent food companies from knowingly including illegal additives in their food products.
- Food Allergy Management – Development of food allergy management guidelines which can be voluntarily implemented.
- Response and Recovery – Preparation of specific response and recovery outline for food-borne illness outbreak. It will be the responsibility of grocery stores to alert customers of latest product recalls.
- Inspection Frequency – The FDA must increase the frequency of its inspection and report to congress annually.
- Tracking Produce – Creation of a method by the FDA to ensure effective tracking and tracing fruits and vegetables in case of any contamination.
- Imported Food Certification – the FDA may require certification or other forms of assurance for high risk food imports. It may refuse food imports that lack the required certification.

- Foreign Regulatory Power – The FDA will have the authority to review the current food safety practices of countries exporting products into the US.
- Funds for Staff Expansion – Additional funding for the FDA to manage its expanded responsibilities.
- Whistleblower protection – Protection for food production company employees who provide information regarding potential violations to the FDA.
- Foreign Inspection Increase – Increase in the FDA inspections of foreign food facilities” (Huffington Post 2010).

This new Act ushers in a more stringent set of regulation for the food industry in the US which will also affect the functional food and natural health products, as well as food products exported to the U.S. To oversee implementation of the Act, the FDA established an implementation management structure consisting of six different teams: “prevention standards; inspection and compliance; imports; federal/state integration; fees; and reports and studies” (Food and Drug Administration 2011b). Though the Act is a step to protect consumers, it may create barriers to investment. Specifically, the Act “is going to prompt the private sector to invest more in food safety research” (Stokstad 2011) which requires large capital expenditures. According to the FDA, the biggest challenge facing the new law will be the access to funds (Stokstad 2011; Olson 2011). However, it has also been argued that “The costs of not protecting our food supply are far greater than the costs of protecting it,” (Olson 2011). Accessibility of the US market will likely be affected. Thus US consumers may not have the luxury of enjoying all kinds of food products, and countries that consider the US as their major export destination (like Canada) may face some challenges (Nakuja et al, 2011). On the other hand, it is possible that this Act will stimulate innovations and investments in

enhancing food safety. Nevertheless, Canadian firms planning to export new functional food products to the U.S. market will need to take into consideration any additional requirements for imported food imposed by the 2011 Food Safety Modernization Act.