

CAIRN Policy Brief

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FUNCTIONAL FOODS AND NATURAL HEALTH PRODUCTS REGULATIONS IN CANADA AND AROUND THE WORLD: A SUMMARY

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The scientific evidence and awareness of the correlation between diet and health, increasingly sedentary lifestyles, aging populations, and ever increasing health care costs in Canada and other countries with publicly funded health care systems have driven the interest in healthier food products. Recent innovations in the agricultural and food sector have produced functional foods and natural health products 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. 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.

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. Enhancing the information to consumers is an important policy response to improving health. Currently, there are many and varied health claims permitted on food products around the globe. Furthermore, there are numerous 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.

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In this project, we summarize the functional foods and natural health product regulations and policy environments in Canada and a number of countries, specifically: 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 and policies with respect to health claims, as well as challenges facing the industry, are explored. We examine disease risk reduction claims, structure/function 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 and make policy recommendations for enhancements to the Canadian regulatory environment. Successful policies from other countries bear consideration in the Canadian context and could help stimulate innovation in the sector. This policy brief summarizes the key points from the full report which is available from the Canadian Agricultural Innovation and Regulation Network (<http://www.ag-innovation.usask.ca/>)⁴.

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)⁵. Health claims can be divided into generic and product-specific claims (Subirade, 2007)⁶. **Generic claims** specify a relationship between a food constituent and a health effect and they can be used on any food provided that 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: disease risk reduction and structure-function claims. A **disease risk reduction** health 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, 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.

⁴ In a related CAIRN report, 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. [See Malla, S., J.E. Hobbs, E.K. Sogah and M T, Yeung. 2013. *Assessing the Functional Foods and Natural Health Products Industry: A Comparative Overview and Literature Review*, Canadian Agricultural Innovation and Regulation Network, 151pp. <http://www.ag-innovation.usask.ca/>]

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. A third category, **therapeutic claims**, is approved in principle in some jurisdictions but with few if any examples of actual product approvals in practice.

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

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, and more broadly within the EU), labelling has been 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 varies from country to country, with some countries’ labelling requirements treating 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. the 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.

⁵ Health Canada 2010. “Food and Nutrition – Health Claims” Accessed 2010

⁶ Subirade, M. 2007. *Report on Functional Foods*. Rome: Food and Agriculture Organization.

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 seven permissible 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 the therapeutic claims category. 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. The approval process involves 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 and must reach unanimous agreement about the safety the food before approval is granted by 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 scope and design of the regulations and the extent to which different health claims are permitted differs markedly among countries. Table A provides a summary of permitted health claims across a number of countries.

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. Canada could permit some form of qualified health claims, and at a minimum, qualified structure/function claims could be used in Canada.

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, have permitted 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 potential health benefits for consumers who are aware of the link between diet and health. Allowing product-specific claims reduces spillover benefits that would otherwise accrue to other firms producing similar food products and have been shown to increase research & development investments by firms. This potential advantage must be balanced with the objective to both inform and protect consumers. 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 a few 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 primary 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 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 best example, restricting functional foods to natural health products and requiring licenses even for venders of the products, not just the producers.

To sum up, it appears that Canada lags behind the rest of the world with respect to health claims for these products. Canada has fairly stringent regulatory requirements for functional foods 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 (albeit increasing to nine in recent years), 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 CLAIMS¹

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 B1 ² , Iron → Red blood formation; Iodine → Thyroid gland formation
United States	SSA Claims²: Soy protein, fruits, vegetables, soluble fibre → Coronary heart disease (CHD); Fat, fibre containing grain products → Cancer; Folate → Neural tube defects. Qualified Claims³: 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	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

¹ For more information and distinction between FF and NHP claims, see Tables 1 & 2 in Appendix 1 of the full report

² 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.

³ 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.

	Authority (EFSA).	Protein→growth and development of bone in children Emerging Scientific Evidence/Request for Proprietary Information (Article 13(5)) Claims 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
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

For a copy of the full report “*Functional Foods and Natural Health Products Regulations in Canada and Around the World*” see the Canadian Agricultural Innovation and Regulation Network at <http://www.ag-innovation.usask.ca>