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Assessing Health Claims in Canada and Around the World

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<u>An Introduction to</u> <u>ATINER's Conference Paper Series</u>

ATINER started to publish this conference papers series in 2012. It includes only the papers submitted for publication after they were presented at one of the conferences organized by our Institute every year. The papers published in the series have not been refereed and are published as they were submitted by the author. The series serves two purposes. First, we want to disseminate the information as fast as possible. Second, by doing so, the authors can receive comments useful to revise their papers before they are considered for publication in one of ATINER's books, following our standard procedures of a blind review.

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Assessing Health Claims in Canada and Around the World

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Abstract

The functional food and natural health products (FFNHP) industry has become an important part of the global food industry. Consumer awareness, attitudes and acceptance towards these products is increasing and the global market is growing. The importance of FFNHP is reflected in the interest in regulation of health claims and standards from industry stakeholders and policymakers. The regulatory situation has evolved across the globe, and countries have formulated policies to promote the sector and to protect consumers. This paper examines FFNHP regulations, policies and key industry trends in Canada and internationally. The current situation with respect to allowable health claims in Canada and several other countries (US, EU, UK, Sweden, Russia, Japan, Australia, New Zealand, Korea, China, Taiwan, Singapore, Malaysia, Hong Kong, India, Thailand, Philippines and Brazil) is summarized. New health claims for credible health benefits could result in significant healthcare savings. Key policy issues include the balancing of consumer protection with the potential to facilitate healthier diets with implications for public health care costs.

Key words: functional food, natural health products, regulations, policies, health claims, industry trends

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Introduction

Growing awareness of the correlation between diet and health, increasingly sedentary lifestyles, an aging population, and ever increasing healthcare costs have increased the interest in healthier food products (e.g., WHO 2002; ADA 2004, IFT Panel 2005; Evani 2009). These include so-called functional foods and natural health products (FFNHP)¹, which offer positive health benefits to consumers. The WHO identifies nutrition as a significant and manageable determinant of chronic disease (WHO 2002). Enhancing the information available to consumers is an important policy response to improve health through changing what individuals eat (e.g., Hawkes 2004, Mariotti et al 2010). As such, there are a number of policy issues regarding the regulatory environment for approval of new FFNHP and the state of labelling regulations for health claims on functional foods and natural health products.

This paper examines FFNHP regulations, policies and key industry trends in Canada and internationally. The paper outlines the market failure arguments pertaining to the consumption of healthier food and the labelling of health claims, summarizes recent industry developments and examines the current situation with respect to allowable health claims in Canada and several other countries (US, EU, UK, Sweden, Russia, Japan, Australia, New Zealand, Korea, China, Taiwan, Singapore, Malaysia, Hong Kong, India, Thailand, Philippines and Brazil). New health claims that encourage the consumption of products with proven health benefits could result in significant healthcare savings. Key policy issues include the balancing of consumer protection with the potential to facilitate healthier diets with implications for public health care costs.

Healthy Eating: Exploring the Market Failures

Two forms of market failure are apparent with respect to the consumption of healthier food. First, a market failure arises from negative externalities generated by the costs of ill health not being fully borne by the individual when there is a publicly funded health care system. This market failure arises when a portion of the financial cost of illness is borne by a third party (in this case, the publicly funded health care system)². Therefore individuals may over-consume unhealthy products, under-consume healthy foods, or engage in less than

¹ Health Canada defines functional foods thus: "*a functional food is similar in appearance to, or may be, a conventional food, that is consumed as part of a usual diet, and is demonstrated to have physiological benefits and/or reduce the risk of chronic disease beyond basic nutritional functions*" (Health Canada, 1998; 3). Nutraceuticals are isolated or purified nutrients sold in medicinal form (e.g. pill form, or more broadly, in doses) and have a health effect (Health Canada, 1998). Natural health products are a group of products which include most nutraceuticals but also homeopathic and traditional medicines (Walji & Boon, 2008).

² This is not intended as a criticism of Canada's publicly funded health care system. A similar moral hazard argument could be made for private health insurance, wherein the insured individual does not bear the full cost of an illness.

optimal exercise regimes. The second market failure arises due to information asymmetry with respect to credibly signalling the health benefits from functional foods. The potential health benefit from a functional food is a credence attribute and as such cannot be identified by consumers without labelling. Thus, consumers may under-consume functional foods if the health benefits are not clearly identified. Providing information (labelling) should increase the demand for functional foods, reducing the size of the negative externality.

Figure 1 illustrates the market failure, and resulting deadweight loss (DWL) to society, of under-consuming healthy foods. When do not bear the full costs of poor health outcomes or are not fully informed about the positive health effects from functional foods consumption, they only take into consideration their immediate known benefit, yielding the private benefit curve(MB_{PR}^{1}). The social benefit (MB_{PB}) is much higher, since healthier diets lead to improved health outcomes thereby reducing the burden on health care costs. Therefore, DWL^{1} is created and economic welfare is decreased relative to the social optimum.

If consumers are informed about the potential health benefits from increased consumption of healthier food, some consumers could be expected to increase their consumption, because although they are not paying for the entire health care cost, their utility is increased from consumption of healthier foods. Hence, the private marginal benefit curve MB_{PR}^{-1} will shift upwards to the right, closer to the public marginal benefit curve (from MB_{PR}^{-1} to MB_{PR}^{-2}). Consequently, increased healthier food consumption reduces the negative externality (DWL²), and thus increases economic welfare (Figure 1). However given that the costs of poor health are not being fully paid by individuals but instead have been borne by others (taxpayers), labelling is expected to address one aspect of the market failure (information asymmetry) but it may not lead to the socially optimal consumption level.

While consumers may be concerned about health, a portion of the costs of poor health are still borne by society—full information/labelling will not provide perfect incentives. Nevertheless, labelling accompanied by consumer education should address the information asymmetry problem. Stronger economic incentives could include subsidizing the consumption of healthier foods or taxing unhealthy foods.

Figure 1. Externality and Deadweight Loss With and Without Labelling



Developments in the FFNHP Sector: Insights from the Literature

The functional food and natural health products industry has become an important part of the global food industry. Consumers' awareness and acceptance of these products is increasing and the global market exhibits an upward trajectory. Depending on the definition of functional food, the global market has been estimated at 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). Reflecting the rapid growth in the sector has been a recognition by industry stakeholders and policymakers that the regulation of health claims and standards deserves closer attention.

The long-run success of the functional food and natural health product industry is largely dependent on how consumers will perceive new functional foods and NHPs. A number of researchers have examined consumer responses to these new products, finding that, generally speaking,, consumers have positive attitudes towards these products and appear willing to pay a premium for them. However, the literature indicates that consumer acceptance depends crucially on the extent to which the claimed health benefits are credible.. In addition to standard socio-economic factors affecting consumption intentions (age, education, income, gender), a range of factors have been identified as important determinants of consumption decisions, including the specific functional properties of the products, taste, price, potential side effects of the products, knowledge and beliefs concerning health outcomes, convenience in meeting nutritional requirements, method of production, credibility of information and efficacy of health claims. (e.g., Herath et al 2008, Hailu et al 2009, Marette et al 2010, Henson et al 2010, Ares et al 2010).

As new products have emerged with new functional components, the regulatory situation has evolved across the globe, and countries have been formulated policies to both promote the sector and to protect consumers. There exist many variations in the regulatory situation regarding these products. There is however evidence, to some extent, of convergence in policies internationally in part reflecting a desire to facilitate trade in these products. An example is the Australia and New Zealand Food Standards Coordination Initiative in which both countries agreed to develop a joint policy on nutrition content and health claims. Health claims have been one of the challenging areas in the functional food and natural health products sector. Policymakers are faced with the dual imperative of protecting consumers while facilitating growth in the sector. A literature review reveals numerous recommendations to improve the regulatory situation including: scientific validation of health claims to ensure safety and efficacy of the products, harmonization of claims internationally, a clear distinction between health and structural/functional claims, and international labelling standards (Veeman 2002, Hobbs 2002, Bech-Larsen and Scholderer, 2007, Herath et al 2008)

Health Claims in Canada and Internationally¹

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 they 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: disease risk reduction and structure/function claims (Subirade 2007). 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

¹ For a more detailed discussion of functional food and natural health product claims, see our report "Functional Foods and Natural Health Products Regulations in Canada and Around the World: Nutrition Labels and Health Claims", which is available from the Canadian Agricultural Innovation and Regulation Network (CAIRN) at <u>http://www.ag-innovation.</u> usask.ca/.

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. A third category, therapeutic claims, is approved in principle in some jurisdictions but with few if any examples of actual product approvals in practice. A therapeutic claim suggests that the consumption of a nutrient, vitamin, or mineral would treat or mitigate disease conditions or restore normal bodily functions.

Currently, in Canada there are seven approved generic disease risk reduction health claims permitted on food which can also be used on natural health products (NHPs) (Table 1). Canada requires a premarket approval for all health claims and has a relatively lengthy and stringent process of new claim approval. There are also 26 approved structure/function claims and no claims approved yet under the therapeutic claims category although therapeutic claims on food are technically permitted in Canada. In addition to these claims, nutrition content claims¹ can also be made. There is also mandatory nutrition labelling² and in most cases labelling must be in both French and English.

Broad regulatory differences exist 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 they initially 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) and direct domestic government regulations on health and nutrition claims.

On the global scene, while most countries regulate the use of health claims on functional food and natural health products, the scope and design of the regulations and the extent to which different health claims are permitted differs markedly among countries. Table 1 provides a summary of permitted health claims across a number of countries.

¹ Nutrition claims describe the presence or absence of a nutrient.

² Nutrition facts tables that display information about levels of nutrients per serving.

COUNTRIES	Disease Risk Reduction Claims	Structure/Function Claims
Canada	Sodium & Potassium \rightarrow high	Coarse wheat bran, Psyllium \rightarrow
	blood pressure; Calcium &	Regularity; Green tea, Selenium,
	Vitamin D \rightarrow Osteoporosis;	Phosphorous, Vitamin C, $E \rightarrow$
	Saturated & trans fat \rightarrow heart	Antioxidant effect on blood; Protein
	disease; Vegetable & fruits \rightarrow	\rightarrow Body tissues or antibodies; Fat,
	cancer; Maximal fermentable	Carbohydrates \rightarrow Energy; ARA,
	carbohydrates \rightarrow dental caries;	DHA \rightarrow Development of brain, eyes
	Phytosterols \rightarrow Cholesterol	and nerves; Calcium, Phosphorous,
	lowering; Oat fibre→reduced risk	Vitamins A, C, D \rightarrow Bones, Teeth;
	of heart disease.	Thiamine, Niacin, Riboflavin,
		Pantothenic and Magnesium acid \rightarrow
		Normal growth, metabolism and tissue
		formation; Folate \rightarrow Fetal neural
		development; Vitamin B12, Iron \rightarrow
		Red blood formation; lodine \rightarrow
United States	SSA Claims ² : Soy protain fruits	Dermitted but the Food and Drug
United States	SSA Claims : Soy protein, iruns,	Administration (EDA) does not keen a
	Coronary heart disease (CHD).	list of the claims
	Fat, fibre containing grain products	
	\rightarrow Cancer: Folate \rightarrow Neural tube	
	defects.	
	Qualified Claims³: Tomatoes,	
	Calcium, Green tea, Selenium,	
	Antioxidants vitamins \rightarrow Cancer;	
	Nuts, Walnuts, omega-3 fatty	
	acids, B-vitamins, corn oil,	
	unsaturated fats from canola oil,	
	monosaturated fatty acids from	
	olive oil \rightarrow Heart disease;	
	Calcium \rightarrow Hypertension;	
	Chromium \rightarrow Picolinate Diabetes;	
	Phosphatidylserine \rightarrow Cognitive	
	dystunction.	

Table 1: Global Health Claims¹

¹ For a more complete discussion of the distinction between FF and NHP claims, see our report "Functional Foods and Natural Health Products Regulations in Canada and Around the World: Nutrition Labels and Health Claims", which is available from the Canadian Agricultural Innovation and Regulation Network (CAIRN) at <u>http://www.ag-innovation.usask.ca/</u>.

²Claim 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.

³These 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.

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. Children's Growth and Development (Article 14(1)(b)) Claims α -Linoleic acid (ALA) & Linoleic acid (LA) \rightarrow normal growth/development if children; Calcium, Vitamin D, Phosphorus, and Protein \rightarrow growth and development of bone in children Emerging Scientific Evidence/Request for Proprietary Information (Article 13(5)) Claims Water-soluble tomato concentrate \rightarrow blood flow
Sweden	Energy \rightarrow Obesity; Hard Fat, Dietary fat (oats), Omega-3 fatty acids, Whole grains, Salt \rightarrow Heart disease; Dietary \rightarrow fibre constipation; Salt \rightarrow High blood pressure; Calcium and/or vitamin D \rightarrow Osteoporosis; Sugar \rightarrow Caries; Iron \rightarrow Iron deficiency	Vitamin C, E, Beta-carotene \rightarrow antioxidants; Vitamin C \rightarrow Iron absorption; Calcium, Vitamin D \rightarrow bone development; Zinc \rightarrow Enzyme systems; Iron \rightarrow blood & hemoglobin production; Dietary fibre \rightarrow normal bowel function; Carbohydrates \rightarrow 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 \rightarrow Heart disease; Calcium \rightarrow Osteoporosis; Folic Acid \rightarrow Neural tube defects.	24 approved claims. E.g. Vitamin $D \rightarrow$ Calcium & phosphorus utilization and absorption; Selenium, Vitamin $E \rightarrow$ Antioxidant; Vitamin $K \rightarrow$ Proper coagulation; Thiamine \rightarrow Normal metabolism of carbohydrates; Riboflavin, Niacin \rightarrow 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	Omage 2 fatty saids > Haset hast4	Luconona) Antiovidanti Distanti
DI aZII	Omega-5 faily acids \rightarrow Heart health,	Lycopene \rightarrow Antioxidant; Dietary
	Dietary nore, Fai, Quitosane,	fibres, Lactulose \rightarrow Normal intestinal
	Phytosterols, Soy protein \rightarrow	function; Inulin, Probiotics, Fructo-
	Cholesterol; Mannitol, Xylitol, or	oligosaccharides \rightarrow Gut flora
	Sorbitol \rightarrow Dental carries.	
Republic of	35 ingredients approved to have	Permitted but no list available
Korea	claims	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 \rightarrow Osteoporosis: Low fat	Permitted but no list available
	food \rightarrow cancer	
Malaysia	Permitted but no list of claims	Folio agid . Crowth and call division:
Walaysia	available	Fone actu \rightarrow Growth and cell division,
	available	Iron, vitamin $B12 \rightarrow Red blood cell$
		formation; Niacin, Vitamin B2, B1 \rightarrow
		Energy; Magnesium, Vitamin $D \rightarrow$
		Calcium absorption and retention;
		Calcium \rightarrow Bone health; Vitamin C \rightarrow
		Iron absorption; Inulin, Oligofructose
		\rightarrow 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 \rightarrow Body tissues: Low lactose
801 C		content \rightarrow Lactose intolerant:
		Calcium Vitamin $D_3 \rightarrow Bone$
		strongth: Iron Energy: Folate
		Strength, from \rightarrow Energy, Forate \rightarrow
		blood calls formation
Destrict	Not Democitie 1	Diood certs formation.
Russia	Not Permitted	Examples of approved health effects:
		Optimization carbonydrates, fat,
		vitamins and other metabolism in
		various functional conditions;
		improvement of the function of the
		numan 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 \rightarrow red blood cell formation;
		calcium \rightarrow bones and teeth

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 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. 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; 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, 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 bettereducated consumers regarding the relationship between diet and health and potentially therefore resulting in healthier consumers. Allowing productspecific claims reduces spillover benefits that would otherwise accrue to other firms producing similar food products. This imperative must be balanced, however, with the objective to better inform consumers and improve health outcomes. Hence, product specific claims are expected to induce investment and also research & development by firms due to the elimination of free ridership. Consequently, a potential step towards encouraging more R&D into functional foods 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 other noticeable differences. Most structure/function claims in Canada have been approved as disease risk reduction claims in other countries. Some examples are: folate and fetal neural development; soluble fibre and heart disease; selenium and antioxidants/cancer (Table 1). 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.

Conclusion

To sum up, it appears that Canada, in some respects, lags behind other developed countries in regards to health claims for these products. Canada has a fairly stringent regulatory procedure in the areas of functional food compared to other countries like the United States, Japan, and the EU. While this is 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 very difficult for a new claim to get approval. The few number of disease risk reduction health claims in Canada, absence of qualified health claims, and the prohibition of product specific claims on food all attest to this fact.

Nevertheless, there remains scope for continued policy development given the evidence of socio-economic potential in the sector. Studies have shown that health claims on food could lead to benefits such as improved health, health care cost reduction and an increase in international trade. 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 and economic development in the sector. Targeted public policies (e.g. a period of exclusivity with respect to health claims, tax incentives and subsidies) can also be used to stimulate R&D on healthier food products

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