

CAIRN Policy Brief

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ASSESSING THE FUNCTIONAL FOODS AND NATURAL HEALTH PRODUCTS INDUSTRY: A COMPARATIVE OVERVIEW AND LITERATURE REVIEW: Summary

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Functional foods and natural health products (NHP) are a relatively new component of the human diet with important policy implications. Functional food refers to food that is intended to be consumed as part of a normal diet and contains ingredients that have the potential to enhance human health or reduce the risk of disease beyond basic nutritional functions. Natural health products (NHPs), also known as nutraceuticals or food supplements or nutritional supplements, are products that have been isolated or purified from food and may include ingredients such as amino acids or vitamins; they tend to be marketed in the form of pills, powders, capsules or tablets.

Significant scientific evidence now demonstrates that some foods and food ingredients provide physiological benefits and/or reductions in the risk of chronic disease beyond basic nutritional functions. Consumers are more conscious of the maintenance of good health through diet, thereby gravitating towards foods that offer additional benefits beyond that provided by conventional food, and are demonstrating a willingness to pay a premium for these products. Interest among policy makers in the functional foods and NHP industry is also increasing due to rising public health care costs, especially in countries with publicly-funded health care systems such as Canada, aging populations, and the growing incidence of diet-related health problems. New R&D applications that promise growth opportunities in the food industry are of interest from an agricultural and food policy perspective.

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The importance of the functional foods and NHP industry is evident in its worldwide growth. Such rapid growth generates a need for appropriate policy and regulatory frameworks and requires a thorough examination of the issues and challenges facing the sector. The complexity of the functional food and NHP sector, in combination with the rapid growth it continues to experience, is a fecund environment for confusion among consumers, policy makers and health professionals, and emphasizes the need for a comprehensive and meaningful assessment of the market and policy environments in which the industry is situated.

The report upon which this policy brief is based aims to help broaden understanding of the functional foods and natural health products sector⁵. Three overarching areas are explored: (i) the variance in definitions and terminologies used for this category of food products; (ii) key industry, market, and research trends; and (iii) an in-depth review of relevant literature regarding consumer awareness and acceptance of functional foods and NHPs, industry and market analysis, product specific studies, and the evolution of regulatory frameworks and policies⁶.

The global market for functional foods and NHPs has been estimated to represent approximately 3% of the total food market (Kotilainen et al, 2006) with the US, EU and Japan the largest markets. The US functional food and beverage market alone had an estimated retail value of US\$59 billion in 2007, representing approximately 8.6% of the total US food and beverage market (AAFC 2009). The EU market was estimated at approximately US\$8 billion in 2006, while Japan's health food industry was expected to grow from US\$16.4 billion to about US\$21.8 billion between 2007–2012 (Datamonitor 2008). It is estimated that the Canadian functional food market has accounted for about 1% of the global market since 1997 (Nutrition Business Journal, 2007). While the functional food and natural health products market has been dominated by developed countries, emerging markets such as Brazil, China, and India have come to represent important potential markets (Nutrition Business Journal, 2007).

⁵ 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/>)¹.

⁶ For a more detailed analysis of the international regulatory environment surrounding health claims for functional foods and NHPs see the companion report to this study by Malla et al., 2013.

A source of confusion regarding the industry is the lack of universally accepted terminology surrounding functional foods or NHPs. The definitions of functional food, although differing across countries, tend to have a common basis; however, the global terminology applicable to NHPs is more diverse. To further compound the complexity, terminology is constantly evolving due to advances in scientific knowledge and growth in international markets. For example, in Canada, what used to be called nutraceuticals are now classified as NHPs (which include amino acids, vitamins and minerals, herbal remedies, traditional medicines and essential fatty acids). Overlapping terminology is also common: for example, in Korea, Taiwan and Russia the definition of functional food is equivalent to a nutraceutical, whereas a nutraceutical is now defined as an NHP in Canada and as a dietary supplement in the United States. The adoption of common terminology in the industry could increase credibility and facilitate trade.

The success of the functional food and natural health products sector is largely dependent on consumer acceptance. Numerous studies have found evidence of positive consumer attitudes toward these products, suggesting the existence of robust potential price premiums. A number of central determinants of consumer acceptance of functional food and natural health products are identified in the literature, the most important of which is the existence of credible health benefits. In most cases, the literature suggests that verification of health claims by governments, stringent approval processes, and communication of health benefits through sources trusted by the consumer are pre-requisites to widespread consumer acceptance.

A variety of other socio-economic factors appear to be significant determinants of consumer acceptance including age, gender, income and geographic location, while tangible product qualities such as the functional properties of the products, taste, side effects and price, remain important. Lastly, intangible attributes such as convenience, method of production and credibility of information regarding health claims were also identified as relevant determinants of consumer acceptance.

Sustained research and development (R&D) is critical to the future growth of the sector, as is adequate and appropriate protection of intellectual property rights (IPR) as the latter will encourage and protect investments in the former. R&D spending is not evenly distributed across product types, firms or markets. The means to fund R&D also varies by market. Evidence from the literature suggests that the EU spends the most on R&D, while Japan utilizes a collaborative cost-sharing R&D approach between private firms and government. A Statistics Canada 2007 survey of Canadian functional food and NHP firms estimated total expenditure on R&D, product development and marketing to be approximately Cdn\$209 million in 2007 with about 70% (\$148 million) spent on product development (Palinic, 2005). EU funding for functional food research is estimated to be approximately 10%-20% of the total EU food and nutrition R&D budget. To put this in context, between 2002 and 2006, the EU spent 753 million Euros on research and development related to food quality and safety, while functional food R&D expenditures totalled around 73 million Euros (Stein and Rodriguez-Cerezo 2008).

Obtaining intellectual property rights protection through patents is a means of ensuring firms protect and capture rents from their R&D investments. The type of IPR protection varies across markets. In some countries patents are popular, while in others trade secrets are more common. For example, the literature suggests that in Canada trade secrets still remain the dominant form of intellectual property protection and that firms in the sector are less likely to register their patents and trademarks than in other countries, whereas patent use is stronger in the US, Europe and Japan. One study finds that, in 2005, 30% of functional food and NHP patents held by Canadian firms were registered with the United States Patent and Trademark Office, 16% with the Canadian Intellectual Property Office, 11% with the European Union patent office, with the remainder registered with other jurisdictions (Palinic 2005).

Differences in patenting rules create challenges for firms selling to multiple markets; for example, in order to patent a product with the United States Patent and Trademark Office an inventor has to only show that the invention is “useful” and “new” and not necessarily that it works (is operative) (Trueman 2009). In contrast, in Canada, an inventor must provide information on the “novelty” (be the first in the world), “utility” (functional and operative) and show inventive “ingenuity” before a product can be patented with the Canadian Intellectual Property Office (CIPO 2010).

In some markets the lack of effective patent protection or well-established property rights protection markedly affects decisions to undertake R&D. The literature suggests that in Canada IPR protection has induced less innovation in the functional food and NHP sector compared to the biotechnology sector, as significant substitution effects may exist whereby, instead of developing their own products, firms acquire them from other developers. The potential need to acquire IPR from other firms can limit the number of product offerings.

In general, suggestions from the literature for further research include improving product quality, improving the benefits offered, research into consumer education and knowledge, research investigating the potential beneficial health effects of known or existing compounds used for other uses or applications. Finally, the substitution relationship between various food products under a tax or subsidy policy, and the resulting health outcomes, is also discussed in some of the policy-oriented research.

International trade is an important aspect of the health food industry. In Canada, most firms in the sector export their products; in contrast, the US market for functional food is mostly domestically driven (Mintel, 2006). The EU is one of the leading importers of crude medicinal plants, while Japan is a global trading hub for functional foods and NHPs, importing intermediate ingredients and exporting finished products.

Disparate regulatory environments pose a significant challenge to the industry as countries have been formulating policies on an individual basis to promote the sector and to protect consumers. The literature shows many variations in regulatory approaches and there currently exists a greater state of international divergence than convergence in the regulations pertaining to functional foods and NHPs. Canada is viewed as having a relatively restrictive regulatory environment for the development and marketing of functional food compared to the US, EU, and Japan. In some jurisdictions efforts are being made to harmonize regulations or to recognize equivalence in regulatory standards, while in other jurisdictions regulatory approaches remain quite distinct. Health claims are an important focus within regulations, and differences in product labelling requirements remain the most significant challenge to harmonization or the establishment of equivalence in labelling standards. The uncertainty caused by international differences in regulatory systems poses a challenge to the growth and development of the industry. Nevertheless, examples of successful harmonization or equivalence are emerging. For example, Korea has aligned its regulatory frameworks to that of Codex Alimentarius, and Australia and New Zealand have taken steps to coordinate their food standards.

A variety of reforms in the regulatory environment for health claims are recommended in the literature. These include recommendations that health claims be scientifically validated to ensure product safety and quality. There is general consensus that there should be a clear distinction between functional and risk reduction claims, which can also reduce waiting times in obtaining approval for functional foods. Additional recommendations include banning or limiting certain unsubstantiated claims, restrictions on the wording of claims, and the inclusion of general disclaimer statements in addition to health claims. Procedures for ex-post evaluation of regulations are suggested. A number of public policy initiatives that can assist the industry's growth are discussed in the literature, including improving and harmonizing health claims regulations; educating consumers about health claims; fostering investment in R&D; providing tax breaks and a period of exclusivity regarding health claims.

A general theme running through the literature is that a collaborative approach involving all industry stakeholders, including consumer groups, in the development of policy is necessary for the growth of the sector and the protection of the public interest. Consultation and dialogue between the research community and government regulators is encouraged in many strands of the literature, as are interactions between the medical community and researchers and the involvement of non-traditional funders such as industry associations, provincial agriculture and health departments.

The functional food and NHP industry has considerable growth potential. There is a need for more research and development to facilitate further growth. The growing burden of health care costs remains a key societal issue in Canada and in other countries with publicly funded health care systems. The potential for the health food sector to contribute towards the maintenance and improvement of consumers' health is therefore of policy relevance. The policy environment needs to strike an appropriate balance between ensuring that consumers are adequately protected while facilitating growth and development within the sector.

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A copy of the full report “Assessing The Functional Foods And Natural Health Products Industry: A Comparative Overview And Literature Review” is available from the Canadian Agricultural Innovation and Regulation Network (CAIRN) at <http://www.ag-innovation.usask.ca/>