

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

By

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EXECUTIVE SUMMARY

Functional foods and natural health products (NHP) have become a relatively new component of the human diet with important policy implications. Increased consumer interest in healthier food products is driven by a variety of factors including growing awareness of the link between diet and health, the desire to age ‘gracefully’ by maintaining good health, greater convenience in meeting nutritional needs and preventing chronic diseases such as diabetes, cancer, cardiovascular diseases and respiratory diseases. 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 amongst 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, increased incidence of chronic and sedentary lifestyle-related diseases, aging populations, new growth opportunities in the food industry, new R&D applications, and an increase in overall income in some countries. Ever increasing health care costs have led governments, health professionals and researchers to examine measures that promote well-being and reduce the risk of disease.

The World Health Organization (WHO) identifies nutrition as a significant and manageable determinant of chronic disease, stressing the need for a shift in nutrient intake towards 'healthier' foods (WHO 2002). Rising health care costs have also spurred research into healthier foods and food ingredients. Significant scientific evidence now demonstrates that some foods and food ingredients provide certain physiological benefits and/or reduction of risk in chronic disease benefits beyond basic nutritional functions. This combination of growing scientific evidence linking the role of diet in maintaining good health and preventing disease, together with increased consumer and industry interest, have raised overall awareness in and the profile of the health food sector.

The importance of the functional foods and NHP industry is evident in its worldwide growth. Such rapid growth in any sector will be accompanied by the need for appropriate policies and regulation and requires a thorough examination of issues and challenges related to consumers, firms/market, and government policies and regulations. The importance and complexity of the functional food and NHP sector, in combination with the rapid growth it has

and continues to experience, is a fecund environment for confusion amongst consumers, policy makers and health professionals around the world and only emphasizes the need for a comprehensive and meaningful assessment.

The objective of this document is to help broaden understanding of the functional foods and natural health products sector. It examines the variance in definitions and terminologies used for this category of food products, assess the key market trends and developments in industry structure, including evidence of consumers' reactions to these products, and presents a comparative analysis of the regulatory environment for functional foods and NHPs across a number of countries¹.

One source of confusion in the industry is the lack of universally accepted terminology and definitions for functional foods and 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: 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 need to adopt common terminology in the industry is apparent, to increase credibility and to facilitate trade.

The global market for functional foods and NHPs is estimated to represent approximately 3% of the total food market (Kotilainen et al, 2006) with the US, EU and Japan being the largest markets. The US functional food and beverage market alone had an estimated retail value of US\$59 billion in 2007, approximately 8.6% of the total US food and beverage market, with an annual growth forecasted at 6.1% (AAFC 2009). The EU market was estimated to be approximately US\$8 billion in 2006 with a total five year forecast of 4.9% growth, 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 has been suggested that the Canadian functional food market has been roughly 1% of the global market since 1997 while exhibiting an upward

¹ 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

trajectory (Nutrition Business Journal, 2007). The functional food and natural health products market has been dominated by developed countries, however, emerging markets such as Brazil, China, and India have come to represent important potential future markets (Nutrition Business Journal, 2007).

It is apparent that trade is an important aspect of the health food industry. Most countries are involved in trade of both final and intermediate (ingredients) products in the health food sector. 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. 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. The uncertainty caused by international differences in regulatory systems poses a challenge to the growth and development of the industry.

Sustained research and development (R&D) is critical to the future growth of the sector, as is adequate and appropriate intellectual property rights (IPR) protection, as the latter will encourage and protect investments in the former. While R&D spending is occurring it is not evenly distributed across product types, firms or markets. The means to fund R&D also varies by market; the EU spends the most on R&D while Japan utilizes a collaborative R&D approach between private firms and government. The types of IPR protection also varies across markets. In some countries patents are popular, while in others trade secrets are more common; in some markets the lack of effective patent protection or well-established property rights protection markedly affects decisions to undertake R&D.

The success of the functional food and natural health product industry is largely dependent on consumer acceptance of these products. Numerous studies have found evidence of positive consumer attitudes toward these products, suggesting the existence of robust potential price premiums. A number of 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 derived from consumption of these products. 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.

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

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

1. INTRODUCTION

Growing scientific evidence of the importance of diet in managing health and disease, together with increased consumer and industry interest, has raised the profile of the health food sector. Functional food and natural health products are a relatively new food category with important policy implications. Conventionally, the primary role of human beings' diet has been the biological provision of nutrients to maintain metabolic function and well-being. 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 (Health Canada, 2009; ADA, 2004; IFIC, 2009; Stein and Rodriguez-Cerezo, 2008). 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 can be marketed in the form of pills, powders, capsules or tablets. NHPs are intended to have a physiological benefit or to provide protection against chronic disease (Health Canada, 1998; EFSA, 2010). Consumption of products from either category provides additional health benefits beyond the supply of basic nutrients.

The objective of this document is to provide an overview of the functional foods and natural health products industry internationally, and present a comprehensive review of literature in three broad areas: consumer attitudes and awareness, industry and market analysis, and regulatory issues.

The remainder of this section outlines the underlying factors driving societal interest in functional foods and NHPs. Section two explains the varying definitions used for these health food products, particularly the characterization of functional foods and NHPs, in Canada, the United States (US), Japan, Korea, the European Union (EU), Australia and New Zealand (NZ), China, India, Brazil, Russia, and Taiwan. Section three examines the development, growth and structure of the functional food and NHP industry in Canada, the US, EU and Japan. Section four presents a comprehensive review of literature addressing consumer awareness and determinants

of willingness to pay, industry and market analysis, product specific studies, and analyses of regulatory frameworks and policies. The report concludes with a discussion of policy implications.

1.1 Diet and Health: Drivers of Interest in Functional Food and NHPs

Scientific evidence increasingly suggests that some foods and food ingredients (functional food and NHPs) provide physiological benefits over and above that of conventional foods (Health Canada, 2009; ADA, 2004; IFIC, 2009). There are diverse drivers of interest in these products, including increased incidence of chronic diseases such as diabetes, cancer, cardiovascular diseases and respiratory diseases; sedentary lifestyles and an increase in lifestyle related diseases; rising public health care costs, particularly in countries with publicly funded health care systems; growing public awareness of the link between diet and health; an aging population; convenience in meeting nutritional needs; new opportunities for growth in the food industry; new R&D applications; and an increase in overall income in some countries (WHO, 2002; ADA, 2004; Evani 2009, West and Larue, 2004; AAFC, 2009; Cinnamon, 2007; Hobbs, 2002; Nutrition Business Journal, 2007a).

Science has shown that diet affects human health. Therefore, healthy diets promote good health. The suggestion that certain food components and nutrients are associated with the prevention/treatment of chronic diseases such as cancer, coronary heart disease (CHD), and osteoporosis has encouraged consumers' interest in functional foods and natural health products (West and Larue 2004, Stein and Rodriguez-Cerezo 2008, ADA 2004, , IFC 2009, IFT Panel 2005, Siegrist et al 2008). There is growing evidence that consumers are willing to pay a premium for health benefits provided by functional foods and natural health products (e.g. West et al 2002, Markosyan et al 2009 and Peng et al 2006). An understanding of consumer attitudes toward functional food and natural health products, including the extent to which traditional influences on consumer acceptance such as convenience and taste remain relevant, is important to the long-run growth of the sector.

Rising health care costs have led governments, health professionals and researchers to examine measures that promote well-being and reduce the risk of diseases (Evani 2009, ADA 2004). Aging populations, combined with sedentary lifestyles, are major drivers of the rising burden of health care costs and have spurred research into healthier foods and food ingredients.

Recent policy responses include measures to better inform consumers about the nutrient content of foods to facilitate healthier eating choices -- (for example, the introduction of mandatory nutrition labelling on pre-packaged foods in Canada in 2005, and the requirement to label the presence of trans fat in these foods.) Enhancing the information to consumers is an important policy response to improving health by changing what Canadians eat (Veeman 2002, Klompenhouwer and Van Den Belt 2003, Hawkes 2004, Mariotti et al 2010). Policies to encourage research and development (R&D) into healthier foods also have a role to play. This may include changing the nutritional composition of diets by lowering the cost of producing food that is more nutritious and by improving the nutrient composition of existing foods.

The importance of functional foods and natural health products is evident in the growth of the industry worldwide. Available food technologies, scientific discoveries, and increased consumer desires/interest for healthier food products provides opportunities for the development of healthier food products, while industry foresighting analysis in Canada and other countries suggests a continued upward trajectory for the industry (IFT Panel 2005; Hobbs 2002; Arias-Aranda and Romerosa-Martinez 2010). Depending on the definition of functional food, the global market size is estimated to be approximately US\$30 to US\$60 billion which represents 1-3% 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). Revenue generated in 2007 by the functional food and natural health product sector in Canada was approximately \$3.7 billion which represented over a 70% increase compared to the previous two years (Cinnamon 2007). The research levels, market size, and revenue generated in the industry are an indication of the growth and importance of the sector (Krakar and Gao - AAFC 2006) Currently, the leading markets in functional food and natural health products are the US, EU, and Japan (AAFC 2009, New Zealand Trade & Enterprise 2007).

The importance of functional food and natural health products is also reflected in the evolving regulatory environment governing health claims and approvals for these products. Various countries permit health claims declaring an association between a food or food ingredient, and a health outcome. (Health Canada 2010). However, different definitions, terminologies and regulations have arisen globally (Health Canada 2007).

The functional food and natural health products industry is not without its challenges, which include firms' financial resources for product development; in some jurisdictions an absence of transparent and enforceable property rights systems to protect patents; regulations that differ across jurisdictions with respect to the number of permissible health claims, slow and cumbersome approval processes, and maintaining consumer confidence regarding safety and efficacy in the face of a proliferation of different products and health claims, all of which can discourage investments and R&D. (Hobbs 2002, Krakar and Gao 2006, Spence 2006, Labrecque et al 2006, Bech-Larson and Scholderer 2007, Subirade 2007, Cinnamon 2007, Stein and Rodriguez-Cerezo 2008, Herath et al 2008, Mariotti et al 2010).

2. DEFINITIONS OF FUNCTIONAL FOOD AND NATURAL HEALTH PRODUCTS

Terms such as functional food, natural health products, novel foods, food for special dietary use, dietary supplements and nutraceuticals are commonly used to denote healthier foods and food products in various countries. This section examines differences in terminology across a number of countries, including: Canada, United States, Japan, Australia, Korea, the European Union, Australia and New Zealand, China, India, Brazil, Russia, and Taiwan.

Japan was the one of the first countries to recognize a different category of healthier food products. In the 1980s the Japanese government formally accepted that food products could positively affect the physiological system of the human body and accepted approved health claims for food (Ministry of Health, Labour and Welfare Website 2010). These foods were classified as “*Food for Specified Health Uses*” (FOSHU). The Japanese government defines FOSHU as food that “is intended to be consumed for the maintenance/promotion of health or for special health uses by people who wish to control health conditions, including blood pressure or blood cholesterol” (Ministry of Health, Labour and Welfare Website 2010). This definition applies to both functional foods and natural health products.

In order for a food be approved as FOSHU, a safety assessment is required and the efficacy of functional attributes must be established. Furthermore, FOSHU can be categorized into: ‘*regular FOSHU*’, ‘*qualified FOSHU*’, ‘*Standardized FOSHU*’, and ‘*Reduction of disease risk FOSHU*’ reflecting different strengths of assurance regarding the link with health benefits.

“Qualified” FOSHU refers to “food with health function which is not substantiated on scientific evidence that meets the level of regular FOSHU, or the food with certain effectiveness but without established mechanism of the effective element for the function” (Ministry of Health, Labour and Welfare Website 2010). Under the “Standardized” FOSHU category, “standards and specifications are established for foods with sufficient FOSHU approvals and accumulation of scientific evidence” (Ministry of Health, Labour and Welfare Website 2010) and products are approved as standardized FOSHU when they meet the standards and specifications. The last category, “Reduction of disease risk” FOSHU refers to products permitted to carry a disease risk reduction claim “when reduction of disease risk is clinically and nutritionally established in an ingredient” (Ministry of Health, Labour and Welfare Website 2010).

The FOSHU claim must be approved by the Ministry of Health, Labour and Welfare (MHLW). Specifically, to qualify as FOSHU, a food has to fulfill the following requirements (Ministry of Health, Labour and Welfare Website 2010):

- “Effectiveness on the human body is clearly proven
- Absence of any safety issues (animal toxicity tests, confirmation of effects in the cases of excess intake, etc.)
- Use of nutritionally appropriate ingredients (e.g. No excessive use of salt, etc.)
- Guarantee of compatibility with product specifications by the time of consumption
- Established quality control methods, such as specifications of products and ingredients, processes and methods of analysis”

Japan has a fairly loose definition of novel foods, referring to them as “foods and food additives that have been produced through the use of recombinant DNA techniques” (Ministry of Health, Labour and Welfare Website 2010).

In Canada, categories of healthier foods and food derivatives have been evolving over time, with references commonly made to functional food, natural health products, nutraceuticals, novel food, etc. According to Health Canada (1998, p.3): “a *functional food* is similar in appearance to, or may be a conventional food, 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”.

In 2003 the Canadian Federal government introduced a new regulation for a category known as *natural health products* (Canada Gazette, 2003). According to the regulation, a natural health product is a substance or a combination of substances in which all the medicinal ingredients are

made up of natural substances. This includes homeopathic medicine or a traditional medicine that is manufactured, sold and represented for use in:

- “The diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in human.
- Restoring or correcting organic functions in humans
- Modifying organic functions in humans such as modifying those functions in a manner that maintains or promotes health” (Canada Gazette, 2003).

Before the natural health product terminology was adopted in Canada many of these products were commonly referred to as *nutraceuticals*. According to an earlier definition from Health Canada (1998, p.3), “a nutraceutical is a product isolated or purified from foods that is generally sold in medicinal forms [pills, capsules or tablets] not usually associated with food. A nutraceutical is demonstrated to have a physiological benefit or provide protection against chronic disease”. Since the introduction of the Natural Health Products Directorate of Health Canada in 2000, the term nutraceutical has been replaced by the broader term, Natural Health Product (NHP) which became official in 2003 (Government of Saskatchewan 2008, Canada Gazette 2003). NHPs include over-the-counter products used to diagnose/treat and/mitigate or prevent diseases such as vitamins and minerals, herbal remedies, traditional medicines and essential fatty acids (Government of Saskatchewan 2008; Canada Gazette 2003; Health Canada 2004; Laeque et al. 2006; Mine and Young 2009; Farrell et al 2009).

In Canada, *novel food* was originally defined by Health Canada in 1999 (Canada Gazette, 1998), and refers to foods resulting from a process not previously used for food. This includes products that do not have a history of safe use as a food. In addition foods that have been modified by genetic manipulation, also known as genetically modified foods, GM foods, genetically engineered foods or biotechnology-derived foods, fall under the novel food category (Health Canada 2010).

In the United States (US), the Food and Drug Administration (FDA) does not provide a legal definition for functional food. However, a number of working definitions have been developed by different organizations including the American Dietetic Association (ADA), the International Food Information Council (IFIC) and the Institute of Food Technologies (IFT). According to these organisations, a functional food is any food that moves beyond necessity (basic nutrition) to provide additional health benefits that may reduce disease risk and/or promote optimal health (ADA 2004; IFIC 2009). The Institute of Food Technologies (2005, p.6) defines functional food

as, “foods and food components that provide a health benefit beyond basic nutrition (for the intended population). These substances provide essential nutrients often beyond quantities necessary for normal maintenance, growth, and development, and/or other biologically active components that impart health benefits or desirable physiological effects”.

In the US there are also *dietary supplements* that would be classified as nutraceuticals or NHPs in Canada. According to the US Dietary Supplement Health and Education Act (DSHEA 1994), *dietary supplement* is a product that is intended to supplement the diet and contains any of the following dietary ingredients: vitamin, mineral, amino acid, etc. Dietary Supplements must also conform to physical criteria, being ‘intended for ingestion in pill, capsule, tablet, powder or liquid form’ and should not be represented for use as a conventional food or as the sole item of a meal or diet (DSHEA, 1994).

In the United States there are other categories of food products with health benefits beyond basic nutrition, including *Medical foods* and *Food for Special Dietary Use*. According to the Orphan Drug Act 1988, *medical foods* are defined as “a food which is manufactured to be consumed or administered entirely under the supervision of a physician and which 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”. In this context, an example of a medical food is Lofenalac, a product that was designed for use in the dietary management of a rare genetic condition known as Phenylketonuria (PKU). To be considered a medical food, a product must, at a minimum, meet very specific criteria: the product must be a food for oral or tube feeding; the product must be labelled for the dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; and the product must be intended to be used under medical supervision (FDA 2010).

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...” (FDA, 2009). Examples include infant foods,

hypoallergenic foods such as gluten-free foods and lactose-free foods, and foods offered for weight reduction.

The FDA does not have a formal definition for novel food. These foods are often referred to as new and emerging food/biotechnology products, and a premarket notification with the FDA is usually recommended FDA (FDA 2005).

In the European Union, the European Commission Concerted Action on Functional Food Science in Europe (FUFOSE) defines a food as *functional* if “it is satisfactorily demonstrated to affect beneficially one or more target functions in the body, beyond adequate nutritional effects, in a way that is relevant to either an improved state of health and well-being and/or reduction of risk of disease. Functional foods must be in the form of conventional foods and they must demonstrate their effects in amounts that can normally be expected to be consumed in the diet: they are not pills or capsules, but part of a normal food pattern” (Stein and Rodriguez-Cerezo, 2008, p. 1).

The EU Food Safety Authority defined NHPs as *food supplements* that are concentrated sources of nutrients or other substances with a nutritional or physiological effect. The purpose of use should be to supplement the normal diet. They are marketed in dose form i.e. as pills, tablets, capsules, or liquids in measured doses etc. (EFSA 2010). In 2007, the European Union formally defined novel food as: “a food that has not been used for human consumption to a significant degree before May 15, 1997” (European Commission Regulation EC No 258, 1998). Novel food in the EU includes genetically modified products.

In Australia and in New Zealand, there is no universally accepted definition for functional food, although the joint food regulation agency in these two countries has a working definition. Food Standards Australia New Zealand (FSANZ) defines *functional food* as being “...similar in appearance to conventional food and intended to be consumed as part of a normal diet, but modified to serve physiological roles beyond the provision of simple nutrient requirements” (FSANZ, 2006). A *nutraceutical* is defined as a food designed to provide health benefits that may contain ingredients such as specific amino acids or vitamins. Nutraceuticals can be marketed in the form of pills, capsules or tablets (FSANZ Website 2001).

Food Standards Australia New Zealand refers to novel food as “*a non-traditional food* for which there is insufficient knowledge in the broad community to enable safe use in the form or context in which it is presented, taking into account:

- a) *The composition or structure of the product;*
- b) *Levels of undesirable substances in the product;*
- c) *Known potential for adverse effects in humans;*
- d) *Traditional preparation and cooking methods; or*
- e) *Patterns and levels of consumption of the product”* (FSANZ 2010);

In general a *non-traditional food* is defined as: “A food which does not have a history of significant human consumption by the broad community in Australia or New Zealand” (FSANZ 2010).

In Russia, food products with health benefits (functional food, and NHPs) 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 the quality of life (Zawistowski 2008). The food products and its components should be natural or identical to natural. They should be consumed along with food and incorporated into food. BAFS are not regarded as medicines and are not meant to treat or diagnose diseases. *Biologically Active Food Supplements* in Russia are equivalent to nutraceuticals in Canada, however, in Russia the definition used for NHPs also applies to functional foods and novel foods.

In Korea, the Health Functional Food Act (HFFA 2004) defines food products with health benefits (functional foods and NHPs) as *healthier food products*. They are defined as food supplements containing nutrients or other substances (in a concentrated form) that have a nutritional or physiological effect whose purpose is to supplement the normal diet. A *healthier food product* in Korea is similar to a NHP in Canada. The Korean Health/Functional Food Act that came into effect in 2004 requires these products to be marketed in measured doses, such as in pills, tablets, capsules, and liquids (Ministry of Health and Welfare, Korea, 2004). The definition used for NHPs and functional foods also applies to novel foods.

The Taiwan Health Food Control Act (HFCA) (2006) refers to both functional food and NHPs as *health foods*. In Taiwan, health food should be in the form of food products or consumed along with food. Health food in Taiwan is defined as food that possesses special nutritious elements (bioactive components) or specific health care abilities to improve and/or reduce the risk of disease. To be considered a health food and granted a permit, these products must satisfy the following conditions:

- Bioactive components that provide the health benefit should be clearly identified. If the specific ingredients cannot be identified, then the health benefits should be listed and research supporting them provided to the health authorities for verification.
- The health benefit should be scientifically proven.
- The product must be safe and harmless to humans when consumed. All manufacturing, effectiveness and safety methods should be approved by health authorities (Health Food Control Act 2006, Part 4, (11)).

Health foods should not be used for mitigation, curing and/or treating human disease. In Taiwan the definition used for NHPs and functional foods also applies to novel foods.

The State Food and Drug Administration (SFDA) in China refers to functional food as *health food*, defining it as “food with specific health functions that are suitable for consumption by specific groups of people and that has the effect of regulating human body functions without treating diseases” (Patel et al 2008, Page 4). *Novel foods* in China are defined as ingredients that have not traditionally formed part of the Chinese diet. There are four different categories of *novel foods*, which usually refer to ingredients used in ready-to-consume products. The first category is for plants, animals and microorganisms. The second is for rarely-used ingredients. The third entails newly discovered microorganisms applied to food processing. The fourth category covers food ingredients whose structure has been modified by new technology (AP-Food Technology 2007). The Chinese Food and Drug Administration has no specific definition for *natural health products*.

In India, *functional foods* are defined as food that encompasses potentially healthful products, including any modified food or food ingredient that may provide a health benefit beyond that of the traditional nutrients it contains (Ministry of Women and Child Development, Government of India, 2010). Novel food on the other hand, refers to an article of food for which safety standards have not been specified but are not unsafe. These products should not contain any food or ingredient that is prohibited under the Food Safety Standards Act 2006 (Food and Safety Standards Act 2006 Chapter IV, article 22). India has no specified definition for *natural health products*.

Brazil has no legal definition for functional foods, NHPs or novel foods. Functional foods and NHPs are generally referred to as any *healthful product* that is not a drug but part of a normal diet and provides a health benefit beyond basic nutrition. *Novel foods* often refer to food with no history of use in Brazil (Lajolo 2002).

The Food and Agriculture Organization (FAO) of the United Nations in 2007 provided a working definition for *functional food*: “foods which are intended to be consumed as part of the normal diet and that, contain biologically active components which offer the potential of enhanced health or reduced risk of disease” (FAO, 2007). The FAO does not have formal definitions for *natural health products* or *novel foods*.

To sum up, since the introduction of healthier foods, different terminologies and definitions have emerged across various countries. Although broadly referencing foods with health benefits or new attributes, there is no consensus among countries regarding the definitions of functional foods, nutraceuticals or NHPs. Neither is there consensus as to what constitutes a “novel” food. Table 1 presents a summary of the terminology used across the 12 jurisdictions discussed in this report.

While there is no universally accepted definition for functional food, some similarities in the terminology used across countries are apparent. The differences in the definitions are often cultural and regulatory in nature. All definitions require that the food provide benefits beyond that of conventional food, and that the food not be perceived as a drug, but should have some physiological functions. In Canada, the US, Australia, New Zealand, the EU, China, India, and Brazil, functional foods are expected to be similar in appearance to conventional food and must provide benefits beyond basic nutrition. Many countries have an official definition for functional foods (e.g., Canada, Japan, EU, China, India), while others have a set of specifications which a food should possess to qualify as a functional food -- in other words a working definition only (e.g., US, Australia and New Zealand, Brazil). Lastly in other countries, there is no distinction made between a functional food and a NHP (e.g., Russia, Korea, Taiwan).

Thus, in Canada, functional food should be part of a usual diet and have physiological benefits and/or reduce the risk of diseases beyond basic nutrition. In the US, foods and dietary components that have health benefits beyond basic nutrition; furnish energy, sustain growth, or maintain vital processes are classified as functional food. In Japan, they are foods containing ingredients claimed to have physiological effects on humans. In the European Union, functional foods are regarded as food that can beneficially affect the human body beyond basic nutrition. In Australia and New Zealand, functional foods should be similar in appearance to conventional foods but modified to provide particular benefits. China refers to functional food as food with

special health functions. Brazil and India refer to functional food as foods that can provide benefits beyond basic nutrition.

Some consensus exists regarding the definitions of nutraceuticals or NHPs. Though the terminology may be different, the underlying intent appears similar among countries. The most common characteristics of nutraceuticals or NHPs are that they should be sold in measured doses and in the form of pills, tablets, capsules, and or liquids, as well as have some physiological benefits or provide certain health benefits. In Canada, NHPs should be in a medicinal form (pills, tablets or capsules) and used for the prevention or treatment of diseases (Canada Gazette 2003). In the US, *dietary supplements* are also marketed in the form of pills, tablets or capsules and are intended to supplement the diet (FDA 2010). In the European Union, like Canada, the US, and Korea *food supplements* (Natural Health Products) should be marketed in a dose form as pills, capsules or tablets. However, in contrast, in Russia (*Biological Active Food Supplements, BAFS*) and Taiwan (*Health Food*) NHPs should be in the form of food products or consumed along with food.

The terminology governing these products is evolving and remains contradictory in places. In Canada nutraceuticals are now classified as a *natural health product*, which is equivalent to a *food supplement* in the EU; is still called a *nutraceutical* in Australia and New Zealand; and is equivalent to a *dietary supplement* in the United States. Confusingly, in Japan, Russia, Korea, and Taiwan, the terminology used for health-enhancing food products applies to both functional food and NHPs (nutraceuticals).

Novel foods are most commonly categorized as foods not previously used by humans or with no history of use in the country in question. Something akin to this definition is used in Canada, US, European Union, Australia, New Zealand, China, India and Brazil. However, in Canada, US, EU, China, and Japan, novel foods also specifically include food products that are genetically engineered or derived through biotechnology. In Japan and US, there is a working definition only for novel foods. In countries like Russia, Korea and Taiwan (without a distinct definition for novel food) the definition used for NHPs and functional foods also applies to novel foods.

The absence of a uniform terminology for these food products/ingredients reflects differences in the underlying approaches to food regulation across different countries, as well perhaps a lack of scientific consensus on the presence, efficacy and measurement of the health

benefits derived from these products. Differences in terminology raise costs and create uncertainty for firms marketing across international borders and as such can act as a brake on the expansion of international trade in these products. Certainly a firm contemplating developing export markets for a functional food or a NHP needs to be fully cognizant of the food category in which its product will be defined and the regulatory approvals that are required for marketing the product with a health claim. A more in-depth discussion of differences in regulatory environments across various countries is provided in section four.

Table 9: Definitions of Functional Foods, ‘Natural Health Products’ and Novel Foods

LOCATION	FUNCTIONAL FOOD	NHPS /NUTRACEUTICALS/MEDICAL FOODS/ FOODS FOR SPECIAL DIETARY USE / DIETARY SUPPLEMENT	NOVEL FOOD
CANADA	<p>“A <i>functional food</i> is similar in appearance to, or may be a conventional food, 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)</p>	<p>“A <i>nutraceutical</i> is a product isolated or purified from foods that is generally sold in medicinal forms not usually associated with food. A nutraceutical is demonstrated to have a physiological benefit or provide protection against chronic disease”. Health Canada 1998)</p> <p>"<i>Natural Health Product</i>" means a “substance or a combination of substances in which all the medicinal ingredients are natural products, a homeopathic medicine or a traditional medicine, that is manufactured, sold or represented for use in</p> <p>(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans; (b) restoring or correcting organic functions in humans; or (c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health”. (Canada Gazette 2003)</p>	<p>Foods resulting from a process not previously used for food. OR Products that do not have a history of safe use as a food. OR Foods that have been modified by genetic manipulation, also known as genetically modified foods, GM foods, genetically engineered foods or biotechnology-derived foods. (Health Canada 2009)</p>

<p>JAPAN</p>	<p>“Foods containing ingredient with functions for health and officially approved to claim its physiological effects on the human body. <i>FOSHU (Food for Specified Health Uses)</i> is intended to be consumed for the maintenance/promotion of health or special health uses by people who wish to control health conditions, including blood pressure or blood cholesterol.” In order to sell a food as FOSHU, a safety assessment is required, along with an assessment of the effectiveness of the functions for health, and the claim must be approved by the Ministry of Health, Labour and Welfare (MHLW 2010) FOSHU: “Regular” “Qualified” “Standardized” “Reduction of Disease Risk”</p>	<p>The terminology for functional food/FOSHU also applies to NHPs.</p> <p>In addition to FOSHU, NHPs may also be categorized into: <i>Food with Nutrient Functional Claims</i>, refers to food products that require no pre-market approval but is restricted to approved vitamins and minerals; <i>Medical Drugs</i> which require prior approval; <i>All other Foods</i>, or general food category includes nutritional supplements and all other food products not in the other categories</p>	<p>In Japan, there is no official definition for novel food but it is often referred to as “foods and food additives that have been produced through the use of recombinant DNA techniques (Genetically modified)” (Ministry of Health, Labour and Welfare 2010)</p>
<p>UNITED STATES</p>	<p>The US Food and Drug Administration (FDA) does not provide a legal definition for the term <i>Functional Foods</i>, which is currently used primarily as a marketing idiom for the category.</p> <p>However, a number of working definitions have been developed by different organizations, including the American Dietetic Association (ADA), the International Food Information Council (IFIC), and the Institute of Food Technologists (IFT).</p> <p>ADA: ADA classifies all foods as <i>functional</i> at some physiological level because they provide nutrients or other substances that furnish energy, sustain growth, or maintain/repair vital processes. However functional foods move beyond necessity to provide additional health benefits that may reduce disease risk and/or promote optimal health (American Dietetic Association 2004)</p> <p>IFIC: The IFIC considers <i>functional foods</i> to include any food or dietary components that may have health benefits beyond basic nutrition (International Food Information Council 2009)</p> <p>IFT: A recent report published by IFT defines functional foods as “foods and food components that provide a health benefit beyond basic nutrition (for the intended population). These substances provide essential nutrients often beyond quantities necessary for normal maintenance, growth, and development, and/or other</p>	<p>A <i>Dietary Supplement</i> as defined by the Dietary Supplement Health and Education Act (DSHEA) as “a product that is intended to supplement the diet and contains any of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical (excluding tobacco), an amino acid, a concentrate, metabolite, constituent, extract, or combination of any of the above. Furthermore, it must also conform to the following criteria: be intended for ingestion in pill, capsule, tablet, powder or liquid form and not represented for use as a conventional food or as the sole item of a meal or diet labeled as a <i>dietary supplement</i>” “US Dietary Supplement Health and Education Act 1994”</p> <p><i>Foods For Special Dietary Use</i> are defined as “a particular use for which a food purports or is represented to be</p>	<p>No definition for <i>novel food</i> but often referred to as new and emerging food biotechnology products. Federal Food, Drug and Cosmetic Act [section 402] (FDA 2005).</p>

	<p>biologically active components that impart health benefits or desirable physiological effects.” (Institute of Food Technologists 2005)</p> <p><i>Medical Foods</i> are defined by the Orphan Drug Act as “a food which is formulated to be consumed or administered entirely under the supervision of a physician and which 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” (US Food and Drug Administration 2010)</p>	<p>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 . . .”</p> <p>Examples of such foods include infant foods, hypoallergenic foods such as gluten-free foods and lactose-free foods, and foods offered for reducing weight.</p> <p>Federal Food, Drug, and Cosmetic Act [Section 411(c)(3)] (FDA 2005)</p>	
EU*	<p>A food can be regarded as <i>functional</i> “if it is satisfactorily demonstrated to affect beneficially one or more target functions in the body, beyond adequate nutritional effects, in a way that is relevant to either an improved state of health and well-being and/or reduction of risk of disease. Functional foods must be in the form of conventional foods and they must demonstrate their effects in amounts that can normally be expected to be consumed in the diet: they are not pills or capsules, but part of a normal food pattern” (European Commission Concerted Action on Functional Food Science in Europe), (FUFOSE,1999)</p>	<p><i>Food supplements</i> are concentrated sources of nutrients or other substances with a nutritional or physiological effect whose purpose is to supplement the normal diet. They are marketed ‘in dose’ form i.e. as pills, tablets, capsules, liquids in measured doses etc. (European Union Food Safety Authority 2010)</p>	<p>“A food that has not been used for human consumption to a significant degree before May 15, 1997”. (European Commission Website 1998)</p>
AUSTRALIA AND NEW ZEALAND	<p>There is no universally accepted definition of a '<i>functional food</i>'. The government body that regulates food in both Australia and New Zealand (ANZFA) defines functional foods as being “...similar in appearance to conventional foods and intended to be consumed as part of a normal diet, but modified to serve physiological roles beyond the provision of simple nutrient requirements”. In other words, according to this working definition, functional foods look like their conventional counterparts but have a nutrient or other health-promoting substance (or substances)</p>	<p>A <i>nutraceutical</i> is a food that has been designed to provide health benefits. It may contain beneficial ingredients such as specific amino acids or vitamins etc. Nutraceuticals can be marketed in the form of pills, capsules or tablets. (Food Standards Australia New Zealand 2001)</p>	<p><i>Novel Food</i> is defined as “a <i>non-traditional food</i> for which there is insufficient knowledge in the broad community to enable safe use in the form or context in which it is presented, taking into account: -</p> <p><i>a) the composition or structure of the product;</i></p> <p><i>b) levels of undesirable substances in the</i></p>

	added, or have undergone some other significant modification to provide a particular health benefit. (Food Standards Australia New Zealand 2006)		<i>product;</i> <i>c) known potential for adverse effects in humans;</i> <i>d) traditional preparation and cooking methods; or</i> <i>e) patterns and levels of consumption of the product”;</i> where a <i>non-traditional food</i> is defined as: “A food which does not have a history of significant human consumption by the broad community in Australia or New Zealand” (Food Standards Australia New Zealand 2010)
RUSSIA	The definition used for NHPs also applies to functional foods.	<i>Biologically Active Food Supplements (BAFS)</i> is defined as nutritive substances and minor food components used to ameliorate deficiencies, decrease risk of debilitating diseases and improve life quality. They are meant to be consumed along with food or be incorporated into foodstuffs. (Zawistowski 2008)	The definition used for NHPs also applies to novel foods.
KOREA	The definition used for NHPs also applies to functional foods.	The term <i>health/functional food</i> (HFF) refers to food supplements containing nutrients or other substances (in a concentrated form) that have a nutritional or physiological effect whose purpose is to supplement the normal diet. The Korean Health/Functional Food Act (2004) requires these products to be marketed in measured doses, such as in pills, tablets, capsules, and liquids. (Health/Functional Food Act, 2004. Ministry of Health and Welfare, Korea).	The definition used for NHPs also applies to novel foods.
TAIWAN	The definition used for NHPs also applies to functional foods.	<i>Health Food</i> is defined as food products that possess ‘special nutritious elements’ (bioactive components) or	The definition used for NHPs also applies to novel foods.

		'specific health care abilities' to improve health, and/or reduce the risk of disease. Health food should be in the form of food products or consumed along with food. These products should not be used for mitigation, curing and /or treating human diseases. (Health Food Control Act 2006)	
CHINA	In China this is referred to as <i>Health Food</i> and is defined as “foods with specific health functions that are suitable for consumption by specific groups of people and that has the effect of regulating human body functions without treating diseases” (Patel et al 2008)	N/A	<i>Novel foods</i> in China are defined as “ingredients that have not traditionally formed part of the Chinese diet”. (AP-Food Technology 2007) Four categories exist: for plants, animals and microorganisms; for rarely used ingredients; newly discovered microorganisms applied to food procession; food ingredients whose structure has been modified by new technology (AP-Food Technology 2007)
INDIA	Food that encompasses potentially healthful products, including any modified food or food ingredient that may provide a health benefit beyond that of the traditional nutrients it contains. (Ministry of Women and Child Development, Government of India 2010)	N/A	An article of food for which standards have not been specified but are not unsafe. These products should not contain any food or ingredient that is prohibited under the Food and Safety Standards Act 2006. [Food and Safety Standards Act 2006. Chapter IV, article 22 (The Gazette of India 2006)].
BRAZIL	In Brazil functional foods have not been defined, but the norms were based on the idea of a product that is a food and not a drug, that is part of a normal diet and that can produce benefits beyond basic nutrition. They are generally referred to as <i>healthful products</i> (Lajolo 2002)	The terminology for functional food also applies to NHPs	Food with no history of use in Brazil (Lajolo 2002)
FAO	<i>Functional foods</i> are generally considered as “foods which are intended to be consumed as part of the normal diet and that contain biologically active components which offer the potential of enhanced health or reduced risk of disease” (Food and Agricultural Organization, 2007)	N/A	N/A

*Most countries in the EU use the EU definition but may have different policies on regulation and product approval

3. INDUSTRY, MARKET AND RESEARCH TRENDS

The controversies and inconsistencies in the definitions for functional food and NHPs create challenges in measuring global market and industry size². This section provides an overview of the functional food and NHP sector, market trends, and research directions in four countries: Canada, the United States, the EU and Japan.

The healthy food sector, while a relatively small component of the global food market, continues to exhibit strong growth. The World Bank in 2004 estimated the global functional food market to range between US\$30 to US\$60 billion depending on the definition of functional food. This represents 1-3% of the total food market (Kotilainen et al. 2006). Major markets include Japan, the United States and Europe (Nutrition Business Journal 2007, Klimas et al. 2008). Table 2 reports estimated market shares for these three countries plus Canada. Data in the table indicate a sector in flux, with the US representing the single largest market for functional foods in 1997 and 2000, while the EU becomes the larger market by 2005. However, there is some discrepancy over global market shares and as such these numbers should be treated with caution. For example, according to AAFC (2009), in 2008 Japan was the largest market for functional foods followed by United States. Moreover, New Zealand Trade & Enterprise (2007) also places Japan as the largest market share in 2006, followed by the United States and Europe. However, Datamonitor (2008) places Japan as the second largest market for functional food and NHPs in 2007. Two factors explain these apparent inconsistencies: differences in the terminology used to define a functional food, and a sector experiencing rapid growth and a shifting landscape of new product development. Nevertheless, the key point remains that Japan, the US and Europe are the leading markets in the functional food and NHP industry.

² In addition, as Kotilainen et al (2006) point out “Statistics on international trade of functional foods are not directly available because functional foods are traded in the tariff code categories of “among other foods”. Similarly, a large portion of botanical ingredients are funnelled into the pharmaceutical, natural medicine or dietary supplement markets, along with the portion used in the production of functional foods making commodity trade figures of limited informational value” (Kotilainen et al 2006, page 11).

Table 10: Estimated Global Market Size for Functional Foods (US\$ Billions)

	1997		2000		2005	
	US\$ BILLIONS	%	US\$ BILLIONS	%	US\$ BILLIONS	%
Canada	0.4	1	0.6	1	1.0	1.1
United States	13.6	35	17.4	34	25.7	28.7
Japan	9.6	24.7	12.8	25	22.6	25.2
European Union	12.3	31.6	16.4	32	34.4	38.4
Rest of the World	3.0	7.7	4.1	8	5.9	6.6
Total	38.9	100	51.3	100	89.6	100

Source: Nutritional Business Journal (NBJ 2007a)

Canada is a relatively small component of the global market for functional foods, at around one percent. One analyst projects the global functional food and drinks market for the year 2015 at \$130 billion (Global Industry Analyst Inc. 2010), although it should be noted that accurate estimates are notoriously difficult to generate and are usually ‘best guess’ estimates. While the US, Japan and the EU have remained the major markets for functional food over the past fifteen years, new emerging economies such as China, India, and other Asia-Pacific countries are expected to become more significant markets in the future (Nutrition Business Journal 2007a, Klimas et al 2008).

An analysis of the functional food industry structure, market development and research trends in Canada, the US, Europe and Japan is presented in the following sections.

3.1. Canada

In Canada the functional food and NHP industry is very broad and the number of firms involved in both functional food and NHPs have increased dramatically over time. Growth in the Canadian sector can be attributed to a number of factors including: the realization of the link between diet and health by consumers; the increasing cost of health care; an aging population; and also the challenge for consumers to meet their daily nutritional needs through conventional food (AAFC 2009, Krakar and Gao 2006). According to Statistics Canada, in 2002 there were about 294 companies involved in both functional food and NHPs; this number represents approximately 3.4% of the total establishments in the food industry (Tebbens 2002). In 2005, there were 389 companies, representing about 4.6% of food companies (Palinic 2005). The number of firms increased to 689 or approximately 8.1% of the food industry by 2007 (Cinnamon 2007). Furthermore, “there were 22,062 functional foods and natural health product

lines on the market in 2007. The majority of the product lines (17,656) were from natural health product firms; 703 product lines from functional food firms; and 3,704 product lines for firms active in both functional foods and natural health products” (Cinnamon 2007, p.26).

Companies in the functional food and NHP industry can be grouped into different categories based on a number of factors that are discussed in more detail below, including: the strategy used in entering the industry, the size of firms as measured by the number of employees or revenue generated, the broad area(s) of specialization (functional food, NHP, both functional food and NHPs or service only), the type of health problem targeted, and the stage of processing.

Categorizing the sector by entry strategy encapsulates both functional food and NHP firms and reveals a number of different and diverse entry strategies. According to Scott Wolfe (2002, p.5), common entry strategies include:

- “Focusing production on whole products that are considered functional (e.g. milling buckwheat or growing ginseng).
- Development of proprietary processes and technologies for extracting functionally active compounds from conventional food (e.g. Omega-3 fatty acid from hemp).
- Production of nutraceuticals like vitamins, mineral supplements, and NHPs like herbs and oil extracts.
- Initiating product extensions to include functional product lines (e.g. Tropicana Orange Juice with Calcium).
- Developing nutraceutical research and development capabilities and divisions to take advantage of the large market, (e.g. Abbott Laboratories).
- Increasing value-added processing. This involves the provision of crop nutrition products, crop protection products, seed, agronomic services, and other crop production products (e.g. Agricore United).
- Dedication of business to the formulation of functional foods. Firms in this category concentrate research on turning conventional foods into functional food.
- Genetically engineering plants to carry improved health nutrition profiles”.

Functional food and NHP firms in Canada can also be classified by their size. Small firms have less than 10 employees, 10 to 49 employees for medium-sized, and 50 and above

employees for large firms. In 2002, about 55% of firms in the industry were classified as small because they had less than 10 employees; 32% had between 10 to 49 employees; while firms that employed 50 or more people made up the remaining 13% of firms (Krakar and Gao 2006). Firm size is also measured by sales revenue, with about 24% of firms generating less than one hundred thousand dollars from sales. These are likely new start-up enterprises engaged in research and development and not yet at the stage of commercialization. Approximately 28% of firms earned between one hundred thousand and a million dollars. Firms that earned between a million dollars and ten million dollars represented about 31% of the total number of firms in the sector. The remaining 17% of firms earned more than ten million in sales revenue. The majority of the Canadian firms are privately owned and the main source of financing was from conventional sources such as banks, initial public offerings and secondary public offerings (Krakar and Gao 2006).

The classification of companies based on area(s) of specialization - functional food, NHP, both functional food and NHP, and service only - is shown in Table 3. In Canada, firms that specialize in only NHPs dominated the industry in the 2000s (Tebbens 2002; Palinic 2005; Cinnamon 2007). In 2002, approximately 46% of firms in the sector specialized in the production of NHPs; 28% of firms specialized in the production of only functional food; and the remaining 26% were involved in the production of both functional food and NHPs (Tebbens 2002). As can be seen in Table 3, through the mid to late 2000s, these proportions changed very little. In addition, in 2007, approximately 7% of firms in the sector specialized in providing services, including quality control services such as claims verification and patent registration (Cinnamon 2007).

Table 11: Distribution of Firms in the Functional Food and NHP Industry in Canada (2002, 2005, 2007)

	FUNCTIONAL FOOD	NHP	BOTH¹	SERVICE ONLY²
2002	28.0%	46.0%	26.0%	NA
2005	30.3%	44.7%	25.0%	NA
2007	25.3%	42.1%	25.7%	6.9%

Source(s): Tebbens 2002, Palinic 2005, Cinnamon 2007

Footnote: 1. Both refers to firms involved in the production of both functional food and NHPs

2. Service only refers to firms that do not exclusively develop, produce or sell functional food or NHP, but specialize in quality control services like claims verification or patent registration.

Firms in the Canadian health food industry can also be categorized by the type of health problem targeted by their product (Table 4). According to a Statistics Canada survey (Statistics

Canada 2005), the greater number of functional food and NHP firms were involved in three main areas of health: vascular or heart health, energy and general nutrition. Furthermore, half of all functional food firms provide general nutrition products, while about one third of NHP firms focus on products for the immune system, gut health and bone health. Other target health areas include: diabetes, cancer, weight control, sexual performance, energy, mental ability and sports performance. Finally, firms specializing in NHPs have wider product lines relative to functional food firms, which is evident in the number of firms in each of the targeted health areas (Statistics Canada 2005).

Table 12: Firms with Functional Foods and NHPs Categorized by Targeted Health Aspects and Development Stage (Number of firms)¹

	Functional foods in development	Functional foods on the market	NHP in development ²	NHP on the market
Vascular or heart health	56	57	56	82
Diabetes	41	16	18	34
Cancer	20	22	33	28
Energy	26	52	25	84
Mental ability	11	9	34	64
Gut health	43	36	48	85
Immune system	30	35	69	96
Sports performance/endurance	18	30	16	58
Bone health	31	31	37	84
Eye health	14	10	29	58
Weight control	46	35	38	66
Sexual performance	5	8	22	38
General nutrition	70	86	53	118
Other	16	12	27	25

Source: Statistics Canada 2005

Footnote: 1. Total number of firms in 2005 was 389. Firms may have products in more than one area. Preliminary data subject to revision (Statistics Canada 2005)

2: NHP: Natural Health Products

Lastly, the functional foods sector in Canada can also be categorized based on the level of processing (Health Canada 2010). The *first* category is “basic foods that contain the natural levels of the functional component” (examples are carrots which contain the natural level of the anti-oxidant beta carotene as well as oat bran cereal containing natural levels of beta-glucan). The *second* category is “processed foods with added ingredients” (for example, calcium-enriched fruit juice). The *third* category is “food enhanced to have more of a functional component than

the natural levels” -- via traditional breeding, special livestock feeding or genetic engineering (examples are: eggs with omega-3 from flax, tomatoes with higher levels of Lycopene, and milk with higher levels of CLA).

Most firms (46%) were engaged in only nutraceutical activities compared to 28% engaged in only functional food activities, while just over a quarter engaged in both. Among firms involved in functional food activities, most of them (44%) used added active ingredients like beta glucan in muffins. The rest of functional food firms used methods like plant breeding, genetic modification and special livestock feeding. Among the firms involved in nutraceutical activities, 51% dealt with plant-based nutraceuticals like beta-glucan from oats and antioxidants from blueberries; 37% dealt with marine-based nutraceuticals like glucosamine products from algae; and 28% dealt with animal- or micro-organism-based nutraceuticals such as essential fatty acids (Tebbens 2002).

In addition to the above categorization of firms in the sector, products and components of functional food and NHPs in Canada are also compiled under different groups according to the type of functional property. Health Canada data for functional food/components is compiled under six different groupings: Carotenoids, Dietary fibre, Fatty acids, Soy Phytoestrogens, Phenolics and Prebiotics and Probiotics (Table 5). An example of a functional component under Carotenoids is Lycopene sourced from tomato products which is believed to reduce the risk of prostate cancer. Insoluble fibre sourced from wheat bran is an example of dietary fibre which is purported to reduce the risk of breast and colon cancer. Furthermore, high oleic canola oil sourced from Nexera, with the potential to reduce coronary heart disease, is an example of functional foods under the fatty acid category. Lactobacillus from yoghurt and other dairy products falls under the category of prebiotics and probiotics and improves the quality of intestinal microflora and gastrointestinal health. Moreover, Isoflavones a form of Soy Phytoestrogen is sourced from soybeans and soy-based products with the potential to reduce the risk of menopausal symptoms such as hot flashes and is also claimed to protect against heart disease and some cancers. Finally, Phenolics is lignin, a functional component sourced from products like flax, rye and vegetables is supposed to prevent the incidence of cancer and renal failure.

Table 13: Examples of Functional Foods in Canada

FUNCTIONAL COMPONENTS	SOURCE/FOOD	POTENTIAL HEALTH BENEFITS
CAROTENOIDS		
Alpha-carotene/Beta-carotene	Carrots, Fruits, Vegetables	Neutralize free radicals, which may cause damage to cells
Lutein	Green vegetables	Reduce the risk of macular degeneration
Lycopene	Tomato products	Reduce the risk of prostate cancer
DIETARY FIBRE		
Insoluble Fibre	Wheat bran	Reduce risk of breast or colon cancer
Beta-Glucan	Oats, barley	Reduce risk of cardiovascular disease. Protect against heart disease and some cancers; lower LDL and total cholesterol
Soluble Fibre	Psyllium	Reduce risk of cardiovascular disease. Protect against heart disease and some cancers; lower LDL and total cholesterol
FATTY ACIDS		
Long chain omega-3 Fatty Acids-DHA/EPA	Salmon and other fish oils	Reduce risk of cardiovascular disease. Improve mental, visual functions
Conjugated Linoleic Acid (CLA)	Cheese, meat products	Improve body composition. Decrease risk of certain cancers
High Oleic Canola Oil	Nexera	Reduces the risk of coronary heart disease (CHD)
PREBIOTICS/PROBIOTICS		
Fructo-oligosaccharides (FOS)	Jerusalem artichokes, shallots, onion powder	Improve quality of intestinal microflora; gastrointestinal health
Lactobacillus	Yogurt, other dairy	Improve quality of intestinal microflora; gastrointestinal health
SOY PHYTOESTROGENS		
Isoflavones: Daidzein Genistein	Soybeans and soy-based foods	Menopausal symptoms, such as hot flashes; protection against heart disease and some cancers; lower LDL and total cholesterol
PHENOLICS		
Lignans	Flax, rye, vegetables	Prevention of cancer, renal failure
Flavones	Fruits/vegetables	Neutralize free radicals; reduce risk of cancer

Source: Health Canada 2010

The Health Canada database for NHPs describes these products by various categories: product name; product license holder; NHP number or homeopathic medicine number; medicinal ingredients; non-medicinal ingredients; dosage form; recommended use; risk information associated with the product's use; and companies that are involved in the production (Table 6). For example, selenium is an NHP which can be sourced from selenium yeast or citrate. It is generally recognized as a factor for maintaining good health and specifically as an antioxidant.

Table 14: Examples of Natural Health Products in Canada

PRODUCT/ INGREDIENT NAME	SOURCE MATERIAL	USES	SELECTED COMPANIES/ ORGANIZATION
Conjugated linoleic acids (CLA)	In triacylglycerol form and free fatty acid form, CLA is derived from processed safflower or sunflower oil	May help to support a modest improvement to body composition and a modest reduction of fat mass when used with a program of reduced intake of dietary calories and increased physical activity.	Herbal Magic Inc. Jamieson Lab. Ltd.
Folate	Folic acid/folacin/folate	General: Helps in the maintenance of good health. Specific: Helps the body to metabolize proteins. Helps to form red blood cells	Nature's Sunshine Products of Canada Ltd.
Selenium	Monohydrate selenium dioxide. Selenium hydrolyzed animal protein chelate. Selenium citrate. Selenium yeast. Sodium selenate	General: A factor in the maintenance of good health. Specific: An antioxidant for the maintenance of good health	1. Flora Distributing and Manufacturing Ltd. 2. Pegasus Pharmaceuticals Group Inc.
Pantothenic acid	Calcium DL-pantothenate. D-Panthenol/ Dexpanthenol. Solaray® Pantothenic Acid.	General: maintenance of good health. Specific: Helps the body to metabolize carbohydrates, fats and proteins. Helps in tissue formation. Prevents pantothenic acid deficiency.	Au Naturel Inc.

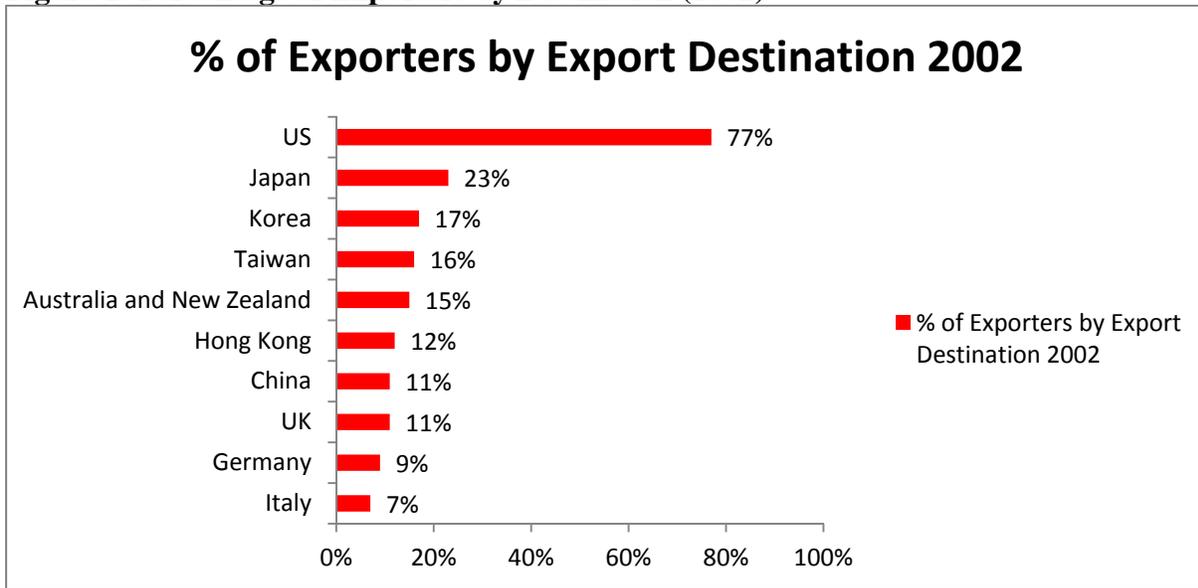
Source: Health Canada 2010

The ingredients used in the production of functional foods and NHPs in Canada are sourced from both domestic and international markets. The prominent ingredients include herbs and spices, oil seeds, grains and cereals, dairy-based, fruits and vegetables and other animal-based ingredients. Most functional food ingredients are sourced from the domestic market. Nearly one third of NHP firms sourced their ingredients internationally. The most imported ingredients are in the areas of herbs and spices, while most oil and grain/cereal products are from the domestic market (Palinic 2005).

As with many other parts of the Canadian food sector, exports are critical to the functional food and NHP industry, with the majority of firms exporting their products. Common destinations include the United States, Japan, Europe, Asia, Australia and New Zealand (Tebbens 2002). In 2007, the United States was the major market for Canadian functional foods, while other countries like Japan, China, Korea, Taiwan, Australia, and the EU comprised the primary export markets for Canadian NHPs (Cinnamon 2007). Specifically, of the total number of firms that exported functional food and NHPs in 2002, 77% exported to the United States, 23% to Japan and 17% to Korea (see Figure 1). Approximately 20% of exporters were exploring the potential in the Chinese market in 2002, and this proportion has likely grown (Tebbens 2002).

By 2005, the primary export destination for approximately 50% of functional foods and NHPs firms was the United States, followed by Korea (10%) and Japan (10%), while the remaining 30% exported to other destinations. However, a quarter of the firms indicated that they were actively searching for new export markets for their products (Palinic 2005). Interestingly, NHPs generated approximately two-thirds of the export revenue in the sector (Cinnamon 2007). Even though this may vary among firms, it seems clear that in 2005, the NHP sector generated a larger proportion of export revenues than the functional food sector, suggesting a stronger export orientation in the NHP sector.

Figure 1: Percentage of Exporters by Destination (2002)



Note: FFNHP stand for functional food and natural health products
Source: Statistics Canada (2002)

In 2007, the total revenue generated by all firms in the functional food and NHP sector was \$21.5 billion from all sources, with 17% (\$3.7 billion) generated directly by functional food and NHP activities. Firms producing NHPs received \$1.8 billion in revenue from functional food and NHP-specific activities compared with \$621 million from firms producing just functional food, while firms active in both fields generated \$1.3 billion in revenue from their functional food and NHP activities. Thus many of these firms were not exclusively focused on the functional food and NHP sector (Cinnamon 2007).

A variety of distribution channels feature in the functional food and NHP sector in Canada, including: wholesalers, retailers, third party distributors, direct sale to consumers, internet sales, mail orders, and networking marketing. The major distribution channel has tended to be direct to retailers, which accounted for approximately 46% of sales of functional foods and NHPs in 2007. Wholesalers accounted for 34% of sales while brokers or third party distributors accounted for 10%, with the other channels accounted for the remaining 10% (Cinnamon 2007). In contrast to functional food firms, NHPs firms were more likely to distribute via wholesalers rather than direct to retailers (Cinnamon 2007). Specifically, 53% of revenue generated by NHP firms was from wholesalers, while only 27% of functional food firms revenue generated were from wholesalers. However, 52% of functional food firms revenue generated came from retailers, while 32% of revenue generated by NHP firms was from retailers (Cinnamon 2007).

These differences are a reflection of the distribution system for food in Canada, with the supermarkets dominating the food retailing sector. With supermarkets vertically integrated into the wholesaling function it is not surprising that a food category such as functional food is more reliant on direct sales to retailers.

Canadian functional food and NHP firms embrace research and development (R&D) for nutritive value and functional properties of plant and animal products (Table 7). One example is the development of technologies for the processing of raw materials such as soy, oats, and other cereals. Technologies and expertise in the extraction, characterization, modification, stabilization and enhancement of products are also well developed (Cinnamon 2007). The support for research and development in the sector has also been trending upwards. The health areas targeted for R&D by firms are moving towards an emphasis on vascular health, weight control, energy, immune system and overall health and well-being (Palinic 2005; Cinnamon 2007).

Table 7 reports R&D and marketing spending by firms included in the Statistics Canada 2007 survey of Canadian functional food and NHP firms. The data show that total expenditure on R&D, product development and marketing was estimated to be approximately \$209 million in 2007, up from \$162 million in 2004 with about 70% (\$148 million) spent on product development and the rest going into marketing, distribution and consumer research activities (Palinic 2005). This compares to approximately 45% of total expenditures on R&D and marketing that were specifically for functional food and NHP R&D three years earlier. The data in Table 7 also show that functional food firms spent approximately 63% (\$62 million) of their R&D and marketing expenditures on functional food product research and development, while, NHP firms spent approximately the same proportion, 63% (\$40.1 million) on NHP R&D, up from 2004..

Table 15: Research and Development and Marketing Expenditures by Functional Food (FF) and NHP Firms (2004 & 2007)¹

2004 ²					2007				
	FF FIRMS	NHP FIRMS	BOTH	ALL FIRMS	FF FIRMS ³	NHP FIRMS ⁴	BOTH ⁵	SERVICE ONLY ⁶	ALL FIRMS
Thousands of dollars(\$)									
Total R&D and marketing Spending⁷	45,612	76,190	41,063	162,865	98,894	64,601	41,527	4,284	209,305
FF R&D					62,018	9,890	16,266	1,723	89,897
NHP R&D	21,186	29,831	23,537	74,554	628	40,749	14,702	1,979	58,058

Source(s): Statistics Canada: The Functional Foods and Natural Health Products Survey, 2005 & 2007

Footnote: 1. Totals may not add up due to rounding

2. 2004 data is preliminary and subject to revision

3. FF (Functional Foods) Firms represent firms producing only functional food products

4. NHP (Natural Health Products) firms represent firms producing only NHPs

5. Firms producing both products

6. Firms providing services like patent registration for other firms in the sector

7. Total R&D and marketing spending consists of expenditures on FF R&D, NHP R&D as well as marketing, distribution and consumer research activities.

Firms in Canada have the option of protecting their intellectual property (IP), patents and trademarks, through registration with intellectual property offices in Canada and in other countries. However, trade secrets still remains the main form of intellectual property protection and firms in the sector have tended not to register their patents and trademarks (Krakar and Gao, 2006). Statistics Canada survey results suggest that in 2007, trade secrets were mostly developed by firms producing only functional food (41%) as a method used to protect intellectual property, while 46% of firms active in both functional food and NHPs developed trade secrets (Cinnamon 2007). Finally, 21% of firms producing only NHPs developed trade secrets, while 8% of service only firms in the sector developed trade secrets (Cinnamon 2007).

In 2004, over 80% of functional food and NHP firms in Canada did not have registered patents for their products, this number increased to 87% in 2007. NHP firms held the largest number of existing patents, while functional food firms had the most pending patents. Overall, combining existing and pending patents, NHP firms had the most patents compared to functional food firms. The majority of Canadian firms with registered patents tended to register them with the United States Patent and Trademark Office, and the remaining few firms registered their patents with the Canadian Intellectual Property Office and the European Union patent office

(Palinic 2005, Cinnamon 2007)³. Table 8 provides a sample of registered patents for products with improved nutrition in Canada. The table provides information on the product to which the patent applied, the owner and country, the process and functional properties of the product, the patent number and the date of filing for the patent.

Table 16: Sampled Registered Patents in Canada

PRODUCT	OWNER/COUNTRY	PROCESS AND PROPERTIES	DATE OF FILING	PATENT NUMBER
Flaxseed	Elixi Oil Oy (FINLAND) Hk Ruokatalo Oyj (FINLAND)	Fibre fraction of flaxseed husks extracted and it is rich in Lignans	2000-03-31	2304303
Functional Fibre Product For Food Applications	Bioriginal Food & Science Corp. (CANADA)	The invention includes a functional fibre oilseed product with high amounts of - soluble and insoluble dietary fibres, omega-3 fatty acids, protein, phytosterols, Lignans, and antioxidants	2004-05-05	2466411
Sunflower seed, plants and oil	Pioneer Hi-Bred International, Inc. (USA)	Reduced saturated fatty acids in an aggregate of mature seeds of sunflower plant	1992-01-07	2058849
Low-Saturate Edible Oils	Kraft Foods, Inc. (USA)	Transesterified vegetable oils having a very low saturated fatty acid content	1990-12-11	2031945
Eggs With Balanced Lipid Composition	Belovo (BELGIUM)	Eggs obtained from a domesticated bird, in particular a layer, having a lipid fraction balanced in seed and green plant-type, omega 6 and omega 3 fatty acids	2001-05-15	2409194
Cereal Beta Glucan	Ceapro Inc. (CANADA)	Simple and efficient methods for formulating cereal beta glucan compositions that retard the natural gel forming properties of hydrocolloids and remain free flowing liquids	2001-12-04	2306537
Reduced Fat Meat Product	Monfort, Inc. (USA)	A reduced fat meat product is provided comprising meat and oat beta-glucan amyl dextrin	1992-07-02	2112801
Low Glycemic	Conagra Foods, Inc (USA)	Bread product comprises a wheat flour product, a	2002-01-25	2369207

³ Specifically, in 2005, 30% of patents were registered with the United States Patent and Trademark Office, 16% with the Canadian Intellectual Property Office, 11% with the European Union patent office and the rest were registered with other jurisdictions.” (Palinic 2005)

Index Bread		grain/seed source of soluble fibre, and a processed source of soluble fibre.		
Immune Stimulating Dietary Supplement and methods of use thereof	Trustees of Tufts College (United States of America)	The dietary supplement is administered to middle aged and elderly individuals in a suitable form for consumption by the individual. Suitable forms of consumption can include a snack bar, tablet, capsule, powder, drink, or dairy products	2000-05-05	2373605
Reduced Fat, Ready-To-Eat Cereal	Quaker Oats Company (The) (USA)	The invention further comprises a process for preparing such a reduced fat, ready-to-eat cereal.	2000-09-12	2138556
Oil and Seeds with Reduced Saturate levels of Fatty Acids	Dow Agrosiences Plc (USA)	The subject invention provides non saturated canola oil. The subject invention also provides seeds that can be used to produce such oils. Plants that produce these seeds are also included in the subject invention. The subject still further provides a plant-optimized delta-9 desaturase gene	2005-10-07	2583380

Source: Canada Intellectual Property Office (2010)

To sum up, the functional food and NHP sector in Canada continued to grow through the mid to late 2000s in terms of products, firm numbers and revenues. In 2005, there were 389 firms in the sector and total revenue generated by the industry was \$2.9 billion (Palinic 2005). The number of firms increased to over 680 in 2007 and generated approximately \$3.7 billion in revenue with over 22,000 product lines (Cinnamon 2007). While more recent data are not currently available, indications are that the sector has continued to grow. NHP firms have outnumbered functional food firms.

The export-oriented nature of Canadian functional food and NHP firms requires the exploration of other markets for their products. Most firms in the sector export their products, with functional food firms mostly exporting to the US, while a broader range of countries represent key markets for NHP firms. .

Growth in the sector is enhanced through continued research and development, which increased from an estimated \$162 million in 2004 to \$209 million in 2007 (Palinic 2005);

Cinnamon 2007). While it is difficult to draw definitive conclusions from observations across only two years of data, it appears that expenditures by functional food firms grew more rapidly in the period 2004-7 than expenditures by firms focused on NHPs. The reasons are unclear, but may reflect differences in the regulatory environment, as well as different stages of development of these two sectors. The existence of an effective property rights protection system would strengthen incentives for investment in R&D, however, Statistics Canada survey data from 2004 and 2007 suggested that few functional food and NHP firms had registered patents for their products, instead using trade secrets as an informal means to protect their intellectual property.

3.2. The United States

The functional food industry in the United States has also been growing and, along with Japan and Europe, is one of the largest in the world (AAFC 2009). Growth in the US functional food sector has been attributed to similar factors as in Canada, including the realization of the link between diet and health by consumers, the increasing cost of health care, the aging US population and the challenge of consumers meeting their daily nutritional needs through conventional food (AAFC 2009). It is estimated that the US functional food and beverage market had a retail value of \$59 billion in 2007, representing approximately 8.6% of the total US food and beverage market. NHPs contributed approximately 26.4% to the total US health food industry sales (Nutrition Business Journal 2007a, Klimas et al 2008).

Previous research has grouped consumers of functional food in the US into five different categories (Table 9): heavy users, regular users, occasional users, rare users, and non-users. Heavy users are estimated to be about 8% of the population, regular users, 17%, and occasional users 48%, with about 31% of the US population being rare or non-users (Nutrition Business Journal 2007b, Klimas et al 2008). According to the Nutrition Business Journal (2007b), in 2005 the total annual spending of the occasional users category was the highest, consistent with a relatively new product category which has a relatively high proportion of experimental users who are trying these products on an occasional basis. The average monthly expenditure on functional food is estimated to range between \$50 for heavy users and \$3 for rare users (Nutrition Business Journal 2007b, Klimas et al 2008).

Several reasons have been attributed to non-use of functional food in the US (Table 9). Overpricing, non-belief in claims and not enough information are among the reasons given by

consumers for not consuming functional food (Mintel 2006). A greater percentage of non- users cited overpricing as the principal reason for not purchasing functional food, followed by scepticism over the veracity of the health claims, and use of alternative means to boost health (vitamins, diet, lifestyle).

Table 9: Reasons for Not Purchasing Functional Foods (2006) (% for each reason)

REASONS	PERCENT ¹
I think they are overpriced	43
I don't believe the claims they make	35
I take vitamin and mineral supplements instead	32
I already maintain a healthy diet and lifestyle	30
I don't know enough about them	29
They cost more than regular versions	28
Regular food or drinks already give me what I need	17
My prescription medication already gives me what I need	11
They could be bad for me	8
Other	7

Source: Mintel (2006)

Footnote: 1. Total may not sum to 100 because respondents could choose more than one reason

Turning to NHPs, heavy users are estimated to be around 4% of the total population, while around 31% are regular users, 22% are occasional users, 18% are rare users and 25% are non-users (Nutrition Business Journal 2007a, Klimas et al 2008). Industry observers claim that consumption of NHPs in the US is being negatively affected by consumer confusion about the number and broad selection of products in the market and lack of education about the products (Nutrition Business Journal 2007a, Klimas et al 2008).

Firms in the health food sector can be categorized into three groups. *First* are the mainstream foods and drink companies such as Danone, PepsiCo and Quaker, which make up the greatest proportion of firms in the industry. The *second* group is comprised of pharmaceutical companies such as Johnson & Johnson, while the *last* group consists of single-product specific companies (Leatherhead Food International 2006).

The US functional food market is dominated by multinational corporations (Table 10 - Mintel 2006). In 2005 PepsiCo had approximately 16% of the US market for functional food; Kellogg Co., Coca-Cola Co. and General Mills followed with approximately 14%, 11%, and 11% respectively. Some of the major firms in the NHPs sector include: NBTY, Leiner Health Products, Pharmavite, Wyeth, Unilever, and Abbott Labs/Ross Products (Nutrition Business Journal 2007a, Klimas et al 2008).

Table 10: Major Functional Food Firms in the US (2005)

MANUFACTURER	SALES (MILLION US\$)	SHARE (%)
PepsiCo	2,397	16.3
Kellogg Co.	2,100	14.3
Coca-Cola Co.	1,591	10.8
General Mills	1,558	10.6
Kraft Foods, Inc.	847	5.8
Group Danone	643	4.4
Nestle USA, Inc.	545	3.7
Ocean Spray	427	2.9
Welch Foods, Inc	330	2.2
Dean Foods	292	2.0
Ferolito Vultaggio & Sons	241	1.6
Red Bull North America, Inc	226	1.5

Source: Mintel, 2006

Functional foods in the US exist across a broad range of categories, including dairy products, bakery products, cereal products, soy products, beverage products, and meat, fish and egg products (Table 11). The dairy functional product markets in the US are relatively small, with cereals, soya and beverages dominating (Leatherhead Food International 2006). Functional dairy products include probiotics and cholesterol-lowering yoghurts, while, bakery products consist primarily of bread and cookies fortified with fibre and omega 3 fatty acids for heart health. The functional properties of cereal products encapsulate calcium fortification, fibre fortification and wholegrain cereals, while soy products are dominated by soya milk for reducing the risk of coronary heart disease. Beverage products feature calcium fortification, extra fibre properties and enhanced waters. Finally, meat, fish and eggs are mainly fortified with omega 3 and fish oil supplements (Leatherhead Food International 2006).

Table 11: Examples of Functional Foods in the US

FUNCTIONAL FOOD AREA	FUNCTIONAL FOOD PRODUCT	COMPANY	BRANDS
Dairy Products	Probiotic yoghurt/kefir	Dannon (Stonyfield Farms)	DanActive (marketed as Actimel outside the US); Activia; YoBaby; All Natural Fruit Blends; YoSelf
		CoolBrands Internationals	Breyers Light! Probiotics Plus Yoghurt
		Lifeway Foods	Lifeway Organic ProBugs Milk Drinks
	Cholesterol-lowering yoghurt	General Mills	Yoplait Healthy Heart
		Dannon	Light'n Fit with Fiber
	Active health drinks	Dannon	Actimel
	Fortified milk	Deans; Borden Dairy Farmers; Mayfield Farms; Kemps; Suiza	None are major, market shares distributed among these.
Bakery Products	Wholegrain (heart healthy) and fortified breads	Sara Lee	Heart healthy Plus; Soft & Smooth
	Breads with omega 3 fatty acids	Wegmans Food Markets; The Baker	None are major, market shares distributed among these.
		Arnold Foods	Arnold Smart & Healthy
	High Fibre Cookies	RD Foods	Right Direction Cookies
		Quaker	Quaker Breakfast Cookies
		Nabisco	Wholegrain Chips Ahoy!, Wheat Thins and Fig Newtons
Cereal Products	Heart health cereals	Quaker	Take Heart Instant Oatmeal
		General Mills	Cheerios; All Big G brands
		Kraft's Post	Grape Nuts; Raisin Bran; Shredded Wheat; Toasties; Bran Flakes
		Kellogg	Smart Start brands; Heart to Heart (under Kashi, Kellogg subsidiary)
	Calcium fortified cereal bars	Quaker	Chewy
		Kellogg	Cereal and Milk Bars
	High fibre cereal bars	Kellogg	All Bran
	Heart Healthy cereal bars	Nature Valley	Health Heart

	Wholegrain pasta	Barilla	Barilla Plus	
		Kraft	Supermac & Cheese Pasta and Sauce	
Soya Products	Soya Milk	White Wave	Silk	
		Odwalla	Odwalla soymilk	
Beverages	Fruit juices and juice blends	Tropicana (PepsiCo)	Pure Premium Orange Juice with Calcium and Extra Fiber; Pure Premium Essentials (Immunity Defence, Healthy Heart, Healthy Kids, Light & Healthy)	
		Minute Maid (Coca-Cola)	Heartwise; Minute Maid Extra	
		Ocean Spray	Cranberry Juice Cocktails	
		POM Wonderful	POM Wonderful	
	Enhanced waters	Gatorade (PepsiCo)	Propel Fitness Water	
		Energy Brands	Glaceau VitaminWater	
		PepsiCo	Aquafina flavoured water; SoBe Life Water	
		Coca-Cola	Dasani	
	Meat, Fish and Eggs	Canned fish with omega-3	Star Kist	None are major, market shares distributed among these.
			Chicken of the Sea	
Fish oil supplements		Bumble Bee and Leiner Health		
Omega-3 DHA enriched eggs		Gold Circle Farms		
		Eggland's Best		

Sources: Leatherhead Food International (2006, p. 135-153), Klimas et al (2008)

Natural health products contributed about 26.4% to the total US health food industry sales in 2006 (Nutrition Business Journal 2007a, Klimas et al 2008). The most common supplements in the US ranked by consumer sales in 2006 included: multivitamins, meal replacements, sports nutrition, calcium, B vitamins, vitamin C, glucosamine/chondroitin, homeopathics, vitamins D & H, others, and fish/animal oil (Nutrition Business Journal 2007a, Klimas et al 2008).

The US market for functional food is mostly domestically driven (Mintel 2006). Thus, most of the functional food products are domestically produced and consumed in the US with a small proportion of the total US production exported. Aside from the sheer size of the US domestic market, one reason for this situation may be the global non-uniformity of health claims (Mintel 2006). Thus, most countries are able to export their products to the United States due to the many health claims permitted, but the United States is not able to access the international

market due to more stringent health claim regulations (Mintel 2006). The rapid development of the US functional food market has been associated with the approval of health claims by the Food and Drug Administration (FDA). The FDA has sixteen approved health claims and over twenty qualified health claims (Food and Drug Administration 2009b).

US functional food manufacturers are heavily engaged in research and development (Price Waterhouse Coopers 2009). Examples of current areas of research include technologies that lead to the development of more stable functional food formulations; technologies that improve the taste and smell of the products; technologies that remove grainy textures of fibres added to beverages; inclusion of probiotics in beverages and baked goods; and healthy oils in dairy products (Price Waterhouse Coopers 2009). Finally, it is estimated that US-based researchers accounted for 24% of the total global functional food-related publications in 2006 (Stein and Rodriguez-Cerezo 2008).

The patenting of functional food in the US has been on the rise. The increasing rate of patenting of products is driven by the regulatory approval of many health claims (Klimas et al 2008). The US had over 28% of the global patent applications or pending patents between 1994 and 2001 (Stein and Rodriguez-Cerezo 2008). However, patenting has mainly been in the areas of extracting and purification, as compared to end-products (Lloyd and Leber 2008). 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 (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” on the product before it can be patented with the Canadian Intellectual Property Office (CIPO 2010).

In summary, the functional food and NHP industry in the United States has been growing for reasons similar to those in Canada, but is also driven by a looser regulatory structure for approval of health claims, and the US is set to become the largest market for functional food and beverages in the near future. Product price and the credibility of health claims associated with the products appear to be the primary deterrents to functional food purchases (Mintel 2006). Consumer acceptance of functional food and NHPs is examined in section 4 of this report.

3.3 Europe

While estimates vary, Europe remains one of the dominant functional food markets globally, alongside Japan and the United States. The European market was estimated to be approximately US\$ 8 billion in 2006, and is expected to account for 10% of the food and drink market with a five year forecast of 4.9% growth (New Zealand Trade & Enterprise 2007), a growth rate that was likely tempered somewhat by the financial crisis of 2008 and subsequent recession. The market for NHPs/supplements was estimated at 5 billion EUROS (US \$6 billion) in 2005 (European Commission (EC) 2008).

The European functional food market is very much concentrated in northern Europe, with the United Kingdom leading in terms of per capita consumption/spending and absolute levels (Table 12). In 2006, the UK value for functional food was estimated to be \$1998 million (US), with a per capita spending on functional food equal to \$33. In 2006, the UK and Germany represented almost half of the total European functional food markets (New Zealand Trade & Enterprise 2007). Between 2001 and 2006, the EU market grew by 36%, while Italy and Sweden had the highest growth rate among the country members with 54%, followed by Spain (49%), Germany (38%), the UK (28%) and France (28%). As Table 12 indicates, in 2006 forecasted growth rates for continued expansion of functional food markets were bullish; however, the reality has likely been tempered by the subsequent economic turmoil in Europe.

Table 12: European Functional Foods Market and Trend by Nation

COUNTRY	2001		2006		PER CAPITA (2006)	GROWTH (2001-2006)
	\$M (US)	%	\$M (US)	%	\$	%
UK	1565	26.7	1998	24.9	33.0	+28
GERMANY	1375	23.4	1890	23.6	23.0	+38
ITALY	677	11.5	1042	13.0	18.0	+54
FRANCE	599	10.2	764	9.5	12.7	+28
SPAIN	401	6.8	598	7.5	15.0	+49
NETHERLANDS	216	3.7	272	3.4	17.0	+26
SWEDEN	140	2.4	215	2.7	23.9	+54
REST OF EUROPE	893	15.2	1235	15.4	NA	+10
EUROPE	5865	NA	8013	NA	NA	+36

(Source: New Zealand Trade and Enterprise 2007)

An estimated 168 companies market at least one functional food in the EU, however, the European functional food industry is dominated by a relatively small number of large multinational companies (New Zealand Trade & Enterprise 2007). Examples include: PepsiCo, GSK, Danone, Nestle, and Unilever (Table 13). The market for functional food in Europe is dominated by soft drinks (energy drinks, juices, enriched milk).

Table 13: Major Players in the European Functional Food Market

COMPANY	PRODUCT(S)
PEPSICO	Quaker Oats, Gatorade, Tropicana
GSK	Lucozade, Ribena
DANONE	Actimel, Activa, Essensis, Senja
NESTLE	Calcium Milk, beta glucans
UNILEVER	Slim Fast,
MULLER	Vitality prebiotics and probiotics yoghurt
YAKULT	Lactobacillus based drinking yoghurt
INNOCENT	Fruit Smoothie
EBRO PULEVA/PULEVA BIOTECH	Omega-3 enriched milk, Euploy-3

Source: New Zealand Trade & Enterprise, 2007

The primary distribution channel for functional foods is food retail outlets, while for NHPs it is health food stores. However, food service outlets are growing in importance as a distribution channel for healthy food options and are beginning to include functional food ingredients on their menus, although functional claims are not yet permitted (New Zealand Trade & Enterprise 2007). The EU Commission is currently in the process of evaluating health claims submitted to the European Food Safety Authority

A previous study identified 385 functional food products in the European market in 2004, containing 503 different ingredients, the most common of which were probiotics, prebiotics and plant extracts (Table 14). Almost 30% of the functional foods contained more than one functional ingredient. Bacteria cultures, which are primarily probiotics, were used in about 45% of all functional food products. Saccharides (mostly prebiotics) were the next most commonly

used ingredient in the European market in about 20% of all products, followed by plant extracts, Terpenes, Fibres, Phenols, Peptides and lipids (Stein and Rodriguez-Cerezo 2008)

Table 14: Functional Products on the European Market in 2004, by Ingredients

Ingredient type	Number of Products	% of all Products
Bacteria cultures (mostly probiotics)	173	44.9
Saccharides (mostly prebiotics)	78	20.3
Plant extracts	53	13.8
Terpenes	41	10.6
Fibres	35	9.1
Phenols	33	8.6
Peptides	30	7.8
Lipids	23	6.0
Miscellaneous	37	9.6
Total	503	130.6 ¹

(Source: Stein and Rodríguez-Cerezo 2008, p. 18)

Footnote: 1. Total greater than 100 percent due to products that contain two or more bioactive ingredients being listed under each ingredient type.

The EU is one of the largest importers of crude medicinal plants (e.g. Lavender *lavandula* spp.; Opium Poppy *Papaver somniferum*; Caraway *Carum carvi*; and Fennel *foeniculum vulgare*), with imports of medicinal plants estimated at 100,000 tonnes and valued at US \$250 million in 2000 (Commonwealth Secretariat 2001). The leading exporters of medicinal plants to the EU are China, India, Singapore, Chile and the United States (Commonwealth Secretariat 2001, Lange 1998).

The European Union supports research and development in the functional food industry, often through fairly large co-operative research projects, for example, Co-operative Research (CRAFT) and Collective Research for small and medium sized firms, Specific Support Actions like the Functional Food Net (FFNet), and Specific Targeted Research Projects (STREPs). Calls for functional food research proposals in the European Union are made occasionally (FunctionalfoodNet-EU 2010). Other private and academic entities are also engaged in functional food research, including The Institute of Food Research (IFR) at Norwich Research Park, the Unilever Health Institute in Vlaardingen and Leatherhead Food International in the United Kingdom (Stein and Rodriguez-Cerezo 2008).

In the EU, research output on functional foods (as measured by academic publications and patents) has been larger than that of big markets like the US and Japan (Stein and Rodriguez-Cerezo 2008). For example, 1.5 times more related academic publications on functional foods

emanated from the EU than from the US between 1994 and 2003, including 387 functional food related publications from the EU or 39% of the total global functional food related publications in 2006 (Stein and Rodriguez-Cerezo 2008). EU funding for functional food research is 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 totally around 73 million Euros (Stein and Rodriguez-Cerezo 2008).

As might be expected with a rapidly evolving sector using new materials and new methods, patenting activity for functional foods is more dynamic than is the case generally in the EU food sector (Stein and Rodriguez-Cerezo 2008). Research activities are evident in the number of innovations and new products that are introduced into the market. The number of European functional food patent applications or pending patents grew from 3.2% to approximately 7.7% of the total food sector applications between 1994 and 2001. Total food sector patent applications or pending patents grew from 500 in 1994 to 1,200 in 2001. Between these same periods, there were 554 patents within the EU and over 41% of the global patent applications (pending patents) on functional food (Stein and Rodriguez-Cerezo 2008).

In summary, as has been the case in Canada and the US, the functional food and NHPs sector in the EU has experienced considerable growth in terms of firms, sales, and new product development, with early growth concentrated in the markets of northern European countries. While the economic downturn following 2008 has likely slowed market growth, investment in R&D has continued and Europe looks set to remain an important source of new product development, as well as an important market for functional food and NHPs.

3.4 Japan

Japan was the first country to introduce government approved health claims for functional foods. Various estimates place Japan as among the top three largest markets for functional food and NHPs, with an estimated value of US\$16.4 billion in 2007 (Datamonitor, 2008). It is estimated that the functional food sub-sector had a market value of US\$ 6.5 billion in 2007 (Bailey 2008). It was anticipated that the health food industry would grow by a further 5.9% over the 2007-2012 period, although data are not currently available to confirm whether this prediction proved accurate in light of the global economic slowdown. Similar factors

account for the growth of the functional food and NHP industry in Japan as in other countries, including increases in incomes, increased consumer awareness of the correlation between food and health in an aging society, and a rise in lifestyle related diseases (Heasman 2004, Groote 2002, Nutrition Business Journal 2007a).

Health foods in Japan are classified into four different categories (Table 15). There is “Food for Special Use” (FOSHU)⁴ which include foods with specified health benefits for which health claims can be labelled. The FOSHU terminology applies to both functional foods and NHPs. “Food with Nutrient Functional Claims” (FNFC) are restricted to approved vitamins, minerals, and nutrients which do not require pre-market approval. The FNFC health food classification equates to nutraceuticals/NHPs in Canada. The final two categories are “medical drugs” and all other foods or, general foods. Medical drugs require prior approval and the general food category includes nutritional supplements (New Zealand Trade & Enterprise 2009).

Table 15: Classification of Health Foods in Japan

FOSHU (Food for Special Health Use)	FNFC (Food with Nutrient Functional Claims)	All other Foods	Medical Drugs
Requires prior approval. Foods that can expect some specified health benefit and may label the claim	Approval not required but restricted to approved vitamins & minerals	Includes nutritional supplements (General foods category)	Requires prior approval

Source: New Zealand Trade & Enterprise (April 2009)

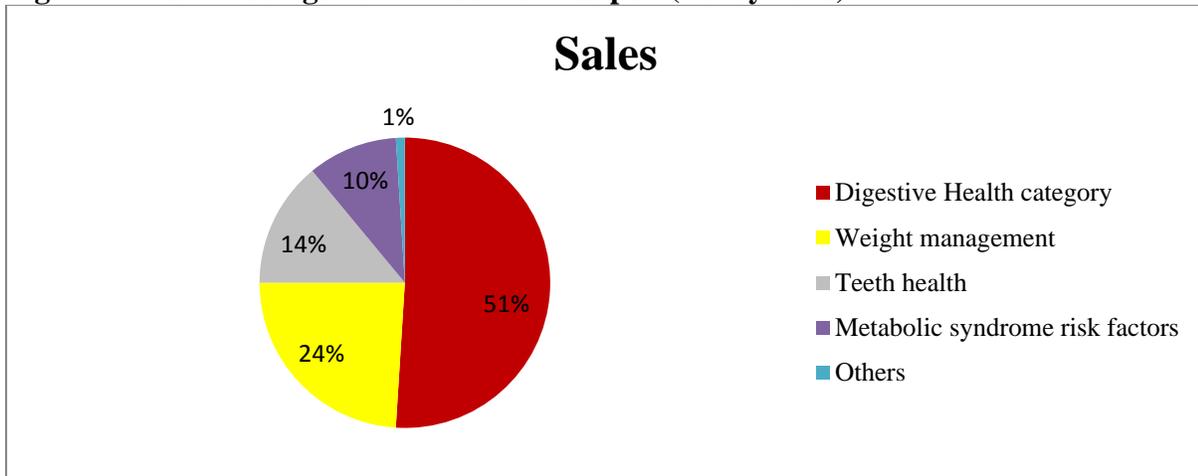
There were about 755 FOSHU approved products in 2007 with an estimated retail value of US\$ 6.5 billion. FOSHU products can either take the form of capsules, tablets or conventional food, however, the majority are in the form of conventional food (Ohama et al 2006). Targeted health categories include digestive health, weight management, dental (teeth) health and metabolic syndrome risk factors. The most commonly used ingredient in FOSHU products is dietary fibre followed by probiotics (Yamaguchi & Associates, 2004). Currently, the ingredients gaining popularity in Japan include soy peptides, green tea catechin and gamma amino butyric acid (Leatherhead Food International 2006). Flax seed oil and processed seed fraction products

⁴ See Section 2 on the definitions of functional foods and NHPs for a detailed discussion on FOSHU: Regular FOSHU; Qualified FOSHU; Standardized FOSHU

are also gaining popularity in the Japanese market, representing a potential opportunity for the Canadian flax seed industry.

Functional foods (FOSHU) in Japan are mainly produced to help in the control and reduction of disease in certain health categories (Figure 2). A greater percentage, 51%, of FOSHU products are mainly for the control and reduction of digestive system health, with 24% of FOSHU products for weight management, while teeth health control and management account for about 14%. This stands in contrast to the emphasis in other markets on products addressing cardiovascular health.

Figure 2: Health Categories of FOSHU in Japan (Bailey 2008)



Functional ingredients used in FOSHU production vary according to the function of the product (Table 16). By 2006 there were about 254 approved products addressing gastrointestinal health. Principal ingredients used in these products include oligosaccharides, lactobacillus, bifidobacterium, psyllium husk, indigestible dextrin and partially hydrolyzed guar gum. Moreover, by 2006 there were approximately 117 high cholesterol/triglyceride and body fat FOSHU products approved in Japan, with the major ingredients including soy protein, low molecular sodium alginate, peptides, plant sterol/stanol and degradation products of globin products. Table 16 provides additional information on the number of approved products by category and key ingredients.

Table 16: FOSHU Functions and Functional Components

FOSHU FUNCTION	NUMBER OF PRODUCTS APPROVED	PRINCIPAL FUNCTIONAL INGREDIENTS
Gastrointestinal health	254	Oligosaccharides, Lactobacillus, Bifidobacterium, Psyllium husk, indigestible dextrin, wheat bran, low molecular sodium alginate, partially hydrolyzed guar gum
High Cholesterol/triglyceride level and body fat	117	Soy protein, Chitosan, low molecular sodium alginate, peptides, diacylglycerol, plant sterol/stanol (esters), green tea catechin, middle chain fatty, Psyllium husk, degradation products of globin protein
High blood glucose	71	Indigestible dextrin, L-arabinose, h-wheat albumin
High blood pressure	64	Gamma amino butyric acid (GABA), Peptides
Dental Health	34	Xylitol, polyols, tea Polyphenols, Casein Phosphopeptide and Amorphous Calcium Phosphate (CPP-ACP)
Bone health	26	Soy isoplavone
Anemia	3	Heme iron

Source: Ohama et al 2006

The large number of companies in Japan makes it difficult to clearly identify the major players in the industry. Many of the products in the Japanese market are local brands with a few foreign brands sold under license. Distribution channels in the Japanese market include drug stores (17%) and health food stores (9%), however, it is reported that direct sales (network/multi-level marketing, mail order and internet channels) account for by far the largest sales channel, accounting for approximately 74% of sales (New Zealand Trade & Enterprise April 2009).

Japan has become a hub in the market for functional foods and NHPs. As one of the biggest global markets for these products, Japan relies on international trade to sustain its functional food and NHPs sector. Most of the ingredients used in these products are sourced from the international market and Japan also exports functional foods and NHPs to other countries. An area of importance to the Japanese market is flax seed oil and processed seed products like canola seed; these are used as ingredients for most of the health foods in Japan.

Canada is one of the main exporters of flax seed and canola seed to Japan (Bailey 2007b, AAFC 2009).

The Japanese government, in collaboration with private firms, conducts research and development of new technologies for functional food and NHPs. Between 1990 and 2002, the Japanese Ministry of Agriculture, Forestry and Fisheries (MAFF) provided approximately C\$403,000 to cost-share programs for the industry (Klimas et al 2008). The program was for the development of new technologies for functional food component isolation and purification. The Ministry of Health, Labour and Welfare also provided financial support to functional food related research (Klimas et al 2008). Moreover, there are non-profit organizations like the Japan Functional Food Research Association (JAFRA) which also embarks on research into functional food. A recent study by Bailey 2007a suggests that many food and beverage firms in Japan have been developing new functional food and NHPs or ingredients used in the production of functional food and NHPs. Finally, in terms of research output, Japan had 42 functional food related publications or, 4% of the total global functional food related publications in 2006 (Stein and Rodriguez-Cerezo 2008). As in other countries, the time and costs involved in obtaining regulatory approvals for new products have been identified as the primary challenges to commercializing R&D in the sector (Bailey, 2007b).

Food in Japan is regulated by a number of laws, including: the Food Safety Basic Law, the Food Sanitation Law, the Abattoir Law, the Poultry Slaughtering Business Control and Poultry Inspection Law, and other related laws (MHLW 2010). The patent law in Japan is based on the “first principle” as in Canada and US. This principle implies that the first person to file the application for a patent for an invention gets the registered patent irrespective of the number of applicants (JPO 2010). Japan had over 22% of the global patent applications or pending patents between 1994 and 2001, with a higher number of patents filed for dairy-based functional foods compared to other functional foods (Stein and Rodriguez-Cerezo 2008; Trueman 2009). Japan’s patent office has more applications for functional food than any other jurisdiction. Between 2001 and 2009, it received approximately 1000 applications (Trueman 2009). The greater number of patent filings/applications has been attributed to the fact that:

“Japanese patents often do not have as many claims as do US patents, which can claim process and formulation within the same patent. Therefore, it may take two or more Japanese applications to cover the same invention claimed in a single US patent. Also, the Japanese filings represented are unexamined applications,

whereas the World patent applications are examined; although, if any of the claims are rejected, that doesn't necessarily preclude the application from being published. PCT applications, as well as European and US applications, are published approximately 18 months after the priority date. This lag would result in the smaller numbers of patents filed with these offices in comparison to the unexamined Japanese abstracts" (Trueman 2009, Page 1-2).

Recent global environmental awareness has had an effect on the industry in Japan, with manufacturers investing in technologies that will reduce emissions and developing environmentally friendly products. Thus, FOSHU companies in Japan invest significantly in their corporate social responsibilities to maintain their credibility. Yakult, a major player in the functional food and NHP industry, established an environmental protection program in 1997 which focused on minimizing energy consumption and waste. Suppliers of functional food and NHP ingredients were selected based on their environmental friendliness (Yakult Annual Report 2007). Nippon-Shinyaku, another major player in the functional food and NHP industry, was IOS14001 (environmental management standard) accredited for its production environmental management systems in 2004 (Nippon-Shinyaku Annual Report 2007).

In summary, Japan represents a significant portion of the global functional food and NHPs industry, with an estimated market value of US\$ 16.4 billion in 2007. Digestive health represents a major category in the Japanese market, with the sector fairly heavily dependent on imported ingredients. The growth potential in the Japanese market is an opportunity for countries like Canada, United States and EU to gain market shares in terms of the provision of ingredients needed for the development of functional food and NHPs in Japan.

The number of approved products and the interest of the government in research and development is an indication of continuous growth in the sector, as is a high degree of patent application activity (Bailey 2007a). There is a lot of collaboration between private firms and government in terms of R&D into new technologies for functional food and NHP development (Klimas et al 2008). In addition there is financial support from the government to support research in the industry; however, R&D is still impeded by financial constraints on the part of firms (Bailey 2007b, Klimas et al 2008).

Section 3 has proved a detailed overview of key industry and market trends in Canada and the three major global markets for functional food and NHPs: the US, Europe and Japan. It is clear from this overview that the sector is becoming increasingly diverse in terms of products,

applications and ingredients. This growth has stimulated an evolving body of research addressing consumer awareness and acceptance of these products, market and regulatory analysis which is the topic of the next section of this report.

4. INSIGHTS FROM THE LITERATURE

The importance of functional food and NHPs has resulted in numerous studies on different aspects of the sector. This section gathers together a comprehensive overview of literature across four broad areas: consumer awareness, acceptance and willingness to pay studies; industry and market analysis studies; product specific studies; and finally studies on regulatory frameworks and policies.

4.1. Consumer Awareness, Acceptance and Willingness to Pay

Since the advent of functional foods, a great deal of research has emerged on consumer awareness and responses. Consumer expectations have been evolving with time and an awareness of the direction of consumer preferences informs stakeholders engaged in research into new healthy ingredients and product development activities. The consumer-related literature on functional food and NHPs has focused on consumer awareness, acceptance and willingness to pay. A selection of studies is presented below and summarized in Table 17.

West et al (2002) assessed Canadian consumers' valuations of functional properties of food focusing on preferences for organic and GM foods with functional properties in relation to conventional foods. Descriptions of tomato sauce with 'anti-cancer' properties, 'heart-healthy' potato chips and 'heart-healthy' chicken breast were incorporated into a stated choice experiment administered via telephone survey to 1008 Canadian household food shoppers. The study found that Canadian consumers generally have a positive attitude towards functional foods and were willing to pay a premium especially when the functional property was added to foods derived from plants (but less receptive in the case of meat). Use of vitamins or herbal supplements was commonplace and Canadians viewed positively the potential illness prevention role of food. However, there is the need for credible information about the safety and benefits of these products from reliable sources outside the food industry, and to that end, government experts and health care experts were identified as the preferred information sources. The study concludes

that, although the probability of purchasing both GM and organic products increases with the addition of a functional attribute, the gain is small such that the market for conventional food is not likely to be significantly affected if current tastes and attitudes remain constant (West et al., 2002). :

Using the same set of respondents, West and Larue (2004) also identify the factors that influence consumers' desire to be among the first to try innovative functional foods. Using an ordered probit estimation technique the researchers show that consumers who strongly believe in the link between food and health, and who already believe in the current nutritional content claims on food, are among the first to try new functional foods. Older consumers and consumers with negative attitudes toward GM foods were not interested in being among the first to try new functional foods. Demographically, the study showed that men, metropolitan consumers, consumers with children present in the household, and consumers residing in Quebec are the most willing to be innovative in the nutritionally enhanced-food market. Women were seen to be hesitant when faced with novel foods. Finally, the study also showed that consumers of all ages will accept these products if there is continuous assurance that the diet-related health claims are not bogus or in any way compromised. The study examined implications for both public and private sector efforts to provide information to consumers, arguing that there is a role for government regulations to reassure consumers that health claims are not bogus but scientifically proven. It was recommended that producers exhibit caution in the development and marketing process because consumer confidence can easily be undermined with claims that lack sufficient scientific evidence.

In another Canadian study, Peng et al (2006) examined consumer attitudes toward and acceptance of (hypothetical) dairy products enriched with CLA. Using data from a telephone survey of 803 consumers, a maximum likelihood ordered probit model was used to estimate the probability of purchasing CLA-enriched milk products. Belief in the healthiness of conventional milk was found to be the main determinant of the acceptance of CLA-enriched dairy products in Canada. The authors argued that the target consumer segment for this product should be health conscious, middle-aged consumers who believe in the healthiness of conventional milk products. The analysis also suggests that interest in a product which is perceived by consumers to be less healthy can be increased through the introduction of a functional health claim.

Consumer acceptance was the primary focus of a study by Verbeke (2005) of 215 grocery shoppers in Belgian households. Respondents were personally interviewed at home. The major determinants of consumer acceptance of functional foods were assessed using a multivariate probit model which enabled the researchers to simulate probabilities of events occurring over a range of explanatory variables. Even though socio-demographic factors such as age, income, literacy and location and also attitudinal and cognitive factors such as beliefs and knowledge affect consumers' acceptance of functional foods, the health benefit was the paramount factor in the acceptance of functional foods. Interestingly, Belgian households with higher education levels were less likely to accept functional food, whereas high income households had a positive attitude towards functional food.

The importance of credible health benefits as a determinant of acceptance is similar across the globe and across cultures, as evidenced in Bech-Larson and Grunert (2003). The effect of cultural values on the demand for functional foods was explored using a sample of American, Danish and Finnish consumers. Specifically, the study assessed the extent to which consumers' perception of food healthiness depends on different types of health claims, functional enrichments, base-products and processing methods (functional or genetically modified). The primary grocery shoppers in five hundred randomly selected households in each country were surveyed using conjoint analysis. The researchers determined that a consumer's perception of functional food is dependent on the healthiness of the base product to a greater extent than the health claim or functional properties. Functional and novel foods with base products that have already been accepted by consumers for their nutritional content or healthiness are most likely to be accepted and stimulate a higher willingness to pay. This perception was consistent across the three cultures; indeed the three sample populations showed only minor differences with respect to the perceived healthiness of functional food. Some cultural differences, however, were apparent: Finnish respondents were generally more positive towards functional food than the Americans and the Danes, while Danish and Finnish consumers had a more negative attitude towards genetically modified products relative to the American consumers. Bech and Grunert (2003) recommended that further studies focus on cross-cultural segments among consumers rather than on the identification of international differences.

Staying in Scandinavia, Urala and Lahteenmaki (2004) examined Finnish consumers' attitudes towards functional foods and factors that predict willingness to use functional foods.

Survey data from 1158 respondents were used to examine a number of factors affecting consumer attitudes towards functional food, including: perceived reward from using functional foods; confidence in functional foods; necessity for functional foods; functional foods as medicines; absence of nutritional risks in functional foods; functional foods as part of a healthy diet; and the health effects of functional foods Vs. their taste. Factor analysis was used to group the attitude statements. Consistent with other studies, the reward (health benefits) associated with consumption of functional food is a major determinant of willingness to pay. The reward from consumption also overshadows the perceived risks associated with consumption. Contrary to the findings of Tuorilla and Cardello (2002) and Verbeke (2006) (discussed below), the study asserted that consumers will compromise on taste if there is a clear promise of lowering the risk of commonly recognized diseases like cardiovascular disease.

Information features prominently in many studies of consumer attitudes toward functional food, with clear and credible messages about health benefits deemed a prerequisite for consumer acceptance. In an Australian study, Cox et al (2004) examine the specific characteristics of messages about functional food and supplements aimed at preventing memory loss that would motivate consumers to buy these products. A survey was administered to 290 consumers between the ages of 40 and 60 years describing a range of products including, natural functional foods, sweetened functional foods, GM functional foods and supplements. An adaptation of Protection Motivation Theory formed the theoretical basis to the analysis. The authors concluded that respondents made no clear distinction between functional foods and supplements, and again consistent with studies in other countries, the health benefit was the major predictor of consumer intentions to purchase these products. However, improving health benefits by genetic modification was not acceptable to most respondents and women had a less favourable attitude towards genetic modifications. Respondents were cautious about attempts to improve the palatability of functional foods, “Even though there was no actual tasting in the study, sweetening functional foods to offset bitterness was not acceptable” (Cox et al 2004, p. 63).

While the majority of studies have focused on attitudes toward functional food, in 2005 a random telephone survey of over 2000 Canadians was conducted for Health Canada to determine awareness, attitudes and consumption behaviours with respect to NHPs [Health Canada (Ipsos-Reid 2005)]. The results of the national survey showed low levels of familiarity with NHPs but a

cautious willingness to use them, for example, more Canadians were unfamiliar (45%) than familiar (36%) with NHPs, with more women unfamiliar (41%) relative to men (30%). Nevertheless, a very slight majority of respondents (52%) indicated a willingness to use NHPs including nutraceuticals to control or influence their personal health, with 20% of the respondents having used NHPs due to a recommendation from a friend or a health professional. Only 29% of the respondents were of the belief that NHPs were safer than conventional medication.

The primary reason for non-use of NHPs was lack of information. The key recommendations emerging from the study pertained to education and the regulatory environment. For example the study recommended that the government focus on the dissemination of NHP information to educate Canadians about choosing NHPs to manage their health, as well as informing the public about the role of NHPs regulations in safeguarding consumers.

NHPs (nutraceuticals) also featured in a Canadian study by Hailu et al (2009). Using a mall intercept survey of over 200 Canadian consumers, the researchers examine consumers' preferences for probiotics using conjoint analysis. Mode of delivery or carrier of the functional ingredient (pill Vs food) was a primary focus of the study. Probiotic products were described in terms of four attributes: mode of delivery, the existence of a health claim, health claim source, and cost. Cluster analysis was used to segment the sample into distinct groups linking consumer characteristics to their preferences for product attributes. The sample was segmented based on attitudes toward the mode of delivery or carriers of the functional food ingredient since this was the most important attribute across the sample. Three segments were identified: "the pill lovers", "Yoghurt lovers" and "the pill loathers". In a common theme across many of these studies, credible health claims is a major determinant of consumers' acceptance of these products. Hailu et al (2008) suggest that consumers prefer claims verified by government over those from manufacturers. However, the three segments differ significantly in the value they place on this health claim source. The value placed on the health claim source is the strongest for "Pill lovers" and weakest for "Pill loathers". Moreover, the study also supported the findings of other studies that the base products of functional ingredients play an important role in consumers' valuation of functional food. It was recommended that future research take into

account the potential substitution effects between functional foods and nutraceuticals (NHPs) with attention to specific product or specific health benefits.

In another Canadian study focused on NHPs, Henson et al (2010) investigated consumers' willingness to purchase food and/or non-prescriptive pills that contain phytosterols as a means to reduce the risk of cardiovascular disease (CVD). The study was based on a mall intercept survey involving 446 respondents which approximately represented the Canadian population demographically. The products used in the survey included: a non-prescriptive pill containing phytosterols; margarine containing phytosterols; low-fat milk containing phytosterols; and bread containing phytosterols. The study used a model which was an adaptation of Protection Motivation Theory (PMT), which the authors describe as "a social recognition model rooted in research on fear appeal in determining health-protective behavior" (Henson et al 2010, p.29). The study focused on the tendency of consumers to behave (consume food and/or pills) in a way that was aimed at reducing blood cholesterol which is an important risk factor for CVD.

Determinants of purchase intentions were broadly grouped into "response efficacy" and "self-efficacy". Response efficacy refers to the effectiveness of the product, or if consumers believe the efficacy of the product. Self-efficacy refers to the ability to consume the products in the prescribed manner. Thus, consumers are more likely to use these products if they believe that these products work, as well as if consumers are able to use the products in the prescribed manner. Perhaps surprisingly it was shown that personal fear of CVD does not appear to significantly affect consumers' purchasing intentions. Thus, consumers with a low fear of developing CVD are as likely to signal a willingness to use products containing phytosterols as consumers with high levels of fear. Furthermore, the study suggests that biomarkers, such as blood cholesterol tests that give an indicator of the risk of CVD, do not significantly affect consumers' willingness to purchase food and/or non-prescriptive pills that contain phytosterols. Hence, the results raise doubts about the effect of biomarkers on consumer food purchasing behaviour.

The study concluded that functional foods and nutraceuticals should be promoted as part of strategies to reduce the incidence of CVD. In addition, communication efforts should focus on the efficacy of the products and on the ease with which the product can be used. Moreover, the authors recommend that communication should focus on the general population with little attention to the high risk segment. Finally, the form and type of products also deserve attention

because “consumers must be presented with these ingredients in a manner that they perceive to be easy to use, such that the desired level of the functional ingredient is delivered” (Henson et al 2010, p. 35).

More generally, health benefits communicated through credible health claims has been found by numerous studies across numerous countries to be the driving force behind consumer acceptance of functional foods In the United States. Teratanavat and Hooker (2006) sampled over 3000 Ohioan consumers to determine consumer valuation and preference heterogeneity for novel functional food attributes. The effect on consumer preferences of four variables was examined: health benefits, organic ingredients, source of nutrients, and price. Using a discreet choice experiment, willingness to pay for the health attributes of functional foods was derived. Sources of heterogeneity in consumer responses were previous purchase experience with healthy foods and organic foods. For example, consumers who regularly purchase functional foods, organic foods, and food with natural ingredients tended to react more positively to novel functional foods. Maintenance of good health and disease prevention were strong motivators for openness toward functional and novel foods with health claims.

In another US study, Markosyan et al (2009) measure consumers’ responses to a specific functional food (apples with enriched antioxidant coatings). Antioxidants may protect cells from damage from free radicals which are believed to lead to cancer. A contingent valuation (CV) survey instrument was administered in face-to-face interviews with 730 US consumers. A dichotomous choice model was used to elicit individual willingness to pay estimates in response to market-type questions. The results indicated that consumers value and are willing to pay for the health attributes of functional foods. Consumers were responsive towards health claims, underlining the importance of credible information dissemination. Anxiety over the utilization of a new technology that was considered unnatural and risky was the primary reason for rejection by some respondents of apples with enriched antioxidant coatings.

While health benefits are clearly the dominant motivator for consumer interest in functional food, other factors have also been found to affect consumer acceptance. In another Belgian study, Verbeke (2006) investigated consumers’ willingness to compromise on taste for health benefits in the case of functional food. Using two surveys conducted in 2001 (255 respondents) and in 2004 (205 respondents), Verbeke (2006) determined that Belgian consumers had developed a somewhat critical attitude towards functional foods. This attitude was evident in

their unwillingness to compromise on taste for health. Specifically, the results showed that the gap between willingness to accept functional foods that taste good and those with a poorer taste relative to conventional food widened across the intervening years between the surveys. Perhaps unsurprisingly, taste is seen as a precondition for the acceptance of functional food. Given that the study was not product specific, the authors recommended further research focusing on specific functional foods rather than functional food as an abstract category.

The extent to which consumers are willing to compromise on taste in exchange for a health benefit was also examined by Tuorila and Cardello (2002), but using real products rather than a hypothetical survey instrument. Fruit juice was chosen as the product of interest based on the expectation that consumers perceive juice to have healthy attributes, as well as the ease with which fruit juice can be adulterated. Seventy eight civilian employees of the US army tasted different formulations of fruit juice with functional attributes. Analysis of variance was used to assess the ratings of liking. The results indicated that the presence of off-flavours in a functional food has a negative effect on the likelihood of consumption regardless of the type of health benefit the product offers. The study also showed that consumer acceptance of functional food based on health benefits depends upon the specific expected health benefit. The study found “physical and cognitive (mental) performance improvement as more likely to motivate consumer acceptance of the product than emotional well-being” (Tuorila and Cardello 2002, p. 567). The study recommended further research on actual consumer usage of functional foods within the context of taste variations and on the benefits of labelling claims to clarify the factors determining consumers’ long term choices.

In an exploratory study to determine the factors that influence the acceptance of functional food as well as to determine the variation in acceptance across cultures, Labrecque et al (2006), sampled and interviewed students from France (170 respondents), the US (161 respondents) and Canada (Quebec) (280 respondents) using a self- administered questionnaire. All respondents were students. Multiple linear regression analysis was used to assess the effect on attitudes toward functional foods of beliefs about health benefits, knowledge, information credibility, and gender. The researchers determined that there was very little difference between Canadian and American consumer attitudes towards functional food. The major determinants of acceptance were health and product related benefits, credible information, and knowledge about the products. The results also indicate that the promotion of other product benefits in addition to

health attributes (such as high quality) will be important to market development. Finally, the study also showed that the French respondents had less knowledge of the term functional food relative to respondents in Canada or the US. The French students reported a less favourable attitude towards functional food than the French Canadian and US students, however, the attitude differences were very small. Hence, the authors conclude that market development should be approached from a global perspective.

In a UK study examining consumers' willingness to pay for enhanced foods, Arnoult et al (2007) conducted face-to-face interviews with 200 consumers. Attitudes toward a number of products were examined, including strawberries and lettuce with higher antioxidant levels, and lamb chops with higher levels of unsaturated fatty acids. The results indicate a viable market for functional foods, balanced with a strong polarization of opinion against anything that is perceived to be artificial or genetically modified. Highly skilled professionals in urban areas, women, and smaller households on lower incomes were more likely to be willing to pay for enhanced products. Supplements in the form of pills (akin to NHPs) were most likely to be rejected by women, white collar workers and households with children under 18. However, larger households with higher incomes or higher education levels tended to exhibit a positive willingness to pay for pills. Finally, it was concluded, somewhat surprisingly, that UK consumers tended to have a stronger willingness to pay for enhanced animal than for enhanced plant products.

As is apparent from many of the studies discussed here, consumers are not homogenous in their preferences and distinct consumer segments exist with different preferences. Sometimes these segments are identified by socio-demographic characteristics, as in the UK study discussed above, while other studies also recognize the importance of psychographic or attitudinal factors in segmenting a consumer population. Herath et al (2008a) surveyed over 1700 Canadian consumers to identify consumer segments that lead the consumption of functional food and nutraceuticals. Cluster analysis and analysis of variance (ANOVA) was applied to data capturing attitudes, motivations and knowledge. The researchers found that factors such as age, location, education and income are prominent determinants of functional food and NHPs consumption in Canada. The most receptive groups for functional food and NHPs were the elderly, the less educated and low income households. "These more receptive consumers tend to be more concerned about a wide range of health issues/diseases and indicate greater willingness to learn

about foods with potential health benefits and make more use of arguably more ‘credible’ sources of information (for example health professionals).” (Herath et al 2008a, pp.263-4). However, the less receptive group consisted of the younger population with higher education and incomes who mostly live in the urban areas. “Members of this group tend to be less concerned about a wide range of potential health issues/diseases, perhaps reflecting the fact that they are younger, and also characterized by higher levels of knowledge about certain diseases” (Herath et al 2008a, p.264). However, the receptive consumers were more interested in knowing the health benefits of these products before making a purchase decision.

In a joint study for the European Commission, Stein and Rodriguez-Cerezo (2008) interviewed consumers in Germany (n=116), Poland (n=110), Spain (n=279) and the United Kingdom (n=121). The objective of the study was to determine consumer awareness, attitudes and willingness to pay for functional food. These countries were strategically chosen to represent all market segments in the EU. Germany was chosen as a continental European country due to its size, the competitive nature of its food market and a history of sceptical consumers. Poland was chosen as an eastern European country and to reflect the development of the functional food market in a new Member State. Spain was chosen as a Mediterranean country with a high volume food market. Finally the United Kingdom was chosen as a western European country, with a high profile food retailing industry. Descriptive analysis techniques were used to conclude that the consistent reason for buying functional food was to stay healthy, although the study acknowledges that there is not one unique determinant of consumer acceptance of functional food. Indeed, taste, convenience, a reasonable price, an attractive design and practical packaging were also widely held expectations by consumers. Functional food awareness and understanding among consumers depends on mediated information which hinges on the credibility that consumers attach to this information. However, the authors conclude that the food industry’s communication policy is weak and food retailers appear to have limited knowledge about the functional food products that they sell.

Regional differences are apparent in the reasons for avoiding functional food. In Poland and Spain, the most predominant deterrent to purchasing was the price of functional products, which was less of an issue in Germany or the United Kingdom. The fear of side-effects was more important among Polish consumers than among consumers in the other countries, while for UK and German consumers taste was the primary concern. The authors recommended further

research into functional food as a potential cost-effective means of addressing health problems in Europe.

In a Swiss study, Siegrist et al (2008) examined the factors that influence consumers' willingness to buy functional foods. Using data from a mail survey conducted in the German-speaking part of Switzerland (n=249), the study used regression analysis to test the significance of factors such as physiological benefits, the carrier or base product of the functional food, as well as socioeconomic factors including age and social trust on a consumer's willingness to pay. The results reinforce the findings of other studies that physiological/health benefits are a major determinant of willingness to buy or acceptance of functional food. Consistent with research discussed earlier in this section, the study also shows that the consumer's prior attitude toward the base product was significant in the sense that consumers are more willing to buy functional food that is derived from an already accepted conventional food with a positive health image. Thus, a consumer's perception of functional food is not independent from the base product. Consumers with higher levels of trust in the food industry are more likely to buy functional food compared to those who do not trust the food industry. Finally, older Swiss consumers were more interested in functional foods than younger consumers.

The motivations and cognitive processes of Greek consumers in their purchasing of functional foods were explored by Krystallis et al. (2008). The study aimed to identify the most frequently purchased functional food products, gain insights into consumers' motives for buying functional foods, and to model relevant cognitive structures in consumers' functional food choices, i.e. "the way that functional food consumption-relevant knowledge is stored and organized in consumers' memories" (Krystallis et al 2008, p. 527). Using means-end chain (MEC) analysis, a pilot study with a sample size of 60 consumers was used to develop the means-end chain framework which was subsequently applied in the main study to a sample of 40 consumers. The sampled consumers were homogenous with at least a university education and were grouped into young adults (25-34 years) and an older group (34-44 years). Two functional foods were used in the study: functional juice with enhanced vitamins and a functional spread with reduced cholesterol risk. The young adult group generally preferred the functional food juice, while the older group preferred the functional spread. According to the authors this result indicated the possibility of a fragmented functional food market.

Both groups shared similar preferences with respect to the attributes deemed the most important, including: quality-related (e.g. pure, safe, healthy, and high quality); label information related (e.g. best before and packaging dates, nutritional value, and health/functional claim); price; and brand name. As to the motives for buying functional foods, the young adults tended to be concerned about enhancing their health status through functional foods that improve their physical condition and energy levels, while the older group was concerned about prevention of disease risks. The authors concluded unsurprisingly that the success of functional food depends on how well they satisfy consumer needs, thus in developing functional foods a solid understanding of consumer expectations is critical.

In a Uruguayan study, Ares et al (2010) examined the effect of price, brand and health claim on consumer choice of functional over regular yoghurt using conjoint analysis (n=103). Cluster analysis of the conjoint results enables the authors to identify consumers with similar attitudes, while a multinomial logit model is used to estimate the utilities of each of the identified clusters. All four of the attributes: the type of yoghurt, brand, price, and health claim influenced consumers' yoghurt choices, however, the effect of these attributes depended on consumers' attitudes toward health issues. Adding a functional ingredient like fibre or antioxidants to the product increased the probability of consumers choosing functional yoghurt. Brands were important: consumers were more likely to choose a familiar brand of yoghurt with functional ingredients compared to unfamiliar brands. There were mixed reactions to price: while in general the probability of choosing a certain yoghurt decreased with an increase in the price, the cluster analysis showed that price sensitivity varies across consumers, with some consumers less concerned about price due to their interest in health issues. Finally, health claims on functional yoghurt appeared to have little effect on consumers and was the least important of the four attributes. Consumers exhibited a stated willingness to purchase functional yoghurt over regular yoghurt even in the absence of health claims.

In contrast, health claims were found to have a positive effect on willingness to pay in a survey of French consumers by Marette et al (2010). These researchers also used yoghurt as the base product, enriched with plant sterols for the lowering of cholesterol which could lead to a reduction in the risk of coronary heart disease. Using 107 respondents, some of whom had cholesterol problems whereas some did not, the study combined a survey with a lab experiment to elicit attitudes and purchase intentions. The researchers found that willingness to pay was

increased as a result of information about cholesterol reduction properties of plant sterols. Consumers in both categories (with and without cholesterol problems) indicated a higher willingness to pay for the enriched yoghurt. The study therefore asserts that “positive health information matters for a question like cholesterol” (Marette et al 2010, p. 423). In addition, information about the uncertainty of the functional ingredient and possible side effects from the intake of plant sterols (e.g., low absorption of vitamins A and E) did not significantly reduce consumers’ willingness to pay for the functional yoghurt. Thus, the study concludes that consumers may not focus much on the scientific uncertainties when buying these products, which can lead to the proliferation of products with unsubstantiated claims into the market. The authors argue that the process of approving health claims on food should be stringent to avoid the introduction of products with unsubstantiated health benefits into the market.

4.1.1. Insights from the Consumer Literature: A Summary

To sum up, a great many factors affect consumer attitudes, acceptance and willingness to pay for functional food and NHPs/nutraceuticals, but the most important determinant is the perceived health benefit. Table 17 summarizes the literature presented in this section. A large number of studies concluded that on average, consumers have a positive attitude towards functional food and NHPs for which they are willing to pay a premium (for example, West et al 2002, West and Larue 2004, Teratanavat and Hooker 2006, Stein and Rodriguez-Cerezo 2008, Markosyan et al 2009, Marette et al 2010). The literature showed that consumer responses to functional food and NHPs depend on a variety of factors including: the belief in the correlation between diet and health, or the health benefits derived from consumption of these products⁵; socio-economic factors such as age, location, education and income levels⁶; functional properties in the products⁷; acceptability of the base product⁸; taste of the products⁹; price and potential side

⁵ West and Larue 2004, West et al 2002, Bech-Larson and Grunert 2003, Ipsos-Reid 2005, Verbeke 2005, Labrecque et al 2006, Stein and Rodriguez-Cerezo 2008, Henson et al 2010, Marette et al 2010

⁶ Peng et al 2006, Herath et al 2008, Labrecque et al 2006, Bech-Larson and Grunert 2003.

⁷ Markosyan et al 2009, Teratanavat and Hooker 2006, Cox et al 2004, Arnoult et al 2007, Marette et al 2010, Henson et al 2010, Ares et al 2010.

⁸ Bech-Larson and Grunert 2003, Peng et al 2006, Siegrist et al 2008, Hailu et al 2009

⁹ Tuorila and Cardello 2002, Verbeke 2006, Siegrist et al 2008, Hailu et al 2009, Urala and Lahteenmaki 2004

effects of the products¹⁰; and finally, health claims ascribed to functional foods and NHPs and the credibility of these claims¹¹.

Consumers have become conscious of the correlation between diet and health, and this trend is evident across the globe¹². Health benefits were shown to be paramount to consumer acceptance of function food and NHPs¹³ and even overshadowed socio-economic determinants like age, education, location, household size, and income¹⁴. Some studies showed that consumer acceptance of health- enhancing products was conditional on the specific health benefit claimed by manufacturers; for example, to consumers reduced risk of cardiovascular disease was of primary importance¹⁵, while others preferred physical and cognitive (mental) health benefits over emotional benefits¹⁶. Thus, the personal health status of the consumer (and his/her family) is likely to be a significant driver of functional food demand by category.

In as much as consumer acceptance of functional food and nutraceuticals is widely evident in the literature, the attitudes of consumers differed among countries as well as within specific countries (Labrecque et al 2006; Bech-Larson and Grunert 2003). Consumers in some countries appear to have a far more positive attitude towards these products than others. For example, surveys suggest that Canadian and American consumers generally have a more positive attitude towards functional foods compared to consumers in France, while French consumers tended to be less knowledgeable about the functional food category (Labrecque et al 2006). In other cross-country comparisons, Finnish consumers had a more positive attitude towards functional food compared to consumers in the US and Denmark (Bech-Larson and Grunert 2003). Nevertheless, broad brush national stereotyping is dangerous and runs the risk of glossing over more nuanced consumer attitudes within a population. Indeed, a number of studies have shown that even within a specific country, social demographic factors such as: age group, location, education, gender, family status, prior beliefs, profession, and income level differ markedly among consumers (Peng et al 2006, Herath et al 2008, Arnoult et al 2007, Henson et al

¹⁰ Stein and Rodriguez-Cerezo 2008, Marette et al 2010, Ares et al 2010.

¹¹ Labrecque et al 2006, Ipsos-Reid 2005, West and Larue 2004, Hailu et al 2009, Ares et al 2010, Henson et al 2010.

¹² West and Larue 2004, West et al 2002, Urala and Lahteenmaki 2004, Cox et al 2004, Verbeke 2005, Ipsos Reid 2005, Teratanavat and Hooker 2006, Stein and Rodriguez-Cerezo 2008, Siegrist et al 2008, Marette et al 2010

¹³ Tuorila and Cardello 2002, Cox et al 2004, Teratanavat and Hooker 2006, Siegrist et al 2008, Hailu et al 2009

¹⁴ Bech-Larson and Grunert 2003, Urala and Lahteenmaki 2004, Ipsos-Reid 2005, Verbeke 2005, Peng et al 2006, Labrecque et al 2006, Stein and Rodriguez-Cerezo 2008.

¹⁵ Urala and Lahteenmaki 2004, Henson et al 2010

¹⁶ Tuorila and Cardello 2002

2010, West and Larue 2004, Verbeke 2005, Stein and Rodriguez-Cerezo 2008, Siegrist et al 2008).

Across a great number of the studies, consumer acceptance of functional food and NHPs is also evaluated in terms of estimated willingness to pay as measure of the marginal utility gained from consumption of these products¹⁷. However, consumer willingness to pay for these products is moderated by the underlying technology embedded in the product, with use of genetic modification or additives likely to temper enthusiasm for the product among some consumers¹⁸

A recurrent theme in the literature is the need to consider the nature of the underlying food product and its primary function as a food stuff first, and a vehicle for delivery of health benefits second. In other words, existing attitudes toward the base product, as well as the taste of the functional food, remain very relevant determinants of consumer acceptance¹⁹. Base products that are already perceived to be healthy have a higher likelihood of acceptance as carriers of a functional component²⁰. Although there was some discrepancy across studies, in general research suggest that consumers are not willing to compromise on taste when purchasing functional food, and firms should take into consideration taste and base products when developing new products²¹.

The credibility of information about the products and their health claims is a leading determinant of acceptance and willingness to pay (Labrecque et al 2006, Teratanavat and Hooker 2006, Markosyan et al 2009, Ipsos-Reid 2005). Studies found that in general, consumers in Canada believed in the safety of functional foods and NHPs but require more credible information (Ipsos-Reid 2005, Labrecque et al 2006). The key word here is 'credible'. Studies have suggested that consumers do place much reliance on unsubstantiated health claims (Marette et al 2010), although American consumers appeared to be more open to functional foods with health claims (Teratanavat and Hooker 2006, Markosyan et al 2009). As such although information dissemination is vital for the growth of the industry, the potential for misleading

¹⁷ For example, West et al 2002, West and Larue 2004, Teratanavat and Hooker 2006, Bech-Larson and Grunert 2003, Markosyan et al 2009, Marette et al 2010, Henson et al 2010, Arnoult et al 2007, Ares et al.

¹⁸ Cox et al 2004, Arnoult et al 2007, Markosyan et al 2009.

¹⁹ See for example, Bech-Larson and Grunert 2003, Peng et al 2006, Siegrist et al 2008, Hailu et al 2009, Tuorila and Cardello 2002, Verbeke 2006, Siegrist et al 2008.

²⁰ Bech-Larson and Grunert 2003, Peng et al 2006, Siegrist et al 2008, Hailu et al 2009.

²¹ Tuorila and Cardello 2002, Verbeke 2006, Siegrist et al 2008.

health claims requires the verification of these health claims by government, stringent approval process and communication through sources trusted by the consumer (West et al 2004, Stein and Rodriguez-Cerezo 2008, Hailu et al 2009, Marette et al 2010).

A host of socio-demographic variables influence attitudes toward functional foods, from age, income level, education, location, gender, family status, and profession, as does product prices and potential side effects. However, there appears to be little consensus on the direction of many of these effects. With respect to age, some Canada studies have shown that older consumers are more receptive to functional food and NHPs than younger consumers (West and Larue 2004, Herath et al 2008), while another study suggests that middle-aged consumers are more likely to buy functional food (Peng et al 2006). In total contrast, other studies from the European Union (UK, Belgium) seem to show that younger consumers have a more favourable attitude towards functional food and NHPs compared to older consumers (Arnoult et al 2007, Verbeke 2005). Yet, older consumers were found to be more interested in functional food than younger consumers in Switzerland (Siegrist et al 2008). Furthermore, Canadian consumers with children and teenagers in their household were more likely to buy health-enhancing products (functional food) (West and Larue 2004, Peng et al 2006) compared to the UK where health-enhancing products (NHPs) were rejected by families with children under the age of 18 (Arnoult et al 2007). It is difficult therefore to draw general conclusions regarding the effect of age on consumer attitudes toward functional food, except to note that the effect of variables such as age must be interpreted within the context of the study (type of product, health issue being addressed).

The same observation pertains to the effect of other socio-demographic variables, such as income and education. Some Canadian studies suggested that lower income households and the less educated appeared to be more receptive to functional food and NHPs compared to the higher income and highly educated people from urban areas (Herath et al 2008). However, a UK study found that it was households with higher income and higher education levels that were more receptive to functional food (Arnoult et al 2007). In Belgium, interestingly households with higher levels of education were less likely to be accepting of functional food, whereas high income households have a positive attitude (Verbeke 2005).

Results for gender also differ across studies, with one UK study indicating that women were willing to pay a premium for functional food but mostly rejected NHPs (pills) (Arnoult et al

2007); whereas some Canadian studies have shown that it was men who were more receptive to functional food (West and Larue 2004) although women were more familiar with NHPs than men (Ipsos-Reid 2005).

With respect to location, there are mixed results in the literature. A study in Canada indicated that urban consumers were more receptive to functional foods (West and Larue 2004) but this result is contradicted by another Canadian study that suggests urban people are less receptive to functional food (Herath et al 2008). A UK study determined characterized urban people as more receptive to functional food (Arnoult et al 2007). These comparisons suggest that demographic profiling of consumer segments, while helpful in building a broad picture of a market, is too broad-brush an approach to yield insights that can be extrapolated across markets and across contexts. Indeed, the context is all important: different functional foods will appeal to different types of consumers depending on the targeted health issue. For example, different health issues may well have different priorities across different age profiles; thus it remains important for researchers to also take into consideration any psychographic variables that capture individual attitudes toward food and health, as well as determinants of trust in information sources.

While the bulk of the literature in this area pertains to functional food, a number of studies do examine NHPs/nutraceuticals. Besides the health benefits being an important determinant, many consumers appear to use NHPs due to recommendations from friends and health professionals (Ipsos-Reid 2005). Common reasons for consumer reticence with respect to NHPs include lack of information about the products or lack of believability of health claims (Ipsos-Reid 2005, West and Larue 2004), inability to distinguish between NHPs and functional foods (Cox et al 2004), and fear of negative side effects (Marette et al 2010).

A number of recommendations emerge from the literature. There is the need for credible information about the benefits of these products and their safety (West et al. 2002). This information should come from reliable sources outside the food industry, with government experts and health care experts as the preferred choices. Efficacy is critical. If consumers do not believe the products are effective, they will not buy them. The form in which the product is delivered is a component of efficacy: people will not consume a functional food or NHP if it is too inconvenient to do so (Henson et al 2010). The need for stringent approval processes for

health claims is emphasized across numerous studies, as is the need for dissemination of information about NHPs and functional food from credible sources.

The literature highlights a host of factors that influence consumer attitudes towards and acceptance of functional foods and NHPs. Many of the products examined in these studies were new or even hypothetical – an inevitability given the nascent state of the market for functional foods and NHPs. Over time revealed preference market data on established products will enable longer term studies of the growth (or demise) of products with specific health benefits. As these markets continue to evolve, and new scientific advances deliver novel products with new health benefits spurring new health claims, there will be a continued need for research - using both revealed preference and stated preference techniques - that helps us understand consumers' responses to new foods with health benefits.

Table 17: Consumer Awareness, Acceptance and Willingness to Pay

AUTHOR	YEAR	LOCATION	AREA	TITLE	CREATED FOR/BY	OBJECTIVE	METHOD	RESULTS/IMPLICATIONS	SOURCE
Tuorila and Cardello	2002	USA	Functional foods	Consumer Responses to an Off-Flavor in Juice in the Presence of Specific Health Claims	NA	To determine consumer willingness to compromise on taste for health benefits	Survey/Descriptive analysis N=78	Consumers are unwilling to compromise on taste for health benefits. Consumer acceptance of functional food depends on the specific health benefit. Cognitive and physical performance improvements are more likely to motivate acceptance of functional food than emotional well-being.	Food Quality and Preference 13 (2002) 561–569
West, Gendron, Larue and Lambert	2002	Canada	Functional Foods/GM Foods /Organic Foods	Consumers' Valuation of Functional Properties of Foods: Results from a Canada-wide Survey	Centre for Research on the Economics of Agri-foods/ Institute for Nutraceuticals and Functional Foods, Laval University	To assess consumers' valuation of functional properties of food in Canada.	Survey/Statistical/Econometric N=1008	Consumers have a positive attitude towards functional foods and are willing to pay a premium for them, especially for plant derived functional foods. However, there is the need for credible information about the safety and benefits of these products. This information should come from reliable sources outside the food industry; government experts and health care experts are the preferred choices. The success of functional food should not only be based on consumer belief in their safety and compositions but also on their efficacy. Majority of Canadians are taking vitamins and herbal supplements. In addition, the probability of Canadians purchasing GM and organic products with added functional property increases at the expense of conventional food.	Canadian Journal of Agric. Economics 50 (2002) 541–558
Bech-Larson and Grunert	2003	Denmark, Finland and US	Functional foods	The Perceived Healthiness of Functional Foods: A Conjoint Study of Danish, Finnish and American	The MAPP Centre, The Aarhus School of Business, Haslegaardsvej 10, DK-8210 Aarhus V,	To assess the extent to which consumers' perception of food healthiness depends on different types of health claims; functional enrichments;	Survey/Statistical/Econometric N=500 in each country	The conjoint results clearly indicate that, consumers' perception of the healthiness of functional foods is more dependent on their perception of the nutritional qualities of the base-product than on any type of health claim or functional properties. The Finnish respondents were generally more positive towards functional foods than the Americans and the Danes. The three samples showed only little differences	Appetite 40 (2003) 9–14

				Consumer's Perception of Functional Food.	Denmark	base-products and processing methods.		regarding the determinants of the perception of the healthiness of functional foods. In addition, the Danish and Finnish consumers had a negative attitude towards genetically modified products compared to the American consumers.	
Cox, Koster and Russell	2004	Australia	Functional foods and supplements	Predicting Intentions to Consume Functional Foods and Supplements to Offset Memory Loss Using Adaptation of Protection Motivation Theory.	Commonwealth Scientific Industrial Research Organization (CSIRO)	To determine what characteristics of a product-message would impact on the motivations to purchase functional foods to prevent memory loss	Survey/Statistical/Econometric N=290	Consumers have no clear distinction between functional food and NHPs. The health benefits of these products were the most important predictor. However, improving benefits of these products through genetic modification was not acceptable. In addition, women had a less favorable attitude towards genetic modifications. Sweetening functional foods to offset bitterness was not acceptable.	Appetite 43 (2004) 55-64
Urala and Lahteenmaki	2004	Finland	Functional foods	Attitudes Behind Consumers' Willingness to Use Functional Foods	NA	To measure/predict the determinants of consumer willingness to pay	Survey/Statistical/Econometric N=1158	The reward (health benefits) associated with consumption of functional food is a major determinant of willingness to pay. The reward from consumption overshadows the perceived risks associated with consumption. Consumers will compromise on taste if there is a clear promise of disease risk reduction.	Food Quality and Preference 15 (2004) 793-803
West and Larue	2004	Canada	Functional foods	Profiling Consumer Trend-setters in the Canadian Healthy-foods Market	NA	To identify and measure the impact of variables affecting consumers likelihood of being among the first to purchase new health-food products	Survey/Statistical/Econometric N=1008	Consumers most interested in foods with enhanced functional health properties and hence first to purchase, are those who believe strongly in the link between food and health and who already believe in current nutritional content claims. Older consumers and consumers with negative attitudes towards GM foods were less likely in being among the first to try functional food. Demographically, men, metropolitan consumers and consumers with children are more receptive to novel foods as opposed to women. Consumers should be convinced that claims on these products are not	Current Agriculture, Food & Resource Issues 5 / 2004 / p. 65 - 82

									gimmicks but scientifically proven.	
Ipsos-Reid (Market Research and Public opinion polling Firm)	2005	Canada	Natural Health Products	Baseline Natural Health Products survey among consumers (Final report)	Health Canada	To determine NHP awareness, attitudes, knowledge, and behavior among Canadian consumers	Survey/Descriptive Analysis N=2000+	“More Canadians are unfamiliar (45%) than familiar (36%) with NHP. Women (41%) compared to men (30%). For reasons to use, 52% is related to the desire to control or influence personal health. 29% on assumption that it is safer than conventional medication. 20% is due to recommendation from a friend or a medical doctor”(Page 38-40). Reasons for non-use were mainly due to lack of enough information about NHP. Attitude towards NHP was that Canadians have the right to use any NHP they want. Key recommendations include: government should focus on the dissemination of NHP information to educate Canadians about their use (manage health); collaboration between government and informed sources about safety and appropriate use of NHP; the government should focus on informing the public about the importance of NHPs regulations	Ipsos-Reid Reports (2005)	
Verbeke	2005	Belgium	Functional foods	Consumer Acceptance of Functional Foods: Socio-Demographic, Cognitive and Attitudinal Determinants		To assess the determinants of consumer acceptance of functional food	Survey/Statistic/Econometric N=215	Health benefit was found to be the main determinant for accepting functional foods. Health benefit far outweighed the impact of socio-demographic determinants like age, literacy, location, income, etc. and attitudinal and cognitive factors like knowledge and beliefs. Interestingly, in Belgium the household education (household with higher education) negatively affect functional food acceptance whereas high income households have a positive attitude towards functional food “The findings from this study reinforce the idea of a rational/cognitive oriented decision-making process for functional foods, including active reasoning”(page 54).	Food Quality and Preference 16 (2005) 45–57	
Labrecque, Doyon, Bellavance and Kolodinsky	2006	United States/ France/ Canada (French)	Functional foods	Acceptance of Functional Foods: A Comparison of French,	NA	To identify whether acceptance of functional foods varies across	Survey/Statistic/Econometric N=611	Minor differences in attitudinal beliefs associated with FFs between Canadian and American consumer. Health and product related benefits, credible information, and knowledge about products were the major	Canadian Journal of Agric. Economics 54 (2006) 647–661	

				American, and French Canadian Consumers		cultures; and the extent to which attitudes influence acceptance of functional foods.		determinants of acceptance. The promotion of other product benefits in addition to health attributes can increase market development. French students reported less favourable attitude towards functional food than the French Canadian and American students. The attitude difference is small across countries so product development should be approached in a global market perspective rather than a local one. <i>Think global act local..</i>	
Peng, West and Wang	2006	Canada	Functional foods (CLA-Enriched Dairy Products)	Consumer Attitudes and Acceptance of CLA-Enriched Dairy Products.	NA	To identify factors that are important in assessing consumer attitudes toward and acceptance of CLA-enriched dairy products.	Survey/Statistic/Econometric N=803	Healthiness of conventional milk was found to be the main determinant of the acceptance of CLA-enriched dairy products in Canada. There is not a significant correlation between gender, education and consumers' acceptances of CLA-enriched dairy products. Middle-aged consumers and consumers with teenagers in the household are more likely to buy this product. The target consumer segment for this product should be health-conscious, middle-aged consumers who believe in healthiness of conventional milk products. Interest in a product which is perceived by consumers to be less healthy, can be increased through the introduction of functional health claim.	Canadian Journal of Agric. Economics 54 (2006) 663–684
Teratanavatt and Hooker	2006	United States	Functional foods	Consumer Valuations and Preference Heterogeneity for a Novel Functional Food	Institute of Food Technologists	Examine consumer valuation and preference heterogeneity for novel functional food attributes and how they are affected by variables like: health benefits, organic ingredients, source of nutrients, and price.	Survey/Statistic/Econometric N=3000+	Consumers value health attributes of FFs and are willing to pay more. Consumers who regularly purchase food groups such as FFs, organic foods, and food with natural ingredients react more positively and are more interested in novel functional food as compared to those who never purchase these types of food. Consumers, in attempt to maintain health and prevent disease, are more open to functional food and novel foods with health claims. Further research should segment population groups that are more interested in novel functional food.	Journal Of Food Science—Vol. 71, Nr. 7, 2006

Verbeke	2006	Belgium	Functional foods	Functional foods: Consumer Willingness to Compromise on Taste for Health	NA	To investigate the determinants of consumer willingness to compromise on taste for health	Survey/Statistic/Econometric (n=255 in 2001) (n=205 in 2004)	Belgian consumers developed a critical attitude towards functional food in general. This attitude was evident in their unwillingness to compromise on taste for health. The acceptance of functional food is being conditioned on taste; consumers are likely to reject functional foods that taste worse than conventional food. This will be one of the challenges for future acceptance of functional food	Food Quality and Preference 17 (2006) 126–131
Arnoult, Lobb, Chambers, Traill and Tiffin	2007	UK	Functional foods	Consumers' Willingness to Pay (WTP) for Functional Agricultural Foods.	Research Council UK/Rural Economy and Land Use	To examine and measure consumers' willingness-to-pay for enhanced foods.	Survey /Statistic/Econometric N=200	There is a viable market for FFs. However, there is a strong polarization against any product perceived by consumers as artificial or genetically modified. Urban consumers with high job positions, women, younger, and smaller households are more willing to pay for enhanced products. Pill supplements were mostly rejected by women, people with white collar employment and households with children. Large households with higher income or education have a positive WTP for pills. WTP is stronger for animal than for plant enhanced food products.	University of Reading. Project Document No. 09 Work package No. 2, Report No. 05 June, 2007
Herath, Cranfield and Henson	2008a	Canada	Functional foods/Nutraceuticals	Who Consumes Functional Foods and Nutraceuticals in Canada? Results of Cluster Analysis of the 2006 Survey of Canadians Demand for Food Supporting Health and	NA	To identify consumer segmentation in relation to consumption of functional food and nutraceuticals	Survey/Statistic/Econometric N=1753	Among Canadian consumers, there is a difference in the likelihood to consume FFs and nutraceuticals; age, location, education, income are the most prominent distinguishing factors. The more receptive groups are the elderly, low income households and less educated. The less receptive group is the younger population with higher education & income who mostly live in urban areas. Those more receptive consumers are interested in knowing the health benefits of these products before they commit themselves to them. The segmentation of consumers will allow using different techniques to change	Appetite 51 (2008) 256–265

				Wellness				attitudes towards these products.	
Krystallis, Maglaras, and Mamalis	2008	Greece	Functional foods	Motivations and Cognitive Structures of Consumers in their Purchasing of Functional Foods	NA	“to identify the most frequently purchased functional food products; to define the most important attributes of functional foods; to gain insights into consumers’ functional food related buying motives; and to model consumers’ functional food selection-relevant cognitive structures, i.e. the way that functional food consumption-relevant knowledge is stored and organized in consumers’ memories” (Krystallis et al 2008, page 527).	Survey/Descriptive N= 100	Young adult group preferred functional food juices, while the older group preferred functional spreads indicating the possibility of a fragmented functional food market. Both young adults and the older group shared similar preferences; the most important attributes were: quality-related (e.g. pure, safe, healthy, and high quality); label information related (e.g. best before and packaging dates, nutritional value, and health/functional claim); price; and brand name. Concerning motives for buying functional foods, young adults were concerned about enhancing their health status, while the older group was concerned about reduction of disease risks. The success of functional food depends on how well they satisfy consumer needs. The study recommends that health claims on functional food should be honest and presented in an attractive way.	Food Quality and Preference 19 (2008) 525–538
Siegrist, Stampfli and Kastenholtz	2008	Switzerland (German – speaking)	Functional foods	Consumers’ willingness to buy functional foods. The influence of carrier, benefit and trust	NA	To examine the factors that influence willingness to buy functional foods	Survey/Statistic/Econometric N=249	Physiological/health benefits of functional food were the main determinant of the willingness to buy or acceptance of FF. The use of an already accepted product with a positive health image as a carrier, and trust in the food industry, positively influenced consumers’ willingness to buy functional food. Older consumers were more interested in FF than younger consumers.	Appetite 51 (2008) 526–529
Stein and Rodriguez-Cerezo	2008	EU	Functional foods	Functional Food in The European Union	IPTS – Institute for Prospective	To examine consumer awareness,	Survey/Descriptive Analysis	The consistent reason for buying functional food was to stay healthy. There is not one unique determinant of consumer	IPTS Technical report series EUR 23380 EN

					Technological Studies/Joint Research Centre (JRC) of the European Commission	attitudes and willingness to pay for FF in the EU.	N=626	acceptance, but the consumption of functional food should improve the health of consumers. Functional food has to fulfill the general expectations regarding food products: good taste, convenience, reasonable price, attractive design, and practical packaging. Consumer understanding of functional food depends on mediated information which hinges on the credibility of information. Food industry's communication policy is weak and food retailers have limited knowledge about the functional food products they sell. Reasons for not buying functional food differ across countries; in Poland and Spain, price was the main reason; in the United Kingdom and Germany consumers were more concerned about taste; Polish consumers fear side-effects. Recommendations: further research into functional food as a way of achieving cost-effective ways of addressing health problems in Europe.	ISBN 978-92-79-09071-4 ISSN 1018-5593 DOI 10.2791/21607
Hailu, Boecker, Henson and Cranfield	2009	Canada	Functional food and Nutraceuticals	Consumer Valuation of Functional Foods and Nutraceuticals in Canada. A Conjoint Study Using Probiotics	NA	To measure consumers preferences over attributes (mode, health claim, health claim source, and cost) of functional food and nutraceuticals with probiotics as the functional compound	Survey N=200 Statistics/Econometrics	Health claim/benefit was an attribute that mainly influence consumer acceptance and preference. Government verified health claims are preferred by consumers. 'Pill lovers' place much value on the health claim source compared to 'pill loathers'. Carrier (base product) of the functional ingredients has a large effect on consumers' valuation of functional food. The results from the study indicated that cost of usage had a negative effect on consumer preference. The study recommends further research into potential substitution effects between FFs and nutraceuticals with attention on specific products or health benefit.	Appetite 52 (2009) 257–265
Markosyan, McCluskey	2009	United States	Functional Food	Consumer Response to	NA	To measure consumers'	Face to Face	Consumers value the health attributes of FFs and are willing to pay more for them.	Canadian Journal of

and Wahl			(Apple Enriched with Antioxidants)	Info. About a Functional Food Product: Apples Enriched With Antioxidants		responses to apples with enriched coatings; and analyze the factors that affect consumers' choices	Interviews N=730 Statistics/Econometrics	Consumers also are responsive to health claims of functional food so dissemination of information to educate consumers about the benefits and safety of these products is vital for the growth of this industry. Reason for rejection was mainly due to the use of new technology (additives) which they feel is unnatural and risky.	Agric. Economics 57 (2009) 325–341
Ares, Gimenes and Deliza	2010	Uruguay	Functional food	Influence of Three Non-Sensory Factors on Consumer Choice of Functional Yoghurts Over Regular Ones	NA	To study the influence of type, brand, price, and health claim on consumer choice of functional yoghurt	Survey/Statistic/Econometric N=103	The type of yoghurt, brand, price and health claim has significant effect on consumers' choice, and also depends on consumers' attitude towards health issues. The influence of brand and type of yoghurt was significantly higher than the effect of price and health claims. Consumers' likelihood of choosing functional yoghurt is increased when functional ingredients like fiber and antioxidants are present. Consumers also prefer familiar brand to unfamiliar brands. Regarding price, there were mixed reactions from consumers, but most consumers are concerned about an increase in price. Health claims had little effect on consumers; this was the least important attribute. The development of FFs should take into account all these attributes to ensure the success of the product.	Food Quality and Preference Volume 21, Issue 4, June 2010, Pages 361-367
Henson, Cranfield, and Herath	2010	Canada	Functional food and Nutraceuticals	Understanding Consumer Receptivity Towards Foods and Non-Prescription Pills Containing Phytosterols as a Means to Offset the Risk of Cardiovascular Disease: An Application of	NA	To better understand consumers' willingness to purchase food and/or non-prescriptive pills containing phytosterols as a means to reduce the risk of cardiovascular disease (CVD) in	Survey/Statistic/Econometric N=446	Factors that affect consumers' intention to consume food and/or nutraceuticals containing phytosterols are twofold: 'Response Efficacy' and 'Self-Efficacy'. Response efficacy refers to how effective the product is or if consumers believe the efficacy of the product. Self-efficacy is about the ability of consumers to consume the products in the prescribed manner. Consumers' fear of CVD and/or the use of biomarkers like blood cholesterol as an indicator of CVD does not significantly affect their purchasing intention. functional food and nutraceuticals should be promoted as one of the effective ways to reduce the incidence of CVD.	International Journal of Consumer Studies Volume 34, Issue 1, pages 28–37, January 2010

				Protection Motivation Theory		Canada		Communication efforts should focus on efficacy and ease at which products can be used; and target the entire population with little attention to high risk individuals. Functional food and nutraceuticals should not only be perceived as effective but also be presented in an acceptable form to consumers.	
Marette, Roosen, Blanchemance and Feinblatt-Meleze	2010	France	Functional food	Functional Food, Uncertainty and Consumers' Choices: A Lab Experiment with Enriched Yoghurts for Lowering Cholesterol	NA	To evaluate the effect of health information on consumers' choice for functional food	Survey/ Lab experiment/ Descriptive Analysis N=107	Food consumption is highly impacted by health concerns. Health claims and labels serve as signal for healthy products and functional food. Information about cholesterol reduction properties of plant sterols increased consumers' willingness to pay. Uncertainty of functional ingredients and possible side effects of plant sterols does not significantly reduce consumers' willingness to pay. Due to consumers not focusing much on scientific uncertainties when choosing these products, there is the possibility of the proliferation of unsubstantiated claims in the market. Thus there is the need for stringent approval process for health claims. Recommendations include the consideration of these results in analysis involving cost and benefit of health claims	Food Policy 35 (2010) 419–428

Notes: FF: Functional food
NHP: Natural health product
FFNHP: Functional food and natural health product
GM: Genetically modified
WTP: Willingness to pay

4.2. Industry and Market Analysis

The increase in consumer awareness of functional food and NHPs poses challenges and presents opportunities for firms in the industry. As consumer interest in health-enhancing food continues to increase, there is the need for firms to introduce new products and marketing strategies so as to capture new market opportunities, increase the profitability of the industry and to satisfy consumer demand. This section reviews literature on industry and market perspectives of the functional food and NHP sector.

Tebbens (2002), in a working paper for Statistics Canada, provided a useful benchmark of the functional food and NHP industry in Canada. The paper was based on data from a survey of 576 Canadian firms (48% response rate) from Agriculture and Agri-Food Canada (AAFC) and Statistics Canada. A total of 294 firms in the survey were engaged in functional food and nutraceutical activities in 2002. The highest number of firms were in Ontario (75), followed by Quebec and British Columbia with 72 firms each and Saskatchewan with 33 firms, while the remaining firms were distributed throughout the rest of the country. Small firms with less than 10 employees accounted for 37% of the total number of firms in the sector; medium sized firms (between 10 and 50 employees) accounted for 31%, while firms with 50 or more employees (who were considered large firms), represented 33% of the total sector. Most firms in the sector are privately owned, with nearly 75% being private corporations, 11% multi-nationals, 10% public corporations, and 8% sole proprietorships.

Most firms (46%) were engaged in only nutraceutical activities compared to 28% engaged in only functional food activities, while just over a quarter were engaged in both. Among the firms involved in nutraceutical activities, 51% dealt with plant-based nutraceuticals such as beta glucan sourced from oats or antioxidants from blueberries; 37% dealt with marine-based nutraceuticals including glucosamine products from algae; and 28% dealt with animal or micro organism- based nutraceuticals such as essential fatty acids. Among firms involved in functional food activities, many (44%) used added active ingredients in food products, beta glucan in muffins for example. The remaining functional food firms utilized methods such as plant breeding, genetic modification and special livestock feeding. Methods of product distribution included the use of wholesalers, third party distributors, retailers, direct sales, internet sales, mail orders and other multilevel marketing. Finally, more than half of the firms indicated that they export their products, with popular destinations including the US, Japan,

Europe, Asia, Australia and New Zealand. The author concluded that there is a great potential for expansion in the sector and as such, there is the need for further research to document the trends and growth in the sector.

Hobbs (2002) discussed factors that influence the evolution of supply chains in the functional food and nutraceutical sector. Supply chains were specifically defined as the relationship between firms that governs the flow of products from input supply through production, processing, and distribution, to the final consumer. The functional food and nutraceutical industry was characterised as being resource-intensive in terms of financial resources, the time for research, technological development and commercialisation; moreover the sector experiences institutional failures such as an under-developed property rights system which provides weak patent protection, thereby discouraging new and existing firms to invest in R&D. Many firms enter into some form of partnership arrangement in order to raise the necessary resources, while there are some issues regarding contractual rights. The ability of firms to capture rents is also hampered given that disputes over property rights are common.

The growth in the functional food and nutraceuticals market provides an opportunity to develop additional health-enhancing food products through collaboration between scientific discovery and consumer interests. Close supply chains will reduce transaction costs and will also provide credible quality assurance guarantees, however, the industry's upstream raw materials supply and downstream food processing characteristics negatively affect the development of such close supply chain relationships. Finally, clearer health claim regulations were identified as important for the growth of the sector; hence the study recommends further research into the role of labelling and quality assurance within the supply chain.

Mark-Herbert (2003) examined strategies for the development and marketing of functional foods in Sweden. Three strategies were recommended by which individual firms can achieve sustainable competitive advantages, which in turn could assist the development of the functional food sector. First, individual firms should seek to acquire proprietary rights to ingredients that have undergone independent clinical studies to gain exclusive rights to sales for a certain period of time, enabling them to capture rents. Second, firms should seek to develop brand recognition and branding of their products to achieve consumer recognition and/or alter consumption. Third, firms should utilize health experts to test their products in order to gain nutritional and health evaluations, which will subsequently increase credibility among

consumers. Mark-Herbert (2003) also proposed a marketing strategy based upon market segmentation for functional foods in order to enable the use of proper advertising which in turn promotes functional foods efficiency and creates consumer awareness. The study, suggested three market segments. The first included consumers who already suffer from a disease; for this group, the author suggested that producers should be targeting health professionals as a means to convey information to consumers. The second segment is the “at risk group” of consumers; health related news and talk shows are recommended vehicles to reach this group. The last group is the “prevention and mass market segment” of consumers; members of this group may already be taking vitamins and minerals, so using the print media and radio to create awareness will be appropriate. The author concluded that the possibility of market segmentation can allow for price discrimination.

In a survey of the functional foods and nutraceuticals industry conducted on behalf of Statistics Canada (response rate 60%), Palinic (2005) provided information on the Canadian functional food and nutraceutical sector, as well as a profile of the industry’s firms. The objective of the study was to provide a benchmark measurement of the industry as well as a better understanding of the scope and nature of the sector. In 2005, there were an estimated 389 firms dealing with nutraceuticals and/or functional foods, of which 118 were involved exclusively in functional foods, 174 firms dealt only with nutraceuticals, while 97 firms were active in both. Total R&D spending on the functional food and nutraceuticals sector was \$162.8 million, with the majority being undertaken by nutraceutical only firms (47% of total spending) as compared to the 28% of total spending undertaken by functional food only firms and the remaining 25% by firms producing both functional foods and nutraceuticals. However, less than half of total R&D spending (\$74.5 million) was spent on product development. The majority of R&D spending was on other areas including marketing, distribution, and consumer research activities.

Further, it was estimated that total annual revenue from the functional food and nutraceuticals industry was \$2.9 billion in 2005. Firms involved in only nutraceuticals generated \$1.6 billion of the total revenue; \$823 million was earned by firms producing only functional foods; while \$442 million was earned by firms producing both. Most of the firms responding to the survey indicated that they export their products: approximately 50% of firms exported to the United States, roughly 10% exported to Korea, another 10% to Japan, while the remaining 30%

shipped to other destinations. A quarter of the firms indicated that they were actively searching for new export markets for their products.

Palinic (2005) noted that functional food firms differ from nutraceutical firms in the distribution channels used. Seventy percent of nutraceutical firms used wholesalers, compared with only 50% of functional food firms. Wholesalers were the most commonly used distribution channel by all firms in the industry. Retailers were used by only 31% of nutraceutical firms, compared with 45% of functional food firms. Finally, 25% of all firms sold directly to the customer²².

Roughly 40% of Canadian firms in the study indicated that they are in partnership agreements with other firms, while almost 50% of all firms were seeking partnership agreements. The purposes of the partnerships were mainly for R&D, production or marketing, and access to distribution channels. The majority of the firms (83.6%) did not have patents for their products and for those firms that did have patents, 30% were registered with the United States Patent and Trademark Office, 16% with the Canadian Intellectual Property Office, 11% with the European Union patent office and the rest were with other jurisdictions.

Palinic (2005) also indicates that in 2003, Health Canada had authorized the use of five generic health claims²³. Health Canada's Natural Health Product regulations are applicable to herbal remedies, homeopathic medicines, vitamins, minerals, traditional medicines, probiotics, amino acids and essential fatty acids. The agency has also established science-based regulations, guidelines and public health policies for novel foods (foods from processes not previously used for food). The study claims that Health Canada's measures and policies have promoted growth in the sector and concludes with a recommendation that the authorization product specific claims would be favourable for the industry. Compared to the analysis of Tebbens (2002) a few years previously, there had been a significant increase in most metrics of sector activity, with the number of firms increasing by 32%, revenue rising by about 15% and R&D on functional foods and NHPs increasing by 29% (Palinic 2005).

The Institute of Food Technologists (IFT) (2005) examined the opportunities and challenges facing the functional food sector in the United States using an expert panel chosen for their scientific, medical and legal expertise. The study asserted that food technology and

²² Percentages may not sum up to a hundred due to rounding of estimates. Firms also may have used more than one distribution channel.

²³ This number has since increased to nine.

nutrition had improved life expectancy over the last 200 years and that the impact of diet on health is far larger than basic nutrition. The increase in consumer interest for healthier food products, the availability of food technology and scientific evidence of correlation between diet and disease prevention, provide opportunities for enormous growth in the functional food industry. However, the lack of exclusivity of health claims which discourages companies from investing in functional food research, as well as the absence of a well-established property rights system to effectively protect patents, were identified as the major challenges facing the industry. This study also confirmed the findings of others that the high cost of developing new functional food is also a major challenge for the industry.

The IFT (2005) made a number of recommendations based on its findings regarding the opportunities and challenges facing the functional food sector, including that government should invest in basic and applied research to promote product development. The panel suggested tax incentives for companies that pursue research in the industry. It was argued that granting periods of exclusivity with respect to health claims and patents would encourage food companies to pursue functional food development by providing them greater periods to recoup their costs and generate a reasonable profit for their investment. The panel concluded that success in the industry will require contributions from academia, government and industry, as well as steps that need to be taken to ensure product safety. As health claims help increase consumer confidence and enable consumers to select products that satisfy their desire to promote self-care and improve health, the report recommended the establishment of scientific, regulatory and business frameworks in order to facilitate the review of new functional ingredients and their health claims for efficacy and safety. Communicating the findings of regulators will ensure informed decision-making on the part of consumers which is important for the success of the functional food sector. Finally, the study suggested that even though the sector is growing, research must identify bioactive compounds and determine their mechanisms of action and effects on health. This knowledge must then be verified through well designed pre-clinical and clinical studies.

Spence (2006) analysed the composition of functional foods and the challenges faced by consumers in tracking the individual properties of functional foods given the ever increasing number and variety of products. It was argued that consumers experience difficulty in determining the particular health benefits of different products, produced by different firms, all of which can contribute towards creating negative attitudes towards functional food products.

The study asserted that maintaining accurate information about functional food composition is a difficult task because firms must maintain a balance between variety and nutrients and “Despite scientific advancement, we may not know all the roles of dietary ingredients particularly the non-traditional or emerging ones” (Spence, 2006, p. S4). Because of the possibility of misunderstanding the role of bioactive food components, the author recommended that functional food designers take a cautious approach when developing products, concluding that “regardless of these changes, there is a continuing need to know the accurate composition of foods, both for nutrients and non-nutrients, and for understanding the amount of these components in foods” (Spence, 2006, p.S6). Thus, there is always the need to know accurate information about functional food composition to maintain the credibility of the industry.

The issue of product development and commercialisation within the functional foods and NHP industry is further complicated due to concerns about property rights. Krakar and Gao (2006) discussed property rights issues in Canada, provided new statistical information on the industry and profiled its firms. The report was based on a 2003 survey of 276 senior managers in the industry conducted by Statistics Canada on behalf of AAFC. These firms were grouped into six categories: scientific R&D, product development/scale up, ingredient manufacturing, consumer product manufacturing, wholesaling and technology provision. The study indicates that trade secrets is the most commonly used method of protecting intellectual property. In 2002, only 10 firms (7%) granted licensing agreements to other firms and only 25 firms (17%) obtained intellectual property rights from other firms. That same year, more than half of existing patents were registered with the European Patent Office, followed by the US Patent and Trademark Office, the Canadian Intellectual Property Office, and the remaining with the patent offices in other jurisdictions. Pending patents were equally distributed around the globe.

Krakar and Gao (2006) also revealed that Canadian firms are mostly small- scale, and mostly involved in nutraceutical activities. The data from the report indicated that 55% of existing firms had less than 10 employees and most were seeking funding to expand their operations. Nearly 90% of responding firms were engaged in partnerships or seeking partnerships. Two-thirds of firms that attempted to raise capital were successful, while less than half of those who were successful reached the targeted level of capital. Generally, most firms in the survey believe that the ability to use health claims on their products will have a positive impact on sales and also increase their willingness to conduct research to support the claims.

Cinnamon (2007) provided information on the functional food and NHP sector in Canada in a Statistics Canada working paper. The objective of the study was to provide indicators that would encourage innovations in the sector. Data for the study was based on a 2007 joint survey by Statistics Canada and AAFC. The functional foods and NHPs sector in Canada continues to grow with more firms entering the industry. In 2007, there were an estimated 689 firms active in the functional food and NHP sector of which 290 firms produced only NHPs, 174 firms exclusively produced functional foods, 177 produced products in both fields while 48 firms were exclusively service providers to either field. In 2007, total annual industry revenue amounted to \$3.7 billion with NHP exclusive firms generating \$1.8 billion in revenue, and functional food firms \$621 million. Revenue from firms active in both functional foods and NHPs totalled \$1.3 billion and the remaining \$20 million came from service-only firms. Hence, the revenue from the sector saw significant growth as compared to earlier studies such as Palinic (2005). In 2007, there were 22,062 functional foods and NHP lines on the market, the majority of which (17,656) were from NHP firms, 703 were from functional food firms and 3,704 product lines from firms active in both functional foods and NHPs.

The study reported the United States as the major export destination for Canadian functional foods firms (\$173.5 million in export revenue) compared to NHP firms whose products were mainly destined towards markets such as China, Europe, Japan and others. Domestic distribution channels used by firms in the industry differ depending on whether firms produce functional foods or NHPs; 53% of revenue generated by NHP firms was from wholesalers and 32% from retailers in contrast to functional food firms for which 27% of revenue was from wholesalers and 52% was sourced from retailers.

Total R&D spending on all areas by both functional food and NHP firms in Canada amounted to \$209 million with approximately 71% (\$148 million) of total R&D expenditure was on products, with specific emphasis in the areas of vascular health, weight control, energy, immune system and overall health and well-being.

Most firms (87%) in the study did not have registered patents for their products and, for those that did, NHP firms utilized patents the most. Trade secrets were mostly developed by functional food firms (41%) as a method to protect intellectual property, while 46% of firms active in both functional food and natural health products developed trade secrets. Finally, 21%

of NHP-exclusive firms developed trade secrets, while 8% of service-only firms developed trade secrets.

Cinnamon (2007) compared its data to Palinic (2005), both of which were reports prepared for Statistics Canada, and revealed significant growth in the industry. The number of firms in the functional food and NHP industry increased by 77% over the 2 year period between the studies; industry revenue increased by 28% while R&D expenditure increased by 98%. Revenue from exports also increased by 34% in 2007 compared to the 2005 study²⁴. Finally, trade secrets continued to be the most commonly used form of intellectual property protection in the functional food and NHP sector in Canada. The author concluded that the sector is experiencing reasonable growth rates but argued that further support is needed from government in term of clarifying regulations.

Stein and Rodriguez-Cerezo (2008) initiated a prospective study on the functional food sector in the EU, based on other independent market studies. The study estimated the value of the EU functional food market in the range of €-20 billion and noted that the EU market is highly segmented by country-specific health and dietary patterns. Dairy products (including yoghurt drinks) have the biggest market share in the European functional food sector followed by beverages, cereals, confectionary, fats and fat supplements, infant foods, bakery, convenience, and miscellaneous products. The range of functional food products in the EU, US, and Japan are considered to be similar, but consumption of functional foods in Japan and the EU is considered to be more sustainable due to genuine consumer interest in these products. In terms of ingredients for functional foods, probiotic bacteria are the dominant bioactive ingredient, followed by dietary fibres and plant extracts. Based on the data used in the research (sourced from market research and consulting companies, such as Frost & Sullivan (2003)) there are at least 168 companies active in the EU functional food sector.

The report indicated that there is a dominance of already well-established conventional agri-food product companies in the EU functional food sector, which can indicate the existence of barriers to entry. Moreover, the withdrawal rate of functional food products from the EU market is roughly 75% within the first two years. The study indicates weight-loss and weight management products, those that improve digestion, support women's health and enhance

²⁴ Of course, both reports were prepared prior to the 2008 financial crisis and subsequent economic slowdown which may have affected industry growth rates post-2008.

immunity are those experiencing high demand. Overall, the most consistent reason for the increasing demand for functional food in the EU was to stay healthy. Collaboration among companies in areas of research, sharing of distribution channels, and protection of supply agreements, where firms may be obliged to produce fixed quantity or supply only to order, were recommended by the authors.

Herath et al (2008b) highlighted some of the challenges Canadian functional food and nutraceutical firms faced as the sector continued to grow. The study was based on a survey of 576 firms conducted by Statistics Canada on behalf of AAFC in 2003 and utilized a Poisson regression model. It corrected for over-dispersion with negative binomial representation to develop a better understanding of the factors that influence development/innovation and commercialization of functional foods and nutraceuticals in Canada. Results indicated that even though increases in the number of product lines and products in the market had a positive effect on the overall market for functional foods and nutraceuticals, it negatively affected new product development (innovation). Thus, the focus of functional food and nutraceutical firms tended to be more on the commercialization of existing products with health attributes than the development of new ones, suggesting that fewer product lines are important for successful new product development. The overall number of products on the market was not affected by the choice of target market.

The study asserts that existing regulations regarding the composition of health-enhancing compounds for nutraceuticals and functional food and label requirements (nutrient labelling) have a negative impact on innovation of functional food and nutraceuticals firms in Canada. The study also showed that industry firms tend to fail in new product development and commercialisation, particularly for novel functional foods and nutraceuticals, for a number of reasons including poor matching between a product's attributes and those sought by consumers, resulting in lack of market acceptance, and clinical trial failures because of the difficulty in proving product efficacy and/or gaining regulatory approval²⁵. The study claimed policy development and regulation reform, including the ability to make generic health claims and the harmonization of compositional and labelling regulations with those of the US, might encourage product innovation by firms. Most firms in the study were in favour of regulatory harmonization

²⁵ Novel functional food requires pre-market approval; hence there is a need for evidence of product safety. Moreover, nutraceuticals require pre-market approval so there is also a need for evidence of safety and efficacy in case claims are made on the product.

with the US in terms of in health claims, labelling and compositional requirements in order to facilitate exports.

Intellectual property rights did not have a significant positive impact on innovation in the functional food and nutraceuticals sector, except in the case of biotechnologically produced products. Patents had a significant negative impact on product lines for functional foods and nutraceuticals; firms that focused on registering patents for their products had fewer product offerings in the market due to the possible need of acquiring intellectual property from other firms. The authors subsequently suggested the presence of “significant substitution effects where firms focused on product development by acquiring products from other developers instead of developing their own” (p. 227).

The growth in the functional food and natural health products sector is occurring on a global scale. In a report for the Canadian government, Evani (2009) provided an overview of the US existing and potential market for functional food and beverages. The report estimated the retail value of the US functional food and beverages market to be approximately \$59 billion in 2008 with an annual growth rate of 6.1% from 2007-2012. The number of functional food introductions in the North American market grew from approximately 200 in 2006 to over 800 in 2008. The report stipulated that growth in the sector is due to factors such as the aging population, increasing health care costs and belief in the positive correlation between diet and health. Functional food ingredients most commonly used in the US market include low-calorie sweeteners, fibre, probiotics, omega fatty acids, anti-oxidants and sodium substitutes. Moreover, most of consumers in the US are turning to functional foods due to time constraints and consuming such products are a convenient means to meet their nutritional needs. The study indicates firms should have consumer demographics in mind when developing functional foods and beverages. Younger consumers represent an important market segment that affects sales as do busy consumers: “Workers are seeking out functional products that provide quick health solutions in a convenient format. New products need to be easy to understand and should avoid displaying a lot of scientific language” (Evani, 2009, p. 12).

A market analysis report by AAFC (2009) highlighted the challenges firms face in their struggle to stay in the market and provided a literature review on the determinants of consumer acceptance of functional foods. According to the report, the market for functional food in Canada is growing at an annual rate of 8-14%, though the exact market size has been difficult to measure

due to differences in criteria used by researchers. It affirmed that the functional food industry is resource-intensive, both financially and in time, especially in R&D. New entrants struggle to gain market share and customer loyalty as the industry is highly concentrated, dominated by a few large companies. Successful commercialization is a challenge for most firms; targeting products for niche markets rather than the entire market place is suggested as a solution.

Arias-Aranda and Romerosa-Martinez (2010) analyse the impact that the relationship between public sector research and industrial development has on innovation in the functional food sector in the Andalusia region of Spain. The study synthesized a variety of studies from various stakeholders including nutrition research centres and industrial business surveys finding that there were over 200 functional food products in the Spanish market. Specifically, in 2007, there were 29 firms producing functional foods in the Andalusia region, and 19 research institutions devoted to functional food research in the region. Growth in the sector is attributed to increased consumer interest in functional foods; Spain has made significant public policy decisions supporting functional food research including provision of subsidies to create technologically based firms. However, these research policies have not translated into innovative activities and a gap was identified between functional food research and application-oriented activities. “The few existing functional food-related companies that do invest in their own R&D still have very limited relationships and knowledge transfers to and from academic research groups in the region. Most of the R&D by firms is outsourced to public and private institutions outside Andalusia” (Arias-Aranda and Romerosa-Martinez, 2010, p. 245). The study recommended the creation of relations between stakeholders which will lead to innovations in the sector; increasing researchers’ entrepreneurial activities; promoting the quantity and quality of international research groups; and stimulating scientific and technological development with government support to contribute to the economic growth of the region.

Finally, Bleiel (2010) completed an analysis to address functional food market failures. The analysis, illustrates that functional foods fail more often than succeed in the commercial marketplace. Product failures are related to consumer rejection as firms often ignore consumer insights at the innovation stage; despite putting the consumer first in product development, firms do not understand the drivers of consumer purchasing behaviour. Consumers are more willing to pay for the wellness benefit but not the ingredient used in producing a functional food. The study cited the example of the claim “Added probiotics” having less meaning to the consumer as

compared to “stronger defences” or “better immunity”. It concludes that firms should communicate the benefits of consuming the product and not emphasize the ingredients used in making the product. Understanding of consumer behaviour needs and unmet desires should form the basis of new product development.

4.2.1. Insights from the Industry and Market Analysis Literature: A Summary

The literature on functional food and the NHP industry indicates an upward trajectory for the industry in Canada and across the globe. Interest and growth in the industry can be attributed to a number of factors. The correlation between diet and disease prevention/health has increased the interest of consumers in health-enhancing products. Concurrently, developments in food technology have enabled the creation of healthier food products to meet this increasing consumer interest. Consumers are also seeking to ameliorate the effects of aging by seeking products they believe will improve their health, well-being and longevity. Convenience factors are also driving consumers to functional foods and NHPs as a means to more easily meet their nutritional and health needs.

In Canada, the numbers of firms and overall industry revenue have been growing and that trend is expected to continue (Tebbens 2002, Palinic 2005, Cinnamon 2007). There are more firms producing NHPs (48%) than functional foods (28%) with the remainder producing both and/or providing services to the industry. The majority of Canadian functional food firms (more than 50%) export their products to the United States, while NHP firms tend to export to Japan, Europe, Asia, Australia, and New Zealand.

The EU is reflecting the same type of industry growth as in North America in terms of product offerings and overall revenue, although the EU functional food market is significantly influenced by regional, country-specific health and dietary patterns (Stein and Rodriguez-Cerezo 2008). EU demand is high for products that help in weight loss, digestion improvement, immunity enhancement, and women’s health support (Stein and Rodriguez-Cerezo 2008). The most heavily used ingredients in the EU functional food sector are dominant bioactive ingredients, dietary fibres, and plant extract (Stein and Rodriguez-Cerezo 2008).

Both in the EU and Canada, the functional food market is dominated by established and internationally active firms. Even though there are greater numbers of small-sized firms in the global functional food and NHP sector, the dominance of large and already established firms in

the industry limit the ability of small firms to gain market share (Stein and Rodriguez-Cerezo 2008, AAFC 2009).

R&D and intellectual property rights are very important to the success of the functional food and NHP sector. In Canada, industry expenditures on R&D have been increasing, and in 2007, of the total \$209 million spent on R&D, 71% (\$148 million) was product oriented rather than on other aspects of the industry, such as marketing. Canadian firms focused this R&D spending on products that affect vascular health, weight control, energy, immune system, and overall health and well-being (Cinnamon 2007).

Most Canadian firms did not patent their products but rather used trade secrets as the means to protect their intellectual property. Functional food firms had the most patents pending compared to NHP firms but NHP firms owned the most registered patents in 2007. Both existing and pending patents tended to be registered in a variety of jurisdictions including the European patent office, the US patent and trademark office, the Canadian intellectual property office and elsewhere. Intellectual property rights protection did not induce innovation in the functional food and NHP sector compared to biotechnologically- produced products, as significant substitution effects may exist, where product development focused firms (firms focused on patents) instead of developing their own products, acquire them from other developers. The potential need to acquire IPR from other firms can limit the number of product offerings.

Challenges faced by the sector include the resource constraints, lack of effective intellectual property rights protection and inadequate R&D. The resource intensity of the industry, in terms of financial and time commitments to R&D, and the inability to raise sufficient capital for expansion is a significant challenge. Most Canadian firms engage in or sought partnerships in the areas of R&D, production, marketing, and access to distribution channels. The absence of a well-established intellectual property rights system for effective patent protection and market/institutional failures worldwide increase the risk of free-ridership and limit firms' ability to capture rents. Firms should seek innovative means to undertake product-oriented R&D (private and public), use greater collaboration among stakeholders and focus on developing strategic product development and marketing plans as well as more collaboration in research, distribution channels, and supply agreements. It is expected that the creation of relationships between stakeholders will lead to innovations in the sector. Increasing entrepreneurial activities on the part of researchers and promoting the quantity and quality of international research groups

are strategies recommended to increase growth in the sector. Market segmentation and the development of products for niche markets should be an integral part of firms' R&D and marketing efforts. Obtaining intellectual property rights protection through patents for ingredients that have undergone independent clinical studies to obtain exclusive rights to sales is a means of ensuring firms protect their investment and capture rents.

Public policy initiatives that can facilitate the industry's development include government investment in basic and applied research to promote product development and more government support in scientific and technology development. Public policy efforts to encourage R&D in the industry must also be transferable to commercial applications through relationships between manufacturers and researchers. Without such transferability, R&D is wasted on products that consumers do not want or that cannot be commercialised. Public policy initiatives that are suggested as means to assist the industry's growth include 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. Allowing new health claims and product specific health claims are other possible means of stimulating R&D and sales in the sector. The establishment of scientific regulatory and business frameworks to review new functional ingredient and their health claims for efficacy and safety would also contribute towards the industry's competitiveness and sustainability.

Maintaining consumer confidence is essential for the continued growth of the industry as a growing array of products and health claims becomes ever more confusing to the consumer. Firms must be highly cognizant of consumer demands and what drives acceptance of products in the market to avoid commercialisation failures. Product failures are more common than successes: the product withdrawal rate in the EU is approximately 75% within the first two years (Stein and Rodriguez-Cerezo 2008). The literature suggests that a need for the industry to work assiduously at maintaining consumer confidence via clear communication and education, particularly in the use of simple language on claims/labelling. Firms must also incorporate consumer insights at the product innovation stage, not only in terms of products demanded but also their ease of consumption, storage and delivery method, for example. Stimulating and maintaining consumer confidence in the industry is an elemental source of growth. Segmenting the market to effectively and efficiently communicate to the target market increases firms' competitiveness. Branding of proven products will garner greater consumer recognition and

contribute to competitiveness. The efficacy of products and ingredients should be tested by independent experts and the results communicated to the consumer. Communicating credible, scientific information about product ingredients will enable consumers to make informative decisions, increase consumer confidence, and ultimately maintain the credibility of the industry (IFT 2005, Spence 2006). Consumer education is even more effective if it is sourced from credible public and health institutions (AAFC 2009).

The inconsistencies and variety of regulatory systems pertaining to nutrient and product labelling, composition and health claims also affects the industry, particularly export-oriented firms which must then comply with multiple regimes. The lack of exclusivity of health claims and differences in regulations regarding them discourages firms from investing in product development (IFT Panel 2005).

Overall, the literature reviewed illustrated the critical role that additional research, particularly in product development, will have in the growth and sustainability of the functional food and NHP sector. Firms must undertake strategic marketing and have institutional support in terms of regulatory clarity pertaining to health claims and regulatory harmonization to ensure their future competitiveness. Table 18 summarizes the literature analysing the functional food and NHP industry and market trends.

Table 18. Summary of Industry and Market Perspective Studies

Author, Year, Location	Area, Title	Objective, Method	Citation, Prepared for
Hobbs, 2002 Canada	Functional foods and nutraceuticals Evolving Supply Chains in the Nutraceutical and Functional Foods Industry	To discuss factors that influences the evolution of supply chains in the FFNHP sector. How firms in the industry get started and the challenges they face. Descriptive Analysis	Canadian Journal of Agricultural Economics, 50(4): 559-568
<ul style="list-style-type: none"> • the functional food and nutraceutical sector is resource intensive • the absence of well-established property rights system discourages R&D by firms. • firms form partnership to raise resources, while there are some contractual rights issues. • disputes over property rights hamper firm’s abilities to capture rents. • developing more healthy products based on consumer interests and through scientific discoveries. • closely coordinated supply chains will reduce transaction costs and provide credible quality assurance. • supply chain development hampered by upstream raw materials supply and downstream food processing. • further research into the role of labelling and quality assurance within supply chains • health claim regulations are important for the growth of the sector. 			
Tebbens, 2002 Canada	Functional foods and nutraceuticals Functional Foods and Nutraceuticals: The Development of Value-added Food by Canadian Firms	To provide a benchmark measurement of the industry and a better understanding of the scope and nature of the sector. Survey/ Descriptive Analysis N=576	Statistics Canada Catalogue no. 88F0006XIE — No. 016 ISSN: 1706-8967 ISBN: 0-662-41612-0
<ul style="list-style-type: none"> • 294 firms engaged in FFNHP activities in Canada: 75 in ON; 72 in Quebec & BC; 33 in SK • 37% were small-sized; 31% medium-sized; 33% large sized • Common method of distribution: wholesalers, third party distributors, retailers, direct sales, internet sales, mail orders. • Most firms privately-owned, Canadian • 57% of firms exported to US, Japan, EU, Asia and Australia, New Zealand • 46% of firms were nutraceuticals only; 28% functional food; just over 25% engaged in both. • 51% of NHP firms deal with plant-based nutraceuticals; 37% with marine based nutraceuticals; 28% with animal or micro organism based nutraceuticals • 44% of functional food firms use active ingredients; remainder use plant breeding, genetic modification, and special livestock feeding. • Further research to document trends and growth in the sector 			
Mark-Herbert 2003 Sweden	Functional foods Development and Marketing Strategies for	To develop strategies for developing and marketing functional foods	AgBioForum, 6(1&2): 75-78. ©2003 AgBioForum Swedish University of Agricultural Sciences, Uppsala

	Functional Foods	Descriptive Analysis	
<ul style="list-style-type: none"> • Three strategic plans proposed for product development: acquisition of property rights to ingredients that have undergone independent clinical studies, giving exclusive rights to sales; development of brand products to achieve customer recognition and/or alter consumption; involvement of health experts in product evaluations to increase product credibility among consumers. • firms should promote functional food efficiency and create awareness through market segmentation and specific marketing channels: 'sufferers' segment marketing via health professionals; 'at risk' utilize health related news and talk shows; 'prevention and mass market' utilize print media and radio. 			
IFT Panel 2005 US	Functional foods Functional Food: Opportunities and Challenges	To further the understanding of the opportunities and challenges posed by functional food development. Descriptive Analysis	http://members.ift.org/NR/rdonlyres/20B9EBDD-93B9-4B1B-B37B-3CF15066E439/0/FinalReport.pdf Institute of Food Technologists (IFT) Expert Report
<ul style="list-style-type: none"> • belief of the correlation between diet and disease prevention/health, availability of food technology and increased consumer desires for healthier food products provide an opportunity for growth in functional food. • lack of exclusivity in health claims discourages companies from investing; absence of a well-established property rights system for effective patent protection; cost of product development are major challenges facing the sector. • government should invest in basic and applied research to promote product development. • policies i.e. period of exclusivity for health claims and patents or tax incentives would encourage food companies to pursue functional food development. • Contributions required from academia, government and industry. • Health claims increase consumer confidence, enable consumers to select products that satisfy their desire to promote self-care and improve health. • recommends the establishment of scientific, regulatory and business frameworks to review new functional ingredients and their health claims for efficacy and safety; communicating the findings of the regulators to educate consumers will ensure informed decision making which is important for the success of functional food; research in the areas of bioactive compounds identification and their effects on health. 			
Palinic 2005 Canada	Functional foods and nutraceuticals Results from the Functional Foods and Nutraceuticals Survey - 2005	To provide a benchmark measurement of the industry and a better understanding of the scope and nature of the sector. Survey/ Descriptive Analysis N=389	Statistics Canada Catalogue no. 88F0006XIE, no. 003 ISSN: 1706-8967 ISBN: 978-0-662-46010-7
<ul style="list-style-type: none"> • an estimated 389 firms in the FFNHP sector in Canada; NHP: 174 firms; functional food: 118 firms; and 94 firms involved in both product categories • Total revenue from the FFNHP industry was \$2.9 billion in 2005: functional food only firms - \$823 million, NHP only firms - \$1.6 billion and both functional food and NHP firms - \$442 million. • Majority of functional food firms (85%) undertake R&D as compared to 66% of NHP. Total spending on R&D was \$162.8 million (\$74.5 million on product development; \$88.3 million on other areas including marketing, distribution, and consumer research activities). • most firms export to the US, Korea, and Japan. • common form of distribution in the sector is wholesalers (70% NHP; 50% functional food) [Retail: 31% NHP; 45% 			

<p>functional food; Direct sale to customer: 25% of FFNHP firms]. Most firms in the sector seek partnership in the areas of R&D; production; marketing; and access to distribution channels.</p> <ul style="list-style-type: none"> • Majority of firms in the sector did not have patents. For firms that did, 30% were registered with the United States Patent and Trademark Office; 16% with the Canadian Intellectual Property Office; 11% with the European Union patent office; and the rest were with other jurisdictions. • The ability to make health claims on product boosted sales. • Compared to an earlier study (Tebbens 2002), firms in the sector had increased by 32%; revenue has risen by about 15%; and R&D on products increased by 29%. • Recommends the allowance of product-specific health claims. 			
Krakar and Gao 2006 Canada	Functional foods and nutraceuticals Summary of the Functional Foods and Nutraceuticals Survey	To provide new statistical information on the functional food and nutraceutical sector; and a profile of firms engaged in functional and/or nutraceutical-related activities in Canada. Survey/ Descriptive Analysis N=276	http://www.agr.gc.ca/pol/index_e.php Publication No. 10080B ISBN No. 0-662-42169-8 Catalogue #A38-4/5-2005E-PDF Project 05-019-r Strategic Research Policy and Planning Team AAFC
<ul style="list-style-type: none"> • Firms mostly made up of small Canadian controlled firms, with more firms engaged in nutraceuticals than functional foods. • Almost 90% of responding firms were engaged in partnerships or seeking partnerships. • Trade secrets seem to be the most commonly used method to protect intellectual property. • Existing patents are registered with the European patent office, followed by the US patent and trademark office, the Canadian intellectual property office, with the remainder registered in other countries. • Pending patents are distributed across the globe. • Most firms believe the allowance of health claims on their products will have a positive impact on sales. 			
Spence 2006 US	Functional foods Challenges Related to the Composition of Functional Foods	To discuss the challenges firms face in the development of functional foods Descriptive Analysis	Journal of Food Composition and Analysis 19 (2006) S4–S6 United States Department of Agriculture
<ul style="list-style-type: none"> • The increase in the number of products makes it difficult for consumers to keep track of the particular composition of products which can shape attitudes towards functional food. • Maintaining accurate information about functional food composition is a difficult task as firms face a challenge of balancing variety and nutrient, and may not know all the functions of dietary ingredients. • Functional food designers should be cautious when developing products because of the possibility of consumers misunderstanding the role of bioactive food components. • There is a need for accurate information about functional food composition to maintain industry credibility 			
Cinnamon 2007 Canada	Functional foods and NHPs Results from the Functional Foods and Natural	To provide indicators that will help with innovations in the sector Survey/ Descriptive	Statistics Canada Catalogue no. 88F0006X, no. 1 ISSN 1921-300X ISBN 978-1-100-13192-4

	Health Products Survey - 2007	Analysis N=689	
<ul style="list-style-type: none"> • There were 689 functional food and NHP firms; 290 NHP only firms; 174 functional food only firms; 177 firms producing both functional food and NHP; and 48 firms providing services. • Total revenue in 2007 amounted to \$3.7 billion with NHP generating more revenue (\$1.8 billion). • There were approximately 22,062 product lines in the market, and majority of the product lines were for NHP. • United States is the major export destination for Canadian functional food firms, while China, Europe and Japan are the major export destinations for NHP firms • NHP firms preferred wholesalers compared to retailers by functional food firm as distribution channels. • Total spending on R&D was approximately \$209 million in 2007 with approximately \$148 million spent on functional food and NHP R&D. • Both functional food and NHP firms indicated health purposes in the areas of vascular health; weight control; energy; immune system; and overall health and well-being were of major importance in terms of R&D. • Most firms (87%) in the paper did not have patents and the trade secret was the common form of IPRs protection used by firms NHP firms had the most patents. • Compared to the 2005 study, there has been significant growth in the sector: The number of firms has increased by 77%; revenue increased by 28%; revenue from trade increased by 34% and expenditure on R&D increased by 98%. • The study recommends government support in the area of regulations 			
Herath, Cranfield, Henson and Sparling 2008b CANADA	Functional foods and nutraceuticals Firm, Market, and Regulatory Factors Influencing Innovation and Commercialization in Canada's Functional Food and Nutraceutical Sector	To develop a better understanding of the drivers of functional food and nutraceuticals innovation. Survey/Econometrics N=576	Agribusiness, Vol. 24 (2) 207–230 (2008) Department of Food, Agricultural and Resource Economics, University of Guelph
<ul style="list-style-type: none"> • Increasing number of product lines and products positively affect the market but negatively affect product development/innovation; firms focus more on product commercialization than new product development. • Existing regulations regarding composition and label requirements have a negative impact on innovation in Canada. Firms face the risk of unsuccessful new product development and commercialization because products may not be accepted in the market or not meet consumers' desires, clinical trial failures because of difficulties proving the efficacy of products, and/or regulatory evaluations approval. Harmonizing health claims and composition and labelling regulations with the US will encourage firms to innovate at the product level. • IPRs do not have a significant positive impact on innovation but patents have a significant negative impact on product lines. IPRs positively affect biotechnologically produced products' R&D. Firms focused on patents have less product lines which might be due to significant substitution effects where, instead of developing their own products, firms acquire products from other developers. The number of products on the market is not affected by the choice of target market. • recommend fewer product lines as important for successful innovation; the development of policies and regulatory reform to enable the efficient use of generic health claims on functional food and nutraceuticals. 			
Stein and Rodriguez-Cerezo,	Functional foods Functional Food	To provide a comprehensive overview of	http://europa.eu/JRC_43851 EUR 23380 EN

2008 EU	In The European Union	functional foods in the EU Descriptive Analysis	ISBN 978-92-79-09071-4 ISSN 1018-5593 DOI 10.2791/21607 European Commission, Joint Research Centre, Institute for Prospective Technological Studies
<ul style="list-style-type: none"> • The market for functional food within the EU is estimated to be EUR 6-20 billion. • Markets differ because of country specific health and dietary needs. • The most consistent reason for increasing demand for functional food in the EU was to stay healthy. • Dairy products have the greatest market share followed by beverages, cereals, confectionary, fats and fat supplements, infant foods, bakery, convenience, and miscellaneous products. • Functional food ingredients: probiotic bacteria are the dominant bioactive ingredient followed by, dietary fibres, and plant extracts. consumption of functional food in Japan and the EU was considered to be more sustainable because of a genuine consumer interest in these products. • dominance of established conventional food product companies in the functional food sector which is taken as a sign of barriers to entry. • The withdrawal rate of products from the market is roughly 75% within the first 2 years. • Demand is high for products that help in weight loss, digestion improvement, immunity enhancement, and women's health. • Recommends collaboration among firms in the areas of research, distribution channels, and supply agreements. 			
AAFC 2009 Canada	Functional foods Market Analysis Report 2009	To provide insights for stakeholders in the functional food industry. Descriptive Analysis	http://www.gov.mb.ca/agriculture/statistics/pdf/marketanalysis%20report_functionalfoods-en.pdf International Markets Bureau
<ul style="list-style-type: none"> • Annual growth rate for the functional food market in Canada is estimated at 8-14%. • R&D in the industry is resource intensive. • New firms struggle to gain market share and customer loyalty in the industry; industry is highly concentrated with the dominance of a few large companies. • industry is growing; firms should seek partnerships with other stakeholders that consumers trust to be a credible source of information. • recommends the development of products for niche markets, and also educating consumers about the health benefits of products in a way consumers find credible, such as the use of public and health institutions. 			
Evani, 2009 US	Functional foods Trends in the US Functional Foods, Beverages and Ingredients Market	To provide an overview of the Unites States functional food and beverage market and its potential. Descriptive Analysis	http://www.ats-sea.agr.gc.ca/eve/5289-eng.htm Institute of Food Technologists and AAFC
<ul style="list-style-type: none"> • North American functional food market grew from approximately 200 products in 2006 to over 800 in 2008. • US functional food and beverages market is estimated to have a retail value of \$59billion in 2008 with estimated annual growth rate of 6.1% from 2007-12. • An aging population, increasing health care cost, belief in the correlation between diet and health, and the convenience to meet nutritional needs by consumers are the major determinants of demand for functional products. 			

<ul style="list-style-type: none"> • Consumer demographic is very important for product development. • Ingredients mostly used in the US market are: low-calorie sweeteners, fibre, probiotics, omega fatty acids, anti-oxidants and sodium substitutes. • Younger consumers represent an important market segment that affect sales; seeking out healthy convenience oriented products that provide quick health solutions • New products need to be easy to understand and use less scientific vocabulary to avoid confusion 			
Arias-Aranda and Romerosa-Martinez, 2010 Spain	Functional foods Innovation in the Functional Foods Industry in a Peripheral Region of the European Union: Andalusia (Spain)	To examine the effect of the relationship between public sector research and industrial development in the functional food sector on innovation Descriptive Analysis	Food Policy 35 (2010) 240–246
<ul style="list-style-type: none"> • There are over 200 functional food products in the Spanish market. • In 2007 there were 29 functional food firms and 19 research institutions devoted to functional food in the Andalusia region. Annual growth rate of the functional food sector is 14% compared to only 3% for conventional food; growth has been attributed to increased consumer interest in functional food. • There have been significant public policies on functional food research but have not translated into innovative activities and application. • very limited relationship between academic research groups and functional food companies investing in R&D; most firms outsource research functions to public and private institutions outside Andalusia). • Recommendations include the creation of relations between stakeholders that will lead to innovation in the sector; increasing entrepreneurial activities on the part of researchers; promotion of international research groups; and stimulating the sector with government support to increase economic growth. 			
Bleiel 2010 NA	Functional foods Functional Foods From the Perspective of the Consumer: How to Make It a Success?	To discuss potential market failures of functional food Descriptive Analysis	International Dairy Journal 20 (2010) 303–306 Food for Health Ireland, University College Cork
<ul style="list-style-type: none"> • Failure of functional food products common because of consumer rejection. • Firms ignore consumer insights at the innovation stage. • Consumers seek the wellness benefits of functional food ingredients, so firms should emphasize the benefits from consuming the product rather than the ingredients used in making the product. • Product development should be based on consumers' behaviour, needs and desires about functional food. 			
Note: FFNHP: Functional foods and Natural Health Products NHP: Natural Health Products IPRs: intellectual property rights			

4.3. Product Specific Studies

The previous section examined studies that focused on consumer responses to functional foods, the functional food and NHP industry, market performance and challenges. This section reviews literature focusing on the development of products with health attributes. The review provides an indication of how consumers are responding to *specific* functional foods and possible ways to improve consumer acceptance of such products, as well as shedding light on firms' development processes for specific products with improved nutrition or enhanced compounds.

Surai and Sparks (2001) conducted a study on the potential of eggs as a functional food. The study claims that incorporating nutritive qualities from eggs into any food enhances its value. Omega-3 enriched eggs is one of the ways that eggs have been modified to increase nutrient value; the authors believe that consumption of one or two omega-3 eggs daily may have health promoting properties by increasing n-3 fatty acids in blood lipids. Marshall et al (1994) is cited, stating that 65% of consumers in five major Texas cities in the US were willing to purchase n-3 fatty acid-enriched table eggs, of which 75% were willing to pay an additional \$0.50 per dozen.

In a subsequent paper, Surai and Sparks (2001) reaffirm that eggs could be considered a functional food, as certain nutrients (i.e. vitamin E and DHA) can be increased such that consumption of a single egg could deliver sufficient nutrients comparable to daily requirements. However, the authors believe the perception that egg consumption leads to a rise in blood cholesterol with negative health consequences is a potential barrier to increased consumption of such so-called 'designer' eggs (especially in western countries). They assert this perception is being negated as expert opinion on the role of dietary cholesterol in the development of heart disease is changing. Further research into improvements in designer egg quality, assessment of designer egg benefits and consumer education regarding the benefits of eating eggs with enhanced nutrients are recommended.

Lutter and Tucker (2002) support the health benefits of salmon genetically modified to include omega 3 fatty acids. The objective was to estimate any potentially overlooked health benefits of this product, especially in reducing the risk of heart disease. The study focussed on four factors: the effect of omega 3 fatty acid consumption on heart disease risk; the consumption of salmon and omega 3 intakes; the price and consumption of salmon; and the retail price and cost of production. The authors argue that GM salmon will reduce the cost of production by half and will also reduce the risk of coronary heart disease by roughly 0.2%, translating into

preventing approximately 1400 deaths per year in the US.. Finally, the study stipulates that regulators and critics of GM salmon often focus on the adverse effects of genetic modification and negative environmental effects (such as impact on endangered salmon species) without taking into account the potential benefits such as access to less inexpensive, healthier food and improvements in public health.

Maynard and Franklin (2003) studied dairy products enriched with conjugated linoleic acid (CLA) and estimated consumers' willingness to pay for cancer-fighting dairy products in the US. A contingent valuation survey was used to measure respondents' willingness to pay for a hypothetical good (sample size 111 respondents). The results suggest consumers are willing to pay more for dairy products enriched with CLA: on average an additional \$0.41 per gallon for high-CLA milk; an additional \$0.38 per pound for high-CLA butter; and \$0.15 per eight-ounce cup more for high-CLA yoghurt. Eighty percent of respondents were willing to pay at least \$0.20 per gallon of milk for the purported cancer-fighting benefits of CLA. The study shows commercial prospects for high-CLA dairy products exist but cautioned that there is a need for additional evidence of health benefits and the support of the medical community is required to increase market opportunities. The paucity of information and scientific evidence available to consumers concerning CLA-enriched products limits their current potential.

In a discussion paper on probiotics, Fitzpatrick (2005) provides an overview of Canadian probiotic research and issues relating to probiotics in Canada. The author defines probiotics as "live microorganisms that when ingested in appropriate quantities, have a beneficial effect in the prevention and treatment of specific medical conditions by improving the host's intestinal microbial balance" (p. 2). The paper was based on interviews with 8 (of 30) researchers contacted across Canada. Findings indicate that extensive Canadian research in probiotics is undertaken but funding for the research has decreased. The eastern regions of the country conduct a significant amount of research in all aspects of probiotics for natural health products, functional food and animal health, while the western region (specifically Alberta) is more focused on dairy-based probiotics. It was recommended that further consultation and dialogue between the probiotic research community and the federal Natural Health Products Directorate (NHPD) was required, as well as interactions between the medical community and probiotic researchers. Finally, Fitzpatrick (2005) recommended that continuous funding for research will

need the involvement of all stakeholders including non-traditional key research funders (for example, industry associations, provincial agriculture and health departments).

Malla et al (2007) valued the potential health benefits of trans-fat free canola oil. The study utilized the COI (cost of illness) approach and presented two methods of estimating the health-care cost savings from a reduction in trans-fat consumption in Canada. The first approach measured the effect of trans-fat consumption on total cholesterol level changes. The second approach calculated cholesterol levels as a percentage of energy intake (LDL and HDL) due to reduced trans fat consumption. The correlation between high cholesterol levels and the consumption of trans-fatty acids (TFA) is garnering much public attention, particularly in countries with publicly funded health care systems. Companies have responded to these TFA concerns by conducting research on new seed varieties containing high oleic content which produce stable oils without the hydrogenation process that creates trans-fats. An example is the new canola variety, Nexera. Nexera is used to make Natroen oil which is regarded as a functional lipid food due to the modification of its fatty acid composition.

The study argued that two forms of market failures are apparent with respect to TFA consumption; firstly, negative externalities exist, when the full costs of diet-related health problems are not fully borne by the individual; and secondly, information asymmetry exists if firms are not required to label the trans fat content of their products. Four steps were utilized to calculate potential savings in social costs from trans-fat free canola oil, each of which have been individually supported by scientific evidence from the medical literature,: estimating potential daily trans fat intake reduction due to trans fat free canola oil; calculating the cholesterol change due to reduced TFA consumption; calculating coronary heart disease (CHD) risk reduction due to changes in cholesterol profile; calculating health care cost changes related to CHD risk reduction. The study estimated an annual health-care savings from the reduction in daily TFA intake of Cdn\$ 1,094 million for a base scenario, with estimated cost savings ranging from Cdn\$ 1,818 million to Cdn\$ 639 million in scenarios based on different assumptions about health outcomes. Consumption of healthier food that contained TFA free oil could lead to significant healthcare cost savings, potentially increasing economic welfare.

The study explored policies including the mandatory labelling of TFA and consumer education to help reduce information asymmetry as a source of market failure, but argued that this policy alone will not lead to socially optimal consumption levels. Stronger economic

incentives could include imposing Pigouvian taxes on TFA foods or a consumption subsidy on TFA free foods. Initial estimates of the size of the economic incentive needed under a tax or subsidy policy were also provided. Other recommendations included regulations to limit the contents of TFA in food and further research on the substitution relationship between various food oils under a tax or subsidy policy, and the resulting health outcomes.

Dean et al (2007) evaluated how consumer perceptions of healthy cereal products is influenced by production methods, gender, nationality, base product (staple vs. fun food), and health claims (generic vs. specific). The study used a survey with a sample size of over two thousand consumers responsible for family grocery purchasing from the UK, Italy, Finland and Germany analysed using analysis of variance (ANOVA) methods. The authors defined functional cereal products as grains, such as wheat, maize, rice, oats, etc. that have been modified to provide health benefits over and above basic nutrition. The chosen products were bread, pasta and biscuits. Bread and pasta represented staple grain foods while biscuits are an 'occasional' food. The health claims specifically chosen were 'cholesterol lowering' and 'added fibre'. The result shows that British, Finnish and Italian consumers perceived bread that lowers cholesterol as more beneficial than did German consumers. Cholesterol-lowering pasta was perceived to be more beneficial by British and Italian consumers than by Finnish and German consumers. Finnish consumers perceived bread with added-fibre as more beneficial than did consumers in the other countries; overall the mean benefit perception among the chosen products was that bread with fibre-added is the most beneficial, with cholesterol-lowering cookies (biscuits) the least.

The results also showed that consumers prefer modified base products, i.e. staple foods such as bread and pasta, over modified occasional foods such as cookies. Consumers also showed preferences for production methods such as fortification and traditional cross-breeding over genetic modification. Finally, men valued products with specific health claims, while women perceived more benefits in products with general health claims. The study confirmed the findings of others in the area of functional food regarding the importance of gender, health claims, nationality, base products, and consumer perceptions and attitudes.

Based on laboratory research, Boue et al (2009) examined the health benefits of the nutrient Phytoalexin in functional foods. Phytoalexin is a plant compound that contains beneficial properties including antioxidant activity, anti-inflammation activity, cholesterol-reducing ability,

and anticancer activity. Phytoalexin increases in plants when they are grown without fertilizer or grown under organic conditions. Although previous research has been conducted on Phytoalexin, only recently has it been explored for its nutritional components and as an ingredient for developing health-enhancing food products. The research concludes that organically grown products reportedly contain high levels of health-enhancing compounds and increase the development of phytoalexins. Somewhat controversially, the study speculates that modern agricultural methods may be limiting the production of health promoting compounds based on the assertion that organic products contain more health enhancing compounds than non-organic products. Phytoalexin-enriched foods is proposed as a new area of research focusing on how plants can produce higher levels of beneficial compounds.

Nepote et al (2009) examine the relationship between overall acceptance and chemical indicators in roasted peanuts harvested from high-oleic peanuts genotypes in Argentina. High-oleic oils can protect against cardiovascular disease by lowering low-density lipoprotein-cholesterol. The study used a panel of 100 consumers between the ages of 18 and 65 with the similar characteristics of being non-smokers, not suffering from allergies and being regular consumers of peanuts. Samples of peanuts with and without high-oleic were roasted under similar conditions and packaged in identical bags. Chemical analysis was conducted on 20g of peanut oil that was cold pressed from each sample. The results indicated that conventional peanuts are more susceptible to lipid oxidation compared to high-oleic peanuts. A low level of lipid oxidation is desirable as it reduces the risk of cardiovascular disease. Overall consumer acceptance for the high-oleic peanuts was higher than that of conventional peanuts. The study recommended the replacement of conventional peanut cultivars with high-oleic peanut lines to gain the advantage of high stability against the lipid oxidation process without negative effects on consumer acceptance, leading to potential health benefits such as the reduction in the risk of cardiovascular diseases among peanut consumers.

4.3.1 Insights from the Product-Specific Literature: A Summary

Overall, the literature on specific health-enhancing food products indicates promising prospects in the functional food and NHP sector. The potential gains from the sector are multi-faceted and could lead to private and social economic benefits as well as health improvements. There is evidence of consumer acceptance of these products and willingness to pay a premium

for their benefits. Consumer acceptance is critical and should in turn lead to additional R&D and product development.

Products such as GM Salmon (enriched with omega-3 which reduces the incidence of heart disease) if it can be produced at lower cost leading to lower retail prices for consumers should generate health and economic benefits for consumers (Lutter and Tucker 2002). In addition, increased consumption of nutrient enhanced products such as trans fat free oil designer eggs, high level CLA dairy products, golden rice, probiotics, functional cereals such as wheat, rice, maize and oats, phytoalexin-enriched foods and high oleic peanuts provide a myriad of important potential health benefits and improvements in areas where considerable health spending occurs (cardiovascular disease, cancer), thereby leading to potential healthcare cost savings and increasing overall economic welfare.

A number of studies have examined consumers' willingness to pay and their acceptance for specific products with health benefits, both are conditional on the health benefits provided and on the credibility of the claims being made. Consumer willingness to pay was illustrated in the cases of designer eggs enriched with omega-3, nutrients such as vitamin A and DHA (Surai and Sparks 2001) as well as CLA enriched dairy products which could reduce the risk of cancer. Nevertheless, the successful commercialization of nutrient enriched foods requires further research with respect to the commercial prospects and the role of credible health claims.

Consumer demand, acceptance and purchasing behaviour for functional food is also determined by the type of product, production method, gender, nationality, and health claim. Consumers prefer the modification of staple foods such as bread and pasta rather than occasional foods and production methods such as fortification and traditional cross-breeding were preferred over genetic modification (Dean et al 2007). Research using peanut consumers in Argentina showed that if taste and cost are comparable to conventional counterparts, nutritionally enhanced or 'better-for-you' products can be the product of choice and the transition from less healthy food products to those with health benefits may be a relatively easy one. If consumer acceptance is not affected by nutritional enhancement and willingness to pay is either unchanged or increases, the introduction of healthier new products can be beneficial for manufacturers in the form of rent capture and governments in the form of savings in health care costs.

In general, suggestions from the literature for further research pertaining to specific products include improving product quality, improving the benefits offered, research into

consumer education and knowledge, and research investigating the potential beneficial health effects of known or existing compounds used for other uses or applications. Consultation and dialogue between the research community and government regulators was encouraged, as were interactions between the medical community and researchers and the involvement of non-traditional key funders such as industry associations, provincial agriculture and health departments. Future research is recommended on the substitution relationship between various food products under a tax or subsidy policy and the resulting health outcomes.

Table 19 summarizes the product specific studies discussed in this section.

Table 19. Studies Pertaining to Specific Functional Foods and NHP

Author, Year Location	Title Area of Focus	Objective, Method	Citation Prepared for
Surai and Sparks 2001 Europe	Designer eggs from improvement of eggs composition to functional food Designer Eggs	To discuss how eggs can be turned into a functional food Descriptive Analysis	Trends in Food Science & Technology 12 (2001)7–16 Avian science research centre. Scotland UK
<p>Eggs are the only food of animal origin consumed by many people worldwide and can be considered a functional food as nutrients such as DHA, vitamin E, lutein and selenium can be enhanced. Consumption of 1-2 omega-3 eggs daily can increase n-3 fatty acids in blood lipid. Consumers are willing to pay a premium for the health benefits of designer eggs. Research into improving designer eggs quality, benefits of designer eggs, and consumer education are recommended. Egg consumption also benefits from the change in experts' opinions countering the belief that egg consumption increases dietary cholesterol and heart disease..</p>			
Lutter and Tucker 2002 US	Unacknowledged Health Benefits of Genetically Modified Food: Salmon and Heart Disease Deaths GM Salmon GM Salmon	To estimate the health benefits of GM salmon focusing on heart disease Incidence of illness approach and benefit cost analysis	AgBioForum, 5(2): 59-64. ©2002 AgBioForum
<p>Omega-3 enriched GM salmon will reduce the cost of production by half and leads to the provision of good nutrition at a reduced cost to consumers. It can also, through the omega 3 content, reduce the incidence of heart disease by roughly 0.2%, translating into an approximate reduction of 1400 deaths per year in the US. Critics of GM salmon usually focus on the adverse health of genetic modification and environmental effects while ignoring the benefits such as access to less costly, healthier food and improved health. Health benefits of GM salmon have significant policy implications.</p>			
Maynard and Franklin 2003 US	Functional Foods as a Value-Added Strategy: The Commercial Potential of "Cancer-Fighting Dairy Products" High level CLA-Dairy Products	To evaluate the commercial viability of functional dairy foods containing high levels of CLA Survey/Contingent Valuation N=111	Review of Agricultural Economics-vol.25, Number 2- pages 316-331
<p>Dairy products containing high levels of CLA (cancer-fighting properties) have good market prospects but there is the need for more scientific evidence of the health benefits. On average, consumers are WTP \$0.41 per gallon more for high-CLA milk; \$0.38 per pound more for high-CLA butter and \$0.15 per eight-ounce cup more for high-CLA yoghurt; 80% of respondents were WTP at least \$0.20 per gallon of milk for the cancer-fighting benefits of CLA. Currently, there is a paucity of information on CLA enriched products which hinders the ability to communicate with and develop attitudes and behaviours of consumers.</p>			
Lusk 2003 US	Effects of Cheap Talk on Consumer Willingness-to-Pay for Golden Rice Golden Rice	To determine consumer WTP for golden rice. Survey/Econometric Analysis N=600	American Journal of Agricultural Economics, Vol. 85, No. 4 (Nov., 2003), pp. 840-856
<p>Golden rice is a type of rice that has been genetically engineered to contain beta-carotene which can be turned</p>			

<p>into Vitamin A by the body. Consumers without knowledge of the product expressed a lower WTP in the presence of a cheap talk script whereas the stated WTP of those with knowledge about golden rice were not affected by the use of a cheap talk script. Cheap talk is a nonbinding communication between a researcher and survey respondent before the administration of the hypothetical questionnaire outlining the issue of hypothetical bias..</p>			
<p>Fitzpatrick 2005 Canada</p>	<p>Probiotics Discussion Paper</p> <p>Probiotics</p>	<p>To provide an overview of probiotic research in Canada</p> <p>Survey/Descriptive Analysis N=8</p>	<p>Report submitted to the Natural Health Products Directorate, Health Canada</p> <p>http://www.hc-sc.gc.ca/dhp-mps/pubs/natur/probio_discuss-travail-eng.php</p>
<p>Probiotics are live microorganisms that if consumed in sufficient quantities can improve the consumer's intestinal state, helping prevent and treat certain medical conditions. While there is extensive research in Probiotics across Canada, funding for such research has decreased. Further areas of focus include consultation and dialogue between the probiotic research community and the governmental department responsible for NHPs, interactions between the medical community and probiotic researchers, and the involvement of non-traditional key funders like industry associations; provincial agriculture and health departments.</p>			
<p>Dean et al 2007 UK, Italy, Finland, Germany</p>	<p>Consumer perception of healthy cereal products and production methods</p> <p>Functional cereals</p>	<p>To evaluate consumer perception concerning bread; pasta; and biscuit enriched with health attributes; and their production methods</p> <p>Econometric/Statistic/Survey N=2000+</p>	<p>Journal of Cereal Science 46 (2007) 188–196</p>
<p>The study defines functional cereal products as grains such as wheat, maize, rice, oats, etc. that have been modified to provide health benefits over and above basic nutrition. Consumer responses to cereal products with either 'cholesterol lowering' and 'fibre added' as health claims were tested. Bread, pasta and biscuits were the products used in the study. . Fibre-added bread is perceived to be the most beneficial with cholesterol lowering biscuits the least. The results showed that people preferred staple foods such as bread and pasta as base products for modification than occasional food like cookies. Consumers illustrated gender and country specific preferences in terms of which health benefit is desired, types of delivery product, as well as means of enhancing the product. British, Finnish and Italian consumers perceived bread that lowers cholesterol as more beneficial than did German consumers. Cholesterol lowering pasta was perceived to be more beneficial by the British and Italians than the Finns and Germans. The Finns perceived fibre-added bread as more beneficial than did consumer in the other countries. Moreover, production methods such as fortification and traditional cross-breeding were preferred over genetic modification. Men tended to value products with specific health claims while women perceived more benefits in product with general health claims.</p>			
<p>Malla et al 2007 Canada</p>	<p>Valuing the Health Benefits of a Novel Functional food</p> <p>Novel functional foods (Trans fat free oil)</p>	<p>To estimate the health care cost saving from a reduction in trans-fat acid consumption and discuss policy implications.</p> <p>Cost of illness approach (COI)</p>	<p>Canadian Journal of Agricultural Economics 55 (2007) 115-136</p>
<p>Healthier food utilizing TFA free oil can lead to significant health-care cost savings and could increase economic welfare. Scientific evidence link consumption of food with trans-fatty acid to elevated cholesterol levels and a higher incidence of CHD. Consumers suffer from information asymmetry related to TFA consumption which may lead to under-consumption of healthy foods and over-consumption of unhealthy foods, as well as a healthcare</p>			

<p>externality where the full costs of poor consumption decisions are not borne fully by the individual. The study estimated a health-care savings from reduction in daily TFA intake equal to Cdn\$1,094 million annually for a base scenario and ranging from Cdn\$1,818 million to Cdn\$639 million annually under various scenarios. The paper examine labelling policies and consumer education as a response to information asymmetry but argues that these steps alone will not lead to socially optimal consumption levels. Stronger economic incentives could include a Pigouvian tax on TFA foods and subsidies on TFA free foods. Future research is recommended on the substitution relationship between various food oils under a tax or subsidy policy and the resulting health outcomes.</p>			
<p>Boue et al 2009 US</p>	<p>Phytoalexin-Enriched Functional Foods</p> <p>Enriched functional foods</p>	<p>To explore the benefits of Phytoalexin-Enriched food</p> <p>Laboratory Research</p>	<p>Journal of Agricultural and food chemistry. 2009, 57, 2614–2622</p> <p>American Chemical Society</p>
<p>Phytoalexin is a plant compound with antioxidant and anti-inflammation benefits, cholesterol-reducing ability and anticancer activity. Phytoalexin is increased in plants when they are grown without fertilizer or grown under organic conditions. The study speculates that modern agricultural methods are, to some extent, limiting the production of such health promoting compounds. The traditional view of such compounds was in their phyto-defensive role for plants, their potential health benefits for humans was unknown. The study proposes a new area of functional food research focusing on products that utilize plant compounds or phytoalexins created either pre- or post harvest</p>			
<p>Nepote et al 2009 Argentina</p>	<p>A Study of the Relationships Among Consumer Acceptance, Oxidation Chemical Indicators and Sensory Attributes in High-Oleic and Normal Peanuts</p>	<p>To determine the relationship between overall acceptance and chemical indicators in roasted peanuts harvested from high-oleic peanut genotypes.</p> <p>Survey/Econometric/Statistic and laboratory research N=100</p>	<p>Vol. 74, Nr. 1, 2009—Journal Of Food Science</p>
<p>High-oleic peanut has an overall higher acceptance amongst consumers over conventional peanuts. High-oleic peanuts possess high stability against the lipid oxidation process leading to health benefits such as the reduction in the risk of cardiovascular diseases. High-oleic peanut oil has the benefit of offering protection against cardiovascular disease by lowering low-density lipoprotein-cholesterol. The study recommended the replacement of normal peanut cultivars with high-oleic peanut lines as there do not appear to be negative effects on consumer acceptance but health benefits are gained. .</p>			
<p>Notes:</p> <p>NHP: Natural health product FFNHP: Functional food and natural health product TFA – trans fat free oil GM – genetically modified CHD – chronic heart disease COI – cost of illness WTP willingness to pay</p>			

4.4. Regulatory Frameworks and Policies

The functional food and NHP industry suffers from widespread inconsistencies in terminology and definitions throughout global markets, inconsistencies that are also prevalent in regulatory and policy environments. An industry experiencing rapid growth and development, combined with the need to protect consumer health and interests, has led to the evolution of a myriad of different regulatory frameworks and policies across multiple markets. Individual countries have developed their own regulatory frameworks and policy agendas concerning labelling and approval of functional food and NHPs, novel food application procedures, nutritional contents, health claims and the enforcement of these regulations. Efforts to harmonize regulations across borders have been hampered by a vast array of differences in approach and systems. This section reviews scholarly articles and policy position papers dealing with regulatory policies affecting the functional food and NHP industry. The section begins with literature charting the evolution of the regulatory environment in Canada, before turning to other jurisdictions²⁶.

A Government of Saskatchewan (2008) document acknowledged the rapid growth of the functional food and NHP industries in Canada and globally, driven mainly by wellness, convenience and quality. In 2006, the global nutrition market, comprising supplements/NHPs, natural and organic foods, personal care products, and functional foods, was valued at an estimated US\$ 228.3 billion, of which functional foods accounted for US\$ 85.0 billion (37.2 %) and supplements/NHPs represented US\$ 68.3 billion (29.9%). The global market of functional food and natural health products grew by approximately 33% and 68% respectively in 2006 with an annual growth of 7% to 10% forecasted. The dominant countries in the global market are United States (34%), Europe (28%), and Japan (21%) with Canada claiming a 2.6% share of the global market in 2008. Newly industrializing countries such as China, India, Brazil, Mexico, Eastern Europe, and Russia, are emerging in the global market for functional food and natural health products. In 2007, there were roughly 400 companies active in the functional food and NHP sector, of which 12% are located in Saskatchewan.

Smith et al (1996) analyzed the regulatory frameworks affecting functional foods in Canada, Japan, United States and the European Union. The study utilized in-depth reviews of

²⁶ For a more detailed analysis of specific differences in health claims and the international regulatory environment for functional foods and NHPs readers are referred to the companion report to this report by Malla et al., 2013.

existing legislation, regulations and guidelines and in-person and telephone interviews of industry and government personnel. The analysis reveals that the international regulatory situation for the functional foods sector was constantly evolving even at this early stage. In Canada, the regulatory procedure governing the manufacture, packaging, labelling, and advertising of functional foods was found to be relatively restrictive, thereby limiting product development and marketing. Few disease-risk-reduction health claims were approved and novel food application requirements are strenuous. The study argued that consumer access to functional foods had been limited while investment and competition in the industry was restricted under the Canada Food and Drug Act which offered the option of licensing and selling of functional foods as “drugs”. In contrast, it is argued that Japan’s regulatory system had evolved through collaboration among many industry stakeholders (firms, consumer groups, government, academia and research organizations). Japan’s regulatory system supports the development and marketing of functional foods; its licensing process for functional foods (classified as Food for Specified Health Use - FOSHU) is seen as well-defined and predictable.

The regulatory framework in the United States, though comparatively restrictive, was classed as more favourable/supportive to the development and marketing of functional foods compared to that of Canada. Legislation pertaining to the approval, labelling and advertising of dietary supplements, which may be applicable to certain functional foods, was well-defined. The regulatory situation in the EU was found to be limited and less restrictive than that of Canada in terms of the commercialization and marketing of functional foods and nutraceuticals due to the fact that adoption and enforcement of functional food legislation varies among the member states. The study’s recommendations for regulatory reform in Canada included the development of a regulatory framework that is supportive of functional food based upon the acknowledgement of consumers’ right of access to functional foods and information about them; regulatory reform undertaken through a collaboration between government and industry;; differentiation of disease-risk-reduction health claims from wellness claims (structural claims) to reduce the processing time of functional food claims approval; and harmonization of health claims with that of the United States. The regulatory environment in Canada has continued to evolve since the publication of Smith et al (1996).

Veeman (2002) focused on the challenges of policy development for functional food and NHPs, comparing the international regulatory situation to that of Canada and making

recommendations to address the challenges. The author noted that the market for functional food and NHPs was growing globally because consumers are motivated to pursue healthy diets, however, the industry suffered from market failures due to uncertainty and information asymmetry associated with health claims on these products. Yet Japan, the US and other nations had implemented policies that enabled manufacturers to make health claims on functional foods, nutraceuticals and NHPs, albeit significant variations in policies existed. The example of Germany where NHPs are treated as drugs and sold through pharmacies as prescription medications was contrasted with the US, where the same products (referred to as dietary supplements) are sold without preclearance and with health claims. S-adenosylmethionene (SAME) is provided as an example of a product that is regarded as a dietary supplement in the US, but at the time was classified as a drug in Canada that required a drug identification number and license from Health Canada, while in Europe it was available as a prescription medication

Policy harmonization is possible however, as the example of the coordination of food standards between Australia and New Zealand illustrates. The study asserts these products are sold on the basis of their credence attributes, where their effectiveness cannot be directly identified pre- or post-consumption, and therefore leave consumers vulnerable to being misled, as their purchase decision is highly influenced by the product's labelling claims, giving producers an incentive to be make misleading claims. Veeman (2002) asserts that government intervention is necessary to address these inefficiencies to balance the interests of both consumers and producers through mechanisms that verify claims and information provided by producers.

Jepson (2002) examined the legislation, regulations and the development of a new regulatory framework for NHPs in Canada, arguing that the absence of a definition of NHPS in the Food and Drug Act of Canada at that point in time had been the source of difficulties. The Food and Drug Act considered any natural health product that made a health claim, (directly or indirectly) as a drug and consequently these products were regulated as drugs in Canada, requiring the acquisition of a Drug Identification Number (DIN) in order to be sold. Difficulty in enforcing the Food and Drug Act regulations as it applied to NHPs led Health Canada to introduce the "Interim DIN Enforcement Directive" in 1998, where a manufacturer without a DIN was sent a letter advising them to get a DIN but without any further enforcement action taken. The study also showed the inequality of enforcement of the Food and Drug Act regulations suggesting that the

eastern and Atlantic provinces tended to have more enforcement incidences compared to the western provinces.

Recognizing the need to overhaul regulations affecting the functional food and NHP sector in Canada, a long process of review and consultation began with the publication of a 1998 Health Canada policy paper (Health Canada, 1998). The paper arose from a joint project involving the Food Directorate, the Therapeutic Products Programme and other stakeholders in the industry including consumer groups, academia, health professionals, and representatives of the food and drug industries. The goal of the project was to develop a policy framework to address the lack of specific regulations related to health claims on nutraceuticals and functional foods. Definitions were proposed for both nutraceuticals and functional foods:

“A *Functional Food* is similar in appearance to, or may be, a conventional food, 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.”

“A *nutraceutical* is a product isolated or purified from foods that is generally sold in medicinal forms not usually associated with food. A nutraceutical is demonstrated to have a physiological benefit or provide protection against chronic disease.” (Health Canada, 1998, p. 3).

The absence of a definition for “health claim” in Canada at that time led the group to use the term in a broader sense similar to its use in the US: “A health claim specifically characterizes the relationship between the nutrient and a disease or medical condition that is related to the diet” (Health Canada, 1998, p. 7). Health claims were further categorized into three distinctions to better focus Canadian definitions: therapeutic, risk reduction, and structure/function claims. The therapeutic claim can apply for both functional food and nutraceuticals and suggests that a product can cure/treat/mitigate/ prevent a disease. The risk reduction health claim was defined as the ability to significantly change recognized risk factors involved in the development of a chronic disease. The structure/function claim was defined as the ability of the product to affect the structure or any function of the human or animal body. Any of these claims can be generic or product-specific: “Product-specific claims are made for a single commercial product. They could not be generalized to other similar products unless acceptable supporting evidence was provided. Generic claims may be applied to any food, provided that it meets the criteria for the claim” (Health Canada, 1998, p. 17-18).

Prior to this policy paper, the status quo practice was to regulate all products with health claims (including food) as drugs. The group proposed a final policy that disease risk reduction and structure/function claims for food and food component products (functional food and nutraceuticals) should be permitted while all other products with therapeutic health claims (said to cure, treat, mitigate or prevent illness) should continue to be regulated as drugs, regardless of their form. The establishment of appropriate standards for evidence and the development of a regulatory framework to measure and ensure compliance with the proposed policy for risk reduction and structure/function claims were also suggested. The policy paper also recommended the development of an implementation strategy, standards of evidence and composition for claims on food in consultation with industry stakeholders..

In 1999 Health Canada committed to evaluate ten generic health claims that were permitted in the United States and developed a discussion paper from a consultation workshop held in July 1999. Based on the 1998 policy recommendation (Health Canada, 1998) to permit risk reduction claims and structure/function claims on foods, and the results from a consultation workshop in 1999 as well as input from industry, Health Canada (2000) proposed conditions for the use of five generic health claims. The five chosen claims were those for which there was scientific agreement. Health Canada (2000) also contains information regarding stakeholders' opinions on the format of the claims, claims credibility, consumer education and scientific review of the claims. The proposed contents of structure/function and risk reduction claims are based on a thorough review of the scientific literature. Requirements and conditions to achieve authorization of claims differ in length and complexity based on the evidence supporting them.

The five claims recommended for approval in 2000 were: sodium and hypertension; calcium and osteoporosis; saturated and trans fat and cholesterol and coronary heart disease (CHD); fruits and vegetables and cancer; and sugar alcohols and dental caries. Health Canada (2000) proposed to not follow the US approach of requiring qualifying and disqualifying amounts in nutrient compositions in the food. The proposed conditions for food to bear health claims in Health Canada (2000) includes firstly, that the food product should fall into one of the four food groups of the Canadian food guide to healthy eating; secondly, be consistent with Nutrition Recommendations for Canadians and its update on Dietary Fat and Children; thirdly, claims should not be permitted on foods that fall into the "Other Foods" category of Canada's Food Guide to Healthy Eating (foods and beverages that are not part of any food group and

include foods that are mostly fats and oils; foods that are mostly sugar; high fat and/or high salty snack foods; beverages such as water, tea, coffee, alcohol, and soft drinks; and herbs, spices, and condiments); fourthly, that the saturated and trans fat to CHD claim should also be permitted on fats and oils that meet the conditions of the claim; fifthly, that specific exclusions or requirements needed for a claim are to be included in the conditions for the claim; and lastly, health claims should not be permitted on food for infants and children under two years. Proposed nutrition labelling required that the entire core list of nutrients and any nutrient mentioned in the claim except alcohol should be declared. Risk reduction claims must include two parts: information on an accepted diet-health relationship and information on the composition of the product relevant to the relationship.

Stakeholders opined seven issues affecting the formatting of the five health claims evaluated in Health Canada (2000): 1) number of claims on one package, where a food product may have more than one health claim provided requisites are met; 2) split claims, where a claim cannot be split on the package of the food to reduce consumer confusion; 3) advertising, where the health claim should appear in its entirety in the advertisement; 4) format standardization, where all elements of the claim must be of the same type face and size, grouped together, and have equal prominence; 5) fortification, where the claim for calcium and osteoporosis may be permitted on foods containing added calcium if the food is permitted to contain added calcium as a nutrient at the level required in the claim; 6) health claims and fresh fruits and vegetables, where banners with this health claim may be permitted for mixed fruits and vegetables as long as excluded foods form a minor part of the display; and 7) preapprovals, where products need not have pre-market approval but manufacturers need to ensure that the food meets the requirements in the health claim.

Health Canada (2000) also presented opinions on claim credibility, consumer education and a review of scientific evidence. To maintain credibility, a food product cannot use the name of Health Canada and any endorsement by third parties should conform to Canada's Guide to Food Labelling and Advertising. The implementation of a consumer education campaign was deemed important, as was a periodic review of the science behind the health claims.

With the successful identification of specific health claims the Bureau of Nutritional Sciences Food Directorate (BNSFD) (2000) proposed a framework for the evaluation of foods with health claims. Specifically, it was proposed that appropriate evidence to support health claims will

ensure ‘product safety’ and ‘claim validity’, as well as ‘quality assurance’ of production methods and procedures for product testing (BNSFD, 2000). All food products should undergo at least a basic evaluation so as to determine the safety of the product, in the areas of nutritional and toxicology impacts of ingesting the food. This evaluation will also consider anticipated exposure to the food product and all bioactive substances components. Further evaluations may be required when the product is novel and/or there are uncertainties surrounding the safety of the product.

In addition, a three step process was proposed to demonstrate the efficacy and effectiveness of the product in order to ensure claim validity: evaluation of the evidence supporting the causal relationship between the food and the claimed benefits through a systematic approach; determination of whether the strength of the evidence is sufficient to support the claim; and determination of whether the total evidence submitted is sufficient to characterize the relationship between the claimed benefit and the food or the bioactive ingredient. Quality assurance evaluations will be based upon the ability to identify, measure and maintain a consistent level of the bioactive ingredient in the product to ensure product safety and efficacy. Quality assurance can also be met via testing and the meeting of established and accepted standards such as good manufacturing practices (GMP), good laboratory practices, good practices about the collection and analysis of human data (clinical and/ or epidemiological practices), and finally documentation.

BNSFD (2001) proposed a regulatory framework based on the recommendations of Health Canada (1998, 2000) and its prior policy paper (BNSFD, 2000) which was to be published in Canada Gazette Part I. The main objective of the proposal was to establish a regulatory framework on the basis of the recognition that consumption of a reasonable quantity of a food containing a biologically active substance could affect the physiological function or structure of the body. The Bureau also used comments and suggestions from Canadians in drafting the framework. The proposal differed from the existing regulatory approach under the Food and Drugs Act and its regulations in Canada. Under the existing Food and Drugs Act, an entire food group may be the subject of a claim (e.g. “a healthy diet rich in a variety of fruits and vegetables may help reduce the risk of some types of cancer”). However, under the proposed framework by the BNSFD, the approach to be taken will be “product specific authorization” for health claims, whereby the product (functional food) with the intended claim is assessed on its own merit.

The key elements of the proposed regulatory framework were that all food (modified and non-modified) that affects the structure of the body or claims to reduce the risk of disease would be required to carry a Claim Identification Number (CIN). The manufacturer should provide proposed claim and product information including ingredients, nutrient composition, processing, intended use and target users which are then assessed for product safety, claim validity and quality assurance before a CIN is issued to the manufacturer. Under the proposed framework, a CIN may be cancelled or suspended when the authorizing conditions are violated, the sale of the product in Canada has been discontinued or new information requires the review of the product or the claim. However, a “product specific health claim” proposal suggested in the earlier 1998 framework (Health Canada, 1998) was rejected. Under the earlier proposal, a product specific health claim is based on the recognition that claims concerning the effect of a food or its ingredient “should not” be generalized to other similar products unless there is acceptable evidence to support them. Health Canada approved only the use of generic health claims which allows a claim to be made on similar products that are approved to carry the specific claim without a new claim application (BNSFD, 2001). There were additional recommendations under the 2000 proposed framework that were not part of the proposals in Health Canada (1998) including transparency of the product review process, facilitating access to information by publishing of approved claims on the Health Canada website, manufacturers may make their research findings public, applicants should inform the directorate of any changes in specified conditions and finally, it was recommended that the CIN should be displayed on the product label to indicate that it has been reviewed.

The Natural Health Products Directorate (NHPD) was created in 2001 with the responsibility of regulating NHPs. In 2004, NHP regulations came into force in Canada. Health Canada (2004) examined the regulatory framework prior to its implementation, defining NHPs as: “vitamins and minerals, herbal medicines, homeopathic medicines, traditional medicines such as traditional Chinese medicines, probiotics, other products like amino acids and essential fatty acids” which are safe to use and need no prescription to be sold. The framework is based on five basic elements. A product licensing system requires all NHPs to display a product identification number on the label, identified by the prefix NPN (or DIN-HM, for homeopathic preparations) after it is approved for sale in Canada. According to Health Canada, these identification numbers will assist in ensuring that quality products are sold to consumers, as well as quick and effective

product recalls can be made when necessary. A site licensing system requires all manufacturers, packagers, labellers, and importers to be licensed to ensure that producers and distributors have the appropriate procedures and facilities in place. Good Manufacturing Practices (GMPs) are to be employed to ensure product safety and quality. Standardised labelling requirements are stipulated, ensuring consumers can make informed choices. The labelling standard requires that information such as the product name, quantity in the container, recommended use and storage conditions are all provided. Finally, an adverse reaction system requires product license holders to monitor all adverse reactions associated with their products and report the serious ones to Health Canada.

The prior regulatory system had restricted the health claims that could be made on vitamins and minerals; the new NHP regulations repealed this by declaring that vitamins and minerals are included in the definition of NHPs allowing health claims. The new regulatory framework allowed a transition period of six years, at the end of which a product should have a product license and all manufacturers and distributors a site license. Within this transition period, all manufacturers, importers, packagers and labellers were expected to employ GMPs and have site licenses at the end of two years, while by the end of six years, NHPs that had a product license as a Drug Identification Number (DIN) were expected to have transitioned to a NPN or a DIN-HM (homeopathic medicine).

Fitzpatrick (2004) presented an overview of functional foods and natural health product regulatory issues in Canada, examining the implications of these regulations for manufacturers of CLA. The study argues that developments in nutrition labelling and health claims, specifically pertaining to fats, have benefits for CLA. The adoption of some of the disease risk reduction claims approved in the United States by Health Canada in 1999 required the provision of nutrition information on food labels in Canada, including information on calories, fat, saturated fat, trans-fat, and cholesterol but nothing about CLA isomers. CLA and other manufacturers of new NHP products need the development of standards of evidence and a guidance document to support the process of seeking validation of new health claims for food. Finally, such manufacturers would benefit from the establishment of appropriate regulatory frameworks to allow product-specific authorizations for health claims on foods, based on the recognition that claims concerning the effect of a food or its ingredients should not be generalized to other similar products so long as acceptable evidence to support them exists. The study concludes that

proposals for nutrition labelling will not consider the two most prominent CLA isomers (*cis*-9, *trans*-11-octadecadienoic acid and *trans*-10, *cis*-12-octadecadienoic acid) as trans fat. Thus trans fat content of a food on a label will not be required to include CLA isomers.

Laeque et al (2006) explored the motivation of corporations to comply with the new natural health products regulations in Canada, interviewing, either in person or by telephone, the person responsible for regulatory affairs in twenty companies selected from across the country. The motivations for regulatory compliance differ, based on the size of the firm (large or small) but four main motivations dominated. First, for both large and small firms, fear is a general deterrent. Large firms fear the negative public coverage for non-compliance with regulations. Small and medium size firms were fearful of punitive actions for non-compliance. The second motivation for compliance with the regulations was legal responsibility and civic duty. The third was social motivation, where firms perceived that compliance will enhance public perception of NHPs; this form of motivation was more prevalent among large firms than small and medium size firms. The fourth motivation for compliance was the ability of the firms to comply: large firms are better able to undertake regulatory compliance because they have the resources and familiarity to do so. Survey findings also noted that enforcement policies such as premise inspection, though strict and likely effective, are very expensive and time consuming for regulatory bodies, and it was suggested that policymakers give greater consideration to consumer perceptions and media coverage when planning compliance strategies. The authors recommend strategies to encourage compliance such as publishing the names of products that have gained approvals or companies that have licensed sites.

Mine and Young (2009) provide an overview of the regulatory environment for Canadian NHPs. The authors used Health Canada's (2003a) definition of NHPs: "vitamin and mineral supplements, herbal and plant-based remedies, homeopathic medicines, traditional medicines (such as traditional Chinese medicines), probiotics, and other products such as amino acids, and omega and essential fatty acids" (Mine and Young 2009, p. 460). The authors examine in some detail the Canadian Natural Health Products Regulations (NHPR), noting that upon successful review of a product license application (PLA), the NHP is approved for sale and issued a natural health product number with the prefix "NPN" or a homeopathic medicine number with the prefix "DIN-HM" which is displayed on the product.

In 2009, Health Canada developed an approach where NHPs are assessed and issued a product license based on their risk level. This approach is known as the risk-based approach (RBA) for NHPs (Mine and Young, 2009). There are two classes of products under the RBA. Class I refers to products that have available and authoritative evidence concerning safety and quality which require minimal assessment. Class II products are considered high risk due to lack of evidence and require thorough assessment for safety, efficacy and quality. The Natural Health Product Directorate (NHPD) oversees the licensing of firms producing NHPs based upon their ability to provide distribution records, product recall procedures, handling, storage and product delivery procedures and evidence of GMPs. Requiring GMPs ensure that staff have the necessary training and qualifications; sanitation procedures are in place; premise and equipment are suitable for production; products meet specified standards; and proper sample retention. Finally, all manufacturers granted a product license are required to implement and maintain an adverse reaction system associated with the NHP as well as report any and all serious adverse reactions to Health Canada. According to the NHPR, natural health products whose effects on humans have not been investigated may be required to undergo a clinical trial to ascertain the safety and efficacy of the product; not all products are required to undergo clinical trials as there does exist an allowance within the NHPR for other ‘range of evidence’ to support an application for an NHP license. The NHPR’s labelling requirements ensure that NHPs are sufficiently labelled to assist consumers in making informed decisions. Labels of NHPs should include product name, quantity, ingredient listing, and recommended conditions of use which include purpose, dosage, route of administration and any cautionary statements.

The NHPR defines a health claim as “a statement that indicates the intended beneficial effect of a natural health product when used in accordance with the recommended conditions of use” (Mine and Young 2009, p. 463). One of the challenges facing the NHPR are the conflicts between products that share both NHP and food characteristics as such products fall under both the NHPR and the food and drug regulations (FDR) that regulate functional food. In the interim, Health Canada classifies products based on their composition, representations, format, public perception and history of use to determine which regulations they fall under. Mine and Young (2009) conclude that, despite some challenges, regulating NHPs in Canada is a positive step in providing Canadians with safe and effective NHPs.

Farrell et al (2009) argue that there still exists confusion and ambiguities surrounding the regulatory framework governing foods and NHPs in Canada, using probiotic yoghurt and green tea as examples. The Food and Drug Act governs food, drug and NHPs while the NHPR were enacted under the FDA in 2004 to address inconsistencies in the regulation of NHPs in Canada. The study argues that the regulatory distinctions between food, natural health products, functional foods and nutraceuticals are unclear. The definition of an NHP does not include conventional foods, however, the influx of NHPs marketed in a conventional food format (e.g. probiotic yoghurt) has become a source of confusion. NHPs are considered a sub-category of drugs in Canada and the NHPR require that the product undergo clinical trials in order to obtain approval from Health Canada. In contrast, clinical trials are not required on food products (including functional foods). The study asserts that firms who conduct trials on food products face uncertainty due to the conflict between regulations. Should the trial results be negative then the product remains a food item; should the results be positive or indicate that the product contains an ingredient with medicinal/health properties, (or health enhanced ingredients) then the ingredient could become a natural health product, requiring further trial and approval. Furthermore, NHPs in Canada require premarket approval while foods in general do not, with the exception of novel foods (foods with no history of use), food additives and infant formulas.

The case of probiotic yoghurt is used to illustrate the confusion surrounding regulations in Canada. Probiotic yoghurt is already sold in the Canadian market without a health claim. Yet the term 'probiotic' is included in the definition of a NHP; should a researcher decided to conduct a clinical trial to ascertain whether probiotic yoghurt can relieve certain gastrointestinal problems confusion exists regarding whether an approval is needed as it will not be clear whether the product is considered a probiotic, and therefore an NHP requiring approval, or yoghurt in which case an approval is not necessary as yoghurt is a food.

The same conflict exists for green tea: since tea is a plant extract it is considered an NHP, but since tea is also a beverage it can be considered as food. This situation creates confusion for consumers and manufacturers as there will be some green tea marketed as an NHP and others as food. The study concludes that existing regulations in Canada do not provide adequate distinctions between food and NHPs, therefore, closer collaboration between the Food Directorate and NHPD is needed. The NHPD is currently reviewing license applications for some food products with health-enhanced ingredients. The study recommends the need for

regulatory reform as the research and commercial interest in functional food and natural health product continues to grow.

The impact of food regulations on the overall Canadian economy was examined by Gray et al (2006). The objective of the study was to examine the impact of a mandatory reduction of trans-fat content (below 2%) in food by estimating the potential health benefits and cost to the food sector. The study used a benefit-cost ratio to examine the potential benefits of mandatory labelling, voluntary labelling and a total ban of trans-fats as possible policy scenarios. Empirically, the study estimated the present value of all costs and health care cost savings of each scenario for the period 2006 to 2025 using a 5% real discount rate. In the most realistic scenario, the benefit-cost ratio for voluntary labelling was 20.4 to 1, this ratio means a 1% increase in cost due to policy implementation will lead to a 20.4% increase in benefits. The benefit- cost ratio for mandatory labelling was 19.1 to 1, while for a total ban, the benefit- cost ratio was 20.8 to 1. The results indicate that for Canada the greatest benefit, measured as the highest benefit- cost ratio, was associated with a total ban of foods with trans-fats. The authors argue that trans-fatty acid labelling alone will not provide consumers with adequate incentives to reduce their trans-fatty acid consumption as long as health care costs are primarily paid for through private or public health care insurance.

Turning to other jurisdictions, Klompenhouwer and Van Den Belt (2003) examined the regulation of functional foods in the European Union (EU), discussing the basic motivations behind the regulation of labelling and advertising. According to the study, the primary basis for functional food regulation in the EU is to inform and protect the consumer; considerable information asymmetry exists between consumers and producers making it extremely difficult for the market to function efficiently without regulations. Proper labelling with correct information and the regulation of claims will ensure consumers are not confused or misled by alleged health or nutritional benefits and will help facilitate their healthy food choices. However, it is argued that the objective of enabling the consumer to make informed choices is subordinated to the objectives of public health and current EU regulations pertaining to functional foods reflect this situation. At the time of the study, the lack of a unified set of EU regulations gave several countries the opportunity to regulate their own functional food industries.

Bech-Larsen and Scholderer (2007) also reviewed the regulatory environment for functional foods in Europe, specifically, the use of health claims in consumer research and

marketing strategies, focusing on the lack of correspondence between new regulations and consumer reactions to health claims. Historically, regulations of functional and health claims on functional foods were inconsistent between EU member states. An attempt to harmonize regulations in 2000 was not consistently enforced throughout the member countries. New health claims legislation was proposed and 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). While the new legislation will reduce uncertainty for firms which in the past, were faced with multiple, differentiated regulatory policies across different EU countries, it may also constrain firms' potential positioning strategies for functional foods, due to the ban on making general well-being claims without scientific evidence (Bech-Larsen and Scholderer, 2007).

Bech-Larsen and Scholderer (2007) observe that companies attempting to enter the functional food industry in Europe lack the necessary successful marketing skills. The study further argues that, while consumer acceptance of functional food is very important, little research has been conducted on consumer acceptance of functional foods in Europe. It concludes that "the lack of harmony between the new health claim legislation, consumer preferences and marketing forces makes the new legislation unlikely to enlarge the European functional food market to the extent that is expected by the European food industry and the European Commission" (Bech-Larsen and Scholderer 2007, p. 233).

Mariotti et al (2010) review the EU regulation of health claims and the possible issues that can cause discrepancies between consumers' perception of health claims and the reality of nutrition. The EU remains at a crossroads regarding health claims on food. In 2006, the EU issued a regulation on nutrition and health claims made on food and food supplements, with two objectives: 1) to keep the regulation standard with that of the international community whereby unsubstantiated health claims will be prohibited and claims that are not approved by the EU Commission will be banned; and 2) to allow health claims on food products whose effects are strongly substantiated. The study therefore asserts that the broad scope in potential use, the sheer number and nature of health claims permitted, will have a dramatic impact on global health communication on food in the EU. "By early 2009, the European call for applications for

inclusion on the claims register had resulted in approximately 10,000 health claims, based on 4,185 main relationships, all of which need to be reviewed.” (Mariotti et al 2010, p. 627). This indicates that there were many overlapping functional ingredient-health claim relationships within the 10,000 applications.

The study benchmarks the average consumer as one who is reasonably well-informed, observant and circumspect; believing claims on food must be understood by consumers and are not meant to mislead them. Six sources of potential consumer confusion were identified by Mariotti et al (2010) upon critical examination of health claims in the EU, all based upon discrepancies in interpretation between what consumers perceive and what the health claim is trying to communicate. The first is a wording issue where the use of jargon and terminology, both scientific and/or industry specific, may be difficult for consumers to understand. The second is “beyond scientific truth” which highlights the discrepancies between the perceptions of consumers about a claim and the scientific evidence assessed by experts. An example is the claim “lipids provide energy to the body”, where an expert assessment would interpret this claim as focusing on caloric provision but among consumers the tendency is to perceive the concept of energy as being energizing and not to do with calorie provision. The third issue is “the matching of consumer understanding and reality: confusion between food and diet” where the effect of a claim as perceived by consumers may be related to overall diet but the claim will be focusing on a specific foodstuff.

The fourth incongruity is “the matching of consumer understanding and reality: Is more better?” which hinges on consumers’ perception of a linear relationship between a nutrient/substance/food and the related effect in the claim hence they often believe ‘more is better’ when this is often not the case. The fifth inconsistency is the matching of consumer understanding and reality: multifactorial effects. This is based on the consumer perception that intake of a nutrient/substance guarantees the associated health effect as stated in the claim, without considering other factors that may influence the outcome of the nutrient/substance intake. The final discrepancy is “the matching of consumer understanding and reality: for which consumers?” which relates to claims that must specifically state the target population, but do not; hence consumers perceive that the specific claim is applicable to the general population. The study asserts that the ideal solution to address these incongruities is to identify and implement options that will ultimately reduce the risk of consumer misperceptions and thereby avoiding

inappropriate food choices. Recommendations from the study include banning or limiting certain claims, restriction on wording of claims, and the inclusion of general disclaimer statements in health claims.

In a report prepared for the World Health Organization (WHO), Hawkes (2004) reviewed existing regulations on nutrition labelling and health claims around the world and provided an overview of approaches to developing and implementing these regulations. The search process used the database of government departments and institutions including the USDA, AAFC, academic journals and personal communications with government officials. After verification, the search revealed regulations in over 70 countries with some degree of harmony but also significant variation. There appears to be a consensus among countries on the need to declare nutritional information on labels, based on the belief that nutritional labelling will help consumers make informed choices. Health claims, however, are more controversial internationally: nutrition function claims are more accepted than function and disease risk-reduction claims based upon the premise that referencing diseases will imply the ability of food to treat or prevent diseases. There are constant changes in health claims (due to ongoing developments in national, regional and international regulations, as well as the possibility of misleading and confusing claims) making regulatory authorities' attempts to harmonize health claims regulations internationally very challenging. Implementation of regulations is usually affected by key issues such as the costs and benefits of voluntary and mandatory labelling, type of products covered by the regulations, information on nutrition labels and the effect of regulations on food choice and diet. The report concludes that nutrition labels and health claims will improve public health if regulations are developed to ultimately improve the long-term dietary intake of consumers.

Winkler (1996) evaluated functional food regulations within the context of consumer policy, grouping issues into four different categories: "efficacy" (whether products actually work); "claims" (whether what the manufacturers say about products is true); "price" (whether products are worthy of their higher prices), and "diet" (how functional food fits into the overall diet). Much research and development is conducted in the sector, both by industry and academia; government support of such research into functional food has been encouraging. The study argues that due to the increased interest in the sector it was essentially guaranteed that good, bad or indifferent products will be offered in the market. It recommends that consumer groups be

involved in policy formulation and current policy debates such that only efficacious products get to the market, claims are always backed by evidence, product prices are affordable, and functional foods contribute to the improvement of the overall diet.

Kim et al (2006) reported on the scope of functional foods, the strength of evidence required pertaining to their effectiveness, the food safety environment and the future prospects in Korea as well as examining the Korean Health/Functional Food Act (HFFA) which was introduced in 2002 and implemented in 2004. The main goal of the HFFA was to improve public health by ensuring the safety of new active ingredients; it created a new category for health and functional foods separate from conventional food. The Act defines health/functional food (HFF) as food supplements containing nutrients or other substances that have a nutritional or physiological effect with the purpose of supplementing normal diet and divides them according to whether they are generic or product-specific foods. The Act contains 37 generic HFFs including vitamins, minerals, essential amino acids, proteins, dietary fibre, and essential fatty acids. Product-specific HFFs refer to all other products not included in the 37 generic category. The HFFA requires these products to be sold in measured doses (e.g. pills, tablets, capsules, and liquids) to ensure GMP, and that claims on nutrients and other functions are compatible with those adopted by the Codex Alimentarius Commission in 2004. The authors argue that current product labelling does not give consumers enough information about the scientific evidence underlying functional claims and believe that labelling standards should conform to those of other countries. The study recommends that health claims and regulations should be focused on the protection of public health.

In a report to the Food and Agriculture Organization of the United Nations (FAO), Subirade (2007) examined the regulatory developments for health, nutrients or functional claims relating to foods, on both a global and regional basis. The report is based on information provided by regulatory authorities in Europe, US, Canada, Japan and other Asian countries. The author acknowledges the rampant confusion and distrust among health professionals and consumers generated by the proliferation of health claims. Most regulations are directed towards health claims, specifically disease risk reduction claims, and the general consensus is that regulations should protect the consumer, promote fair trade and innovation in the industry. The report indicates that the EU has moved from a prior state of inconsistency in regulations among member states to that of harmonized regulations, which were adopted in 2006 and are managed

by the European Food Safety Authority (EFSA). Under the 2006 regulations, medicinal claims such as the treatment, prevention or curing of disease are not permitted unless the product is classified as a medicine by the European Community Code relating to medicinal products for human use. Nutrient content claims and structure/function claims are permitted.

In the US, the Food and Drug Administration oversees the industry and has established 3 categories of permitted claims: 1) health claims (disease risk reduction) describe the relationship between a food and a disease or health-related conditions; 2) nutrient content claims use labelling to indicate the level of a nutrient in a food; 3) structure/function claims describe how a nutrient or dietary supplement intends to affect the normal structure or function in humans (Subirade, 2007).

In Canada, the Food Directorate regulates functional foods, and the Natural Health Products Directorate regulates NHPs. Canada's regulatory framework, like the US, also categorizes claims into disease risk reduction health claims, structural/functional claims and nutrient content claims. A disease risk reduction health claim in Canada relates the consumption of a food or ingredient and health. Structural/functional claims on the other hand, describe the nutrient's importance in promoting normal and healthy growth and functioning. Nutrient content claims describe the level of a nutrient(s), vitamin(s) and mineral(s) in a food. Current permitted health claims on food in Canada are considered generic claims in the sense that post-approval, anyone can use the claim. However, while all claims that are used on food can also be used on NHPs, any firm wanting to label and market a NHP with what is a permitted generic claim for a food product, must receive individual approval to do so, hence health claims on NHPs are considered product specific.

Subirade (2007) further claims that Japan is the most developed market for functional foods. In a move to regulate claims on food labels, Japan introduced the FOSHU concept. FOSHU refers to food with ingredients that affect health, and are officially approved to make claims of effects on the human body. A food is approved as FOSHU after it has been scientifically evaluated to determine its effectiveness and safety. According to the report, the Japanese Ministry of Health, Labour and Welfare, in an attempt to facilitate applicants for FOSHU approval, introduced qualified FOSHU and standardized FOSHU (qualified FOSHU are for foods that have a function with no conclusive scientific evidence, and standard FOSHU applies to food possessing ingredients that are well established in FOSHU claims). Japan

introduced a new regulatory system, Food with Health Claims, which is a combination of the existing FOSHU system and a new system known as Food with Nutrient Function Claims (FNFC). The FNFC refers to all food that is labelled with the nutrient function claims stipulated by the Ministry of Health, Labour and Welfare. The study also examined the regulatory example of Korea, with very similar findings as Kim et al (2006).

Subirade (2007) identifies a regulatory consensus amongst most countries that health claims should be scientifically validated. Regulatory frameworks should focus on the protection of consumers, promotion of fair trade and innovation in the sector. The report recommends identifies a need for greater harmonization and uniformity in nutrition descriptions, disease-risk reduction health claims, structure/function claims; and terminologies internationally. Thus there should be a clear distinction between functional and health claims (disease risk reduction) as well as the international harmonization of claims.

Palthur et al (2009) examined the regulatory framework concerning functional food and nutraceuticals (FFN) in India. The study examines the development of a new FFN regulatory regime, reviews speculation on its implementation and makes recommendations on approaches to regulating FFN in India. Prior to 2006, no single regulatory body and or body of food law regulated the food sector in India. In 2006 the government of India responded to pressure from stakeholders and the industry by enacting the Food Safety and Standards Act 2006 (FSSA), transforming the regulation of food in India. The FSSA defines foods for special dietary uses/functional foods/ nutraceuticals/health supplements as:

“foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition or specific diseases and disorders.....wherein the composition must differ significantly from the composition of ordinary foods of comparable nature..... does not claim to cure or mitigate any specific disease, disorder or condition (except for certain health benefit or such promotion claims) as may be permitted by the regulations made under FSSA” (Palthur et al 2009, p. 4).

The effective implementation of the FSSA faces several challenges, including the inability of small and medium scale firms to identify and comply with regulations due to lack of capacity and access to information; the regulatory vacuum that will be created once the old regime is repealed and before the new FSSA takes effect; and education and competency requirements for firms and regulators (Palthur et al 2009). Specifically, the study identified three specific capacity gaps that will affect the implementation of the new regulatory framework: lack

of qualified technical personnel; inadequacy of skills of existing personnel; and lack of well-equipped laboratories for analysis. The authors make a number of recommendations to ensure successful implementation of the new regulatory regime, they propose the “development of overarching objectives for regulation; greater collaboration between departments and agencies; seeking industry input on choice and design of regulatory instruments; greater consideration of non-prescriptive types of regulations; sufficient resources for an effective infrastructure to support the regulatory process; harmonization with major trading partners; design of legislations that provides for more regulatory flexibility; a comprehensive examination that evaluates using agreed upon principles and; ex-post evaluation of regulation; and commitment to implement required changes” (Palthur et al 2009, p. 10). The study concludes that the functional food and nutraceuticals sector has a very important role in the future health of the population in India through the provision of less expensive, regulated, innovative products and technologies which may lead to a reduction in public health care costs.

4.4.1 Insights from the Regulatory Framework Literature: A Summary

Overall, the consensus within the literature is that increased consumer interest, industry growth and market opportunities in the functional food and natural health product industry have led to many firms entering the sector, offering a greater variety of products, thereby necessitating greater regulation for a number of reasons. These include the need to inform consumers, protecting and ensuring consumer safety, eliminating or reducing market failures that arise due to uncertainty and information asymmetry, promoting fair trade, increasing innovation and facilitating the sector’s continued growth.

The market for functional food and natural health products is growing globally because consumers are motivated to pursue healthier diets. Such growth in interest could result in bad or indifferent product offerings as firms seek to capitalize on this opportunity. Consensus exists among countries that nutritional information should be declared on product labels, based on the belief that nutritional labelling will help consumers make informed choices. There is also consensus that information given to consumers through proper labelling must not mislead consumers by alleging certain health or nutritional benefits of the foods they buy.

Regulatory frameworks in the sector present both opportunities and challenges and have been evolving globally. Countries have been formulating regulatory policies with a great variance in approaches, implementation and enforcement. According to a number of studies,

Japan and the US are considered as having well-advanced regulatory regimes for functional foods and NHPs in comparison to others such as Canada and the EU (Smith et al 1996, Veeman 2002, Subirade 2007, Bech-Larsen and Scholderer 2007, Mariotti et al 2010). 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, while Japan's regulatory system is viewed as the most supportive with high levels of collaboration between government, industry, academia and research organizations. The US regulatory framework, though restrictive, is generally regarded as supportive of product development and marketing; there are specific and well defined legislations for approval, labelling and advertising of products. The EU does have restrictive regulations but in practice is ineffective because enforcement in member states is voluntary (Smith et al 1996).

Regulations in most countries are centred on health claims, of which there are three main types: disease risk reduction claims; structure/function claims and nutrient content claims. In addition to these three claims, Canada has a category of "therapeutic claims" which suggest that a product (when consumed as directed) can cure/treat/mitigate/prevent a disease, however, none have been approved for use on functional foods and they would have to undergo the same evaluation procedure as disease risk reduction claims (Health Canada 1998, Bureau of Nutritional Sciences Food Directorate 2001, Mine and Young 2009).

The US also has the three categories of health claims: disease risk reduction, structure/function and nutrient content. In the European Union, while the three types of claims are permitted, there is now a consensus to not permit the use of medicinal claims on products unless they are classified as drugs. Japan utilizes FOSHU claims which refers to 'food' with ingredients that affect health and are officially approved to make claims of effects on the human body. The regulatory framework in Korea focuses on ensuring the safety of new active ingredients and permits claims similar to nutrient content, structure/function and disease risk reduction claims that are compatible with those adopted by the Codex Alimentarius Commission. In India, the functional foods and nutraceuticals are defined as being different in composition than conventional food; while nutrient content claims are more accepted by consumers than disease risk reduction, structure/function, and therapeutic claims. .

Governments are aware that different developments and approaches in national, regional and international health claim regulations create the possibility of misleading and confusing

consumers, therefore harmonizing health claims regulations internationally (or establishing equivalence) would be beneficial, however, there currently exists a greater state of international divergence than convergence in the regulations pertaining to functional foods and NHPs. Even in the EU, the absence of uniform regulations caused several member countries to take individual initiatives in regulating their functional food industries. This lack of regulatory consistency confuses consumers and imposes significant transactions costs upon the industry which must cope with uncertainty while accommodating several regulatory regimes for the same product.

The proliferation of health claims, and the variety in terminology and claims made, also causes confusion and distrust among health professionals and consumers. Policy makers need to create regulations that can balance consumer protection while addressing issues such as product efficacy (whether these products actually work), labelling/claims (whether what manufacturers say about their products are true), pricing (whether these products are worth their higher prices) and diet (how functional food fits into the overall diet). Discrepancies in interpretation in terminology used in claims and in the industry in general cause further confusion. Discrepancies between the actual scientific meaning of a claim and consumer perception of the meaning appear to be the most significant but associative discrepancies also cause confusion. Examples include interchanging the words 'food' (product specific) and 'diet' (generalized), the consumer belief that consuming 'more-is-better' contrary to actual product usage, or attaching the concept of 'energizing' to the word 'energy' rather than caloric provision. The uncertainty associated with health claims continues to challenge policy makers, both domestically and internationally.

Finally, despite information provision and attempts to foster informed choice amongst consumers, studies have shown that the use of regulatory measures alone may not lead to socially optimal results. If the objective of consuming healthier diets is to promote a healthier population, labelling may not be sufficient to motivate consumers to make the most health-oriented choices if they do not directly bear the consequences of their choices. If the consequence of choosing a less healthy diet is potential illness and its associated costs, consumers should logically choose a healthier diet. However, when the consequences of poor decisions (i.e. illness) are borne by a third party (i.e. public health care or private health insurance), their ability to act as a motivator for socially optimal choices is diluted. Policy makers may need to consider additional policy tools to help foster more socially optimal decisions.

The greatest challenge pertaining to international regulatory harmonization is product labelling but with the increased trade of these products, examples of successful harmonization are emerging. For example, Korea aligned its regulatory frameworks to that of Codex Alimentarius. Harmonization (or recognition of equivalence) in regulations between important trading partners would be a beneficial first step, as Australia and New Zealand achieved in coordinating their food standards. Areas where harmonization could have a significant impact include conformity in labelling standards, and uniformity in nutrition and health claims in description and terminology.

In Canada, the regulatory situation surrounding functional food and national health products is evolving. Prior to 1998, no definitions of, or specific regulations pertaining to, functional foods and nutraceuticals existed in Canada. Any product that made a health claim was considered a drug with the exception of structure/function claims. Some issues such as product definitions and health claim categories have been addressed. Health Canada allows risk reduction and structure/function health claims but all other products with therapeutic health claims are regulated as drugs; proposed health claims may be generic or product-specific. After the categorization of health claims, Health Canada evaluated 10 and following consultations, initially adopted 5 disease risk reduction health claims that were already permitted in the United States. Additional health claims have been added and currently, there are now 9 disease risk reduction health claims permitted in Canada (Health Canada 2010; Health Canada, 2012a; Health Canada 2012b). A framework to evaluate foods with health claims was also created to ensure product safety and claim validity, as well as establish procedures for product testing to support health claims. The framework is based on the product specific “authorization” approach, where the product with the intended health claim will be assessed on its own merit instead of an entire food group being the subject of a claim. All products with health claims, once approved, will be required to carry a claim identification number (CIN).

Prior to the enactment of the NHPR in Canada in 2004 NHPs were also not officially defined (only nutraceuticals were defined), such that by default all NHPs that carried health claims were regulated as drugs. With the NHPR in place, there is greater clarification regarding the categorization and regulation of NHPs. Currently, a major challenge facing Health Canada concerns the development of new products that have both food and NHP characteristics and the conflicts that arise due to the inability to properly categorize or define them. When a product

with both food and NHP characteristics wishes to carry a health claim, there is confusion as to which regulations should apply. Health Canada currently classifies these controversial products based on their composition, representations, format, public perception and history of use to determine which regulations apply. This incongruity exists in other areas, causing further conflicts. For example, some NHPs must undergo clinical trials²⁷ in order to obtain approval from Health Canada but food products do not; NHPs require premarket approval whereas in general, food does not, with the exception of novel food (foods with no history of use), food additives and infant formulas. The last area where the incongruity of food vs. NHP causes controversy is in health claims which can be made on both food products and NHPs. However, health claims on functional foods are generic and do not require proof of ingredients nor premarket approval but health claims on NHPs are product specific, for which manufacturers must prove ingredient content in order to obtain mandatory premarket approval.

A number of recommendations regarding health claims and regulations flow from the literature. Policies and regulations in general should focus on firms' and consumers' interests, including consumer protection and public health, ensure efficient markets, and promotion of innovation. Nutrition labels and health claims will improve public health if they facilitate an improvement in the long-term dietary intake of consumers. A collaborative approach involving all industry stakeholders, including consumer groups, in the development of policy is usually considered essential for the growth of the sector and the public interest. Legislation should be sufficiently flexible to accommodate future changes and allow for the ex-post evaluation of regulations.

A variety of reforms in the regulatory environment for health claims are recommended in the literature. Health claims should be scientifically validated to ensure product safety and quality; the truthfulness and efficacy of health claims should also be validated (Health Canada 2000, Veeman 2002, Korthals 2002, Kim et al 2006, Subirade 2007, Bech-Larsen and Scholderer 2007, Farrell et al 2009). There should be a clear distinction between functional and risk reduction claims, which can also reduce waiting times in obtaining approval for functional foods (Smith et al 1996). Additional recommendations include banning or limiting certain unsubstantiated claims, restrictions on the wording of claims, and the inclusion of general

²⁷ Not all products are required to undergo clinical trials because the NHPD does allow other range of evidence to support an application for a natural health product license

disclaimer statements in addition to health claims (Mariotti et al 2010). Procedures for ex-post evaluation of regulations are suggested (Palthur et al 2009).

Table 20 summaries the policy and regulatory findings of the literature review.

Table 20. Studies on Functional Food/NHP Policies and Regulations			
Author Year Location	Title Area	Objective Method	Citation Created for
Smith et al 1996 Canada, Japan, EU and US	A Comparative Analysis of the Regulatory Framework Affecting Functional Food Development and Commercialization Functional food	To analyze the opportunities and challenges of current regulatory frameworks affecting functional foods in Canada, Japan, EU, US Descriptive Analysis/ interview (personal and telephone)	Inter/Sect Alliance Inc. Agriculture and Agri-food Canada
Canada has a relatively restrictive regulatory framework environment for the development and marketing of functional food compared to the US, EU, and Japan. The regulatory system in Japan is the most supportive, well defined, predictable, and has established collaboration between government, industry, academia and research organizations; the US regulatory framework though restrictive is supportive with specific well defined regulations; the EU has restrictive regulations but in the past has been ineffective because enforcement in member states was voluntary. The study recommended the establishment of health food associations in Canada to involve the private sector in the regulation of functional food as it exists in Japan; collaboration of government and the industry for regulatory reform (with consumers in mind); differentiation of disease risk reduction health claims from wellness claims (structural claims) to reduce the processing time for functional food claims approval; and harmonization of health claims with that of the US			
Winkler 1996	Functional Foods: Challenges for Consumer Policy Functional food	To evaluate the regulatory situation of functional food regarding challenges facing consumer policy Descriptive Analysis	Consumer Policy Review; Nov/Dec 1996; 6, 6; ABI/INFORM Global pg. 210
The study grouped the challenges facing consumer policy into four categories: efficacy, claims, price, and diet. R&D in the sector has increased and the support from all stakeholders has been encouraging. Increased interest in the sector could lead to good, bad, or indifferent products getting to the market. There is the need for consumer groups to get involved in policy formulation and debates so that, efficacious products get to market; claims are backed by evidence; product prices are affordable and FF contribute to improvements in overall diet.			
Health Canada 1998 Canada	Nutraceuticals / Functional Foods And Health Claims On Foods Nutraceuticals/functional foods	To analyze the Canadian environment for nutraceuticals/functional foods and health claims; review alternative policy options and recommend a framework for regulations Descriptive Analysis	
No definition existed for 'health claims' prior to 1998 hence all products with health claims were regulated as drugs (structural/function claims exempted). Health claims were categorized into 3 distinctions: therapeutic, risk reduction, and structure/function claims. The final policy decision asserted that functional/structural and risk reduction claims for "food" and "food components" (functional food and nutraceuticals) should be permitted; and all other products with therapeutic health claims should be regulated as drugs. The proposed recommendations included communicating the policy to stakeholders; development of implementation strategy; and standards of evidence and composition in consultation with stakeholders in the industry.			
Health Canada 2000 Canada	Consultation Document on Generic Health Claims Food	To examine proposals on five selected health claims and stakeholder's opinions on the format of the claims, credibility of claims, consumer education and scientific review of the claims.	http://www.hc-sc.gc.ca/fn-an/alt_formats/hpfb-dgpsa/pdf/label-etiquet/health_claims-allegations_sante-eng.pdf

		Descriptive Analysis	
<p>Proposals were based on the policy framework developed by Health Canada (1998) to permit risk reduction claims and structure/function claims on foods. Proposals were made on conditions for the use of five generic health claims: Sodium and Hypertension, Calcium and Osteoporosis, Saturated and Trans Fat and Cholesterol and CHD, Fruits and Vegetables and Cancer, and Sugar Alcohols and Dental Caries. Proposals included: food should fall into one of the four food groups of Canada's food guide to healthy eating; be consistent with Nutrition Recommendations for Canadians and its update on Dietary Fat and Children; claims should not be permitted on foods that fall into the "Other Foods" category of Canada's Food Guide to Healthy Eating; saturated and trans fat to CHD claim should also be permitted on fats and oils that meet the conditions of the claim; specific requirements for a claim be included in the claim; and health claims should not be permitted on food for infants and children under two years. The core list of nutrients and any nutrient mentioned in the claim except alcohol should be declared. To clarify risk-reduction benefits, information on an accepted diet-health relationship & information on the composition of the product relevant to the relationship should be included. Stakeholders expressed their opinions on the health claims in the areas of: claims format, claim credibility, and consumer education and scientific review</p>			
<p>Bureau of Nutritional Sciences Food Directorate</p> <p>2000 Canada</p>	<p>Standard of Evidence for Evaluating Food with Health Claims: A Proposed Framework</p> <p>Food</p>	<p>To propose a framework for the evaluation of foods with health claims</p> <p>Descriptive Analysis</p>	<p>http://www.hc-sc.gc.ca/fn-an/alt_formats/hpfb-dgpsa/pdf/label-etiquet/consultation_doc-eng.pdf</p> <p>Health Canada</p>
<p>Argued that there should be appropriate evidence to support health claims which will ensure product safety, claim validity and quality assurance, as well as production methods and procedures for product testing. All foods should undergo at least a basic evaluation to determine the safety of the product. Further evaluations may be required when the product is novel and/or there are uncertainties surrounding the safety of the product. There will be a three step process to demonstrate the efficacy and effectiveness of the product, validating its claims. For quality assurance purposes, there should be a demonstration of the reliability of the tests performed.</p>			
<p>Bureau of Nutritional Sciences Food Directorate</p> <p>2001 Canada</p>	<p>Product-Specific Authorization of Health Claims for Foods</p> <p>Food</p>	<p>To propose approaches to regulating health claims for food/proposed in a regulatory framework)</p> <p>Descriptive Analysis</p>	<p>http://www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/final_proposal-proposition_final01-eng.php</p> <p>Health Canada</p>
<p>The proposed regulatory framework was based on the recognition that consumption of a reasonable quantity of a food containing a biologically active substance could affect the physiological function or structure of the body. The approach taken was "product specific authorization" for health claims whereby the product (functional food) with the intended claim is assessed on its own merit. The health claims approved were generic. Key elements of the proposed regulatory framework: all food (modified and non-modified) that affects the structure of the body or claims to reduce the risk of disease would be required to carry a Claim Identification Number (CIN); manufacturer should provide product information & the proposed claim and information required for assessing product safety, claim validity and quality assurance; CIN may be cancelled or suspended when there is a violation of the specified conditions; applicants should notify the directorate of any changes in specified conditions. There should be transparency in the product review process.</p>			
<p>Jepson</p> <p>2002 Canada</p>	<p>Regulation of Natural Health Products in Canada</p> <p>Natural Health Products</p>	<p>To examine the current regulatory situation of natural health products and its enforcement as well as the new proposed regulations.</p> <p>Descriptive Analysis</p>	<p>Food and Drug Law Journal Volume 57, Issue 1</p>
<p>The existing regulatory situation was deemed unsatisfactory for all stakeholders including regulators, manufacturers and marketers. The Canada Food and Drug Act did not define NHPs, hence any NHPs that made health claims were considered as drugs under the Act and needed a drug identification number (DIN). The NHP Directorate was created to resolve some of the inconsistencies; it introduced a draft regulation regarding product licensing, site licensing, GMPs, labelling and packaging and adverse reaction reporting. NHP regulations were expected to be an improvement over the status quo by providing certainty and protection for all stakeholders.</p>			
<p>Klompshouwer and Van Den Belt</p>	<p>Regulating Functional Foods in the European Union:</p>	<p>To examine the functional food regulatory situation in</p>	<p>Journal of Agricultural and Environmental Ethics 16:</p>

2003 EU	Informed Choice Versus Consumer Protection? Functional Foods	the European Union Descriptive Analysis	545–556, 2003.
Information asymmetry and the absence of unified regulations in the EU forced several member countries to regulate their own functional food industry. The objective of consumers making informed choices was subordinated to public health objectives. Regulations should be explicit on whether informed choice or public health deserves priority in food labelling. There is the need to make sure that information given to consumers through proper labelling does not mislead them by alleging certain health or nutritional benefits of the foods they buy.			
Korthals 2002 International	The Struggle over Functional Foods: Justice and the Social Meaning of Functional Foods Functional Foods	To discuss the claims, risk and social issues concerning functional foods and the need for intervention Descriptive Analysis	Journal of Agricultural and Environmental Ethics 15 : 315–324, 2002.
Given the central role played by food, impartial intervention in the food market is needed.. Policy is required to facilitate the establishment of safety conditions in an objective and impartial way and create an environment where various types of food (conventional, functional, nutraceutical) can coexist. Functional food claims should be tested against food safety and health standards to create impartial safety standards. Food professionals should be made accountable by establishing of institutions that will forge alliance between consumers and producers in the food chain.			
Veeman 2002 Global	Policy Development for Novel Foods: Issues and Challenges for Functional food Functional Foods	To compare the international regulatory situation to Canadian and make recommendations Descriptive Analysis	Canadian Journal of Agricultural Economics 50 (2002) 527–539
Recognizes that the market for FFNHP is growing globally because of consumers' motivations for healthy diets. There are market failures due to the uncertainty and information asymmetry associated with health claims on these products. Health claim policies were well advanced in countries like Japan and the US compared to Canada. However, there are some differences in approaches to national policies and regulations internationally. For example, S-adenosylmethionene (SAME) was regarded as a dietary supplement in the US but classified in Canada as a drug that needed a drug identification number and license from Health Canada, and available in Europe as prescription medication. However, policies on health claims in many nations are converging; for example, the Australia and New Zealand Food Standards. The study concluded that there should be government intervention to deal with inefficiencies and failures and should balance the interest of both consumers and producers through designed mechanisms to verify claims and information provided by producers.			
Health Canada 2004 Canada	A Regulatory Framework for Natural Health Products NHPs	To provide a glance shot of the new NHP regulatory framework in Canada Descriptive Analysis	http://www.hc-sc.gc.ca/dhp-mpps/prodnatur/about-aperpos/glance-apercu-eng.php
NHP regulations included provisions on a product licensing system that requires all NHPs to display a product identification number; site licensing which involves the licensing of all manufacturers, packagers, labellers, and importers; GMPs to ensure product safety and quality; standard labelling requirements that include basic information such as product name, quantity in container, recommended use and storage conditions; and an adverse reaction reporting system to help monitor adverse reactions associated with products. In two years, all manufacturers, importers, packagers and labellers will employ GMPs and have site licenses; it was envisioned that in six years, NHPs would have a NPN or a DIN-HM (homeopathic medicine).			
Hawkes 2004 Global	Nutrition Labels and Health Claims: The Global Regulatory Environment Labelling and health claims	To provide an overview of international, regional and national regulations regarding nutrition labelling and health claims Descriptive Analysis	http://whqlibdoc.who.int/publications/2004/9241591714.pdf World Health Organization (WHO)
The global regulatory environment around nutrition labelling and health claims is characterized by a certain amount of harmony but there is also a lot variation. Nutritional labelling helps consumers make informed choices. Nutrition claims are more accepted than function and disease risk reduction claims because referencing to a disease in a claim might imply the ability of food to treat or prevent diseases. There are constant changes of health claims due to ongoing developments in national, regional and international regulations & the possibility of misleading and confusing claims which have made			

regulatory authorities recommend international harmonization of health claims. Nutrition labels and health claims will improve the public health if regulations are developed to ultimately improve the long-term dietary intake of consumers.			
Fitzpatrick 2004 Canada	Regulatory Issues Related to Functional Foods and Natural Health Products in Canada: Possible Implications for CLA Manufacturers Functional Foods and Natural Health Products	To present an overview of FFNHP regulatory issues and implication for CLA producers in Canada Descriptive Analysis	Am J Clin Nutr 2004; 79(suppl):1217S–20S.
In 1999, Health Canada undertook initiatives on health claims for food. The following proposals were suggested: 1. Adoption of some of the disease risk reduction claims approved in the US 2. Develop standards of evidence and guidance document on data requirements for supporting the validation of new health claims for foods. 3. Develop an appropriate regulatory framework to allow product specific health claims for food. NHPs will be allowed to be manufactured, sold and represented for use in the diagnosis, treatment, mitigation or prevention of a disease or its symptoms in humans. All NHPs will be required to be registered with the NHPD, to obtain a distinct identification number, PIN (product identification number) and to carry a label health claim.			
Gray, Malla, and Perlich 2006 Canada	Economic Impacts of Proposed Limits on Trans Fats in Canada Trans Fat	To examine how mandatory reduction of trans fat content will impact the agri-food sector; and compare the results to mandatory labelling and voluntary labelling Benefit to cost ratio	Current Agriculture, Food & Resource Issues N u m b e r 7 / 2006 / p. 1 4 9 - 1 6 1
Benefits from a ban on industrial trans fat outweigh the costs. The benefit to cost ratio was higher (20.8 : 1) for total ban of TFA, followed by voluntary labelling (20.4 : 1), with lowest ratio (19.1 : 1) associated with mandatory labelling. The greatest benefit was associated with trans-fat ban. The study concluded that mandatory labelling alone will not provide incentives for reduction in TFA consumption as long as health care costs are paid for through private or public health care insurance.			
Kim, Kim and Lee 2006 Korea	Regulations on Health/Functional Foods in Korea Health/functional foods (HFF)	To report on the scope of functional foods, the strength of the evidence required for their effectiveness, safety considerations and future perspectives in Korea Descriptive Analysis	Toxicology 221 (2006) 112–118
The Health/Functional Food (HFF) Act in Korea was enacted in 2002 and came into effect in 2004. The main goal of the act was to improve public health. The Act defines HFF as food supplements containing nutrients or other substances that have a nutritional or physiological effect with the purpose of supplementing normal diet in measured doses (e.g., pills). The Act made HFFs a new food category separate from conventional foods. HFFs are divided into generic and product-specific HFFs: Product-specific HFFs refer to all products that are not in the 37 generic ones. Claims on nutrients, other functions and disease risk that are compatible with Codex Alimentarius Commission (2004) may be used for labelling. Labelling standards should to be in conformity with that of other countries. Health claims and regulations should be focused on the protection of public health.			
Laeque, Boon, Kachan, Cohen, and D'Cruz 2006 Canada	The Canadian Natural Health Products (NHP) Regulations: Industry Compliance Motivations Natural Health Products	To explore the motivation of corporations to comply with new natural health products (NHP) regulations in Canada Survey/Descriptive Analysis	eCAM 2006; Page 1 of 6 doi: 10.1093 /ecam/nel090
Four main motivations for firms to comply with the new NHP regulations in Canada are identified. First is the general deterrent of fear: large firms fear negative media coverage and small/medium firms fear government actions. Second, the duty to comply as a legal responsibility and a civic duty. Third, social motivation which will enhance public perception of NHPs. Fourth is the ability of firms to comply: large firms with the resources and access to information pertaining to the regulations are better able to comply. Policymakers should factor in consumer perceptions and media coverage when planning compliance strategies. Enforcement policies such as premise inspections are expensive. Strategies that can stimulate motivation such as making public			

or publishing approved products and companies with site licenses could enhance the likelihood of compliance.			
Bech-Larsen and Scholderer 2007 Europe	Functional foods in Europe: Consumer Research, Market Experiences and Regulatory Aspects Functional foods	To review consumer research, market experiences and the regulatory aspects regarding the use of health and nutrition claims for functional foods in Europe Descriptive Analysis	Trends in Food Science & Technology 18 (2007) 231e234
<p>The EU FFNHP industry suffered from inconsistencies in the regulations of European countries. A proposed harmonized regulation on nutrition and health claims is discussed (later came into effect in December 2012). The 'proposed' regulation involves the distinction of health claims that are scientifically proven and those that lack scientific evidence. Novel food will require individual scientific evaluation and pre-market approval. Health claims that are not clear and accurate will not be permitted. The legislation was expected to reduce the uncertainty facing firms but will constrain the potential positioning strategies for functional foods. Companies that are attempting to enter the functional food industry in Europe lack the necessary successful marketing skills. Consumer acceptance has received little attention. Inconsistencies between the new health claim legislation, consumer preferences and marketing forces makes the new legislation unlikely to enlarge the European functional food market.</p>			
Subirade 2007 Europe, US, Canada, Japan and Other Asian countries	Report on Functional Foods Functional Foods	To present an overview of the functional foods regulatory systems for healthy nutrients and functional claims in Europe, US, Canada, Japan and other Asian countries Descriptive Analysis	http://www.fao.org/ag/agn/agns/files/Functional_Foods_Report_Nov2007.pdf Food Quality and Standards Service (AGNS), Food and Agriculture Organization of the United Nations (FAO)
<p>There is confusion and distrust among health professionals and consumers about FFNHP products generated by the proliferation of claims. Most regulations have been on health claims (disease risk reduction claims). Canada and the US permit disease-risk-reduction health claims, nutrient content claims and structure/function claims. Disease risk reduction claims relate the consumption of a food or ingredient to health; structural/functional claims describes the importance of nutrients in promoting normal and healthy growth and functioning, and nutrient content claims describe the level of nutrients in a food. In Canada, health claims on food are generic; however, health claims on NHPs are product-specific. In the EU, disease risk reduction claims on food are prohibited. Nutrient content claims and structure/function claims are permitted. Japan is the most developed market for functional food, allowing FOSHU claims, which refer to food with ingredients that affect health; qualified FOSHU claims for foods that have a function with no conclusive scientific evidence; standard FOSHU for food possessing ingredients that are well established in FOSHU claims; and Food Nutrient Function Claims. In Korea, health/functional food have been standardized into generic and product specific categories. Products that contain ingredients named in the Food Act are generic and those that contain new ingredients are product specific. Uniform descriptions of types of nutrition, health claims and terminologies internationally were recommended, as were a clear distinction between functional and disease risk reduction claims; health claims should be scientifically validated; protection of consumers; promotion of fair trade; and innovation in the sector.</p>			
Government of Saskatchewan 2008 Canada	Natural Health Products and Functional foods Fact Sheet – Food Safety	To provide an overview of the regulations and market perspective of NHP and FF Descriptive Analysis	http://www.agriculture.gov.sk.ca/Natural_Health_Products Saskatchewan Ministry of Agriculture
<p>In 2006, the global functional food sector accounted for an estimated US\$ 85.0 billion (37.2% of the global nutrition market) and NHPs represented US\$ 68.3 billion (29.9%). From 2000 to 2006, the global market of functional foods and NHPs grew by 33% and 68% with an annual growth of 7% to 10% forecasted. The US, Europe, and Japan had the greatest share in the global market with 34%, 28%, and 21% respectively. New emerging countries in the industry include: China, India, Brazil, Mexico, Eastern Europe, and Russia. The term nutraceuticals was replaced by NHP which also includes vitamins and minerals, herbal remedies, traditional medicines and essential fatty acids used to treat and/or prevent diseases in 2000. The NHP regulation was implemented in 2004. The major components of the regulations are site licensing, GMPs, product licensing, packaging/labelling, clinical trials (involving human subjects) and adverse reaction reporting. Companies marketing NHPs in Canada require a</p>			

product licence. The study claims there are about 400 companies in the Canadian FFNHP sector of which 12% are located in Saskatchewan.			
Farrell, Ries, Kachan, and Boon 2009 Canada	Foods and Natural Health Products: Gaps and Ambiguities in the Canadian Regulatory Regime Functional food and NHP	To analyze the current regulatory framework governing (functional) foods and NHPs in Canada, as well as highlights the confusion and ambiguities surrounding the regulatory framework Descriptive Analysis	Food Policy 34 (2009) 388–392
The regulation of food, drugs and NHPs is under the CFDA. NHPs are defined by the NHPR based on function (e.g. diagnose, treat, mitigate or prevent a disease) and substance (e.g. vitamins, minerals, amino acids, probiotics). The regulatory distinctions between food, NHPs, functional foods and nutraceuticals are unclear. The influx of NHPs in conventional food format in the Canadian market has become a source of confusion. The NHPR require clinical trials involving NHP to obtain approval from Health Canada; food does not. NHPs require a premarket approval, while foods in general do not, with the exception of novel foods (foods with no history of use), food additives and infant formulas. NHP health claims are: therapeutic claims, disease risk reduction claims and structural/function claims. The case of probiotic yoghurt and green tea illustrate the confusion surrounding regulations in Canada. There is the need for closer collaboration between the food and NHP directorate; regulatory reform as the research and commercial interest in functional food and NHP continue to grow.			
Mine and Young 2009 Canada	Regulation of Natural Health Products in Canada NHPs	To provide an overview of the Canadian natural health product regulatory situation Descriptive Analysis	Food Sci. Technol. Res., 15 (5), 459 – 468, 2009
Increased interest in NHPs by Canadians and the need for regulations and accessibility led to the formation of the NHPD. The NHPD introduced the NHPR in 2004. The NHPR outlines the requirements regarding product licensing, site licensing, GMPs, adverse reaction reporting, clinical trials, labelling and packaging, health claims, and safety issues. In 2009, Health Canada developed an approach where NHPs are assessed and issued a product license based on their risk level [risk based approach: Class I (low), II (high risk: require thorough assessment for safety, efficacy and quality)]. NHPs whose effects on humans have not been investigated may be required to undergo a 'clinical trial' to ascertain the safety and efficacy of the product (other range of evidence could also support an application). A major challenge facing Health Canada is to clarify which regulations should govern products that have both food and NHP characteristics (NHPR, FDR). NHPR provide safe and effective NHPs. The study recommends that, there is the need for Health Canada to continue maintaining transparent and open dialogue with all stakeholders in the sector			
Palthur, Palthur and Chitta 2009 India	Emerging Product Categories in India: A Regulatory View Functional food and NHPs	To examine the development of new functional food and nutraceutical regulatory regime; make speculations on the regime's implementation; and make recommendations on the approach to regulating FFN in India Descriptive Analysis	Food and Drug Law Journal, 64 Food Drug L.J. 677, 2009
Before 2006, there was no regulatory body or food law in India. The FSSA 2006 gives definition to foods for special dietary uses or functional foods or nutraceuticals or health supplements. Implementing the FSSA faces challenges which include: the inability of small and medium scale firms to identify the procedural and compliance changes in the Act; the regulatory vacuum that will be created when the old regime is repealed; education and competency requirements for firms and regulators. The capacity gaps include lack of qualified technical personnel; inadequacy of skills of existing personnel; lack of well-equipped laboratories for analysis. The study recommended the development of over-arching objectives for regulation; greater collaboration between departments and agencies; non-prescriptive types of regulations; sufficient resources; harmonization with major trading partners; comprehensive & ex-post evaluation of regulation.			
Mariotti, Kalonji, Huneau, and Margaritis	Potential pitfalls of health claims from a public health nutrition perspective.	To analyse and review discrepancies between consumer perception of health claims and the reality	Nutrition Reviews Vol. 68(10):624–638

2010 EU	Functional food	of public health nutrition	
<p>Descriptive Analysis</p> <p>There are over 10, 000 health claim applications based on 4,185 main relationships for inclusion in the EU register. There are six potential incongruities related to health claims in the EU which are: “lexical terms” that consumers find difficult to understand; “beyond scientific truth”, discrepancies between scientific meaning of a claim and consumer perception; “consumer understanding and reality” which includes confusion between the concepts of food and diet; consumers’ misguided belief that ‘more is better’, multifactorial effects and target population. Solutions should reduce the risk of consumer misperceptions that can lead to inappropriate food choices. Recommendations include banning or limiting certain claims; restriction on wording of claims; and the inclusion of general disclaimer statements in health claims.</p>			
<p>Notes:</p> <p>NHP: Natural health product FFNHP: Functional food and natural health product HFF: health and functional food</p>			

5. SUMMARY AND CONCLUSIONS

The remarkable growth of the functional foods and natural health products industry can be attributed to consumers' ever increasing interest in eating healthier diets. The timeliness of this interest, combined with a number of factors, has spurred the industry's development and expansion. Greater scientific evidence in support of some foods and food ingredients providing certain physiological benefits over and above that of conventional foods, and growing public awareness of the link between diet and health, have coincided with technological developments, new opportunities for the food industry, and new R&D applications, all of which have enabled the industry's growth. This growth brings challenges and opportunities for the industry, consumers and policy makers.

Consumers are increasingly aware of the correlation between diet and health and seek functional foods and natural health products mostly for the maintenance of good health. As consumers' attitudes towards functional foods and natural health products are continuously evolving, ongoing study of consumer preferences and willingness to pay for functional foods and NHPs is necessary. Besides the health benefits that influence consumer behaviour, other factors that have been shaping consumer attitudes towards these products include age location, education, gender, price, income levels, base products, knowledge and beliefs, taste, method of production, efficacy, and side effects.

The market for these products is global, with the highest retail value and growth rates found in the US, EU and Japan. While Canada is a comparatively small market internationally, the functional food and natural health products industry is a growing contributor to Canadian exports and the domestic market. Newly industrializing countries also present market opportunities for the industry.

Trade is an essential component of the growth in the functional food and natural health products industry. In Canada most firms in the sector are export-oriented, with the US being a primary destination for functional food firms, while Japan, Korea, Taiwan, Australia, and the EU have been major destination for NHP exports. Emerging economies like China, India and Brazil are potential markets for Canadian firms. In contrast, the US functional food sector is mostly domestically driven (Mintel, 2006) while the EU is one of the leading importers of crude medicinal plants. Japan is a hub in the market for functional foods and natural health products as

one of the most significant markets for the industry, Japan relies on international trade to supply the majority of ingredients used in its domestic production of these products. For example, Canada is Japan's main supplier of flax and canola seed, two important ingredients in the Japanese health food industry.

Industry growth relies upon continued research and development, consequently the protection of intellectual property rights on an international basis is important. Firms have tended to rely upon trade secrets or patents to protect their R&D investments, registering patents in multiple markets. Innovation and research and development have been hampered by the absence of a well-established property rights system for effective patent protection, as well as market/institutional failures which have led firms to use strategies like trade secrets as a means of intellectual property protection.

Health claims on functional food and natural health products help communicate the product's benefits to consumers. However, the growth of the industry has spurred a proliferation of claims which consumers often find confusing. Industry stakeholders have been trying to formulate policies that will protect consumers while promoting the sector. Many firms believe that the harmonization of global health claims will increase sales and allow the sector to realize its full potential. Recommendations to address the regulatory divergence include the scientific validation of health claims, the international harmonization of claims, and the clear distinction between health and functional claims and international labelling standards (Veeman 2002, Bech-Larsen and Scholderer 2007).

International trade is vital to industry growth, yet it is hindered by inconsistencies, a large part of which are due to variations in definitions and terminologies for the sector's products. The international harmonization of definitions and terminologies has been proposed in order to better facilitate international trade in the industry. The definition of functional foods is more controversial than that of natural health products or nutraceuticals, both of which enjoy somewhat greater consensus on definition, though terminology may still differ. Additional terms such as health food, biological active food substance, natural health product, food supplements, dietary supplements, novel foods, have different connotations in some countries but may be considered equivalent in others. The diversity in terminology is confusing for policy makers, the industry, and consumers alike.

International harmonization, not only in definitions and terminology, but also in regulatory regimes has been discussed. The uncertainty and differences in regulations internationally have limited many firms from accessing the international market. While most countries have been formulating policies to protect and promote the sector, these vary greatly from nation to nation in terms of approach, framework and governance. Functional foods and natural health products can be treated as a unique category of food, a subcategory of conventional food, an over the counter drug or a prescription drug, generally or on a product-specific basis, depending on the country. Some efforts to harmonize regulations are occurring, as with the Australia and New Zealand Food Standards Coordination Initiative (Veeman 2002) but international regulatory harmonization remains a challenging prospect.

Beyond the issues in the regulatory environment, and despite enjoying the benefits of growth in interest and demand for their products, firms are faced with multiple challenges. Many small and medium-sized firms are constrained in terms of financial resources and the amount of time required for product development (Hobbs 2002 and Krakar and Gao 2006). They must negotiate the fickleness of consumers who are growing more confused by the ever expanding range of available products and health benefits. They must also meet an evolving regulatory environment where policy makers are rushing to catch up with an industry experiencing exponential growth. Many recommendations on behalf of firms emerge from the literature. These include the branding of products to obtain consumer recognition (Mark-Herbert 2003); establishment of scientific, regulatory and business frameworks to review products and their health claims (IFT 2005); consumer education (AAFC 2009); market segmentation and development of products for niche markets (Mark-Herbert 2003, AAFC 2009); obtaining patents for clinically tested products (Mark-Herbert 2003); seeking of partnership between stakeholders (AAFC 2009, Stein and Rodriguez-Cerezo 2008, Arias-Aranda et al 2010); involvement of health experts in product evaluations (Mark-Herbert 2003); seeking government support in the form of tax breaks, basic and applied research, and regulation of health claims (IFT 2005, Tebbens 2002, Hobbs 2002, Palinic 2005, Cinnamon 2007, Arias-Aranda et al 2010); harmonization of global health claims (Herath et al 2008b); avoiding scientific terminology on labels of new products and make products labelling easy to understand (Evani 2009); a greater attention to consumers' needs, behaviours, and understanding of functional food at the product

development stage (Spence 2006, Bleiel 2010); and the provision of accurate information about product compositions to maintain industry credibility (Spence 2006).

Policymakers acknowledge the benefits of the industry in the reduction of health care costs as consumers' state of health improves due to the consumption of functional foods and natural health products, which in turn increases economic welfare. Studies have explored the extent to which improved diet from the use of functional foods and natural health products can lead to disease risk reduction and consequently health care cost savings. Policy makers therefore have an interest in the continued growth and success of the functional food and natural health products industry. However, governments must balance a dual role of ensuring protection for consumers while providing an operating environment for manufacturers conducive to commercial success.

In summary, the functional food and natural health product industry exhibits significant growth potential. The need for more R&D and for appropriate regulatory environments is a prerequisite for sustained growth. The literature examined in this document suggests an ongoing need for further studies in the areas of consumer behaviour, market analysis, and regulatory development.

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