



GEORGE MORRIS CENTRE

*Canada's Independent Agri-Food Think Tank*

**International Market Trends Analysis for the Functional Foods and  
Natural Health Products Industry in the United States, Australia, the  
United Kingdom and Japan**

**FINAL REPORT**

Prepared for: Nutri-Net Canada

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## EXECUTIVE SUMMARY

The world market for functional foods and natural health products has been expanding and is driven by demographic, economic and social trends. There are a number of key factors driving this growth in demand, as well as changes in the supply chain. These factors include:

- Aging populations, particularly the large baby boom generation; increasing interest in 'healthy living';
- Increasing affluence and education among world populations;
- Increasing understanding of the link between nutrition and health;
- Emphasis on preventative measures to control health care costs;
- Increased acceptance and utilization of 'alternative' treatments;
- General consumer dissatisfaction with conventional treatments, therapies and drugs;
- Rising acceptance among doctors, pharmacists and other health professionals;
- Expanding body of scientific and clinical research to validate effectiveness and safety;
- Expanding press coverage of such research;
- Increased marketing and advertising activities by suppliers and,
- Evolving public policy and regulatory environments.

(Scott Wolfe Management Inc., 2002)

There are a number of different definitions for functional foods and natural health products. The discrepancies in definitions can lead to confusion when discussing and analyzing the industry. For the purpose of this report, we identified definitions for functional foods, natural health products and nutraceuticals, which are provided in [Section 1.0](#) of the report.

The primary objective of this project is to provide evidence of the market opportunities that exist for the Canadian agri-food industries from improved FFNHP regulation. Using market research reports and data provided by Nutri-Net Canada, complemented by publicly available studies and information identified through an exhaustive literature search, the purpose of this research is to conduct a comprehensive analysis of selected foreign markets for functional foods and natural health products, to be used as evidence of market potential for Canada. The markets include: the United States, Australia, the United Kingdom (UK)<sup>1</sup> and Japan. The collected information was intended for two key purposes:

1. Provide a point of comparison with the Canadian market for FFNHPs.
2. Assist in identifying opportunities for growth and advancement of Canada's FFNHP Sector.

The specific objectives of this research are to:

- Create a profile of the FFNHP industries in selected international markets, including the United States, Australia, the United Kingdom (UK) and Japan.
- Analyze industry development and size in these markets which operate under different regulatory environments for FFNHPs.

The report is organized as follows:

- [Section 1.3](#) presents and overview of the regulatory environments for the four jurisdictions profiled. A more detailed regulatory profile is presented in [Appendix A](#).
- Sections 2.0-5.0 present the market profiles for each of the jurisdictions from a demand and supply perspective. Each profile highlights the following: On the demand side, consumer perceptions and awareness of functional foods and natural health products, sales and key trends; On the supply side, the nature and number of firms is discussed,

<sup>1</sup> The United Kingdom has been selected as an indicator of the EU market.

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major functional food and natural health product brands are highlighted, contributions of the functional food and natural health product industries to the economy are identified, and key trends from a supply perspective are discussed.

- Research and development of new products for each of the jurisdictions is presented in [Appendix B](#).
- Section 6.0 presents the summary of the research and analytic conclusions.

**Overview of the Functional Food Markets and Relevant Regulatory Issues for the US, Australia, United Kingdom and Japan**

	US	Australia	UK	Japan
<b>Demand</b>				
Consumer Perceptions and Awareness	-Annual spending greatest for the occasional consumer group -Top reasons for FF purchases: Make up for less than healthy eating habits; Weight loss/weight maintenance; Supplement already healthy eating habits -Top reasons for not purchasing FF: Overpriced; Don't believe the claims they make; Take vitamin and mineral supplement(s) instead	- FF awareness and perceptions regarding level of quality is very high -But 40% never purchase common FF products -Top reasons for no FF purchase: Disbelief in health benefits; Dislike of taste	-Driven by media (especially media scares)	-High sales attributed to tradition of use, convenience, age-related ailments (aging population) and government education programs
Sales	-US\$5.3 to 28.5 billion (2005) -US\$31.4 billion (2006)	-C\$327 to 696 million (2005)	-£1,089 million (C\$2,403 million) in 2005 -Yogurts and drinks / breakfast cereals were top product categories in 2005	-US\$15 to \$20 billion in 2005/2006 (US\$5 billion FOSHU)
Trends	-10.2% growth in 2006 -Forecast additional 5.2% growth by 2010	-Global share growing at 8-14% per year -Convenience sales growing	-Between 2000 and 2005, sales grew by 143% (2.43 times) -Dairy category fastest growing (soya dairy-alternative sector grew 700% between 2001 and 2005)	-12% average annual growth between 1995 and 2003 -Growth slowing (only 2% between 2005 and 2006) from a maturing market
<b>Supply</b>				
Nature and Number of Firms	-Primary structure: multinational corporation -Top sales: PepsiCo, Kellogg Co., Coca-Cola Co., and General Mills -Mainly domestic due to the non-uniformity of health food claim regulations from country to	-Multinationals provide a range of products	-Suppliers focus on one product category -Top suppliers: Danone, Unilever, Nestle, PepsiCo and Ocean Spray	-Between 3,000 and 5,000 FFNHP companies in Japan without established brands (competitive market) -Many market both functional products and ingredients

	US	Australia	UK	Japan
	country			
R&D	- Product introductions have generally been increasing since 2001	-95% of R&D funding from industry -R&D dominated by large companies	-130 new products launched between January 2005 and January 2006 (43% in dairy area) -Driven by large multinational companies such as Danone and Unilever	-MAFF <sup>2</sup> provides cost-share programs for industry to promote development of new technologies for FF component isolation and purification
Key Trends / Industry Issues	-Market development driven by FDA approval of health claims (majority of approvals in heart health) -Cereal market declining -Beverage market growing	-Marketing opportunities driven by allowed health claims (i.e., evidence to support health claims exists)	-The growing and innovative sports nutrition sector faces publication of the long awaited, and potentially restrictive, 'Sports Nutrition Directive', in early 2008. -Development of the "community list of permitted claims" for functional ingredients, targeted for mid-2009, will impact marketing ability	-Factors that may be contributing to market stagnation: large number of firms without established brands (lack of market share); focus on few functional components; falling prices -However, there is opportunity for expansion in sales with expected approval of new Anti-Fatigue FOSHU category
Regulatory Issues	-Food fortification only loosely regulated – only voluntary notification of marketing required	-High transparency and efficiency in marketing approval system	-Nutrition and Health Claims Regulation that entered into force in January and requires prior approval of all health claims will have a major impact on the market as unprepared companies eventually 'lose' valuable health claims. -Novel foods: This legislation threatens to halt, at least temporarily, various 'superfoods' and sports	-Industry interest turning to cosmetic market due to growing complexity and cost of entering the <i>Tokuho</i> (FOSHU) market for foods with allowed health claims

<sup>2</sup> Japanese Ministry of Agriculture, Forestry and Fisheries

	US	Australia	UK	Japan
			nutrition ingredients for which pre-1997 consumption in the E.U. is increasingly difficult to prove -Newly implemented food fortification positive listing regulatory system may impact ability to market fortified foods	

**Overview of the Natural Health Product Markets and Relevant Regulatory Issues for the US, Australia, UK and Japan**

	US	Australia	UK	Japan
<b>Demand</b>				
Consumer Perceptions and Awareness	-Highest percent are regular users (31%) -Recent sales driven by age-related ailments	-Over 50% use at least one NHP -Level of usage among highest in the world	-Over 40% took supplement within last 12 months -Use most popular among 50-65/over 65 age group	-As with FF, sales impacted by tradition of use, convenience, age-related ailments (aging population) and government education programs
Sales	-US\$22.460 billion (2006) (US\$21.320 billion in 2005)	-US\$1.530 billion (2006) (US\$1.440 billion in 2005)	-US\$1.537 billion (2006) (US\$1.502 billion in 2005)	-US\$10 to 11 billion in 2006 -NBJ estimate: \$11.180 billion (2006) (US\$11.640 billion in 2005)
Trends	-Declining growth -5.4% growth in 2006 -Forecast 4.5% growth by 2010	-5.9% growth in 2006 -Sales strong in weight loss category -Increasing focus on health instead of disease	-3.9% between 1999 and 2006 -Recent growth minimal (i.e., 0.9% in 12 months ending August 2006)	-Falling growth (11.3% in 2004; 3.8% in 2005) -Sales <i>decreased</i> (negative growth) between 2005 and 2006 (-3.9%)
<b>Supply</b>				
Nature and Number of Firms	-Top supplier: Natures Bounty, Sundown, Oseto-Bi-Flex (NBTY)	-95% of complementary medicines domestically due to the stringent and complex regulatory environment	-Top supplier is Merck KgaA ( <i>Seven Seas</i> fish oil)	-Top suppliers: Amway Japan, DHC, Miki Shoji -55% share of market belongs to top 20 suppliers (focus on a single, high value-added product) -Mainly direct marketers through

	US	Australia	UK	Japan
Key Trends / Industry Issues	-Declining market due to: Insufficient volume and credibility of science; Clinical test data lacking/conflicting; Relative lack of government funding on health 'prevention'			network/MLM <sup>3</sup> and mail order/internet channels - Negative growth trend attributed to regulation, food safety, contamination and lack of new ingredients and product introductions to excite consumers
Regulatory Issues	-Regulations restrict claims, distribution and new products -Industry positions fragmented and diluted by various/numerous association voices	-Regulations cited as most stringent in the world (regulated under the same authority as pharmaceuticals and prescription drugs) -Commercialization of a product can be slow if the active ingredient of that product is not already on the "Approved List" -However, government shows flexibility in product definitions to facilitate approval	-Stagnation of growth partly due to "uncertainty over the regulatory details of EU vitamin and herbal directives"	-Growth may be negatively affected by government enforcement of new <i>Health Promotion Act</i> (limits expression of health benefits on nutritional products) -Old Pharmaceutical Affair Law may also be damaging: "It seems that the government is trying to put a cap on the nutrition industry to benefit the pharmaceutical industry" -Concerns for consumer safety due to non-regulation of so-called health foods

<sup>3</sup> Multi-level marketing, i.e., door-to-door and product demos and mail order channels

In conclusion, the market profile information and analysis reveals the following key conclusions regarding the functional food and natural health product industry sizes, development and relevant regulatory environments for the United States, Australia, the United Kingdom and Japan. These points serve to provide a point of comparison with the Canadian market and to assist in identifying opportunities for growth and advancement of Canada's FFNHP Sector in related research.

### *Overview of Functional Food Markets*

#### **United States**

- |                        |   |
|------------------------|---|
| Market Demand          | <ul style="list-style-type: none"><li>• Sales of approximately US\$30 billion (2006)</li><li>• Occasional consumers drive sales</li></ul>       |
| Market Supply          | <ul style="list-style-type: none"><li>• Large domestic multinationals dominate supply</li></ul>   |
| Market Development     | <ul style="list-style-type: none"><li>• Product introduction rate increasing</li><li>• Driven by regulatory approval of health claims</li></ul> |
| Regulatory Environment | <ul style="list-style-type: none"><li>• Health claim – efficient</li><li>• Food fortification – non-restrictive</li></ul>                       |

#### **Australia**

- |                        |   |
|------------------------|---|
| Market Demand          | <ul style="list-style-type: none"><li>• Sales of approximately C\$300-700 million (2005)</li></ul>                                |
| Market Supply          | <ul style="list-style-type: none"><li>• Multinational firms provide range of products</li><li>• Industry driven R&amp;D</li></ul> |
| Market Development     | <ul style="list-style-type: none"><li>• Increasing global share</li></ul>   |
| Regulatory Environment | <ul style="list-style-type: none"><li>• Efficient regulatory approval process</li></ul>   |

#### **United Kingdom**

- |                        |   |
|------------------------|---|
| Market Demand          | <ul style="list-style-type: none"><li>• Sales of approximately C\$2.5 billion (2005)</li><li>• Media dominated awareness and perception</li></ul> |
| Market Supply          | <ul style="list-style-type: none"><li>• Large multinationals focus on one product category</li><li>• Industry driven R&amp;D</li></ul>            |
| Market Development     | <ul style="list-style-type: none"><li>• Industry may be impacted by introduction of new regulations</li></ul>                                     |
| Regulatory Environment | <ul style="list-style-type: none"><li>• Industry faces complex and incomprehensive regulatory environment</li></ul>                               |

#### **Japan**

- |                        |   |
|------------------------|---|
| Market Demand          | <ul style="list-style-type: none"><li>• Sales of approximately US\$15 to \$20 billion (2005/2006)</li><li>• High consumer awareness (tradition of use and government education)</li></ul> |
| Market Supply          | <ul style="list-style-type: none"><li>• Lack of market share (large number of companies without established brands)</li></ul>   |
| Market Development     | <ul style="list-style-type: none"><li>• Growth slowing drastically</li></ul>  |
| Regulatory Environment | <ul style="list-style-type: none"><li>• Industry faces increasingly complex and costly system</li></ul>   |

## Overview of Natural Health Product Markets

### United States

- Market Demand
  - Sales of approximately US\$20 billion (2006)
  - Regular users drive sales
- Market Supply
  - NBTY (Natures Bounty, Sundown, Oseto-Bi-Flex) is the leading US supplier (almost double the sales of its nearest competitor)
- Market Development
  - Forecast for declining growth through 2013
- Regulatory Environment
  - Regulations may restrict claims, distribution and new products

### Australia

- Market Demand
  - Sales of approximately US\$1.5 billion (2006)
  - High rate of consumer use
- Market Supply
  - Domestic companies dominate
- Market Development
  - Growth of 6.6% in 2005, 5.9% in 2006
- Regulatory Environment
  - Industry faces among most stringent systems in the world

### United Kingdom

- Market Demand
  - Sales of approximately US\$1.5 billion (2006)
  - High supplement use
- Market Supply
  - Top supplier is Merck KgaA (*Seven Seas* fish oil)
- Market Development
  - Growth stagnating (recently less than 1% annual)
- Regulatory Environment
  - Industry faces complex and uncertain regulatory environment; system may be contributing to market stagnation

### Japan

- Market Demand
  - Sales of approximately US\$10 to 11 billion (2006)
  - High consumer awareness (tradition of use and government education)
- Market Supply
  - Top 20 companies have more than 50% market share
  - Direct marketing through network/MLM<sup>4</sup> and mail order/internet channels dominates
- Market Development
  - Growth slowing drastically; Recent *decrease* in sales (-3.9% between 2005 and 2006)
- Regulatory Environment
  - Uncertain: safety concerns due to unregulated “so-called health foods”; Perception that government restricts NHP industry in favour of pharmaceutical industry

<sup>4</sup> Multi-level marketing, i.e., door-to-door and product demos and mail order channels  
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## 1.0 Introduction and Background

The world market for functional foods and natural health products has been expanding and is driven by demographic, economic and social trends. There are a number of key factors driving this growth in demand, as well as changes in the supply chain. These factors include:

- Aging populations, particularly the large baby boom generation; increasing interest in 'healthy living';
- Increasing affluence and education among world populations;
- Increasing understanding of the link between nutrition and health;
- Emphasis on preventative measures to control health care costs;
- Increased acceptance and utilization of 'alternative' treatments;
- General consumer dissatisfaction with conventional treatments, therapies and drugs;
- Rising acceptance among doctors, pharmacists and other health professionals;
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- Expanding press coverage of such research;
- Increased marketing and advertising activities by suppliers and,
- Evolving public policy and regulatory environments.

(Scott Wolfe Management Inc., 2002)

There are a number of different definitions for functional foods, nutraceuticals and natural health products. The discrepancies in definitions can lead to confusion when discussing and analyzing the industry.

The distinction between functional foods and natural health products may be difficult to make because, according to (Groote, 2002) (p. 6), definitions of functional foods and other health product categories differ between jurisdictions and no international definition for these kinds of products exists. Depending on the jurisdiction, functional foods and nutraceuticals, often lumped together in analysis, can include one or a combination of the following:

- Dietary supplements
- Vitamins and minerals
- Botanicals and herbs
- Traditional medicines
- Amino and fatty acids
- Traditional "value-added" food products such as branded cereals.

As such, according to Groote (2002), "direct comparisons among different jurisdictions is a complex task as different countries have taken very different approaches to developing or applying existing definitions and regulations."

NBJ (2007b) adds that "since "functional foods" and "nutraceuticals" are essentially marketers' terms and not recognized in law or defined in any dictionary, market researchers tend to use them inconsistently." To avoid adding to this inconsistency, for the purpose of this report, the following definitions of functional foods and natural health products are used. These definitions are those provided by the literature that is the basis for much of the information in the report.

### *Functional Foods*

Leatherhead Food International (2006), a source we draw on extensively in this report (for the functional food analysis), uses two definitions of functional foods in its analysis. Its strict definition is, "everyday food and drink products (not pills or potions) that bear a health claim

implying that the product has a physiological effect over and above that of just nutrition (for example, can help lower cholesterol as part of a low-fat diet, helps maintain a healthy heart, improves the body's natural defences, etc.)” This strict definition includes products such as wholegrain cereals, probiotic and prebiotic products, soya products, products with omega-3 fatty acids, etc., where claims can and are being made.

The broad definition of functional foods to which Leatherhead Food International also refers is, “products that have a healthy or functional positioning and may be perceived to be functional, but do not necessarily make claims...this will include products fortified with calcium, vitamins, etc., also antioxidants, cranberries, other botanicals, etc., where their content/use is highlighted but no specific reference is made to potential health benefits.”

Leatherhead Food International (2006) includes the following key functional product areas in its market profiles:

*Dairy products* - including probiotic, prebiotic, vitamin- and mineral-fortified and other enriched products, mainly in the yoghurt, probiotic drinks and drinking milk markets.

*Fats and oils* – covering cholesterol-care and cholesterol-lowering margarine and spread products in the US, Europe and Australia and functional cooking oils in Japan.

*Bakery products* – including fibre-enriched, probiotic and vitamin- and mineral fortified lines, primarily in the bread and biscuits sectors.

*Cereal products* – including fibre-enriched and wholegrain breakfast cereals, as well as fortified cereals and cereal bars.

*Soya products* – mainly focusing on soya milks and soya desserts that are now either being fortified with calcium or promoted on heart or bone health platforms.

*Beverages* - including soft drinks (primarily juice-based drinks and water fortified with vitamins, minerals and other nutrients, as well as juices with intrinsically healthy content, e.g. cranberry, pomegranate), green and other health teas and cocoa drinks.

*Confectionery* – looking mainly at vitamin and mineral-enriched sugar confectionery and fortified chewing gum products, plus chocolate products marketed on health benefits of cocoa.

*Meat, fish and eggs* – focusing primarily on omega-3 and DHA-fortified products, promoted on heart health and brain and nervous system function platforms.

NBJ (2007b) defines functional foods as, “food fortified with added or concentrated ingredients to a functional level, which improves health and/or performance or products marketed for their ‘inherent’ functional qualities. They include some enriched cereals, breads, sports drinks, bars, fortified snack foods, baby foods, prepared meals and more.”

Mintel (2006) defines functional foods as “products that make a distinct, written health claim. They may be foods that are enhanced in some way...or which have been enhanced through the act of processing...to have a beneficial effect on the body in general or on a particular function of the body.”

Mintel adds that, according to its definition, functional foods “may bear approved claims from the FDA” regarding specific health benefits of added ingredients. However, since Mintel’s definition

does not require that a claim exist, it fits within the broad Leatherhead definition of functional foods.

As a Canadian comparison, Health Canada and Agriculture and Agri-Food Canada both define functional foods as, “similar in appearance to – or may be – conventional foods, are consumed as part of a usual diet, and are demonstrated to have physiological benefits and/or reduce the risk of chronic disease beyond basic nutritional functions” (AAFC, 2007; Scott Wolfe Management Inc., 2002). Furthermore, functional foods are created through a variety of means, including:

- Fortification with vitamins and/or minerals to provide added health benefits (e.g. fortified soy beverages and fruit juices with calcium).
- Addition of bioactive ingredients (e.g., muffins with beta glucan, yogurts with probiotics and drinks with herb blends).
- Bioactive-component enhancement through plant breeding, processing, or special livestock feeding techniques (e.g., omega-3 eggs, milk and meat, canola oil high in carotenoids, and wheat with enhanced lutein levels).

(AAFC, 2007)

As a comparison of the Canadian functional food definition to Leatherhead’s strict and broad definitions, the wording “foods...[that] are *demonstrated* to have physiological benefits and/or reduce the risk of chronic disease...” may imply that a claim is necessary, especially since Leatherhead’s broad definition uses the term “perceived to be functional” instead of “demonstrated” functionality. Therefore, it is likely that Canada’s definition corresponds to Leatherhead’s strict definition of functional foods.

### *Natural Health Products*

Agriculture and Agri-food Canada (2007) define natural health products as “usually sold in dosage form for the purpose of diagnosing, treating or preventing disease; restoring or correcting function; or maintaining or promoting health”. Examples of natural health products include:

- Products extracted or purified from plants (e.g., beta-glucan from oats, antioxidants from blueberries, sterols from wood pulp, essential fatty acids from marine or vegetable oil, and soluble fibre from fenugreek).
- Products ground, dried, powdered and pressed from plant materials (e.g., Echinacea, fenugreek, valerian and ginseng).
- Products produced, extracted or purified from animals and micro-organisms (e.g., essential fatty acids, enzymes, carotenoids and probiotics).
- Products comprised from marine sources (e.g., glucosamine, chitosan and fish oils).
- Products comprised solely of vitamins and minerals.

However, it is important to note that the term “natural health products” is vague internationally, since the term is not specifically defined in regulatory systems of jurisdictions outside of Canada. Instead, other jurisdictions have developed systems focused on “dietary supplements”, or terms such as “traditional, alternative or complementary medicines” (Australia’s equivalent to natural health products).

To develop the international natural health product industry profiles, we rely heavily on NBJ’s 2007 Global Nutrition Industry Report. Therefore, the NBJ natural health product definition, below, adds context to the discussion:

NBJ (2007a) defines the Dietary Supplements by its six main product categories: Vitamins, Minerals, Herbs, Meal Supplements (liquid meal replacements), Sports Nutrition Supplements (mostly protein), and Specialty Supplements (including homeopathic remedies). It should be noted that, as the definition of natural health products illustrates, these products are, for the most part, separate from food products. However, in our review, when trying to reconcile these concepts in an international context, we found that this definition of natural health products often overlaps with the definition of functional foods and the two product areas are difficult to distinguish. For example, under the Leatherhead definition, a functional food product has “a physiological effect over and above that of just nutrition” which implies that this product may have health maintenance, preventative or treatment functions. Sports nutrition supplements, for example, which fall under NBJ’s definition of natural health products, could be interpreted to include sports drinks, which fall under Leatherhead’s definition of functional foods. Therefore, for the most part, the natural health product market profiles in this report are based on data for dietary supplements, as defined by NBJ above (and the term “supplements” is used). If the data are not specifically for supplements (i.e., the literature refers to “natural health products” without specifying what these products encompass), we use the term natural health products.

A related concept to natural health products is nutraceuticals. Some literature reviewed in this report refers to nutraceuticals as a subcategory or component of natural health products. The Bureau of Nutritional Sciences of the Food Directorate of Health Canada proposes the following definition for nutraceuticals:

- 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.

(Scott Wolfe Management Inc., 2002; Health Canada, 1998)

### *Regulatory Background*

According to AAFC (2006), “Health Canada regulates the functional food and nutraceutical industry and the Canadian Food Inspection Agency enforces these regulations”. There are two directorates within Health Canada between which this responsibility is divided. The Food Directorate regulates functional foods indirectly via the regulation of health claims, which are used to identify foods as functional, while the Natural Health Products directorate regulates nutraceuticals<sup>5</sup> and natural health products (AAFC, 2006). Within these regulations, only certain aspects of functional foods are regulated. For example, health claims on the label of a product are regulated, but there is not a legislated definition of functional foods.

As described by Health Canada in its October 2006 Blueprint for Renewal report, the department recognizes that there is a need for change in the current regulatory structure. “Increasingly, Canada’s approach to the regulation of health products and food is out of step with international best practices and, more fundamentally, with the needs and expectations of Canadians” (Health Canada, 2006).

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<sup>5</sup> The Bureau of Nutritional Sciences of the Food Directorate of Health Canada proposes the following definition for nutraceuticals: “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.” (Scott Wolfe Management Inc., 2002a)

Nutraceuticals are often discussed in conjunction with functional foods and natural health products in regulatory and market profile contexts. As such, separation of data on nutraceuticals from the other two areas of food can be difficult and some information in the market profiles will refer to several of the food areas.

There are currently no regulations and no regulatory processes which deal specifically with functional foods in Canada. There is no indication if and when specific regulations for functional foods will come into force (Halliday, 2006). Rather, there is a pre-market evaluation framework (standards of evidence) for generic and product-specific health claims (Health Canada, 2007a). The five product-specific health claims allowed for use in Canada are as follows:

- A healthy diet low in saturated and trans fat may reduce the risk of heart disease.
- A healthy diet with adequate calcium and Vitamin D, and regular physical activity, help to achieve strong bones and may reduce the risk of osteoporosis.
- A healthy diet rich in a variety of vegetables and fruit may help reduce the risk of some types of cancer.
- A healthy diet containing foods high in potassium and low in sodium may reduce the risk of high blood pressure, a risk factor for stroke and heart disease.
- Statements pertaining to dental health such as, “Won’t cause cavities,” “Does not promote tooth decay” and “Noncariogenic.”

(Douaud, 2007; Food and Drug Regulations)

In contrast, Natural Health Products are regulated by the *Natural Health Product Regulations*; these regulations are administered by the Natural Health Product Directorate (NHPD), Health and Food Branch of Health Canada. The enabling legislation for these regulations is the Food and Drugs Act. The NHP regulations establish the requirements for a variety of activities associated with the production and distribution of NHPs such as manufacturing, packaging, labelling, sales and distribution. Nutraceuticals fall under the NHP regulations as do many other goods that are classified as “natural health products”. Of particular note are products known as “hybrids” which are both a NHP and one or more of the following: a drug, a food, a cosmetic or a medical device. The most significant hybrids with respect to this research are those that contain both NHPs and foods. Such products would fall under both the *Natural Health Product Regulations* and the *Food and Drug Regulations* (Health Canada, 2003). For hybrid products, the regulatory restrictions in the use of health claims for food in conjunction with the established NHP regulations provides a complex regulatory system within which the functional food and NHP industry has been attempting to function.

It can be difficult to market functional foods and NHPs in Canada as regulations currently allow manufacturers to make only the five health claims identified above. It has also been reported that marketing of foods with health benefits and natural health products is more difficult in Canada because of the “lengthy and expensive” approval process (Lewis, 2006). This is most likely due to the higher standards of evidence required in Canada and the slow pace of the registration process.

Health Canada has recognized these difficulties and has established a long list of objectives to address the concerns identified above, one of which is to “establish clear and consistent policies for health claims, including aligned policies for the management of the food/natural health product interface” (Health Canada, 2007b). In light of Health Canada’s regulatory modernization initiatives, it is widely expected among functional food and natural health product (FFNHP) stakeholders that an internationally competitive regulatory framework for functional foods will be designed and implemented within Canada. It is also expected that proposed amendments to Health Canada’s newer Natural Health Product Regulations will improve the business climate for the functional food and natural health product value chains.

Nutri-Net Canada, a coalition of trade associations, research institutions and government organizations, has committed to the development of a strategic plan for the Canadian functional food and natural health product sector. The Canadian Health Food Association, on behalf of

Nutri-Net Canada, has commissioned the George Morris Centre to conduct the following research:

- Conduct an analysis of selected international functional food and natural health product markets.
- Conduct an analysis of the Canadian market for functional foods and natural health products.
- Prepare a profile of Canada's functional foods and natural health products industries (the FFNHP sector) and describe the opportunities that would arise for agri-food value chains through growth of the FFNHP sector in Canada facilitated in part by a more modern FFNHP regulatory framework.

This report outlines the international market profiles.

### **1.1 Purpose and Objectives**

The primary objective of this project is to provide evidence of the market opportunities that exist for the Canadian agri-food industries from improved FFNHP regulation. Using market research reports and data provided by Nutri-Net Canada, complemented by publicly available studies and information identified through an exhaustive literature search, the purpose of this research is to conduct a comprehensive analysis of selected foreign markets for functional foods and natural health products, to be used as evidence of market potential for Canada. The markets include: the United States, Australia, the United Kingdom (UK)<sup>6</sup> and Japan. The collected information was intended to have two key purposes:

3. Provide a point of comparison with the Canadian market for FFNHPs.
4. Assist in identifying opportunities for growth and advancement of Canada's FFNHP Sector.

It should be noted that this report, although used as a basis for Canadian analysis, does not refer to the Canadian FFNHP regulatory system or the Canadian FFNHP industry profile, as both are presented in a separate report<sup>7</sup>.

The specific objectives of this research are to:

- Create a profile of the FFNHP industries in selected international markets, including the United States, Australia, the United Kingdom (UK) and Japan.
- Analyze industry development and size in these markets which operate under different regulatory environments for FFNHPs.

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<sup>6</sup> The United Kingdom has been selected as an indicator of the EU market.

<sup>7</sup> Refer to the following George Morris Centre research for more information on the Canadian market profile: Klimas et al., 2008. "Opportunities for the Canadian Agri-Food Industries in Functional Foods and Natural Health Products"

## 1.2 Report Outline and Caveats of the Research

As identified above, one of the objectives of this project is to analyze functional food industry development and size in competing international markets which operate under different regulatory environments for functional foods. Specifically, the next four sections of the research will review the functional food industries in the United States (US) (Section 2.0), Australia (Section 3.0), the United Kingdom (UK) (Section 4.0) and Japan (Section 5.0).

The specific components of each section are:

- A brief description of the regulatory systems for functional foods and natural health products in each of the relevant jurisdictions. Note that, since most jurisdictions do not regulate functional foods directly, the regulation of health claims represents the indirect regulatory system for these food products.
  - A brief outline of the regulatory system is presented in Section 1.3 below, with a more detailed discussion presented in [Appendix A](#).
- A profile of the functional food and natural health product industries in each of the relevant jurisdictions. Each profile will provide a description of the development and size of the functional food and natural health product industries in each of the relevant markets from a demand and supply perspective.
  - Appendix B presents research and development of new products within the profiled jurisdictions. Although important to the market profile, it is not specific to the profile and as a result has been included in [Appendix B](#). Where new products could potentially influence supply, it is referred to in the main body of the profile.

Note that, since literature on international functional food industries and natural health product often overlaps, and sometimes fails to distinguish market profile data between functional food and natural health products, we have structured the market profile discussion (for each section of the profile as identified above) as follows. A review of the functional food industry is presented first, when data specific to the industry exists. This is followed by a review of the natural health product data. When the distinction between the two areas is unclear, or when data on both industries are combined, we discuss these data together.

The market profile data are presented in nominal US or Canadian dollars. US dollars are used where data is presented in this currency in the literature (much of the reviewed literature used US dollars in presenting data, and since the value of the US dollar is understandable to most readers, conversions to Canadian dollars were not made). When local currency was used in the literature (i.e. Japanese Yen, UK Pound, or Australian Dollar), we converted the values to Canadian dollars using Bank of Canada average annual exchange rates<sup>8</sup> for the applicable year (i.e., nominal sales values).

## 1.3 International Regulatory Overview (Background)

This section provides an overview of the regulatory systems for functional foods and natural health products in the United States, Australia, the UK and Japan. Much of the overview is an excerpt from similar research that the George Morris Centre is conducting on food regulatory systems in several jurisdictions.

The regulatory overview is in the form of three tables summarizing the key regulatory definitions and marketing approval/regulatory processes applicable for each of the following regulatory

<sup>8</sup> [http://www.bankofcanada.ca/en/rates/exchange\\_avg\\_pdf.html](http://www.bankofcanada.ca/en/rates/exchange_avg_pdf.html)  
George Morris Centre

systems: health claims (Table 1.1), food fortification (Table 1.2) and natural health products (Table 1.3). The tables compare these aspects of the regulatory systems for each of the reviewed jurisdictions. A more detailed description of the regulatory information is provided in Appendix A (United States – [Appendix A.1](#); Australia – [Appendix A.2](#); United Kingdom – [Appendix A.3](#); Japan – [Appendix A.4](#)).

Note that, since most jurisdictions do not regulate functional foods directly, the regulation of health claims represents the indirect regulatory system for these food products<sup>9</sup>. The health claim regulatory system information is derived from the CANTOX (2007) report “International Comparison on the Management of Health Claims and Novel Foods.” In the United Kingdom, legislation, including food standards, is made by the national Government(s), in compliance with EU legislation. Therefore, the overview for the UK is for the EU health claim regulatory environment.

For the United States and the European Union (i.e., UK), an overview of the discretionary food fortification regulatory environment is also provided, since this system is applicable to some functional foods, as defined in the literature (for example, orange juice fortified with calcium). The food fortification regulatory system overview is also an excerpt from similar research that the George Morris Centre is conducting on food regulatory systems in several jurisdictions (but not attributed to CANTOX).

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<sup>9</sup>Health claims are used to identify functional foods as functional on the market. Therefore, the health claim regulatory system applies to Leatherhead’s strict definition of functional foods: “everyday food and drink products (not pills or potions) that *bear a health claim* implying that the product has a physiological effect over and above that of just nutrition.” The health claim regulatory system; however, does not apply to functional foods that do not make health claims, as defined by Leatherhead’s broad definition. These foods are not typically regulated (unless they fall under other regulatory obligations, as in the case of novel food/food ingredients, food additives etc., which is outside the scope of this research).

**Table 1.1 Comparison of Health Claim Regulatory Environments for the United States, Australia, the European Union (for the UK) and Japan (based on CANTOX, 2007)**

Country	United States	Australia	EU	Japan
<b>Definitions</b>	<p>-The Office of Nutritional Products, Labelling &amp; Dietary Supplements receives and evaluates health claim petitions.</p> <p>-NLEA was designed to make available scientifically valid information, to consumers, about the foods they eat.</p> <p>Among other provisions, NLEA authorized FDA to allow statements that describes the relationship between a nutrient and a disease or health related condition on foods and dietary supplements, i.e., health claims (U.S. FDA, 1999a).</p> <p><b>Classified as Health Claims:</b></p> <p>-Authorized Health Claims</p> <p>-Qualified Health Claims</p> <p><b>Not Classified as Health Claims:</b></p> <p>-Structure/Function Claims</p> <p>-Nutrient Content Claims</p>	<p>-Currently, FSANZ is consulting regarding a new framework for the regulation of Nutrition, Health and Related Claims. The following discusses the proposed framework.</p> <p><b>Classified as Health Claims:</b></p> <p><i>-General Level Claims</i></p> <p>Refers to the presence of a nutrient or substance in a food and to its effect on a health function. For e.g., “Calcium is good for strong bones and teeth, when consumed as part of a healthy diet containing a variety of foods.” “Exercise and a diet high in calcium helps build stronger bones when combined with a healthy diet containing a variety of foods.”</p> <p><i>-High Level</i></p> <p>A health claim that directly or indirectly refers to a serious disease or a biomarker. For e.g., “This food is high in calcium. Healthy diets high in calcium may increase bone mineral density, which has particular importance for women.”</p> <p><b>Not Classified as Health Claims:</b></p> <p><i>-Nutrient Content Claim</i></p> <p>Statements regarding the amount of a nutrient, energy or a biologically active substance in the food.</p>	<p>-A new regulation for nutrition and health claims on foods (Reg. (EC) No. 1924/2006) came into force Jan. 2007. This new law is intended to harmonize laws across Member States.</p> <p>-EFSA is the independent risk-assessment agency funded by the EU that will evaluate health claims.</p> <p><b>Classified as Health Claims:</b></p> <p><i>Article 13 Claims:</i></p> <p>Refer to the role of a nutrient or substance in growth, development, body functions, psychological or behavioural functions, weight control or loss.</p> <p><i>Article 14 Claims:</i></p> <p>Claims that relate to disease risk reduction or children’s development and health.</p> <p><b>Not Classified as Health Claims:</b></p> <p><i>Nutrient Claims:</i></p> <p>Refer to the amount of calories of a nutrient or a substance.</p>	<p>-The Ministry of Health, Labour and Welfare (MHLW) provides standards and regulations pertaining to foods.</p> <p><b>Types of foods classified with Health Claims:</b></p> <p><i>Foods with Nutrient Function Claims (FNFC):</i></p> <p>-Structure/function claims – function of nutrients.</p> <p>-Prohibited from making exaggerated, misleading claims, and claims that are not substantiated by evidence.</p> <p>-Pre-approved claims.</p> <p><i>Foods for Specific Health Uses (FOSHU):</i></p> <p>-Refers to the function of nutrients or other food ingredients.</p> <p>-Structure/function claims or disease-reduction claims.</p> <p>-Approved by MHLW through a standard, qualified or individual route of approval.</p> <p><i>So-Called Health Foods:</i></p> <p>-Are not regulated.</p>
<b>Marketing Approval</b>	<p><b>Authorized Claims:</b></p> <p>-Approval by FDA required</p> <p>-Regulatory amendment required</p> <p><b>Qualified Health Claims:</b></p>	<p>-Only High Level Health Claims require FSANZ pre-market approval in order to change the Code, even though evidence for claim should be held by food manufacturers for other</p>	<p>-EFSA approval is required for Article 13 and 14 claims.</p> <p>-EC is accepting a list of Article 13 claims from Member States until Jan. 31 2008. EC will then review</p>	<p>-MHLW approval is required for FOSHU products.</p> <p>-FNFC are pre-approved by MHLW.</p> <p>-So-called Health Foods are not regulated.</p>

Country	United States	Australia	EU	Japan
	<p>-Approval by FDA is required</p> <p>-FDA will indicate if it does/does not object to the claim</p> <p><b>Structure/Function and Nutrient Content Claims:</b></p> <p>-Must notify FDA of claim being used.</p>	<p>claims.</p>	<p>the lists and adopt a list of claims. After this list has been created, claims can be added by going through the application process with EFSA.</p>	
<b>Applicant Requirements</b>	<p>-Different levels of scientific support are required for Authorized and Qualified Claims.</p> <p>-Authorized: High level of scientific support is required</p> <p>-Qualified: Moderate, low or extremely low evidence is allowed.</p> <p>-Information required includes efficacy and limited info on quality and safety.</p> <p>-Food with health claims must meet nutrient profile criteria.</p>	<p>-Efficacy of claim must be demonstrated and the quality of the research must be ranked. The amount of proof will be determined on a case-by-case basis, but High Level claims will require 'convincing' evidence while General Level claims will require 'probable' evidence.</p> <p>-Research can be used from listed credible sources to simplify the process.</p> <p>-FSANZ is considering that food with health claims must meet a minimum nutrient profile to qualify.</p>	<p>-A formal scientific substantiation dossier is required for an Article 14 application. This includes proving efficacy, quality and safety in the case of novel foods.</p> <p>-Article 13 applications will require validity of the claim.</p> <p>-EFSA is considering that food with health claims must meet a minimum nutrient profile to qualify.</p>	<p>-FOSHU applications must demonstrate efficacy, quality and safety.</p> <p>-Data requirements are ranked in order of decreasing science (A, B or C).</p> <p>FOSHU:</p> <p>-Standardized: Rank A data required</p> <p>-Individual: Rank A or B</p> <p>-Qualified: Rank C</p> <p>FNFC: Rank A data required.</p>
<b>Performance Indicators</b>	<p>Communication:</p> <p>-FDA regularly communicates with applicants.</p> <p>-Federal Register includes daily updates on decisions.</p> <p>-Guidance document available</p> <p>Transparency:</p> <p>-High level of transparency</p> <p>-3<sup>rd</sup> party reviewers are brought in to maximize resources.</p> <p>-FDA prioritizes petitions based on public health benefit.</p>	<p>Communication:</p> <p>-FSANZ is required to notify applicants at various stages of process, up to seven times</p> <p>-Very good guidance document to help applicants</p> <p>Transparency:</p> <p>-All reasons for decisions must be made public.</p>	<p>Communication:</p> <p>-Guidance document created for Article 14 submissions.</p> <p>Transparency:</p> <p>-EFSA is legally obliged to be transparent and post decisions on applications that have been assessed, accepted and rejected on its website.</p>	<p>Communication:</p> <p>-MHLW provides no info on application procedure.</p> <p>-Japan Health Food and Nutrition Food Association provides guidance documents.</p> <p>Transparency:</p> <p>-No info provided.</p> <p>Consumer confusion regarding difference in FOSHU and JHFNFA seals of approval.</p>

Definition of Acronyms:

- EFSA - European Food Safety Authority
- FDA – Food and Drug Administration

- FNFC - Foods with Nutrient Function Claims
- FOSHU - Foods for Specific Health Uses
- FSANZ - Food Standards Australia New Zealand
- JHFNFA - Japan Health Food and Nutrition Food Association???
- MHLW - Ministry of Health, Labour and Welfare
- NLEA - *Nutrition Labeling and Education Act*

**Table 1.2 United States and European Union (for the UK) Food Fortification Regulatory Environments**

Country	United States	European Union
<b>Definitions</b>	<p>-Vitamins and mineral nutrients are regulated under Fortification Policy (CFR, Title 21, Part 104 – Nutritional Quality Guidelines for Food). However, according to Smith (2007), “the guidelines are not prescriptive and thus permit the loosely regulated addition of vitamins and minerals to many foods.”</p> <p>-The 1980 guidelines remain the most recent fortification regulations to date.</p>	<p>-Regulation 1925/2006 was officially adopted in July 2007.</p> <p>-Deals only with the voluntary fortification of foods by food manufacturers, not mandatory fortification of certain foodstuffs. Mandatory fortification rules differ among member states and these rules and regulations will remain within the member states’ jurisdiction.</p>
<b>Marketing Approval</b>	<p>The Fortification Policy Statement of Purpose CFR 104.20 is:  <i>The Food and Drug Administration does not encourage the indiscriminate addition of nutrients to food, nor does it consider it appropriate to fortify fresh produce; meat, poultry, or fish products; sugars; or snack foods such as candies and carbonated beverages. To preserve a balance of nutrients in the diet, manufacturers who elect to fortify foods are urged to utilize these principles when adding nutrients to food.</i></p> <p>- According to the policy, a <i>nutrient...may appropriately be added to a food:</i></p> <ol style="list-style-type: none"> <li>1) <i>to correct a dietary insufficiency</i></li> <li>2) <i>to restore such nutrient(s) to a level(s) representative of the food prior to storage, handling and processing...</i></li> <li>3) <i>to balance the vitamin, mineral, and protein content...</i></li> <li>4) <i>to avoid nutritional inferiority when replacing a traditional food</i></li> </ol> <p>-Since food fortification is only loosely regulated, there is no process for approval.</p>	<p>-Sets out a positive list of vitamins and minerals that can be added to foodstuffs and a positive list of sources of vitamins and minerals that may be used in the Community Register.</p> <p>-There will be a transitional phase for products that are on the market that do not meet the requirements.</p> <p>-Information on the label must comply with article 4(1), group 2, of Directive 90/496/EEC on nutrition labeling (Brans, 2006).</p> <p>-Labels can have statements regarding the addition of the vitamins and/or minerals but these statements must not be misleading.</p> <p>-Nutrients added to foods without a desirable nutritional profile (with a high sugar, fat or salt content) will not be able to make a claim as outlined in the new nutrition and health claims regulation.</p> <p>-Minimum and maximum amount levels must be met.</p>

Definition of Acronyms:

- CFR - Code of Federal Regulations

**Table 1.3 Comparison of Natural Health Product Regulatory Environments for the United States, Australia, the European Union (for the UK) and Japan**

Country	United States	Australia	EU	Japan
<b>Definition</b>	<p>-Generally fall into category of “dietary supplements”.</p> <p>-Alternatively, could fall under vitamins and mineral nutrients.</p>	<p>-NHPs, also known as traditional or alternative medicines, are classified as complementary medicines and are defined in the <i>Therapeutic Goods Act (1989)</i> – section 52F.</p> <p>-However, if they are sold as food they may be classified as caffeinated beverages or food drinks.</p> <p>-The category of complementary medicines includes herbs, minerals, nutritional and dietary supplements, homeopathic medicines and aromatherapy oils.</p>	<p>-European Parliament and the Council of the EU define food supplements as: <i>...foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities.</i></p>	<p>-In Japan, products are classified as food or drugs; there is no in-between category for products considered as dietary supplements.</p>
<b>Marketing Approval</b>	<p>-Manufacturers of dietary supplements do not have to get approval of products from the FDA. However, they are responsible for submitting “a premarket notice and evidence of safety for any supplements they plan to sell that contain dietary ingredients that were not marketed as dietary supplements before DSHEA was passed—except that the premarket notice is not needed if the new dietary ingredient had previously been used as an ingredient in food” (CANTOX, 2007).</p>	<p>- Regulated under therapeutic goods/products legislation which is administered by the Therapeutic Goods Administration (TGA) division of the Department of Health and Ageing.</p> <p>-The <i>Therapeutic Goods Act 1989</i> lays out the provisions of complementary medicine registration and use.</p> <p>-TGA maintains the Australian Register of Therapeutic Goods (ARTG) database which lists the therapeutic goods, including complementary medicines, which are legally allowed to be imported into, supplied in, or exported from Australia.</p> <p>-Some complementary medicines are exempt from the database but are allowed to be provided in Australia (some aromatherapy oils, for example).</p>	<p>-EU has harmonized its regulatory process for food supplements, but not all natural health products.</p> <p>-Regulated under Food Supplements Directive 2002/46/EC.</p> <p>-Annex I and Annex II of this directive provide a list of the vitamins and minerals that can be used in the manufacture of food supplements.</p> <p>- Label and any associated advertising must not attribute to the supplement the property of preventing, treating, or curing a disease.</p> <p>- To ensure compliance with the labeling requirements, manufacturer/ importer may be required to submit label draft to each EU member country where it plans to market.</p>	<p>-The majority of supplements fall under the “so-called health foods” non-regulated category of products, so marketing approval does not apply.</p> <p>-However, on-label health claims are not allowed on these products.</p>

Definition of Acronyms:

- DSHEA - *Dietary Supplement Health and Education Act*
- TGA - Therapeutic Goods Administration
- ARTG - Australian Register of Therapeutic Goods

## 2.0 Description of the Functional Food and Natural Health Product Industry in the United States

This section presents a profile of the functional food and natural health product industries in the United States. The profile provides a description of the development and size of the functional food and natural health product industries from a demand (2.1) and supply (2.2) perspective.

### 2.1 Demand for Functional Food and Natural Health Products in the United States

Section 2.1 looks at the demand for functional food and natural health products in the United States. This section is broken down into three areas: Section 2.1.1 examines consumer perceptions and awareness of FF and NHPs; Section 2.1.2 reports on the sales in the FFNHP industry, and Section 2.1.3 outlines key trends in the demand for FFNHP in the United States.

#### 2.1.1 Consumer Perceptions and Awareness of Functional Food and Natural Health Products

This section describes literature on consumer perceptions and awareness of functional foods and natural health products.

##### Functional Foods

A global survey by AC Nielsen found that U.S. consumers are less likely than the average global consumer to purchase functional food products such as yogurts with acidophilus cultures/probiotics, fermented drinks containing good bacteria and soy milk (AC Nielsen, 2005a). However, U.S. consumers were more inclined to purchase functional foods such as whole grain, high fibre products (50% versus 40% global average), cholesterol reducing oils and margarines (36% versus 31% global average) and bread with added supplements/vitamins (24% versus 17% global average). Table 2.1 shows the percent of consumers who regularly buy functional foods versus the global average.

**Table 2.1 Percentage of Consumers Who Regularly Buy Functional Foods, by Key Category, 2005**

Functional Food	Global Average	US Consumers
Whole grain, high fibre products	40%	50%
Iodine enhanced cooking salt	33%	30%
Cholesterol reducing oils & margarine	31%	36%
Fruit juices with added supplements/vitamins	29%	29%
Yogurts with acidophilus cultures/probiotics	25%	21%
Milk with added supplements/vitamins	18%	25%
Bread with added supplements/vitamins	17%	24%
Fermented drinks containing good bacteria	16%	4%
Soy milk	14%	8%
Cereal with added folate	11%	14%

(AC Nielsen, 2005a)

Among US consumers who do not buy functional foods, the most frequently cited claims were uncertainty about the products' health claims, and taste (AC Nielsen, 2005a).

Table 2.2 shows consumer functional food use in 2005 by monthly spending, annual totals as well as the percentage of the market that is represented by heavy, regular, occasional, rare and non-users for functional foods. Total annual spending was greatest for the occasional consumer group (US\$10,154 million total spending per year), followed by the regular consumer group (US\$9,686 million total spending per year) and the heavy consumer group (US\$4,871 million total spending per year).

**Table 2.2 Summary of United States Consumer Functional Food Use, 2005**

Consumer Type	Population (millions)	Percent of Population	US\$ Spent per Month	Annual Total (millions US\$)	Percent of Market
Heavy consumers	8.1	3.4	50	4,871	18.3
Regular consumers	40.4	17.1	20	9,686	36.3
Occasional consumers	112.8	47.8	7.5	10,154	38.1
Rare users	54.3	23	3	1,954	7.3
Non-users	20.4	8.7	0	-	0
<b>Total</b>	<b>236</b>	<b>100</b>		<b>26,665</b>	<b>100</b>

Source: (NBJ, 2007b)

In order to find out why US consumers purchase functional foods, Mintel (2006a) asked 566 adults who had bought a functional food in the past three months and had internet access to respond to the following statement, “Please tell us whether you buy functional foods for any of the following reasons.” Table 2.3 shows the consumer response rates for the given purchasing reasons. As the table illustrates, the primary reason to purchase functional foods was to make up for less than healthy eating habits (48% of the respondents agreed with this purchasing reason).

**Table 2.3 Reasons for Functional Food Purchases, 2006**

Reason for functional food purchase	Percent who purchased functional food for the given reason
Make up for my sometimes less than healthy eating habits	48
Weight loss/weight maintenance	44
Supplement my already healthy eating habits	35
Address specific health issues like heart health, fatigue, or digestive cleansing	30
Avoid eating empty calories	26
In place of a meal	16
Other	7

Source: (Mintel, 2006a)

Mintel (2006a) also asked 1,315 adults who had not purchased a functional food in the past three months and had internet access to respond to the following statement, “Please tell us whether you have not bought functional foods or drinks in the past three months for any of the following reasons.” Table 2.4 illustrates the participant response rates for the given reasons for not purchasing functional foods. The primary reason for not purchasing functional foods was because the respondents felt functional foods were over priced (43% of respondents).

**Table 2.4 Reasons for Not Purchasing Functional Foods, 2006**

Reason for not purchasing functional foods	Percent who did not purchase functional foods for the given reason
I think they are overpriced	43
I don't believe the claims they make	35
I take vitamin and mineral supplement(s) 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, 2006a)

### *Natural Health Products*

According to the Nutrition Business Journal (2007a) estimates, 4% of the US population are heavy users of supplements, 31% are regular users, 22% are occasional users, 18% are rare users and 25% are non-users of supplements.

NBJ (2007a) attributes high sales of vitamins and dietary supplements in many key global markets in 2006, and specifically in the United States (and Japan), to age-related ailments such as arthritis, prostate problems, osteoporosis and menopause, a result of the aging population.

However, generally speaking, NBJ (2007a) reports a declining growth trend in consumer sales of supplements in the US, and attributes this trend to the following consumer and media-related factors.

#### Consumer Issues:

- New consumer acquisition became harder to attain as the industry moved into conventional retail.
- The beginnings of 'saturation' of enlightened consumers—and their accustomed retail establishments.
- There existed a relative lack of sophistication and acceptance of supplements by consumers.
- Customer confusion resulted from the high number and broad selection of products in the market.
- Consumers lacked proper education and expectations for supplements.
- Consumers failed to receive tangible results from supplement consumption based on unrealistic drug-type expectations (glucosamine and ephedra are notable exceptions).
- Nutrition/supplementation obtained from food and functional food products and not supplements.
- Perception that supplements were a 'luxury' item not a health necessity.

#### Media Issues:

- Media coverage tended to be negative on herbs which also had an effect on other categories.
- Lack of breakthrough products in certain years limited positive exposure for all supplements.

(NBJ, 2007a)

### 2.1.2 Sales of Functional Food and Natural Health Products

This section describes literature on sales of functional foods and natural health products.

#### *Functional Foods*

Nutrition Business Journal (2007b) estimates that retail sales of functional food products were worth US\$31.4 billion in 2006 (US\$28.5 billion in 2005). This represents 5.5% of the total food sales. According to Leatherhead Food International (2006), the size of the US market for functional foods is between US\$5.3 billion (2005) and US\$9.75 billion, depending on the breadth of the definition used. Leatherhead notes that estimates for even less conservative definitions go as high as US\$20 billion, or 4% of the total foods market. The breadth of the definition may explain why Leatherhead's estimate is much lower than NBJ's estimate. It appears that NBJ uses a much broader definition of functional foods, although this is not evident from the definitions listed in [Section 1.0](#).

Table 2.5 shows the US sales of functional foods by type of functional food for 2005, as presented by Leatherhead.

**Table 2.5 US Functional Food Market Size (2005 \$'s) by Type of Functional Food**

Functional food type	Market size estimate by strict definition (US million 2005\$)	Market size estimate by broad definition (US million 2005\$)
Dairy products	315	1,050
Yellow fats	40	40
Bakery products	Neg.	1,115
Cereal products	2,850	3,204
Soya products	950	1,175
Beverages	1,044	2,190
Confectionery	Neg.	Neg.
Meat, fish and eggs	108	978
<b>Total</b>	<b>5,307</b>	<b>9,752</b>

Source: (Leatherhead Food International, 2006)

According to Leatherhead Food International (2006), cereal, beverages and soya products make up 85 percent of the US functional foods market due to FDA approved claims that can be applied to these products (for example, claims such as "whole grain" or "oat" for cereal products). The cereal products, by the strict definition (products making claims) of functional foods, have a 50 percent share of the functional foods market in the United States. Within the cereal market, breakfast cereals are the largest product area and the only area that falls under the strict definition of functional foods. Breakfast cereal claims based on digestive health have received little attention and calcium claims related to bone health haven fallen in popularity since a peak in the late 1990s. However, 'heart health' has been a growing area of interest with breakfast cereal products containing FDA approved claims related to oatmeal, cholesterol reduction/heart health, psyllium, wholegrains, soya proteins and omega-3 acids (Leatherhead Food International, 2006). According to Leatherhead (2006), breakfast cereals with heart health related claims are valued at US\$600 million a year.

Unlike Europe, where functional food markets are well developed in dairy products, the US has a relatively small dairy product functional food market, especially with respect to products such

as functional yogurts and health drinks. The US functional foods market also distinguishes itself from these markets in Australia, Japan and Europe by its greater focus on dietary supplements (Leatherhead Food International, 2006).

According to Leatherhead Food International (2006), the US functional soft drinks industry is the largest in the world due to the popularity of sports drinks. Even when soft drinks and energy drinks are excluded, the market still remains relatively large. However, by the strict definition of functional foods (products making claims), the value of this market is cut by half. The Nutrition Business Journal (2007) estimates energy drink growth at 48% in 2006, to a value of US\$3.7 billion and functional water and soda growth at 35%, to a value of US\$1.35 billion.

The US functional food confectionary market has remained small in the areas of fortified chewing gum and sugar confectionary but has included confectionary-supplement hybrids such as calcium chews. The market for health benefiting chocolates has been growing.

The US functional food market for meat, fish and egg products has been successful in the area of canned tuna, worth US\$1.5 billion a year. However, these sales have been declining and industry is responding with omega-3 health claims to boost sales. The value of canned oily fish marketed on the basis of omega-3 health benefits is US\$870 million. There has also been marketing activity in the area of fish oil supplements. A recent example of this kind of initiative is the development of Bumble Bee branded fish oil supplements, a collaboration of the Bumble Bee canned fish brand and Leiner Supplement Company. The meat, fish and egg market also includes a well-established omega-3 fortified egg sector.

#### *Natural Health Products*

NBJ (2007a) cites global supplement sales in the United States as \$21.32 billion in 2005 and \$22,460 million in 2006. This represents a growth of 5 percent between 2005 and 2006. This report clearly shows that these supplement sales comprise vitamins & minerals, herbs/botanicals and sports, meal, homeopathic & specialty supplements. The following table shows 2006 consumer sales of supplements and percent growth in sales by product type. Vitamin supplements are the leading product type, with \$7,513 million in sales, followed by herbs/botanicals at \$4,591. However, the leading product types in terms of 2006 percent growth in sales are specialty/other supplements<sup>10</sup>, followed by sports nutrition.

**Table 2.6 US Supplement Consumer Sales and Percent Growth by Product Type, 2006**

Product Type	2006 Consumer Sales (\$M)	2006 % Growth
Vitamins	7,513	4.9
Herbs/Botanicals	4,591	4.1
Sports Nutrition	2,355	6.2
Minerals	1,849	2.0
Meal Supplements	2,362	2.7
Specialty/Other	3,790	11.0

<sup>10</sup> Specialty supplements are: Supplements that do not fit into the other supplement sub-categories, including: glucosamine, melatonin, probiotics, DHEA, fish oils/shark cartilage, bee products, CoQ10, 5HTP, amino acids, homeopathic remedies, SAME, chondroitin, probiotics, prebiotics, colostrum, other oils, other enzymes, other hormones, etc. (NBJ, 2007a)

<b>Supplements Total</b>	<b>22,460</b>	<b>5.4</b>
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\*Percent growth =  $[(\text{Sales}_{\text{Year N}} - \text{Sales}_{\text{Year N-1}}) / (\text{Sales}_{\text{Year N-1}})] \times 100$

Source: (NBJ, 2007a) and GMC calculations

### 2.1.3 Key Trends

This section describes literature on key demand trends of functional foods and natural health products.

#### *Functional Foods*

Table 2.6 below shows the growth of total functional food sales between 1998 and 2006 (Nutrition Business Journal, 2007) and Nutrition Business Journal's (2007) estimates for sale growth between 2007 and 2010. The Journal forecasts that the growth of functional food sales in the US will decline in the next several years, from approximately 10.2% in 2006 to an estimated 5% growth in 2010.

**Table 2.7 Growth of Total Functional Food Sales in the United States between 1998 and 2006 and Growth Estimates to 2010**

Year	Functional Food Sales Growth
1998	10.2
1999	11.1
2000	10.4
2001	9.0
2002	8.6
2003	8.5
2004	7.4
2005	8.7
2006	10.2
2007 <sup>1</sup>	8.5
2008 <sup>1</sup>	6.5
2009 <sup>1</sup>	5.4
2010 <sup>1</sup>	5.2

Notes: <sup>1</sup>Sales growth forecasts

Source: Nutrition Business Journal, 2007, p. 112

According to Nutrition Business Journal (2007), the 2006 growth rates for functional foods were greatest for functional food beverages (15% growth) and functional food condiments (6% growth). The Journal estimates that beverages and bread and grain functional food products will comprise 70% of US total functional food sales by 2010.

#### *Natural Health Products*

The following table shows US supplement sales between 2001 and 2006 (NBJ, 2007a). As the table shows, the sales trend for natural health products has been uncertain, fluctuating between approximately 3% and almost 6% since 2001. However, sales increasingly grew between 2004 and 2006. According to NBJ (2007a), the large supplement sales growth between 2002 and 2003 (5.7%— higher than 2005-2006 growth even though the trend is of increasing growth), was due to the fact that 2003 “uniquely benefited from JAMA’s high profile publication of a positive

multivitamin study—“the single and perhaps only influential positive media event of the decade.” Sales in 2004, on the other hand, were negatively impacted by the ephedra ban.

**Table 2.8 US Supplement Sales by Year and Percent Growth, 2001-2006**

Year	Sales (\$M)	% Change*
2001	18,078	-
2002	18,755	3.7
2003	19,821	5.7
2004	20,390	2.9
2005	21,316	4.5
2006	22,460	5.4

\*Percent growth =  $[(\text{Sales}_{\text{Year N}} - \text{Sales}_{\text{Year N-1}}) / (\text{Sales}_{\text{Year N-1}})] \times 100$

Source: (NBJ, 2007a) and GMC calculations

NBJ (2007a) also offers growth forecasts for the supplement industry up to 2013. These forecasts, in terms of annual consumer sales estimates between 2007 and 2012, are shown in the table below. According to this forecast, US sales growth will slow through 2013.

**Table 2.9 Annual US Consumer Sales of Supplements Forecast, 2007-2013 (millions US\$)**

	2007	2008	2009	2010	2011	2012	2013
Supplements Total	23,417	24,578	25,754	26,910	28,034	29,189	30,374
Growth (%)	4.3	5.0	4.8	4.5	4.2	4.1	4.1

Source: (NBJ, 2007a)

Sale trends by supplement product type offer insight into the specifics of growing demand, and present a basis for future market opportunities in the US industry. The following table demonstrates supplement sales between 1999 and 2006, by product category, and the forecasted compounded annual growth rate between 2007 and 2010 for each product category.

**Table 2.10 US Supplement Consumer Sales by Product Type, 1999-2006 and Forecasted Growth Between 2007-2010\* (millions US\$)**

Products	1999	2000	2001	2002	2003	2004	2005	2006	CAGR* '07-10
Vitamins	5,904	5,979	6,025	6,180	6,658	6,892	7,163	7,513	3.7%
Herbs/Botanicals	4,110	4,260	4,397	4,276	4,178	4,321	4,411	4,591	2.7%
Sports Nutrition	1,450	1,590	1,720	1,819	1,963	2,097	2,217	2,355	4.6%
Minerals	1,290	1,350	1,396	1,527	1,765	1,738	1,812	1,849	4.7%
Meal Supplements	1,909	2,070	2,305	2,571	2,522	2,329	2,300	2,362	8.0%
Specialty/Other	1,795	2,020	2,230	2,372	2,728	3,013	3,414	3,790	7.1%
<b>Supplements Total</b>	<b>16,458</b>	<b>17,269</b>	<b>18,073</b>	<b>18,745</b>	<b>19,814</b>	<b>20,390</b>	<b>21,316</b>	<b>22,460</b>	<b>4.7%</b>

\*CAGR = Forecasted Compound Annual Growth Rate

Source: (NBJ, 2007a)

Generally, according to the NBJ Global Nutrition Industry Report (2007a), growth of all supplement product types has been increasing. However, if the trend in sales is extended back to 1995, as NBJ points out, the 5% growth in 2000 is minimal compared to the 14% growth in 1995 (NBJ, 2007a). NBJ (2007a) offers many factors that may have contributed to this decline in growth, both from a consumer perspective and an industry and regulatory perspective. The demand side issues affecting this growth trend were listed in the consumer perception and awareness section of this market profile ([Section 2.1.1](#)). The industry and regulatory issues are presented in more detail in the supply key trends section ([section 2.2.5](#)) at the end of the US market profile.

## **2.2 Supply of Functional Food and Natural Health Products**

Section 2.2 looks at the supply side of the functional food and natural health product industry in the United States. This section is divided into four sub-sections. Section 2.2.1 looks at the nature and number of FFNHP firms in the United States. In Section 2.2.2, major FFNHP brands in the United States are examined. Section 2.2.3 looks at the contribution of FFNHP industries to the United States industry. Finally, Section 2.2.4 highlights key trends in the FFNHP industry, as they relate to the supply side.

### 2.2.1 Nature and Number of Firms

This section describes literature on the nature and number of firms in the United States markets for functional foods and natural health products.

#### *Functional Foods*

Leatherhead Food International (2006) generally divides functional food firms into three groups: mainstream food and drink companies (Kellogg, PepsiCo, Danone), pharmaceutical companies (Johnson & Johnson) and one-product specialists. In the United States, acquisition in the functional food area has been increasing with the growth of the functional food market. Some of the major suppliers of functional food products in the United States include:

- Danone
- McNeil
- Belovo
- Kao
- Unilever
- Quaker
- PepsiCo
- Yakult.

According to Mintel (2006), the US market for functional foods is mainly domestic due to the non-uniformity of health food claim regulations from country to country. That is, domestic products are consumed primarily by US consumers and US consumers primarily consume US products with little exporting and importing taking place. Mintel (2006, p. 40) adds that “Companies based overseas – Group Danone, Nestle, Red Bull, Cadbury Schweppes, and Unilever Bestfoods – are well entrenched in the US.”

The primary firm structure of the US functional food market is multinational corporations. Some of these corporations market individual brands within specific segments of the functional food market, but many also offer multiple brands across segments (Mintel, 2006).

Table 2.7 shows the top functional food and beverage sales by manufacturer, as listed by Mintel (2006). PepsiCo, Kellogg Co., Coca-Cola Co., and General Mills lead functional food sales with 16.3%, 14.3%, 10.8% and 10.6% of the share of 2005 sales, respectively.

**Table 2.11 Top Manufacturer Food, Drug and Mass Merchandiser Sales of Functional Foods and Beverages in the United States, 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
Sunny Delight Beverages Co.	217	1.5
H.J. Heinz Co. (The Hain Celestial Group)	186	1.3
Cadbury Schweppes	166	1.1
Eggland's Best	156	1.1
Unilever Bestfoods	139	0.9
Old Orchard Brands	121	0.8
Campbell Soup Co.	118	0.8
Hansen Natural, Inc.	91	0.6
Private label	1,024	7.0
Other	1,289	8.8
<b>Total</b>	<b>14,703</b>	<b>100</b>

Notes:

1) Data may not equal totals due to rounding;

2) Excludes sales through Wal-Mart

Source: Mintel, 2006

### Natural Health Products

The following table lists the top 25 US supplement companies as ranked by NBJ (2007a) according to 2006 US supplement sales. The table includes the 2004, 2005 and 2006 sales for each company. NBTY (Natures Bounty, Sundown, Oseto-Bi-Flex) is the leading US supplement company, with a 2006 sales value of \$1,052 million, almost double that of its nearest competitor.

**Table 2.12 NBJ's Top 25 Supplement Companies in U.S., 2006 (ranked by 2006 US supplement sales)**

	Company	2004 US Supp Sales (\$ M)	2005 US Supp Sales (\$ M)	2006 US Supp Sales (\$ M)
1	NBTY (Natures Bounty, Sundown, Oseto-Bi-Flex)	906	908	1,052
2	Leiner Health Products*	500	500	553
3	Pharmavite*	474	500	540
4	Wyeth (Centrum, Caltrate)	512	483	463
5	Abbott Labs/Ross Products (Ensure, EAS, ZonePerfect)	243	258	451
6	Unilever (SlimFast)	333	341	355
7	GNC Manufacturing	116	115	312
8	Perrigo*	161	196	224
9	Schiff Nutrition Int'l (formerly Weider)	188	187	198
10	VitaQuest Intl (Garden State, Windmill)*	116	130	160
11	Bayer (One A Day, Flintstones)	156	151	156
12	Nutraceutical International	143	150	150
13	Optimum Nutrition	110	125	140
14	Enzymatic Therapy	109	125	131
15	Natures Way Products (B&T)	95	110	128
16	Healthy Directions (Doctor's Preferred)	100	114	124
17	Now Foods	98	110	120
18	Ideasphere (TwinLab, Metabolife)	0	140	115
19	Country Life (Biochem, Desert Essence)	101	105	108
20	Metagenics	62	74	104
21	Matrixx Initiatives (Zicam)	60	90	96
22	Basic Research (Zantrex, Zoeller, etc)	130	110	95
23	Atkins Nutritionals	180	120	95
24	Knight-McDowell Labs (Airborne)	30	65	92
25	lovate (MuscleTech)	55	65	91

Notes: Revenues listed are wholesale for supplements only (including contract mfg.) not entire company and not including raw material and MLM firms. Some revenues are estimates that have been compiled through information provided by company executives, industry analysts and reputable published materials. Although NBJ made every effort to be accurate, revenue figures are not the result of audits and therefore are not guaranteed to be accurate. Errors and omissions are unintentional.

\*Companies with a substantial portion of revenues from contract manufacturing supplements for other companies or private labeling. In the company universe table depicting wholesale sales, company revenues for contract manufacturing were subtracted to avoid double counting.

Source: (NBJ, 2007a)

## 2.2.2 Major Functional Food and Natural Health Product Brands

This section describes literature on the major brands of functional foods and natural health products.

### Functional Foods

Table 2.8 shows popular brands of functional foods in the United States and the companies that provide them by type of functional food product. The table was compiled using information from Leatherhead Food International (2006).

**Table 2.13 Functional Food Brands in the United States by Type of Functional Food and Company, 2005**

Functional Food Area	Functional Food Product	Company	Brands
Dairy Products	Probiotic yogurt/kefir	Dannon (Stonyfield Farms)	DanActive (marketed as Actimel outside the US) ; Activia; YoBaby; All Natural Fruit Blends; YoSelf
		CoolBrands Internationals	Breyers Light! Probiotics Plus Yogurt
		Lifeway Foods	Lifeway Organic ProBugs Milk Drinks
	Cholesterol-lowering yogurt	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	
		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	Healthy Heart	
Wholegrain pasta	Barilla	Barilla Plus	
	Kraft	Supermac & Cheese Pasta and Sauce	
Soya	Soya milk	White Wave	Silk

Functional Food Area	Functional Food Product	Company	Brands
Products		Odwalla	Odwalla soymilk
Beverages	Fruit juices and juice blends	Tropicana (PepsiCo)	Pure Premium Orange Juice with Calcium and Extra Fiber; Pure Premium Essentials (Immunity Defense, 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	
		Chicken Of the Sea	
	Fish oil supplements	Bumble Bee and Leiner Health	
	Omega-3 DHA enriched eggs	Gold Circle Farms	
		Eggland's Best	

Source: Leatherhead Food International (2006, p. 135-153)

### Natural Health Products

The following table shows the most popular supplements, as identified by NBJ based on 2000-2006 consumer sales, the 2006 sales value by supplement and the 2006 percent growth in sales by supplement. MultiVitamins are the most popular supplement, with 2006 sales valued at \$4,315 million. However, by percent growth, fish/animal oils are leading with a massive 36.3% growth in 2006. As a matter of fact, of the top 45 supplements listed by NBJ, the growth rate of fish/animal oils was over 10% higher than their nearest competitor (probiotics ranked second in terms of 2006 percent growth at 23.3%).

**Table 2.14 Top 10 US Supplements, Sales and Percent Growth, 2006 (ranked by 2000-2006 consumer sales)**

Supplement	2006 Sales (US\$M)	% Change (from 2005)
MultiVitamins	4,315	3.8
Meal Replacements	2,362	2.7
Sports Nutrition	2,355	6.2
Calcium	1,007	-0.3
B Vitamins	1,002	6.9
Vitamin C	863	3.3
Glucosamine/Chondroitin	818	1.0
Homeopathics	673	8.7
Vitamin D, H, Others	624	16.5
Fish/Animal Oils	489	36.3

Source: (NBJ, 2007a)

No information was found on specific brand names of US supplements.

### 2.2.3 Contribution of Functional Food and Natural Health Product Industries to the Economy

This section describes literature on the contribution to the economy of functional foods and natural health products.

#### *Functional Foods*

According to the Nutrition Business Journal (2007b), functional foods comprised US\$31,400 million of the US\$566,232 million total retail food industry sales in 2006. This sale contribution accounts for 5.5% of total retail food industry sales. The 10.2% sales growth of functional foods in 2006 contributed substantially to the 2.4% total food growth for that year (the market standard food sale growth was only 1.1%). As a point of comparison, in 1997, functional food sales comprised US\$14,087 million, or 3.2%, of the total US\$444,985 million retail food industry sales. The Journal forecasts that the 2010 contribution of functional food sales to total retail food industry sales will increase to 6.5%.

According to Leatherhead Food International (2006), the US functional food market value represented 32.9% and 26.9% of the world functional food market values, under the strict and broad definitions of functional foods, respectively. These percentages of world market value represent US\$5,307 million (2005), under the strict definition, and US\$9,752 million (2005), under the broad definition, second in the world after Japan's functional food market.

#### *Natural Health Products*

Based on NBJ Global Nutrition Industry Report data (2007a), the contribution of supplements to the US nutrition industry in 2006 was 26.4% (US\$22,460 million in supplement sales divided by US\$84,952 million in total nutrition industry sales x 100).

### 2.2.4 Key Trends

This section describes the key supply trends of functional foods and natural health products.

#### *Functional Foods*

According to Leatherhead Food International (2006), although the US breakfast cereal market has the biggest market share of functional foods in the US with sales valued at US\$9 billion a year, the industry has been declining steadily over the last five years. Leatherhead Foods International blames this decline on the growing popularity of breakfast foods "suitable for eating on the move" (2006, p. 141). That being said, the market for cereal and snack bars has been growing.

US market development in functional foods has been driven by FDA approval of health claims associated with food ingredients. The majority of these FDA approvals have been in the area of heart health. Development in the area of heart healthy cereal products began with FDA approval of the claim that products with oatmeal could lower cholesterol and development in this area continued to grow with FDA approval of claims related to psyllium, soya protein and wholegrains (Leatherhead Food International, 2006). However, not all FDA approvals of claims have promoted market development. For example, although the industry reacted to the 2000 FDA approval of health claims related to plant sterol/stanol esters by focusing on developing and marketing cholesterol-lowering margarine products, this market is now stagnant.

The beverage market for functional foods, which includes soft drinks and tea, has been growing due to the increasing popularity of enhanced waters and tea. Enhanced waters; however, cannot be included in the strict definition of functional foods because they do not use health-related claims. Marketing in the area of antioxidant-containing teas is also increasing, with the value of this sector expanding from US\$3 million in 2004 to US\$35 million in 2005. Nutrient-enhanced tea products have also been growing in popularity reaching sale values of US\$186 million in 2005.

On the other hand, the traditionally popular chilled orange juice sector of the functional food beverage market has been “at best static” (Leatherhead Food International, 2006), with the market share of calcium-fortified orange juices constant at approximately 20%. According to Leatherhead Food International, juice products that have been growing in popularity include cranberry and pomegranate juice, marketed on the basis of their intrinsic health benefits. Since 2002, the value of the pomegranate juice market has increased from US\$46 million to US\$74 million in 2005. The Nutrition Business Journal (2007b) estimates sales of the Palm Juice brand at US\$80-90 million in 2006, with a starting sales value of US\$13 million in 2003.

### *Natural Health Products*

NBJ (2007a) offers a thorough list of factors contributing to the declining growth trend of supplement sales between 1995 and 2006. The following is a list of supply-related issues, as identified by NBJ, affecting growth over the last decade (consumer and media-related factors are listed in the demand section of the profile, [Section 2.1.1](#)).

#### Industry Issues:

- The novelty of products (in general) wore off.
- Boom & bust cycles of specific products (St. John’s wort, Black cohosh, etc.) curtailed consistent overall supplement growth.
- Growth and entrance of mainstream manufacturers lead to more competition.
- Critical penetration of mainstream channels achieved in the late ‘90s.
- Private labelling exacerbated ‘commodity’ perception and price erosion at the shelf.
- Conspiracy theorists argue that pharmaceutical companies and others were attempting to discredit supplements that threatened the markets their pharmaceuticals served.
- Lack of advocacy (and reimbursement) by the healthcare industry, insurance, Health Maintenance Organizations (HMO) and others which could have enhanced consumer use and sales.

#### Science Issues

- Science not of sufficient volume or credibility to back supplement usage.
- Clinical test data lacking in some areas or conflicting in other areas.
- Relative lack of funding by government on health ‘prevention’.

#### Quality Issues

- Lack of confidence in product dosages, quality material and consistency with label claims.
- Exposure by Consumerlab.com and others of dosages inconsistency with labels.

#### Marketing Issues

- Marketing of supplements generally not effective in conveying health benefits.
- Lack of effective branding and marketing strategies by leading manufacturers.
- Lack of marketing investment to generate and recruit new customers.

- Marketing focused on trade instead of consumers as companies used 'distribution-push' rather than 'consumer-pull' approaches.

#### Regulatory Issues

- Regulations restricted claims, distribution and new products.
- Industry positions were fragmented and diluted by various and numerous association voices.

#### Economic Issues

- Growth rates inevitably fell as the industry matured.
- Price declines and/or lack of increases kept dollar sales from growing.
- Economic growth curtailed at the end of the 90s and into 2001 leaving less discretionary income for consumers.

Source: (NBJ, 2007a)

### **3.0 Description of the Functional Food and Natural Health Product Industry in Australia**

This section provides a description of the development and size of the functional food and natural health product industries in Australia from a demand (3.1) and supply (3.2) perspective.

#### **3.1 Demand for Functional Foods and Natural Health Products in Australia**

Section 3.1 looks at the demand for functional food and natural health products in Australia. The section is broken down into three areas: Section 3.1.1 examines consumer perceptions and awareness of FF and NHPs; Section 3.1.2 reports on the sales in the FF and NHP industry, and Section 3.1.3 outlines key trends in the demand for FF and NHP in Australia.

##### **3.1.1 Consumer Perceptions and Awareness of Functional Foods and Natural Health Products**

This section describes literature on consumer perceptions and awareness of functional foods and natural health products in Australia.

###### *Functional Foods*

A 2005 AC Nielsen survey found that Australians are one of the least likely in the Asia Pacific region to purchase functional foods. The survey polled more than 500 Australian participants on their attitudes towards functional foods.

Participants were asked to indicate whether they purchased each of the 10 following products 'regularly', 'somewhat', 'never', or 'hadn't heard of the product':

- Cholesterol reducing oils and margarines
- Fermented drinks containing 'good' bacteria
- Yogurts with Acidophilus cultures/probiotics
- Soy milk
- Milk with added supplements/vitamins
- Bread with added supplements/vitamins
- Whole grain, high fibre products
- Cereal with added folate
- Fruit juices with added supplements/vitamins
- Iodine enhanced cooking salt

(Sultana, 2005)

Results from the AC Nielsen survey found that participants 'regularly' or 'sometimes' purchased wholegrain high fibre products (89%), cholesterol reducing oils and margarines (73%), and yogurts with Acidophilus cultures (69%). However, overall, 40% of Australians indicated that they 'never' purchase any of the ten products listed; in particular, Australians stated that they do not purchase soy milk (67%), milk with added supplements/vitamins (52%), and fermented drinks (40%).

These results were surprising given the following two facts: 1) the distribution of functional foods in Australian supermarkets is well above regional and global averages, and 2) Australian's awareness of functional foods and their perceptions regarding the level of quality they offer is very high (Sultana, 2005). This could be explained by the fact that the AC Nielsen survey (2005) found that the most common reason cited for not purchasing functional food

products was disbelief in the products' health benefits (38%). The second most common reason for not purchasing functional foods was dislike of the taste, followed by price.

More recently, the Australian Functional Foods landscape report by the National Centre of Excellence in Functional Foods (2006) suggested an increasing growth in the Australian Functional Food market. In their summary of food trends in Australia, the USDA Foreign Agricultural Service reported that the following trends were driving Australian consumers:

- Health – the momentum of the trend towards health cannot be doubted and health (or wellness) is becoming the new standard for the food industry.
- Daily-dose and the power of packaging innovation.
- Bars & Beverages – over the past few years the largest growth in nutritional products has been in bars and single-serve beverages, i.e., products consumed by individuals who are on-the-go, in a hurry, and/or most often eating alone.
- Out of the supplement aisle – increasingly ingredients traditionally found in the supplement aisle are finding their way into beverages. For example, calcium has just been approved as an additive for beverages, soups and biscuits.
- Personalized nutrition is here to stay – products that allow customers to choose a snack that meets particular health needs.
- Children nutrition crisis – as in the United States this issue is at the forefront of parents' minds. The pressure is on to produce healthier options for children's snacks.

### *Natural Health Products*

According to information collected by NBJ (2007a), an estimated 52% of Australia's population use at least one non-medically prescribed complementary medicine, i.e., a natural health product and within that, nearly 70% of Australians under the age of 35 regularly consume these products. It was also reported that Australians spend four times as much on complementary healthcare products compared to their spending on prescription drugs.

The largest percentage (40%) of natural health products is sold through pharmacies. To increase consumer awareness and confidence in the products, many pharmacies are employing in-store naturopaths.

Market research in Australia has found that the supplements industry is showing strong growth, with 74% of Australians over the age of 14 used one or more vitamin, mineral, herbal or nutritional supplement in 2004. This level of usage is amongst the highest in the world (NBJ, 2007a).

#### 3.1.2 Sales of Functional Food and Natural Health Products

This section describes literature on sales of functional foods and natural health products.

### *Functional Foods*

The Australian market is driven by taste, convenience, disease prevention, nutrition individualization, and snacking. It is evident that health and wellness is important to the marketplace because in 2004, of seven food categories experiencing double digit growth, six were marketed on a platform of health or wellness. Other nutrition platforms that have been successful within the Australian market included: Omega-3 enriched foods and beverages, antioxidant containing foods, plant sterols, low glycaemic index foods and more recently whole grains. In addition, products that have been enriched with DHA (Docosahexaenoic acid), have

a low GI (Glycaemic Index), are wholegrain or are pro/pre biotics have been successful in the Australian market (National Centre of Excellence in Functional Foods, 2006).

Indications from the Australian market suggest that for a product to be successful it must taste good and be convenient, although many other factors contribute to gaining market share. Two important factors are: marketing to a health need and ensuring that the consumers are aware of and understand that need. Second, it is important to select a price point that is desirable to the consumer (National Centre of Excellence in Functional Foods, 2006).

Although detailed information on the size of the Australian functional food market is relatively limited, in 2003 a US based firm Health Strategy Consulting (HSC), estimated that the Australian and New Zealand nutrition industry represented approximately AU\$2.9 billion (C\$2.64 billion) of the global nutrition market. Of that, functional foods comprised AU\$1 billion (C\$0.91 billion) (35.1%), organics was AU\$0.8 billion (C\$0.73 billion) (27.8%), supplements was AU \$0.9 billion (C\$0.82 billion) (30%), and natural personal care was AU\$0.2 billion (C\$0.18 billion) (7.2%) (National Centre of Excellence in Functional Foods, 2006).

In a more recent study, Leatherhead Food International (2006) estimates the value of the functional food market in Australia to be between AU\$354 and AU\$753 million (C\$327.20 and C\$695.99 million), depending on the definition of functional food. Functional food under the strict definition includes four key markets, bakery, dairy, soya products and yellow fats, which make claims regarding the health benefits related to the product. On the other hand, the broad definition (and higher value) includes products that do not make direct nutritional claims. As the value of functional food is realized, the number of products making claims is expected to increase. This has already been seen in soya products where the scientific evidence of heart and bone health has increased rapidly. As the number of claims increase it is expected that the value of the industry under the strict definition will constitute a larger share of sales (Leatherhead Food International, 2006).

**Table 3.1 Australia Functional Food Market by Type, 2005 (AU\$ M (C\$ M))**

	Strict Definition	Broad Definition
Dairy products	107 (98.90)	151(139.57)
Yellow products	65 (60.08)	65(60.08)
Bakery products	110 (101.67)	210(194.10)
Cereal products	neg.	93(85.96)
Soya products	72 (66.55)	108(99.82)
Beverages	neg.	40(36.97)
Confectionery	neg.	neg.
Meat, fish and eggs	neg.	86(79.49)
Total	354 (327.20)	753(695.99)

Notes: Neg. refers to negligible.

Source: (Leatherhead Food International, 2006)

## *Natural Health Products*

NBJ (2007a) reports sales for supplements in Australia & New Zealand<sup>11</sup> at US\$1,440 million and US\$1,530 million in 2005 and 2006, respectively. In the same document, it is reported that the latest estimate for sales of supplements in Australia are showing growth of 14.7% and are currently worth US\$720 million in retail value. Of all supplements, the largest growth in sales was seen in glucosamine and fish oil, with both experiencing a 50% increase in sales in 2005.

### 3.1.3 Key Trends

This section describes literature on key demand trends of functional foods and natural health products in Australia.

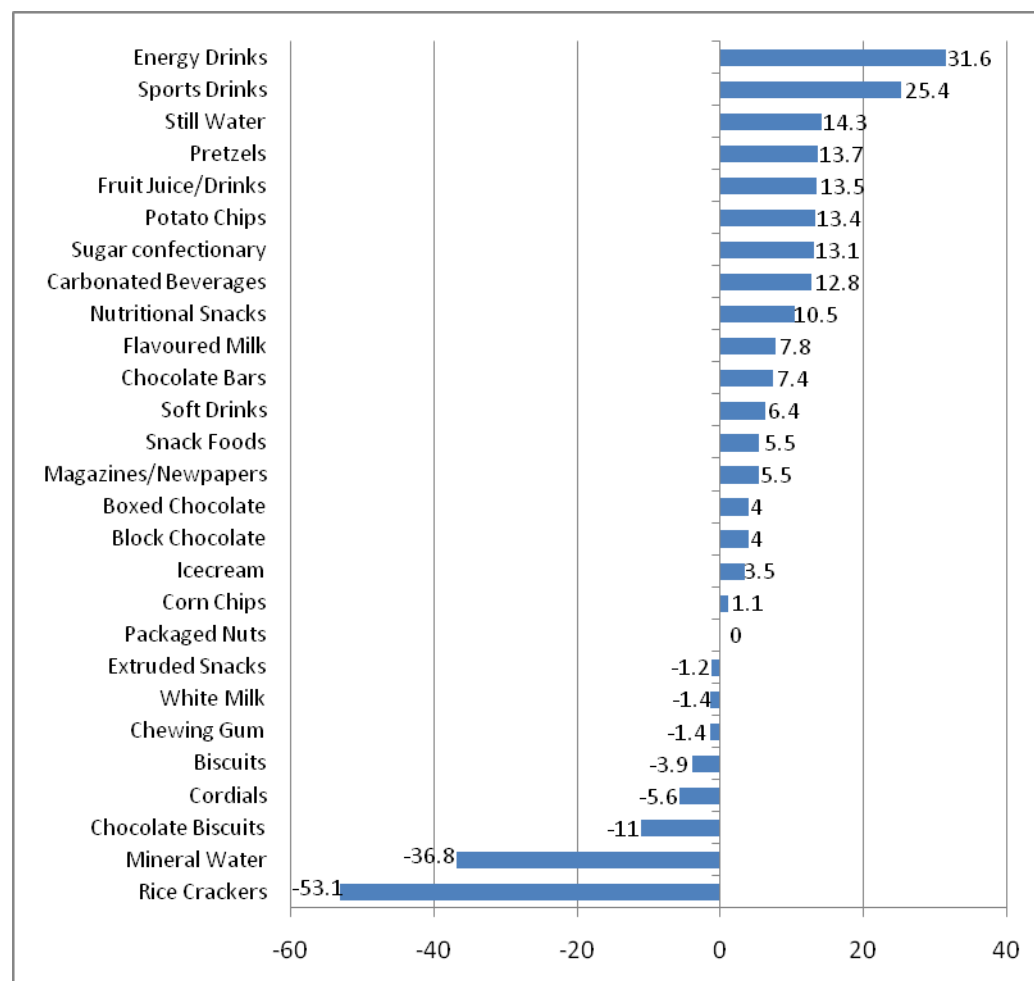
#### *Functional Foods*

In a report by the USDA, Australia's share of the global functional food market was estimated to be growing at a rate of between 8 and 14% per year (Tapsell et al., 2005). Although growth within the industry has been strong, there has been variability across segments of the industry. According to research conducted by AC Nielsen in 2005 (refer to Figure 3.1 below), sales of functional foods in convenience stores saw significant growth when compared to other convenience category foods. For example, energy and sports drink sales saw a 31% and 25% increase respectively and nutritional snack sales grew by 10.5%. In fact, energy drinks and sports drinks were the fastest growing sale products in the convenience category. This data imply that convenience is a characteristic that may be important for future growth of the functional food industry.

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<sup>11</sup> New Zealand had a population of 4.1 million in 2006, while Australia had a population of approximately 20 million, therefore, based on population alone NZ accounted for a little over 1/6<sup>th</sup> of the Australia/NZ market (NBJ, 2007a). Note that the population data was confirmed with the Census of Population for both New Zealand and Australia.

**Figure 3.1 Percentage Change of Australian Convenience Categories, Year Ending March 2005**



Source: (AC Nielsen.2005 as cited by National Centre of Excellence in Functional Foods, 2006)

### Natural Health Products

Table 3.2 shows the sales of supplements as well as the percent change in these sales between 2001 and 2006. Between 2002 and 2003, sales dropped by 2.2 percent; however, sales continued to grow between 2004 and 2006. A specific trend was noted by NBJ (2007a) that sales have been strong in the weight loss category of supplements. NBJ (2007a) reports that with 60% of Australian adults overweight, even the leading NHP brands (e.g. Blackmores and Herron) who have previously not had products in this category, entered this segment of the market in 2005. NBJ (2007a) also notes that there is a growing trend amongst the Australian population to concentrate on health rather than disease. The focus on “wellness” is no longer an alternative view. Some of the products that are “hot” within the Australian market are glucosamine, fish oils, phytoestrogens, plant sterols, antioxidants and targeted multivitamins.

**Table 3.2 Australia/New Zealand Supplement Sales by Year and Percent Growth, 2001-2006**

Year	Sales (US\$ M)	% Change*
2001	1,285	-
2002	1,329	3.4
2003	1,300	-2.2
2004	1,354	4.2
2005	1,443	6.6
2006	1,528	5.9

\*Percent change =  $[(\text{Sales}_{\text{Year N}} - \text{Sales}_{\text{Year N-1}}) / (\text{Sales}_{\text{Year N-1}})] \times 100$

Source: (NBJ, 2007a) and GMC calculations

### 3.2 Supply of Functional Foods and Natural Health Products in Australia

Section 3.2 looks at the supply side of the functional food and natural health product industry in Australia. This section is divided into four sub-sections. Section 3.2.1 looks at the nature and number of FFNHP firms in Australia. In Section 3.2.2, major FFNHP brands in Australia are examined. Section 3.2.3 looks at the contribution of FFNHP industries to the Australian industry and Section 3.2.4 looks key trends from a supply perspective.

#### 3.2.1 Nature and Number of Firms

This section describes literature on the nature and number of firms in the Australian markets for functional foods and natural health products.

##### *Functional Foods*

Multinational companies providing a range of vitamin and mineral enriched products, plant sterol enriched spreads, omega-3 enriched products and a range of pro and pre-biotic dairy products dominate the Australian functional food market. Table 3.3 shows some examples of the key small and medium enterprise (SME) functional food companies in Australia. In 2004/05, these companies offered products ranging from raw and unprocessed snack bars, high protein drinks to indigenous juices and antioxidant extracts. Their turnovers ranged from AU\$500,000 (C\$479,100) to AU\$15 million (C\$14.37 million).

**Table 3.3 Examples of Successful Small and Medium Enterprise Functional Food Companies in Australia, 2004/05**

Company	Products	Selling Proposition	Turnover, AU\$ in 2004/05 (C\$)
Megaburn	Bars	These functional food products are raw, unprocessed food and beverage products	\$800,000 (C\$766,560)
Aussie bodies	Bars/Drinks	Specialize in high protein foods and drinks	\$15 million (C\$14.37 million)
Australian Harvest	Pates, Jus and Jellies	Bio-grape (extract of grape skin) high in antioxidants and is organic	\$500,000 (C\$479,100)
Vitality brands	Bars	Wellness bars on fruit and vegetables	\$4 million (C\$3.83 million)
Vic Cherkoff	Spice & Seasoning	Australian native botanicals which have high antioxidants and anti-fungal properties	-
Australian food innovators	Indigenous Juices	Native botanicals such as desert line, rivermint, muntries etc	\$4-5 million (C\$3.8-4.8 million)
Tarac technologies	Ingredients	Antioxidant extracts from grapes	-

Source: (National Centre of Excellence in Functional Foods, 2006)

### *Natural Health Products*

Approval of natural health products in Australia is very different than it is for functional foods. As a result, international companies with NHPs cannot easily gain access to the Australian market. NBJ (2007a) reports that due to the stringent and complex regulatory environment that exists in Australia, a vast majority (95%) of complementary medicines (i.e., supplements/NHPs) are manufactured by local companies. A discussion of the regulatory system that maintains the dominance of local companies is in [Section A.2.2](#).

### 3.2.2 Major Functional Food and Natural Health Product Brands

This section describes literature on the major brands of functional foods and natural health products found in Australia.

#### *Functional Foods*

Some of the major international functional food brands, and their suppliers, with markets in Australia include (Leatherhead Food International, 2006):

- Activia, sold under Danone Daily name in Australia (Danone)
- All Bran (Kellogg)
- Pro.activ (Unilever)
- So Good (Sanitarium)
- Yakult (Yakult)

In addition to initiatives from multinationals such as Nestlé and Unilever, Australian companies such as Goodman Fielder, National Foods and Berri have all been highly innovative in this area, although National Foods and Berri are now part of a larger group, having been merged under the ownership of San Miguel of the Philippines (Leatherhead Food International, 2006).

The following table (Table 3.4) shows some of Australia's key functional food brands and their suppliers by functional food area.

**Table 3.4 Australia's Key Functional Food Brands and their Suppliers by Functional Food Area**

Functional Food Area	Functional Food Product	Company	Brands
Dairy Products	Probiotic yoghurt/drinks	Parmalat	Vaaliala
		Yakult	Yakult
		National Foods	Yoplait Yoplus/Optimal
		Dairy Farmers	Danone Daily
			Danone Vitalite
	Omega-3 yoghurt and milk	Jalna	Pro-Heart yoghurt
		PB Foods	Brownes Heart Plus milk
	Fortified milk	Dairy Farmers	Shape
			Brownes Calcium Plus milk
		PB Foods	Brownes Performance Plus milk
Murray Goulburn			Devondale Smart Milk Plus
Bakery Products	Wholegrain (heart healthy) and fortified breads	George Weston	Burgen Oatbran & Honey
			Tip Top Up Calcium
	Breads with omega 3 fatty acids	George Weston	Tip Top Up
			Burgen Soy-Lin
	High-fibre white bread	Quality Bakers Australia	Goodman Fielder's Wonder White
George Weston		Tip Top HyFibe	
Breakfast Cereals	Ready-to-eat treat/energy	Kellogg	NutriGrain
			Coco Pops
	Ready-to-eat health	Kellogg	Just Right
			Special K
	Ready-to-eat biscuit	Sanitarium	Weet-bix
	Ready-to-eat staple	Kellogg	Cornflakes
	Ready-to-eat bran	Kellogg	All Bran
Sultana Bran			
Heart health	Uncle Toby's	Healthwise for the Heart	
Soya Products	Soya milk	Sanitarium	So Good
		National Foods	Vitasoy
		So Natural	So Natural
		Pauls/Parmalat	Soy Life
Beverages	Fruit juices and juice blends	Berri/National Foods (San Miguel)	Berri Multi-V
			Harmonics
			Fruitful Superjuice
	Teas with antioxidants	Campbell Soup	V8; V8 Bone Health; V8 Plus (Cleanse, Startup)
			Tetley
Lipton	Green Tea		
Meat, Fish and Eggs	Canned fish with omega-3	Heinz	Greenseas
	Frozen fish with omega-3	Simplot	I & J Captain's Catch Trim Fish
	Omega-3 DHA/lutein enriched eggs	Pace Farms	GoldPlus+
		Farm Pride	Aussie Pride

Source: Leatherhead Food International, 2006

### *Natural Health Products*

The leading companies in the NHP brands in Australia are Blackmores, Mayne (this company includes Natures Own, Natural Nutrition, Bio-Organics and Cenovis) and Herron Pharmaceuticals which is controlled by the parent company Sigma (NBJ, 2007a). Nature's Own is the most popular brand in Australia followed by Blackmores, Natural Nutrition, Bio-Organics, Bullivants, Cenovis and Naturopathica (NBJ, 2007a).

#### 3.2.3 Contribution of the Functional Food and Natural Health Product Industries to Australia's Economy

This section describes literature on the contribution to the Australian economy of functional foods and natural health products.

##### *Functional Foods*

The food industry as a whole contributes approximately AU\$125 billion (C\$119.78 billion) to the Australian economy. Food and beverage manufacturing is the largest manufacturing sector in Australia (Tapsell et al., 2005).

Currently, there are no data on the contribution of Australia's functional food industries to the economy. However, Tapsell et al. (2005) imply that functional foods may have potential to contribute substantially to Australia's economy in the future, in light of the fact that Australia is a net exporter of food, with a trade surplus of AU\$16.4 billion (C\$15.71 billion). Australia's trade surplus in food products is due mainly to primary food (not transformed) product exports, which do not include functional foods. As a matter of fact, Australia is currently ranked 7<sup>th</sup> in the world in "minimally transformed food" exports and 11<sup>th</sup> in "substantially or elaborately transformed" food exports and is a net importer of these foods. Therefore, Tapsell et al. (2005) suggest that a growth in Australia's functional food industries lies in the development of larger "transformed food" export markets.

##### *Natural Health Products*

No information was found on the contribution of the NHP industry to the Australian economy.

#### 3.2.4 Key Trends

Due to the stringent regulation of NHPs in Australia, products can legally make health claims, for example, a product could indicate that it "relieves arthritic pain". Because there is trust in the regulation behind these claims, many doctors in Australia have studied and are familiar with the modality of complimentary medicines. The fact that these products are accepted by doctors also means they are recognized by most of the major health insurance providers. The Australian Medical Association has acknowledged that complimentary medicines (NHPs) have a role to play within the medical system and continue to urge doctors to increase their education and knowledge with regard to these products (NBJ, 2007a). Therefore, although the regulatory system is more stringent, once approved, the market opportunities are greater because of the acceptance within the medical community.

## 4.0 Description of the Functional Food and Natural Health Product Industry in the United Kingdom (UK)

This section provides a description of the development and size of the functional food and natural health product industries in the United Kingdom from a demand (4.1) and supply (4.2) perspective.

### 4.1 Demand for Functional Food and Natural Health Products in the United Kingdom

Section 4.1 looks at the demand for functional food and natural health products in the United Kingdom. The section is broken down into three areas: Section 4.1.1 examines consumer perceptions and awareness of FF and NHP; Section 4.1.2 reports on the sales in the FF and NHP industry, and Section 4.1.3 outlines key trends in the demand for FF and NHP in the UK.

#### 4.1.1 Consumer Perceptions and Awareness of Functional Food and Natural Health Products

This section describes literature on consumer perceptions and awareness of functional foods and natural health products.

##### *Functional Foods*

The UK consumer awareness and demand for functional foods are a response to concerns for unhealthy lifestyles, an increased perception that “we are what we eat,” a trend towards self-diagnosis and a growing mindset that “prevention is better than a cure” (Mintel, 2006b).

According to Mintel (2006b), one driving force behind UK consumer awareness of functional foods is health headlines from the media. Some examples of recent health-related headlines in the UK that may be promoting functional foods include (Mintel, 2006b):

- *Atkins-style diets can be life-threatening, doctors warn; Ban from September for school junk food (Guardian Unlimited, March 2006)*
- *Obesity 'can be caught like a cold (Daily Telegraph, January 2006)*
- *Warning over male breast cancer (BBC News, Feb 2006)*
- *Stress at work linked to heart disease and diabetes (Guardian, January 2006)*
- *Why your waistline is a clue to heart disease (Daily Mail, March 2006).*

Data on UK perceptions of functional foods are scarce. However, AC Nielsen (2005b) provides a summary of its consumer perception survey which identifies country specific responses for the top ten 'highest agreement' responses for each question category. The survey included respondents from 38 countries. The UK respondent sample size was 1,011 (total number of respondents was 21,261). The points of the survey that are relevant to UK consumers are as follows (AC Nielsen, 2005b):

- 31% of UK respondents indicated that the main reason for not purchasing cholesterol reducing oils and margarines was that they were too expensive.
- 45% of UK respondents indicated that they never purchase fermented drinks containing 'good' bacteria.
  - 25% of UK respondents indicated that they never purchase fermented drinks containing 'good' bacteria because they were too expensive.
- 37% of UK respondents never purchase yoghurts with acidophilus cultures/probiotics.
  - 21% of UK respondents indicated that the main reason for not purchasing yoghurts with acidophilus cultures/probiotics was that they were too expensive.
- 37% of UK respondents indicated that they never purchase soy milk.

- 24% of UK respondents indicated that the main reason for not purchasing soy milk was that they do not believe it offers additional health benefits.
- 77% of UK respondents indicated that they never purchase milk with added supplements/vitamins.
  - 45% of UK respondents indicated that the main reason for not purchasing milk with added supplements/vitamins was that they don't believe it offers additional health benefits.
- 56% of UK respondents never purchase bread with added supplements/vitamins.
  - 49% of UK respondents indicated that the main reason for not purchasing bread with added supplements/vitamins was that they do not believe that it offers additional health benefits.
- 20% of UK respondents indicated that the main reason for not purchasing whole grain, high fibre products was that they were too expensive.
  - 43% of UK respondents indicated that the main reason for not purchasing cereal with added folate was that they do not believe it offers additional health benefits.
- 38% of UK respondents indicated that they never purchase fruit juices with added supplements/vitamins.
- 52% of UK respondents indicated that the main reason for not purchasing fruit juices with added supplements/probiotics was that they do not believe they offer additional health benefits.
- 54% of UK respondents indicated that they never purchase iodine enhanced cooking salt.
  - 31% of UK respondents indicated that they have never heard of iodine enhanced cooking salt.
  - 41% of UK respondents indicated that the main reason for not purchasing iodine enhanced cooking salt is that they do not believe it offers additional health benefits.

It should be noted, however, that some of the consumer trends identified in the AC Neilson survey above do not correspond to the sales values and increased growth identified in the section below (4.2.2). This is particularly true for the dairy sector. This could be a function of the 1,011 sample not representing the larger UK consumption patterns. For example, high sale values in certain sectors may be due to price premiums on those products within the sector, targeting high income consumers, rather than the mainstream (Intel, 2006b). Therefore, the survey results above may not represent the true proportion of consumers of certain functional foods, such as soy milk.

### *Natural Health Products*

According to a TNS consumer survey, as reported by NBJ (2007a), 43% of respondents took supplements in the last 12 months, while 56% did not. Those who took supplements chose cod liver oil (23%) and multivitamins (23%). Forty-seven percent of respondents within the age group of 50-65, had taken supplements in the last 12 months. This was the most popular age group for supplement use.

Another consumer survey discussed by NBJ (2007a) (survey by Key Note in August 2006) revealed that over 25% of the survey respondents took supplements at least weekly and two thirds of the respondents never took supplements. This may imply that supplement users are either dedicated to taking supplements often, or do not take supplements at all; few take supplements from time to time. The Key Note survey also found that those in the 'over 65' age group were most likely to be regular users. Since the UK population is aging, according to NBJ

(2007a), there may be an opportunity for a growth trend in supplements targeting age-related ailments.

#### 4.1.2 Sales of Functional Foods and Natural Health Products

This section describes literature on sales of functional foods and natural health products.

##### *Functional Foods*

In 2005, the UK functional food market reached a value of £1,089 million (C\$2,403 million) (Mintel, 2006b). Table 4.1 below shows the value of the UK functional food product market by sector. Leatherhead Food International (2006) cited the size of the functional food market in the UK in 2005 to be £935 million (C\$2,063 million) a year. Although this estimate is lower than the Mintel estimate, Leatherhead uses the strict definition of functional foods (as discussed in the background section of this report). Under the broad definition, the value of the UK functional food market (in 2005) was estimated to be £2,251 million (C\$4,967 million).

Functional yogurts and drinks had the largest sales in 2005, valued at £275 million (C\$606.8 million) and represented 25% of the functional food market share. This sector was followed by breakfast cereals with sales of £250 million (C\$551.7 million) and 23% of the market share. Other functional food sectors, in order of their sales values within the UK include (refer to the Table below): spreads, stimulation drinks, juice, juice drinks and dilutables, soya dairy-alternative products, eggs, bottled water and beverages (Mintel, 2006b).

**Table 4.1 United Kingdom Retail Sales of Functional Food and Drink Products, by Sector and Value, 2005**

Functional Food or Drink Sector	2005 Sales (£ millions)	2005 Sales (C\$ millions)
Yogurts and drinks	275	606.84
Breakfast cereals	250	551.67
Spreads	190	419.27
Stimulation drinks	168	370.72
Juice, juice drinks and dilutables	121	267.01
Soya dairy-alternative products	32	70.61
Eggs	18	39.72
Bottled water	14	30.89
Beverages	4	8.83
Other <sup>1</sup>	17	37.51
<b>Total</b>	<b>1,089</b>	<b>2,403.09</b>

<sup>1</sup> Includes bread, cereal bars and cheese (Mintel, 2006b)

Dairy, which includes the yogurts and drinks, spreads and soya-based alternative sectors, is the largest functional food category, representing 45% of all functional food sales in the UK (Mintel, 2006b).

##### *Natural Health Products*

According to NBJ (2007a), UK supplement sales in 2006 were valued at US\$1,537 million. These sales were broken down by supplement category as follows: vitamin and mineral sales

constituted US\$564 million of the sales; herbs/botanical sales were US\$408 million and sales in the category of sports, homeopathic, meal and specialty supplements were US\$565 million.

#### 4.1.3 Key Trends

This section describes literature on key demand trends of functional foods and natural health products.

##### Functional Foods

Table 4.2 illustrates UK growth rates of functional food sales value, assuming an initial index of 100, between 2000 and 2005. During this time period, sales of functional foods have increased almost two and a half times from £448 million (\$1,007.9 million) in 2000, to just over £1 billion (C\$2,403 million) estimated for 2005.

**Table 4.2 Change in United Kingdom Functional Food Sales Values, 2000-2005**

Year	Sales Value (£ millions)	Sales Value (C\$ millions)	Index	% Change from Year to Year
2000	448	1,007.94	100	
2001	667	1,487.24	149	49%
2002	731	1,723.83	163	10%
2003	835	1,910.72	186	14%
2004	960	2,288.82	214	15%
2005 (estimate)	1,089	2,403.09	243	13%

(Mintel, 2006b)

Broken down by sector, the dairy category of functional foods (which includes the yogurts and drinks, spreads and soya-based alternative sectors, as discussed above) is the fastest growing functional food area in the UK. This trend in the dairy category is primarily driven by the soya dairy-alternative product sector which had an incredible growth of 700 percent between 2001 and 2005 (Mintel, 2006b). The yogurts and drinks sector has also grown significantly, with a percent change of 183.5 in the same time period (Mintel, 2006b). Mintel (2006b) attributes this growth to the Joint Health Claims Initiative (JCHI) approval of the generic soya health claim in 2002.

Aside from the functional yogurts and drinks sector, the largest growth of functional food products between 2003 and 2005 was seen in the juice, juice drinks and dilutables sector, with a growth of 30.1%. This sector has an 11% share of the functional food market and, according to Mintel (2006b), is “in a strong position to compete with yogurt drinks”.

##### Natural Health Products

The following table shows UK annual supplement sales, by category, for the years 1999 to 2006. UK sales of all categories of supplements were relatively stable between the years 1999 and 2006. Vitamins and mineral sales as well as herbs/botanical sales fell slightly, but a rise in sports, homeopathic, meal and specialty supplements compensated for this drop, resulting in a small increase in total supplement sales between 1999 and 2006. Overall, the trend of supplement sales has been relatively constant. Applying these NBJ (2007a) data to calculate percent growth of sales between 1999 and 2006 reveals that sales grew by only 3.9% in that

time period<sup>12</sup>. NBJ (2007a) reported that in the 12 months ending August 2006, sales had grown by only 0.9% and indicated that, “uncertainty over the regulatory details of EU vitamin and herbal directives has contributed to a degree of market stasis”.

**Table 4.3 United Kingdom Supplement Sales by Category, 1999-2006 (\$M)**

Supplement Category	1999	2000	2001	2002	2003	2004	2005	2006
Vitamins & Minerals	630	624	599	579	556	550	556	564
Herbs/Botanicals	410	402	394	392	392	396	404	408
Sports/Homeop/ Meal/Spec Supps*	440	453	458	467	490	520	543	565
<b>Total</b>	<b>1,480</b>	<b>1,479</b>	<b>1,450</b>	<b>1,438</b>	<b>1,438</b>	<b>1,466</b>	<b>1,502</b>	<b>1,537</b>

\*Sports, Homeopathic, Meal and Specialty Supplements

Source: (NBJ, 2007a)

## 4.2 Supply of Functional Foods and Natural Health Products in the United Kingdom

Section 4.2 looks at the supply side of the functional food and natural health product industry in the United Kingdom. This section is divided into four sub-sections. Section 4.2.1 looks at the nature and number of FFNHP firms in the UK. In Section 4.2.2, major FFNHP brands in the UK are examined. Section 4.2.3 looks at the contribution of FF and NHP industries to the UK. Finally, Section 4.2.4 pinpoints key trends in the FF and NHP industry, as they relate to the supply side.

### 4.2.1 Nature and Number of Firms

This section describes literature on the nature and number of firms in the United Kingdom markets for functional foods and natural health products.

In the UK, it is becoming increasingly difficult to distinguish between functional food products and natural health products as “natural” foods adopt health claims and other health foods start adding more functionality in an attempt to add value...therefore, blurring and overlap between the sectors is not uncommon” (Mintel, 2006b). Although blurring between natural health food product and functional food product sectors exists, the providers of these products tend to focus on one food category. Mintel (2006b) lists Benecol/Tropicana as the exception to this trend.

#### Functional Foods

The major functional food suppliers in the UK include Danone, Unilever, Nestle, PepsiCo and Ocean Spray (Leatherhead Food International, 2006).

#### Natural Health Products

According to NBJ (2007a), the top supplement supplier in the UK is Merck KgaA (*Seven Seas* fish oil). NBJ (2007a) also reported that higher-dose supplements, mostly provided by smaller companies through the natural retail channel, constitute 12% to 15% of the supplement market. Vitabiotics and Viridian Nutrition are two other strong players in the UK supplement market.

<sup>12</sup> Percent growth =  $((1,537-1,480)/1,480) \times 100$ .

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#### 4.2.2 Major Functional Foods and Natural Health Products Brands

This section describes literature on the major brands of functional foods and natural health products.

##### *Functional Foods*

The following is a breakdown of the major UK functional food brands of the two largest food and drink categories: dairy and drinks (including juices). Table 4.4 shows the major functional dairy brands in the UK. The Table also includes the functional ingredient and basic health claim corresponding to each brand. The major dairy brands marketed in the UK include Alpro/Provamel, Benecol, Danone, Flora (Unilever), Muller, So Good and Yakult.

**Table 4.4 Major Functional Dairy Brands in the United Kingdom and Corresponding Functional Ingredients and Basic Health Claims, 2006**

Brand/Supplier	Product	Functional Ingredient	Basic Health Claim
Alpro/ Provamel	Dairy-free soya alternatives -Milk -Soy flavoured drinks -Yofu yogurt -Ambient desserts -Soya Fruity smoothy -Custard -Soya Dream cream	Soya protein	<i>At least 25g soya protein per day as part of a diet low in saturated fat can help reduce blood cholesterol levels.</i>
Benecol (McNeil Consumer Nutritionals)	-Buttery taste spread -Light spread -Olive spread -Light cream-cheese style spread -Yogurt drink -Low fat bio yogurts	Plant stanol ester	<i>Proven to reduce cholesterol as part of a healthy diet.</i>
Danone	-Actimel probiotic yogurt drink	Lactobacillus casei Imunitass®	<i>Helps support your body's natural defence; Daily Probiotic defence.</i>
	-Activia probiotic yogurts	Activia: Bifidus Essensis®	<i>Proven benefits to your digestion; Clinically tested to keep your digestive system healthy.</i>
	-Danacol cholesterol lowering yogurt drink	Plant Sterol	<i>Significantly lowers cholesterol.</i>
Flora (Unilever)	Flora, Flora Light, Flora Extra Light, Buttery spread, Low-salt Flora, Diet Flora and standard Flora	Flora range: Polyunsaturates, no hydrogenated oils, alpha-linolenic acid (ALA); vitamin E, folic acid, vitamin B6 and vitamin B12	<i>As part of a healthy diet can help lower cholesterol; Help to keep your heart healthy.</i>
	Flora pro.activ spread	Flora pro.activ - Plant sterol esters	<i>Clinically proven to lower cholesterol.</i>
	Flora pro.activ mini yogurt drinks	AmealPeptide.	<i>With daily peptides proven to help control blood pressure.</i>
Muller	Vitality yogurt and yogurt drinks	Live probiotic: La 5® and Bb 12® cultures; prebiotics, omega 3	<i>Can help to maintain a healthy digestive system.</i>
So Good	Chilled non-dairy milk -UHT non-dairy milk Soya choc -UHT chocolate drink	Soya protein	<i>Helps lower cholesterol; Helps build strong bones; Helps maintain a healthy heart.</i>
Yakult	-Fermented milk drink	Lactobacillus casei Shirota	<i>Helps to maintain the natural balance of the digestive system.</i>

(Mintel, 2006b)

Table 4.5 shows the major functional drink brands in the UK. The Table also includes the functional ingredient and basic health claim corresponding to each brand. The major functional

drink brands in the UK include Lucozade Hydro Active, Tropicana (Calcium, Multivitamins, Fibre, and Essentials) and Red Bull.

**Table 4.5 Major Functional Drink Brands in the United Kingdom and Corresponding Functional Ingredients and Basic Health Claims, 2006**

Company	Brand	Functional Ingredient	Basic Health Claim
GSK (Glaxo SmithKline)	Lucozade Hydro Active	Calcium and vitamins	<i>Helps replace the fluid you lose during exercise.</i>
Pepsico	Tropicana Calcium	Calcium	<i>Helps support strong bone development in children and teenagers.</i>
	Tropicana Multivitamins	Vitamins A, B1, B2, B6, C, E	<i>Helps to maintain a healthy nervous system and heart function and to promote healthy skin and bones.</i>
	Tropicana Fibre	soluble fibre from fruits, carrots and added fibre	<i>Helps to keep your digestive system regular and helps to keep you healthy on the inside.</i>
	Tropicana Essentials	Benecol	<i>Helps to reduce cholesterol.</i>
Red Bull	Red Bull stimulation drink	Taurine, caffeine and B vitamins	<i>Provides enhanced mental and physical benefits, boosting physical endurance, improving concentration and reaction speed, improved vigilance and stimulates metabolism.</i>

(Mintel, 2006b)

#### Natural Health Products

Some of the brands in the UK supplement market include: *Pregnacare*, *Menopace*, *Perfectil* (hair, skin and nails), *Osteocare*, *Jointace* and *Cardioace* (provided by Vitabiotics) and *Hyaluronic Acid* (provided by Viridian Nutrition).

#### 4.2.3 Contribution of Functional Foods and Natural Health Product Industries to the Economy

This section describes literature on the contribution to the UK economy of functional foods and natural health products.

#### Functional Foods

The UK functional food market's contribution to the economy can be shown by its contribution to the overall food sector growth. Table 4.6 compares the growth of functional food sector sales to the corresponding overall sector sales between 2003 and 2005. Although the food market experienced growth in each sector during the time period, functional food sales growth generally exceeded overall sector sales growth. The largest functional food contributors to the overall sector included the functional yogurts and drinks (almost five times the growth of the overall yogurt sector) and functional juices, juice drinks and dilutables (over twice the growth of the overall juice sector) (Mintel, 2006b).

**Table 4.6 Growth Rates of Overall Food and Drink Categories Compared to Growth Rates of Functional Food and Drink Products, 2003-2005**

Main Food and Drink Categories	Overall Sector Sales % Change (2003-2005)	Functional Sales % Change (2003-2005)
Probiotic yogurts and drinks	+19	+92
Juice, juice drinks and dilutables	+14	+30
Eggs	+22	+29
Soya dairy alternatives	+28 <sup>1</sup>	+23
Breakfast cereals	+4	+16
Spreads	+6	+12
Stimulation drinks	+8	+10
Bottled water	+10	+8

<sup>1</sup> Total dairy-free, 2002-2005 (Mintel, 2006b)

#### Natural Health Products

No information was found on the contribution of NHPs to the UK economy.

#### 4.2.4 Key Trends

This section describes the key supply trends of functional foods and natural health products in the United Kingdom.

#### Functional Foods

Mintel (2006b) forecasts that functional food expenditures in the UK will more than double by 2010 as compared to 2005 expenditures, from £1,089 million (C\$2,403) to an estimated £2,225 million (C\$4,780.8 (conversion used 2007 exchange rate)). Table 4.7 shows the projected functional food expenditures between 2005 and 2010.

**Table 4.7 Forecast for the Expenditure of Functional Foods, 2005 to 2010**

Year	2005	2006	2007	2008 <sup>13</sup>	2009	2010
Expenditure (£ millions)	1,089	1,241	1,443	1,686	1,950	2,225
Expenditure (C\$ millions)	2,403.1	2,591.9	3,100.51	3,622.6	4,189.9	4,780.8

Mintel (2006b) proposes that certain opportunities, if followed, could promote the growth trend in the UK functional food market. First, the development of the “community list of permitted claims” for functional ingredients, targeted for mid-2009, will impact the ability of marketing functional foods. Research and development into new links between food and health to establish new health claims by manufacturers would also drive market growth (anti-aging, for example). Related to this, is the idea of developing beauty foods and beverages. Additionally, the use of established functional claims in new food categories would expand the functional food market. Finally, the market could benefit from targeting products to specific gender and age groups.

<sup>13</sup> Conversion rates for 2007 were used to convert the 2008, 2009 and 2010 expenditure values to Canadian dollars.

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### *Natural Health Products*

David Adams, Director of Health Food Manufacturers Association (HFMA), in an interview with NBJ (2007a), identified the following as key issues facing UK suppliers of natural health products, and, therefore, are likely to impact supply trends in the future:

- The Nutrition and Health Claims Regulation that entered into force in January 2007 and requires prior approval of all health claims will have a very major impact on the market as unprepared companies eventually 'lose' valuable health claims.
- The growing and innovative sports nutrition sector faces publication of the long awaited, and potentially restrictive, 'Sports Nutrition Directive', likely in early 2008.
- Novel foods: This legislation threatens to halt, at least temporarily, various 'superfoods' and sports nutrition ingredients for which pre-1997 consumption in the E.U. is increasingly difficult to prove.
- Non-regulatory concerns include regular, high-profile media 'health scares' often based on a distorted interpretation of suspect research or meta-analysis (albeit the frequency of such scares does encourage consumer skepticism).
- Growth in imports of products from offshore suppliers, particularly based in the Channel Islands where suppliers do not have to comply with U.K. or E.U. legislation, can make 'medicinal' claims and benefit from specific tax concessions.
- General 'commoditization' of natural health products as increasing regulatory burdens stifle product and marketing innovation.

Source: (NBJ, 2007a)

## 5.0 Description of the Functional Food and Natural Health Product Industry in Japan

As a preamble to this section, the Japanese FFNHP industry and regulatory system differ from their international counterparts. This restricts our ability to present a Japanese regulatory system overview and market profile consistent with those in the rest of the report. To facilitate understanding of the complexities, the following discussion, based on information from Nakajima (2007), provides some highlights of the distinguishing features of this system. For more complete details on the regulatory environment in Japan, refer to [Appendix B.4](#).

To begin with, the Japanese nutrition product regulatory system is divided into foods that can state health claims and those that cannot state health claims. Within the category of foods that can state health claims lie Foods for Special Dietary Uses, Foods for Specified Health Use (FOSHU), and Foods with Nutrient Function Claims (FNFC). The non-health claim category includes all other types of “food” (including “so-called health foods” or dietary supplements). However, the development of the Japanese FFNHP market profile is complicated by the fact that supplements are included in various categories of Japanese “food products”. For example, according to Nakajima (2007), Foods with Nutrient Function Claims (FNFC), although called “foods” can be the form of “capsules, tablets, powder, liquid form (beverages), and any other type of processed food”. Therefore, supplements can fall within the FNFC category (regulated) or the non-health claim category (not regulated). However, according to CANTOX (see discussion below), FOSHU and FNFC products are generally in conventional food form, and not in supplement form. This implies that the majority of supplements fall under the “so-called health foods” non-regulated category of products.

Further complexity arises from the fact that although functional foods are widespread in Japan, FOSHU products, often exclusively cited in the literature, are only one portion of this market. These are the foods with claims identifying them as functional (seemingly analogous to Leatherhead’s strict definition of functional foods). Although the FOSHU product market has become relatively well documented, the non-FOSHU market, which comprises the products that are functional but do not carry a FOSHU claim (i.e., Leatherhead’s broad definition of functional foods), is not well documented. Much of the literature proposing Japanese functional food market value estimates warns that this market is difficult to define and quantify. For example, according to Leatherhead (2006), “with the lack of a clear boundary between standard foods, health foods and functional foods, it is very difficult to estimate the non-health claims sector of the functional foods market.” However, we will try to reconcile the various data by making these distinctions within the market profile discussion.

Since we rely heavily on Bailey’s 2007 “Functional Food and Natural Health Product Trade and Investment Opportunities in Japan” report for the Japanese market profile discussion, it is useful to include Bailey’s definitions of these products. Note that, as Bailey states, these are Canadian definitions of functional foods and natural health products, since Bailey’s intention was to make his findings relevant in the Canadian context. As such, natural health products, when discussed by Bailey, are comparable to the category of dietary supplements in other jurisdictions and encompass both those supplements in the FNFC category of products and the non-health claim “so-called health foods” category of products in the Japanese system/industry.

**Functional Foods** (FF) are similar in appearance to, or may be conventional foods, are consumed as part of a usual diet, and are demonstrated to have physiological benefits and/or reduce the risk of chronic disease beyond basic nutritional functions. They are created through various means, such as:

- fortification with vitamins and/or minerals to provide added health benefits (e.g., fortified soy beverages and fruit juice with calcium).
- addition of bioactive ingredients (e.g., muffins with beta-glucan, yoghurt with probiotics, and drinks with herb blends).
- enhancement through plant breeding techniques, processing, or special livestock feeding techniques to contain more of a bioactive component (e.g., omega 3 eggs, milk and meat; canola oil high in carotenoids; and wheat with enhanced lutein levels).

**Natural Health Products (NHP)** are usually sold in dosage form for the purpose of diagnosing, treating, or preventing disease; restoring or correcting function; or maintaining or promoting health. Examples include:

- products extracted or purified from plants (e.g., beta-glucan from oats, anthocyanins from blueberries, sterols from wood pulp, essential fatty acids from marine or vegetable oil, and soluble fibre from fenugreek).
- products ground, dried, powdered and pressed from plant materials (e.g., Echinacea, fenugreek, valerian, and ginseng).
- products produced, extracted or purified from animals and micro-organisms (e.g., essential fatty acids, enzymes, carotenoids and probiotics).
- products produced from marine sources (e.g., glucosamine, chitosan and fish oils).
- products comprised solely of vitamins and minerals.

(Bailey, 2007b)

Section 5.0 provides a description of the development and size of the functional food and natural health product industries in Japan from a demand (5.1) and supply perspective (5.2).

### **5.1 Demand for Functional Food and Natural Health Products in Japan**

Section 5.1 looks at the demand for functional food and natural health products in Japan. This section is broken down into two areas: Section 5.1.1 examines consumer perceptions and awareness of FF and NHPs and Section 5.1.2 reports on the sales in the FF and NHP industry, while 5.1.3 describes key trends for the Japanese market from a demand perspective.

#### **5.1.1 Consumer Perceptions and Awareness of Functional Food and Natural Health Products**

This section describes literature on consumer perceptions and awareness of functional foods and natural health products.

##### ***Functional Foods and Natural Health Products***

In Japan, the functional food concept emerged in the 1980s in response to health concerns of the aging population (Heasman, 2004). Demand for functional foods in Japan, even those without FOSHU approval (of the functional food sales in Japan, only 10-15% is FOSHU acclaimed (Jarvis et al (2001)), is high largely due to high consumer awareness of health attributes of foods. Groote (2002) attributes the consumption of non-regulated functional food products to “Japan’s long history and experience of use for natural medicinal products.”

Consumer awareness of functional foods in Japan may also be a result of government educational programs regarding the health benefits of functional foods. For example, the Ministry of Health, Labour and Welfare spends about ¥1.5M (C\$19,500) each year on educational pamphlets and media coverage for FFNHP (Groote, 2002).

Although the Japanese diet has traditionally been healthier than Western diets, the Japanese development of food supplements was originally in response to a lack of nutrition in basic foods (Groote, 2002). However, the current focus for food supplement consumption is becoming similar to the Western motivation: to compensate for poor nutrition due to the increased consumption of convenience food (Groote, 2002). However, NBJ (2007a) still attributes recent (i.e., 2006) high sales of vitamins and dietary supplements in many key global markets, and specifically in Japan, to age-related ailments such as arthritis, prostate problems, osteoporosis and menopause as a result of continuing aging populations.

Bailey (2007a) supports the claim that consumer awareness and perception of FFNHP are affected by government education, but states that consumer trust of MHLW endorsement of regulated products drives demand. On the other hand, according to Bailey, the industry tends to drive the unregulated product demand, especially for natural health products.

### 5.1.2 Sales of Functional Food and Natural Health Products

This section describes literature on sales of functional foods and natural health products in Japan.

#### *Functional Foods*

A recent Japanese FFNHP trade and investment study (Bailey, 2007b) indicated that the Japanese functional food market is valued between US\$15 billion and US\$20 billion<sup>14</sup> per year at retail. The study provides the example of the ready-to-drink green tea beverage retail market as one substantial portion of this market, valued at US\$4 billion. Bailey (2007a) specifies that the FOSHU (Foods for Specified Health Uses) category of functional foods in Japan is valued at US\$5.25 billion and this estimate is collaborated by a US\$5.5 billion value presented by Nakajima (2007) (for 2005). Other categories of foods that involve the use of health claims (Foods for Special Dietary Uses, Foods with Nutrient Function Claims, and Qualified FOSHU Claims) also contribute to the Japanese functional food market value.

According to the NBJ 2007 Global Nutrition Industry Report (NBJ, 2007a), the functional food sales in 2005 and 2006 were US\$19,058 million and US\$19,439 million, respectively. This estimate corresponds well with Bailey's estimate (above) of approximately US\$15-20 billion.

Other recent data indicate that Japan has the largest functional food market in the world, by value, with market sales of ¥630 billion (C\$6.95 billion) in 2005 (Leatherhead Food International, 2006). Although this represents 35.5% of the global functional food market (under Leatherhead's strict definition), the estimate is much lower than those proposed by NBJ and Bailey. However, this is due to the fact that Leatherhead's strict definition includes only those functional foods with health claims (FOSHU products), whereas non-FOSHU products can also be functional. Leatherhead reports that the FOSHU and non-FOSHU market, although difficult to quantify, may be valued at US\$15.9 billion, which is closer to the estimates provided by NBJ and Bailey. When this broader definition of functional food products is used, Japan garners 43.8% of the global functional food market (Leatherhead Food International, 2006). Also of interest is the fact that of all national markets, the average Japanese consumer spends the largest amount per annum on functional food, with each consumer spending approximately C\$70 per year on functional foods (Heasman, 2004).

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<sup>14</sup> Bailey (2007a) uses an exchange rate of \$1 USD = 120 JYen  
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Despite any discrepancy in specific sales values and uncertainty over the size of the non-FOSHU functional market, all commentaries on the Japanese market agree that it is the most sophisticated functional food market which has seen significant growth in sales.

In terms of functionality categories, the biggest supply of FOSHU in Japan in 2003 (in terms of number of products) was the gastrointestinal health use category, constituting 48% of the market by volume. Functional foods used for cardiovascular health were the second largest category by volume, constituting 13% of the market (Paul Yamaguchi & Associates, 2004). A similar structure was presented by MacDonald (2004) and Leatherhead (2006). Macdonald (2004) reported that gastrointestinal and cardiovascular health categories remained the two largest having 195 and 59 products with FOSHU approval, respectively. Leatherhead (2006) again identifies the gastrointestinal category as the most significant within the Japanese market, although its share of the market has been dropping and fell to 60% in 2005 (down from 79% in 2001) as newer categories increase their sales (Leatherhead Food International, 2006).

By sales value, the structure of the Japanese market in 2003 looked a little different. Gastrointestinal remained the dominate category (64% of the market by value); however, tryglyserides are the second largest by value (11% of the market) and the cardiovascular sector despite having significantly large volumes, is actually one of the smallest categories by value, at 2% (Paul Yamaguchi & Associates, 2004). 2005 FOSHU sales by category, as presented by NBJ (2007a), were as follows. Products targeted at gastrointestinal health lead with sales of US\$3,369 million. This category was followed in sales by dental health (US\$874 million) and triglyceride/body fat targeting products (US\$801).

Not surprisingly, dietary fibre was the most common ingredient in FOSHU products; 35% of products were fortified with dietary fibre (in 2003). It is included in products that claim a variety of functionalities e.g. gastrointestinal, diabetes, and hypertension. The second most common ingredient in FOSHU products were probiotics (in 2003). Fifteen percent of products have probiotics in them (Paul Yamaguchi & Associates, 2004). Interesting to note is the fact that many consumers are not familiar with the ingredients in the products, but trust the health claims on the package and the FOSHU label (Paul Yamaguchi & Associates, 2004).

#### *Natural Health Products*

According to Bailey (2007b), the Japanese NHP market is valued at US\$10 billion at retail. He attributes a large portion of this value to dietary supplements. Bailey (2007b) claims that the NHP *ingredient* market “is somewhat more difficult to define”. However, he values the vitamin and mineral market at US\$1 billion in manufacturer’s sales.

NBJ (2007a) valued Japanese supplement sales at US\$11.64 billion in 2005 and \$11.19 billion in 2006. This compares closely with Bailey’s estimate of approximately US\$10 billion for the NHP retail market plus \$1 billion in vitamin and mineral sales.

Table 5.1 shows 2005 and 2006 supplement sales in Japan, by supplement category. The vitamin and mineral category of supplements had the highest sales of the three categories in both 2005 and 2006. However, sales are relatively evenly distributed between the three categories.

**Table 5.1 Japanese Supplement Sales by Category, 2005 and 2006**

Supplement Category	2005 Sales (US\$M)	2006 Sales (US\$M)
Vitamins & Minerals	4,628	4,443
Herbs/Botanicals	3,261	3,065
Sports, Homeopathic, Meal and Specialty	3,751	3,676
<b>Total Supplements</b>	<b>11,640</b>	<b>11,185</b>

Source: (NBJ, 2007a)

### 5.1.3 Key Trends

This section describes literature on demand trends of functional foods and natural health products in Japan.

#### Functional Foods

Paul Yamaguchi & Associates (2004) reported that between 1995 and 2003 the average annual growth of the Japanese functional food market was 12%. Included in this percentage were both regulated and unregulated functional foods; interestingly, the growth rate of government approved functional foods (FOSHU) was considerably higher at 20% (Paul Yamaguchi & Associates, 2004). Although there has been considerable growth in the Japanese market historically, Leatherhead (2006) suggests that the growth has slowed, thus indicating a maturing of the market. This conclusion is collaborated by NBJ (2007a), who reported a minimal 2% growth in functional food sales between 2005 and 2006. However, the Leatherhead report also notes that the arrival of a new trend can stimulate significant market growth in Japan.

In terms of categories of functionality, a trend of growth has been constant in the gastrointestinal health target category over the last decade; overall, sales have increased from US\$1,092 million in 1997 to US\$3,369 million in 2005. The other significant growth trends have been in the areas of dental health (no sales in 1997; US\$874 million in sales in 2005) and triglyceride/body fat (no sales in 1997; US\$801 million in sales in 2005). These three categories are leading in growth and in market share in terms of value of sales (as discussed in [Section 5.1.2](#)) (NBJ, 2007a).

#### Natural Health Products

The following table illustrates the percent change in sales of supplements in Japan between 2001 and 2006. Annual growth of supplement sales in Japan was very strong between 2001 and 2005. However, the peak in growth between 2003 and 2004 was followed by a drastic drop in growth and a decrease in sales between 2005 and 2006.

**Table 5.2 Japanese Supplement Sales by Year, and Percent Growth, 2001-2006**

Year	Sales (\$M)	% Change*
2001	8,840	-
2002	9,366	6.0
2003	10,078	7.6
2004	11,214	11.3
2005	11,640	3.8
2006	11,185	-3.9

\*Percent change =  $[(\text{Sales}_{\text{Year N}} - \text{Sales}_{\text{Year N-1}}) / (\text{Sales}_{\text{Year N-1}})] \times 100$

Source: (NBJ, 2007a) and GMC calculations

2006 percent growth by supplement category is shown in the following table. This breakdown helps to identify where the recent stagnation in the market lies, in terms of categories of supplements with decreasing sales. The largest fall in sales was in the area of herbs/botanicals, followed by vitamins and minerals. Sports, homeopathic, meal and specialty supplements experienced the smallest growth decrease, but sales fell by 2% nonetheless. As such, no positive growth was experienced in any supplement category in 2006. This appears to be the trend for the whole nutrition industry in Japan. According to NBJ (2007a), the industry grew by a significant 22% between 2000 and 2001, began to slow in 2005 (2% growth), and actually contracted by 2% in 2006.

**Table 5.3 Japanese Supplement Sales Percent Growth, by Category, 2006**

Supplement Category	% Growth
Vitamins & Minerals	-4.0
Herbs/Botanicals	-6.0
Sports, Homeopathic, Meal & Specialty	-2.0
<b>Total Supplements</b>	<b>-3.9</b>

Source: (NBJ, 2007a)

Considering that sales of supplements in Japan are very large compared to other jurisdictions, a saturation of the demand could be possible, resulting in stagnating growth. As mentioned above, Leatherhead refers to the Japanese decreasing sales trend as an indication of a “maturing market.” However, according to NBJ (2007a), other factors are at play:

*“There are plenty of sources to blame for the shrinking market. The most damaging was the government, particularly the enforcement (unfairly, in our opinion) of a new Health Promotion Act that severely limits expression of health benefits on nutritional products. An old Pharmaceutical Affair Law didn’t help either. It seems that the government is trying to put a cap on the nutrition industry to benefit the pharmaceutical industry. “It may be doctors, drug companies and pharmacists who are adding pressure to government agencies, particularly influencing the Ministry of Health Labor and Welfare (MHLW) to limit the rapid growth of the nutrition industry,” reported Japan’s largest nutrition industry newspaper, The Health Industry News (HIN). This may have been the single biggest cause of negative growth of our industry in 2006.”*

## **5.2 Supply of Functional Food and Natural Health Products in Japan**

Section 5.2 looks at the supply side of the functional food and natural health product industry in Japan. This section is divided into four sub-sections. Section 5.2.1 looks at the nature and number of FF and NHP firms in Japan. In Section 5.2.2, major FFNHP brands in Japan are examined. Section 5.2.3 looks at the contribution of FF and NHP industries to the Japanese industry. Finally, Section 5.2.4 pinpoints key trends in the FF and NHP industry, as they relate to the supply side.

### 5.2.1 Nature and Number of Firms

This section describes literature on the nature and number of firms in the United States markets for functional foods and natural health products.

There are between 3000 and 5000 companies in Japan without established brands in both the Functional Foods and the Natural Health Product industry resulting in a highly competitive market (Groote, 2002).

The larger food and pharmaceutical companies tend to be the industry leaders with regard to newer and innovative ingredients. This is largely due to the cost of the development process which includes R&D, proof of efficacy and government approval (Paul Yamaguchi & Associates, 2004). Bailey (2007a) collaborates this point for suppliers of regulated products, stating that, “the regulations are developed in part, recognizing that they are likely to be more readily utilized by the larger companies with access to more scientific and financial resources. Smaller and medium size companies can and do participate in these regulated categories, but often with more difficulty.” On the other hand, unregulated product suppliers are less limited by financial restrictions since, according to Bailey, they “often borrow science (and considerable “non-science”) from overseas, particularly for ingredients new to Japan.”

The plethora of companies in Japan makes it difficult to identify the major players. Leatherhead (2006) lists a number of major companies within the functional yoghurts and fermented milks sub-sector (Table 5.5 below). Majority of the market is dominated by Japanese brands. However, there are a few western brands within the market although they are often made and sold under licence within Japan.

Many large food and beverage FFNHP companies also market “fine chemicals” (food ingredients and food additives). This functional food ingredient development often takes place within small independent organizations internal to the companies (Bailey, 2007b).

A recent study of opportunities for trade and investment in the Japanese FFNHP market involved company interviews with 20 large and 10 small to medium food and beverage companies active in the Japanese FF and NHP markets. The interviewees, although not a comprehensive representation of FFNHP firms, are examples of some Japanese FFNHP market key players. The interviewed firms included:

- Toyo Shinyaku
- Nippon Suisan
- FANCL Corporation
- Meiji Food Materica
- Fuji Oil
- Ito En
- Oryza Oil & Fat Chemical
- QP Corporation
- SS Pharmaceutical
- Nisshin Pharma
- Nippon Meat Packers
- Kyowa Hakko Kogyo
- Maruha
- Lotte Bussan
- Ito Life Science
- Otsuka Pharmaceutical
- Asahi Food & Health Care
- Yakult Honsha
- Riken Vitamin
- Fujicco
- Suntory, Ltd.
- Nestle Japan
- Nitta Gelatin
- Ajinomoto
- Matsutani Chemical Industry
- Hayashibara
- Lion Corporation
- Nippon Flour Mills
- Sapporo Beer
- Kikkoman

(Bailey, 2007b)

Bailey (2007a) also identified the top eight small and medium enterprise companies, ranked based on the number of FOSHU approvals (as of December 2006). These were (including number of FOSHU approvals):

- Toyo Shinyaku (49)
- Calpis (18)
- Ajinomoto General Foods (17)

- Fuji Oil/Toraku (11)
- Ezaki Glico (11)
- Maruwa (10)
- Cadbury Japan (10)
- Senmi Ekisu (10)

*Natural Health Products*

The following table shows NBJ's top 10 nutritional product producers, based on 2006 sales. These producers are all suppliers of supplements, although not all supply exclusively supplements.

**Table 5.4 NBJ's Top 10 Japanese Nutritional Product Producers Supplying Supplements, Ranked by 2006 Sales**

Company	Sales (US\$M*)	% Change (from 2005)
Amway Japan	1,060	0.5
DHC	958	15
Miki Shoji	836	3
Funci	678	8
Kirindo	603	16
Neways Japan	585	24
Lotte Bussan	570	18
Nuskin Japan	561	-2
Sunny Health	417	-10
Orbis	393	-17

\*Exchange rate: 110 yen to US dollar.

Source: (NBJ, 2007a)

According to NBJ (2007a), a 55% share of the supplement market belongs to the top 20 suppliers of dietary supplements in Japan. Most of these companies are direct marketers through network/multi-level marketing (MLM), i.e., door-to-door and product demos and mail order channels. As a matter of fact, 34% of 2005 sales were through the network/MLM channel and an additional 34% were through the Internet and mail order channel. A smaller amount, 24% of sales, was through the pharmacy and drugstore channel (NBJ, 2007a). The top Japanese supplement companies are also likely to focus on a single, high value-added product.

5.2.2 Major Functional Food and Natural Health Products Brands

This section describes literature on the major brands of functional foods and natural health products in Japan.

*Functional Foods*

Japan has one of the world's most sophisticated functional foods markets representing a number of major brands. According to Bailey (2007b), there are over 600 FOSHU products on the Japanese market (about double the number of products that were on the market in 1999). Table 5.1 lists the major companies in the functional yoghurts and fermented milks sector, while Table 5.2 lists the products that have been approved as FOSHU in the functional ingredients category.

**Table 5.5 Major Japanese Companies in Functional Yoghurts and Fermented Milks, 2006**

Company	Products and Benefits
Calpis Co	Calpis, Calpis Kids and Ameal S fermented milk drinks
Calpis Ajinomoto Danone	Danone Bio/Activa yoghurt, Danone Vitalina fortified yoghurt with fibre
Kagome	Labio Bifidus, Nomu, Yogurcare for women and DHA fermented milks
Meiji Milk	Meiji Bulgaricus LB81, Meiji LG21 probiotic yoghurts
Morinaga Milk	Morinaga Bifidus Nomu, BB536 and Lactoferrin yoghurts
Nestle Snow	Nestle LC1 probiotic yoghurt
Nippon Luna	Luna LAB Power drinks
Yakult Honsha	Yakult, Bifiene and Pletio fermented milk drinks, Joie and Bifiel Probiotic yoghurts

Source: (Leatherhead Food International, 2006)

**Table 5.6 Number of Approved Products by FOSHU Functional Ingredient Category, as of June 2004**

Category	Number of Approved Products
Gut Regulation	195
Cholesterol	59
Blood sugar levels (diabetes)	57
Blood Pressure (hypertension)	38
Dental Care	29
Triglycerides	19
Mineral Absorption	14
Bone Health	11

Source: (MacDonald, 2004)

### Natural Health Products

Bailey (2007a) estimates that, although difficult to quantify, there are probably over 50,000 “unregulated” health products on the market (health foods in tablet, capsule, and powder forms). Although there was no information found on specific supplement brands supplied by Japanese companies, the following is a discussion of some of the key ingredients constituting the market in 2005. Specialty supplements lead with 37% of the market, closely followed by herbs and botanicals at 35%. Nineteen percent of the market was comprised of vitamins and minerals. Finally, meal replacements represented 9% of the supplement market in Japan in 2005 (NBJ, 2007a).

The specialty market supplement products of choice in 2005 were royal jelly, chlorella, mushrooms and joint health products like glucosamine, chondroitin and CoQ10. In terms of condition-specific products, the general health category constituted the largest portion of the market (28%). Ingredients in this category included royal jelly, chlorella, panax ginseng, garlic, CoQ10 and green juice. Eighteen percent of the market was attributed to the weight loss condition-specific category. The ingredients within this category were glucomanna, agar, garcinia cambogia, gymnema and amino acids. Meal replacements also fell into this category. The immunity/anti-cancer category represented 15% of the market in terms of condition-specific products. This category was followed by vitamin/minerals for nutritional support, eye health and blood circulation, joint health, and skincare (NBJ, 2007a).

### 5.2.3 Contribution of Functional Food and Natural Health Product Industries to the Economy

No information on the FFNHP industry's contribution to the Japanese economy was found.

### 5.2.4 Key Trends

This section describes literature on supply trends of functional foods and natural health products in Japan.

#### *Functional Foods*

Although Japan's functional food market is one of the best developed markets of its kind in the world, its growth has been stagnating. This observation of a slowing or maturing Japanese functional food market has since been noted by Leatherhead (2006) as mentioned in [Section 5.1.2](#).

With regard to product trends, Japan is evidently the market to examine precisely for the reasons mentioned by Groote (2002) and Leatherhead (2006). It is a mature market in which consumers are comfortable with functional food products but the competition within the market means that if a product achieves significant market share in Japan there are great possibilities in a global market for a similar product. Leatherhead (2006) reports that the most recent "fashion ingredients" in Japan are soy peptides, green tea catechins and gamma amino butyric acid (GABA).

Another area of growing interest in the Japanese FFNHP market is flax seed oil and processed seed fraction products. The growing interest is illustrated by the growing number of flax product exhibitors at Japanese trade shows. Interestingly, the Japanese perception regarding Canada in this product area is that it is "the primary global source of high quality flax seed" (Bailey, 2007b). Therefore, this trend in Japan, if it continues, may increase the opportunity for trade and investment in Japan for the Canadian flax seed industry.

According to Bailey (2007b), future potential areas of Japanese FFNHP market expansion will be a reflection of demand drivers influenced by changing demographics, especially aging of the declining population. One substantial opportunity for expansion in Japanese functional food sales is the expected approval of a new Anti-Fatigue FOSHU category by the Ministry of Health, Labour, and Welfare. Bailey projects that this category will be followed by the emergence of other stress-related health claim categories. Furthermore, expansion is expected in the area of weight management (currently "unregulated"), including prevention of weight related health problems such as high blood pressure and blood sugar. Since disease cure claims are not a part of the Japanese regulatory framework, development will focus on products with claims for prevention of diseases.

#### *Natural Health Products*

As discussed above, the natural health product industry is facing a significant decrease in sales (the 2006 market was smaller than the 2003 market). A "mature" market was one reason given for this decline, which implies that consumer demand is driving this stagnation. Although NBJ (2007a) admits that consumers may be losing interest in supplements, many of the factors contributing to this negative trend appear to be on the supply side. According to NBJ (2007a), "regulation, food safety and contamination were the main causes of the negative growth, but most damaging was a lack of new ingredients and new product introductions to excite

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consumers.” Therefore, it appears that a decreasing trend in supplement research and development is one supply trend of the Japanese industry.

## **6.0 Summary and Conclusions**

The primary objective of this project was to provide evidence of the market opportunities that exist for the Canadian agri-food industries from improved Functional Food and Natural Health Product regulation. Specifically, this research was to conduct a comprehensive analysis of foreign functional food and natural health product markets, including the United States, Australia, the United Kingdom (UK)<sup>15</sup> and Japan. The intent of the market profiles was to provide a point of comparison with the Canadian market (for FFNHPs) and to assist in identifying opportunities for growth and advancement of Canada's FFNHP Sector (in a separate research report). The specific objectives of this research and the corresponding results are presented in the following paragraphs.

### **6.1 Summary of the International Market Profiles**

The first objective of this report was to create a profile of the FFNHP industries in selected international markets, including the United States, Australia, the United Kingdom (UK) and Japan. This objective was met in Sections 2.0 to 5.0 of the report. These sections present profiles for functional food and natural health product markets in the specified jurisdictions, addressing both the demand and supply sides of these markets. As a summary of these results, Tables 6.1 and 6.2 provide an overview of the functional food and natural health product markets and related key regulatory issues, as identified in the literature, for the US, Australia, UK and Japan. This comparative overview fulfills the overall research purpose of providing a point of comparison with the Canadian market for FFNHPs. It also serves to facilitate future analysis of industry development and size in jurisdictions operating under different regulatory environments.

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<sup>15</sup> The United Kingdom was selected as an indicator of the European Union market.  
*George Morris Centre*

**Table 6.1 Overview of the Functional Food Markets and Relevant Regulatory Issues for the US, Australia, United Kingdom and Japan**

	US	Australia	UK	Japan
<b>Demand</b>				
Consumer Perceptions and Awareness	-Annual spending greatest for the occasional consumer group -Top reasons for FF purchases: Make up for less than healthy eating habits; Weight loss/weight maintenance; Supplement already healthy eating habits -Top reasons for not purchasing FF: Overpriced; Don't believe the claims they make; Take vitamin and mineral supplement(s) instead	- FF awareness and perceptions regarding level of quality is very high -But 40% never purchase common FF products -Top reasons for no FF purchase: Disbelief in health benefits; Dislike of taste	-Driven by media (especially media scares)	-High sales attributed to tradition of use, convenience, age-related ailments (aging population) and government education programs
Sales	-US\$5.3 to 28.5 billion (2005) -US\$31.4 billion (2006)	-C\$327 to 696 million (2005)	-£1,089 million (C\$2,403 million) in 2005 -Yogurts and drinks / breakfast cereals were top product categories in 2005	-US\$15 to \$20 billion in 2005/2006 (US\$5 billion FOSHU)
Trends	-10.2% growth in 2006 -Forecast additional 5.2% growth by 2010	-Global share growing at 8-14% per year -Convenience sales growing	-Between 2000 and 2005, sales grew by 143% (2.43 times) -Dairy category fastest growing (soya dairy-alternative sector grew 700% between 2001 and 2005)	-12% average annual growth between 1995 and 2003 -Growth slowing (only 2% between 2005 and 2006) from a maturing market
<b>Supply</b>				
Nature and Number of Firms	-Primary structure: multinational corporation -Top sales: PepsiCo, Kellogg Co., Coca-Cola Co., and General Mills -Mainly domestic due to the non-uniformity of health food claim	-Multinationals provide a range of products	-Suppliers focus on one product category -Top suppliers: Danone, Unilever, Nestle, PepsiCo and Ocean Spray	-Between 3,000 and 5,000 FFNHP companies in Japan without established brands (competitive market) -Many market both functional products and ingredients

	US	Australia	UK	Japan
	regulations from country to country			
R&D	- Product introductions have generally been increasing since 2001	-95% of R&D funding from industry -R&D dominated by large companies	-130 new products launched between January 2005 and January 2006 (43% in dairy area) -Driven by large multinational companies such as Danone and Unilever	-MAFF <sup>16</sup> provides cost-share programs for industry to promote development of new technologies for FF component isolation and purification
Key Trends / Industry Issues	-Market development driven by FDA approval of health claims (majority of approvals in heart health) -Cereal market declining -Beverage market growing	-Marketing opportunities driven by allowed health claims (i.e., evidence to support health claims exists)	-The growing and innovative sports nutrition sector faces publication of the long awaited, and potentially restrictive, 'Sports Nutrition Directive', in early 2008. -Development of the "community list of permitted claims" for functional ingredients, targeted for mid-2009, will impact marketing ability	-Factors that may be contributing to market stagnation: large number of firms without established brands (lack of market share); focus on few functional components; falling prices -However, there is opportunity for expansion in sales with expected approval of new Anti-Fatigue FOSHU category
Regulatory Issues	-Food fortification only loosely regulated – only voluntary notification of marketing required	-High transparency and efficiency in marketing approval system	-Nutrition and Health Claims Regulation that entered into force in January and requires prior approval of all health claims will have a major impact on the market as unprepared companies eventually 'lose' valuable health claims. -Novel foods: This legislation threatens to halt, at least temporarily, various	-Industry interest turning to cosmetic market due to growing complexity and cost of entering the <i>Tokuho</i> (FOSHU) market for foods with allowed health claims

<sup>16</sup> Japanese Ministry of Agriculture, Forestry and Fisheries

	US	Australia	UK	Japan
			<p>'superfoods' and sports nutrition ingredients for which pre-1997 consumption in the E.U. is increasingly difficult to prove</p> <p>-Newly implemented food fortification positive listing regulatory system may impact ability to market fortified foods</p>	

**Table 6.2 Overview of the Natural Health Product Markets and Relevant Regulatory Issues for the US, Australia, UK and Japan**

	US	Australia	UK	Japan
<b>Demand</b>				
Consumer Perceptions and Awareness	-Highest percent are regular users (31%) -Recent sales driven by age-related ailments	-Over 50% use at least one NHP -Level of usage among highest in the world	-Over 40% took supplement within last 12 months -Use most popular among 50-65/over 65 age group	-As with FF, sales impacted by tradition of use, convenience, age-related ailments (aging population) and government education programs
Sales	-US\$22.460 billion (2006) (US\$21.320 billion in 2005)	-US\$1.530 billion (2006) (US\$1.440 billion in 2005)	-US\$1.537 billion (2006) (US\$1.502 billion in 2005)	-US\$10 to 11 billion in 2006 -NBJ estimate: \$11.180 billion (2006) (US\$11.640 billion in 2005)
Trends	-Declining growth -5.4% growth in 2006 -Forecast 4.5% growth by 2010	-5.9% growth in 2006 -Sales strong in weight loss category -Increasing focus on health instead of disease	-3.9% between 1999 and 2006 -Recent growth minimal (i.e., 0.9% in 12 months ending August 2006)	-Falling growth (11.3% in 2004; 3.8% in 2005) -Sales <i>decreased</i> (negative growth) between 2005 and 2006 (-3.9%)
<b>Supply</b>				
Nature and Number of Firms	-Top supplier: Natures Bounty, Sundown, Oseto-Bi-Flex (NBTY)	-95% of complementary medicines domestically due to the stringent and complex regulatory environment	-Top supplier is Merck KgaA ( <i>Seven Seas</i> fish oil)	-Top suppliers: Amway Japan, DHC, Miki Shoji -55% share of market belongs to top 20 suppliers (focus on a single, high value-added product)

	US	Australia	UK	Japan
				-Mainly direct marketers through network/MLM <sup>17</sup> and mail order/internet channels
Key Trends / Industry Issues	-Declining market due to: Insufficient volume and credibility of science; Clinical test data lacking/conflicting; Relative lack of government funding on health 'prevention'			- Negative growth trend attributed to regulation, food safety, contamination and lack of new ingredients and product introductions to excite consumers
Regulatory Issues	-Regulations restrict claims, distribution and new products -Industry positions fragmented and diluted by various/numerous association voices	-Regulations cited as most stringent in the world (regulated under the same authority as pharmaceuticals and prescription drugs) -Commercialization of a product can be slow if the active ingredient of that product is not already on the "Approved List" -However, government shows flexibility in product definitions to facilitate approval	-Stagnation of growth partly due to "uncertainty over the regulatory details of EU vitamin and herbal directives"	-Growth may be negatively affected by government enforcement of new <i>Health Promotion Act</i> (limits expression of health benefits on nutritional products) -Old Pharmaceutical Affair Law may also be damaging: " It seems that the government is trying to put a cap on the nutrition industry to benefit the pharmaceutical industry" -Concerns for consumer safety due to non-regulation of so-called health foods

<sup>17</sup> Multi-level marketing, i.e., door-to-door and product demos and mail order channels

## 6.2 Analysis of International Functional Food and Natural Health Product Markets

The second objective of this report was to analyze industry development and size in these markets, which operate under different regulatory environments for FFNHPs. The purpose of this objective was to assist in identifying opportunities for growth and advancement of Canada's FFNHP Sector. The tables above are a starting point for this analysis as they provide an overview of key market indicators of the industries and key regulatory issues facing these industries in the reviewed countries. The information in these tables, and the market profile information presented in the report in general, will be used in the following brief analyses of functional food and natural health product markets in the four reviewed jurisdictions.

### *Analysis of Functional Food Markets*

To further facilitate the analysis of the functional food markets in the reviewed jurisdictions, Table 6.3, below, summarizes the annual 2005 functional food sales values for the comparative countries (based on the market profiles). We assume that these sales values are, at least in part, a reflection of the local functional food regulatory frameworks. However, per capita sales and total sales in a given jurisdiction, for that matter, are unlikely to be dependent exclusively on the local regulatory environment. Factors such as culture, demographics and income will affect the level of demand for functional foods in that jurisdiction. Therefore, low per capita sales may simply indicate a low demand rather than an insufficient supply due to regulatory barriers. However, a quantitative analysis is more applicable than a qualitative analysis to fulfilling the objective of assisting the quantification of Canadian market opportunities, which is the underlying purpose of this report.

To develop Table 6.3, we used Leatherhead Food International (2006) 2005 sales values for the four international markets, to maintain consistency. Since Leatherhead identifies sales values for these markets under both strict<sup>18</sup> and broad<sup>19</sup> definitions of functional foods, we derived conservative and liberal estimates of per capita functional food sales. We use the terms "conservative sales estimate" and "liberal sales estimate" to represent strict and broad definitions of functional foods (as described by Leatherhead), respectively. In other words, a conservative definition of functional foods would encompass a smaller number of products, and, as such, would result in lower functional food sales than a liberal definition of functional foods that would encompass a larger number of food products. Note that these terms are not related to the type of regulatory environment in question.

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<sup>18</sup> "Everyday food and drink products (not pills or potions) that bear a health claim implying that the product has a physiological effect over and above that of just nutrition (e.g., can help lower cholesterol as part of a low-fat diet, helps maintain a healthy heart, improves the body's natural defences, etc.)"

<sup>19</sup> "Products that have a healthy or functional positioning and may be perceived to be functional, but do not necessarily make claims...this will include products fortified with calcium, vitamins, etc., also antioxidants, cranberries, other botanicals, etc., where their content/use is highlighted but no specific reference is made to potential health benefits."

**Table 6.3 Functional Food Sales in the United States, Australia, United Kingdom and Japan, 2005**

Country	Sales* C\$ M (Conservative)	Sales* C\$ M (Liberal)	Population* ('000)	Per Capita Sales C\$ M (Conservative)	Per Capita Sales C\$ M (Liberal)
United States	6,430	11,816	299,846	21.4	39.4
Australia	327	695	20,310	16.1	34.2
United Kingdom	2,062	4,965	60,245	34.2	82.4
Japan	6,945	19,252	127,897	54.3	150.5

\*Source: Sales values were obtained from (Leatherhead Food International, 2006) and the population statistics were obtained from (United Nations Population Division, 2007).

The Leatherhead sales estimates were converted to Canadian dollars using an average American exchange rate of C\$1.21 in 2005.

The following paragraphs are a high level discussion of some key connections between these derived per capita sales and the functional food regulatory systems for these jurisdictions. To supplement the quantitative dependence of the analysis (considering the weaknesses of the assumption that sales are exclusively dependent on the regulatory environment of the given jurisdiction, as discussed above), we refer to demand side factors that may be at play when these appear relevant, as per the consumer awareness and perception sections of the market profiles.

As Table 6.3 suggests, Japan is the leader in terms of per capita functional food sales, both under the conservative and liberal sales estimates. Japan is followed by the United Kingdom, the United States, and, finally, Australia. It is important to note; however, that all four jurisdictions are global leaders in terms functional food markets. Hence, this discussion is focused on using the comparative analysis to draw out the contributors to each market's success, rather than ranking the jurisdictions.

Some conclusions can be made regarding the success of the Japanese market based on the difference in its sales under the two definitions of functional foods. As discussed before, according to Leatherhead's definition, functional foods under the strict definition are those that make health claims. Therefore, health claims regulations apply to these foods. In Japan, liberal per capita sales values are almost three times the conservative per capita sales values. Since the Japanese health claim regulatory system is quite complex, the industry often resorts to selling products without the Ministry of Health, Labour and Welfare certification (i.e., health claims). As Bailey (2007b) states, there is concern from the industry "that the *Tokuho* [FOSHU] regulatory requirements for new functional ingredients and new *Tokuho* products are getting more complex, and complying with those regulations is becoming very expensive." Therefore, it appears that the industry has been successful precisely because Japanese consumers are highly aware of functional foods due, perhaps, to a long tradition of use of these products and a widespread government education program on health and nutrition. This may imply that the high per capita sales in Japan are not necessarily the result of an exemplary health claim "functional food" regulatory system in Japan; rather, demand side factors, supported by government spread information, are key to the success of this market. However, it is important to note that the growth of this market has slowed significantly in the last half decade, perhaps indicating that the complexity of the FOSHU regulatory system has taken its toll.

The United Kingdom market has been quite successful; however, once again, the success appears counter indicative considering the highly complex regulatory system that the industry

faces. Furthermore, UK consumers appear sensitive to media “scares” regarding functional foods. The supply side of the market may explain high sales. The country’s industry is comprised of large multinationals that launch many new products annually. Therefore, new product introductions stimulating consumer interest may be a strength for this market.

The US market is also comprised of multinationals with a trend of increasing product introductions. The market is driven by approval of health claims, but communication and transparency exist in the regulatory system, facilitating marketing approval. Furthermore, food fortification marketing notification is voluntary, which reduces burden on the industry in commercialization of products.

Although Australia’s per capita sales are lower than those in the other reviewed jurisdictions, Australia’s global market share is growing at 8-14% per year, making it a strong competitor in this area. Australian consumer awareness of functional food is very high. Furthermore, the market is driven by allowable health claims, and since the regulatory system is said to be highly efficient and supportive of industry competitiveness, the market likely benefits in this respect.

#### *Analysis of Natural Health Product Markets*

Table 6.4, below, summarizes the annual 2006 natural health product sales values for the comparative countries. Again, we assume that these sales values are, at least in part, a reflection of the local natural health product regulatory frameworks. However, as discussed above, per capita sales and total sales in a given jurisdiction are unlikely to be dependent exclusively on the local regulatory environment. Factors such as culture, demographics and income will affect the level of demand for natural health products in that jurisdiction. Therefore, low per capita sales may simply indicate a low demand rather than an insufficient supply due to regulatory barriers. However, a quantitative analysis is more applicable than a qualitative analysis to fulfilling the objective of assisting the quantification of Canadian market opportunities, which is the underlying purpose of this report.

To develop Table 6.4, we used NBJ (2007a) 2006 sales values for the four international markets, to maintain consistency. Unlike the values presented in Table 6.3, these sales values are in US dollars, as presented by NBJ.

**Table 6.4 Natural Health Product Sales in the United States, Australia, United Kingdom and Japan, 2006**

Country	Sales* (US \$M)	Population* ('000)	Per Capita Sales (US \$M)
United States	22,460	299,846	74.9
Australia	1,530	20,310	75.3
United Kingdom	1,537	60,245	25.5
Japan	11,180	127,897	87.4

\*Source: Sales values were obtained from (NBJ, 2007a) and the population statistics were obtained from (United Nations Population Division, 2007).

The following paragraphs are a high level discussion of some key connections between these derived per capita sales and natural health product regulatory systems for these jurisdictions. To supplement the quantitative dependence of the analysis (considering the weaknesses of the assumption that sales are exclusively dependent on the regulatory environment of the given

jurisdiction, as discussed above), we refer to demand side factors that may be at play when these appear relevant, as per the consumer awareness and perception sections of the market profiles.

As Table 6.4 shows, as with functional food sales, Japan comes out on top in terms of per capita natural health products sales. This is not surprising considering the non-regulated nature of this market, and the fact that consumer awareness of health products in general is very high among Japanese consumers. However, it is important to note that the Japanese government is concerned about the safety issues surrounding the lack of regulation of natural health products, and that market sales may be deeply impacted by this issue, both in terms of consumer wariness and the potential introduction of regulations. As a matter of fact, Japan has recently experienced a decline in supplement sales.

Australia and the United States have similar per capita sales. US companies do not have to obtain market approval from FDA to market dietary supplements; however, growth of the market is slowing. Factors attributed to this trend may include the insufficient volume and credibility of science, the lack of and conflict in clinical test data and a lack of government funding on health 'prevention'. Furthermore, the regulatory system in the US may be restrictive in allowable claims, retarding product launches.

Australia's per capita sales may compare to those in the US due to its stringent and complex regulatory environment (regulated under the same authority as pharmaceuticals and prescription drugs). However, the market's success on a global scale may be the result of high consumer supplement use; over 50% of Australians use at least one supplement, implying high consumer awareness and perception.

The UK lags behind the other jurisdictions in per capita sales, possibly because it faces a more complex and uncertain food supplement positive listing regulatory system. However, the market may persevere regardless of regulatory burdens due to demand side factors in the form of widespread UK consumer use of supplements; over 40% of the population had used a supplement in the last year.

### **6.3 Conclusions**

In conclusion, the market profile information and analysis reveals the following key conclusions regarding the functional food and natural health product industry sizes, development and relevant regulatory environments for the United States, Australia, the United Kingdom and Japan. These points serve to provide a point of comparison with the Canadian market and to assist in identifying opportunities for growth and advancement of Canada's FFNHP Sector in related research.

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## Overview of Functional Food Markets

### **United States**

- |                        |   |
|------------------------|---|
| Market Demand          | <ul style="list-style-type: none"><li>• Sales of approximately US\$30 billion (2006)</li><li>• Occasional consumers drive sales</li></ul>       |
| Market Supply          | <ul style="list-style-type: none"><li>• Large domestic multinationals dominate supply</li></ul>   |
| Market Development     | <ul style="list-style-type: none"><li>• Product introduction rate increasing</li><li>• Driven by regulatory approval of health claims</li></ul> |
| Regulatory Environment | <ul style="list-style-type: none"><li>• Health claim – efficient</li><li>• Food fortification – non-restrictive</li></ul>                       |

### **Australia**

- |                        |   |
|------------------------|---|
| Market Demand          | <ul style="list-style-type: none"><li>• Sales of approximately C\$300-700 million (2005)</li></ul>                                |
| Market Supply          | <ul style="list-style-type: none"><li>• Multinational firms provide range of products</li><li>• Industry driven R&amp;D</li></ul> |
| Market Development     | <ul style="list-style-type: none"><li>• Increasing global share</li></ul>   |
| Regulatory Environment | <ul style="list-style-type: none"><li>• Efficient regulatory approval process</li></ul>   |

### **United Kingdom**

- |                        |   |
|------------------------|---|
| Market Demand          | <ul style="list-style-type: none"><li>• Sales of approximately C\$2.5 billion (2005)</li><li>• Media dominated awareness and perception</li></ul> |
| Market Supply          | <ul style="list-style-type: none"><li>• Large multinationals focus on one product category</li><li>• Industry driven R&amp;D</li></ul>            |
| Market Development     | <ul style="list-style-type: none"><li>• Industry may be impacted by introduction of new regulations</li></ul>                                     |
| Regulatory Environment | <ul style="list-style-type: none"><li>• Industry faces complex and incomprehensive regulatory environment</li></ul>                               |

### **Japan**

- |                        |   |
|------------------------|---|
| Market Demand          | <ul style="list-style-type: none"><li>• Sales of approximately US\$15 to \$20 billion (2005/2006)</li><li>• High consumer awareness (tradition of use and government education)</li></ul> |
| Market Supply          | <ul style="list-style-type: none"><li>• Lack of market share (large number of companies without established brands)</li></ul>   |
| Market Development     | <ul style="list-style-type: none"><li>• Growth slowing drastically</li></ul>  |
| Regulatory Environment | <ul style="list-style-type: none"><li>• Industry faces increasingly complex and costly system</li></ul>   |

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## Overview of Natural Health Product Markets

### United States

- |                        |  |
|------------------------|--|
| Market Demand          | <ul style="list-style-type: none"><li>• Sales of approximately US\$20 billion (2006)</li><li>• Regular users drive sales</li></ul>   |
| Market Supply          | <ul style="list-style-type: none"><li>• NBTY (Natures Bounty, Sundown, Oseto-Bi-Flex) is the leading US supplier (almost double the sales of its nearest competitor)</li></ul> |
| Market Development     | <ul style="list-style-type: none"><li>• Forecast for declining growth through 2013</li></ul>   |
| Regulatory Environment | <ul style="list-style-type: none"><li>• Regulations may restrict claims, distribution and new products</li></ul>   |

### Australia

- |                        |   |
|------------------------|---|
| Market Demand          | <ul style="list-style-type: none"><li>• Sales of approximately US\$1.5 billion (2006)</li><li>• High rate of consumer use</li></ul> |
| Market Supply          | <ul style="list-style-type: none"><li>• Domestic companies dominate</li></ul>   |
| Market Development     | <ul style="list-style-type: none"><li>• Growth of 6.6% in 2005, 5.9% in 2006</li></ul>  |
| Regulatory Environment | <ul style="list-style-type: none"><li>• Industry faces among most stringent systems in the world</li></ul>                          |

### United Kingdom

- |                        |  |
|------------------------|--|
| Market Demand          | <ul style="list-style-type: none"><li>• Sales of approximately US\$1.5 billion (2006)</li><li>• High supplement use</li></ul>                                  |
| Market Supply          | <ul style="list-style-type: none"><li>• Top supplier is Merck KgaA (<i>Seven Seas</i> fish oil)</li></ul>  |
| Market Development     | <ul style="list-style-type: none"><li>• Growth stagnating (recently less than 1% annual)</li></ul>   |
| Regulatory Environment | <ul style="list-style-type: none"><li>• Industry faces complex and uncertain regulatory environment; system may be contributing to market stagnation</li></ul> |

### Japan

- |                        |  |
|------------------------|--|
| Market Demand          | <ul style="list-style-type: none"><li>• Sales of approximately US\$10 to 11 billion (2006)</li><li>• High consumer awareness (tradition of use and government education)</li></ul>                               |
| Market Supply          | <ul style="list-style-type: none"><li>• Top 20 companies have more than 50% market share</li><li>• Direct marketing through network/MLM<sup>20</sup> and mail order/internet channels dominates</li></ul>        |
| Market Development     | <ul style="list-style-type: none"><li>• Growth slowing drastically; Recent <i>decrease</i> in sales (-3.9% between 2005 and 2006)</li></ul>  |
| Regulatory Environment | <ul style="list-style-type: none"><li>• Uncertain: safety concerns due to unregulated “so-called health foods”; Perception that government restricts NHP industry in favour of pharmaceutical industry</li></ul> |

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<sup>20</sup> Multi-level marketing, i.e., door-to-door and product demos and mail order channels  
George Morris Centre

## Appendix A: Regulatory Overview by Jurisdiction

This appendix provides an overview of the regulatory systems for functional foods and natural health products in the United States, Australia, the UK and Japan. The overview is an excerpt from similar research that the George Morris Centre is conducting on food regulatory systems in several jurisdictions.

Note that, since most jurisdictions do not regulate functional foods directly, the regulation of health claims represents the indirect regulatory system for these food products<sup>21</sup>. The health claim regulatory system information is directly based on the CANTOX (2007) report “International Comparison on the Management of Health Claims and Novel Foods.” For some jurisdictions, an overview of the discretionary food fortification regulatory environment is also provided, since this system is applicable to some functional foods, as defined in the literature (for example, orange juice fortified with calcium). The food fortification regulatory system overview is also an excerpt from similar research that the George Morris Centre is conducting on food regulatory systems in several jurisdictions (but not attributed to CANTOX).

### **A.1 Regulatory System for Functional Foods and Natural Health Products in the United States**

The following is an overview of the regulatory systems that apply to functional foods and natural health products in the United States. Section A.1.1 describes the functional food regulatory background and section A.1.2 describes the NHP regulatory background for the United States.

#### A.1.1 United States Regulatory System for Health Claims and Food Fortification

This section is an excerpt from the CANTOX (2007) report “International Comparison on the Management of Health Claims and Novel Foods.” The references used within the text are those cited by CANTOX and can be found in the original report. Note that, since most jurisdictions do not regulate functional foods directly, the regulation of health claims represents the indirect regulatory system for these food products. The section concludes with a description of the discretionary food fortification regulatory environment in the United States, since this system is applicable to some functional foods, as defined in the literature (for example, orange juice fortified with calcium). The food fortification regulatory system overview is an excerpt from similar research that the George Morris Centre is conducting on food regulatory systems in several jurisdictions (and not attributed to CANTOX).

#### *Organization and Function of Relevant Regulatory Bodies*

The Office of Nutritional Products, Labelling, and Dietary Supplements (ONPLDS), Center for Food Safety and Applied Nutrition, Department of Health and Human Services, United States Food and Drug Administration (FDA) is responsible for developing policy and regulations for dietary supplements; nutrition labelling; development of food standards; and, scientific

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<sup>21</sup>Health claims are used to identify functional foods as functional on the market. Therefore, the health claim regulatory system applies to Leatherhead’s strict definition of functional foods: “everyday food and drink products (not pills or potions) that *bear a health claim* implying that the product has a physiological effect over and above that of just nutrition.” The health claim regulatory system, however, does not apply to functional foods that do not make health claims, as defined by Leatherhead’s broad definition. These foods are not typically regulated (unless they fall under other regulatory obligations, as in the case of novel food/food ingredients, food additives etc., which is outside the scope of this research).

evaluation to support regulations and policy development (U.S. FDA, 2007b). ONPLDS receives and evaluates health claim petitions.

### *Relevant Legislation*

The *Federal Food, Drug and Cosmetic Act*, the *Food and Drug Administration Modernization Act* (FDAMA) of 1997; the *Code of Federal Regulations* (CFR), and the *Nutrition Labelling and Education Act* (NLEA) of 1990 are relevant food legislation in the United States (U.S. FDA, 2006e).

NLEA was designed to make available scientifically valid information, to consumers, about the foods they eat. Among other provisions, NLEA authorized FDA to allow statements that describe the relationship between a nutrient and a disease or health related condition on foods and dietary supplements – *i.e.*, health claims (U.S. FDA, 1999a).

FDAMA amended the *Federal Food, Drug, and Cosmetic Act* relating to the regulation of food, drugs, devices, and biological products to adapt FDA's operations to the 21<sup>st</sup> century's advances in technology and trade. FDAMA eliminated the requirement of FDA's pre-market approval for most food packaging and substances that come into contact with food, and expanded procedures for the authorization of health claims and nutrient content claims (U.S. FDA, 1998a).

### *Profile and Regulation of Health Claims*

Health claims refer to an implied or expressed statement on foods that represent a relationship between a substance (*i.e.*, specific food or component of food) and a disease (damage to an organ, part, structure, or system of body) or health-related condition (a state of health that leads to a disease) (U.S. FDA, 2006d).

Foods and dietary supplements that permissibly characterize a relationship of a food to a disease or health-related condition are not regulated as drugs solely because they contain such claims (U.S. FDA, 2004).

Health claims are of two types: qualified (by FDA) or authorized (by FDA, a federal scientific body or the National Academy of Sciences). Structure/function claims and nutrient content claims are not considered health claims. All claims can be made for foods and dietary supplements (U.S. FDA, 2003b).

Although structure/function claims are not classified as health claims, they can describe a relationship between food and health (*e.g.*, health maintenance, general well-being) or conditions associated with various life stages that naturally occur (*e.g.*, menopause symptoms). Structure/function claims must not express or imply a disease state or conditions/processes/symptoms/signs that lead to or are characteristic of a disease that are not also characteristic of a non-disease state.

Conventional foods differ in their eligibility for structure/function claims compared to dietary supplements in that the subject of the claim for the former must have "nutritive value" (a value in sustaining human existence by such processes as promoting growth, replacing loss of essential nutrients, or providing energy) - a criterion not required for dietary supplements. Additionally, for conventional foods, FDA does not have to be notified of structure/function claims nor is a disclaimer required; the disclaimer for dietary supplements making structure/function claims must state "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease" (U.S. FDA, 2002a,

2003b).

Prior to FDAMA, companies could not use a health claim or nutrient content claim in food labelling unless FDA published a regulation authorizing such a claim. FDAMA permits distributors and manufacturers to use such claims on foods, without a published regulation, if such claims are based on current, published, authoritative statements from certain federal scientific bodies or the National Academy of Sciences and upon notification to, and without rejection by, the FDA (U.S. FDA, 1998b).

#### *Application of Regulatory System to Functional Foods*

Currently, FDA has neither a definition nor a specific regulatory framework for foods marketed as “functional foods”. FDA regulates functional foods under the same regulatory framework as conventional foods.

FDA does not consider dietary supplements to be encompassed by the term functional foods. Dietary supplements have their own definition in the regulatory framework prescribed by Congress in the Dietary Supplement Health and Education Act of 1994 (DSHEA). DSHEA specifically excludes from the definition of dietary supplement any product that is “represented for use as a conventional food or as a sole item of a meal or the diet” (U.S. FDA, 2000).

Although FDA is confident that the existing provisions of the *Federal Food, Drugs and Cosmetic Act* are adequate to ensure that conventional foods being marketed as functional foods are safe and lawful, FDA held a public hearing December 6, 2006 to examine how functional foods fit into existing regulatory regimes and how FDA should regulate functional foods (U.S. FDA, 2006f). The comment period on this topic was extended to March 5, 2007 (U.S. FDA, 2007c). The FDA has also discussed and deliberated issues pertaining to structure/function claims given the proliferation of functional foods. In a February 2000 meeting (U.S. FDA, 2000), interested parties met to discuss a conceptual framework for structure/function claims on food, raising lucrative questions<sup>22</sup>.

Unlike dietary supplements, conventional foods and functional foods (since they are regulated under the same framework of conventional foods), can include structure/function claims without notifying the FDA and which do not require a FDA disclaimer stating that the product is not intended to diagnose, treat, cure, or prevent any disease, as is required for dietary supplements.

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<sup>22</sup> Is there need for another category – e.g., functional foods?

How can structure/function claims be distinguished from other claims – e.g., drug claims, health claims?

Would a requirement of GRAS and/or a food additive status be an appropriate and adequate safety net with or without additional criteria?

Is it possible or important to distinguish “naturally occurring” ingredients from “added ingredients”?

Is there a distinction between: a) materials derived from plant or animal food sources?; b) materials derived from sources other than plants or animals (e.g., mineral sources, chemical synthesis)?

Is the requirement for a food component (i.e., active ingredient) to have “nutritive value” for structure/function claims an appropriate and adequate anchor for providing guidance and evaluating structure/function claims?

How can drugs be kept distinct from foods?

Should there be disqualifying nutrients or disqualified vehicles?

What is the role of consumer research in evaluating understanding, interpretation, and effectiveness of claims?

Should disclaimers be required? Do they have any impact?

Should there be pre- and post-market notification requirements?

Should positive lists of permitted claims be maintained? Should the requirements for permitted claims be specified?

What is a “gold standard” vision for a conceptual framework for structure/function claims on conventional foods?

Although structure/function claims should be used to describe the role of a nutrient or dietary ingredient intended to affect normal structures or functions in humans or describe general wellbeing (signs, symptoms that are characteristic of non-disease states) (U.S. FDA, 2003b), their wording can easily be perceived by consumers to imply disease risk reduction or reduction of signs/symptoms associated with disease (U.S. FDA, 2000).

### *Regulatory Process for Discretionary Food Fortification*

This is an excerpt from similar work the Centre is conducting on food regulatory systems in several jurisdictions.

In the United States, vitamins and mineral nutrients are regulated under Fortification Policy (CFR, Title 21, Part 104 – Nutritional Quality Guidelines for Food) (Smith, 2007a). However, according to Smith (2007), “the guidelines are not prescriptive and thus permit the loosely regulated addition of vitamins and minerals to many foods.” The 1980 guidelines remain the most recent fortification regulations to date. The Fortification Policy Statement of Purpose CFR 104.20 states that “

*“The Food and Drug Administration does not encourage the indiscriminate addition of nutrients to food, nor does it consider it appropriate to fortify fresh produce; meat, poultry, or fish products; sugars; or snack foods such as candies and carbonated beverages. To preserve a balance of nutrients in the diet, manufacturers who elect to fortify foods are urged to utilize these principles when adding nutrients to food.”*

*According to the policy, a “nutrient...may appropriately be added to a food”:*

- 1) “to correct a dietary insufficiency”, as long there is “sufficient information ...to identify the nutritional problem and the affected population groups, and the food is suitable to act as a vehicle for the added nutrients.”*
- 2) “to restore such nutrient(s) to a level(s) representative of the food prior to storage, handling and processing...”*
- 3) “to balance the vitamin, mineral, and protein content...” (goes further to explain criteria)*
- 4) “to avoid nutritional inferiority” when replacing a traditional food”*

Historically, food fortification was a public health initiative devised to remedy nutritional deficiencies in target population groups. For example, milk was fortified with vitamin D to prevent childhood rickets and flours and breads were fortified with B vitamins to remedy against nutritional deficiencies. More recently, grain-based cereals were required to be fortified with folate to reduce neural tube birth defects. Food and beverage companies have since seen the opportunity in fortifying foods now that consumers are looking for ‘functional foods’ to attain added health benefits.

The FDA had tried to tighten its grip on food fortification but was restricted by the 1994 Dietary Supplement Health Education Act (DSHEA), which further allowed industry to make health claims without pre-market approval (Cannon, 2006). To summarize, FDA fortification principles are guidelines and therefore the FDA has little authority to regulate voluntary food fortification.

### *A.1.2 United States Regulatory System for Natural Health Products (Dietary Supplements)*

This is an excerpt from similar work the Centre is conducting on natural health product regulatory systems in several jurisdictions. The section describes the governing authority, structure and responsibility and market approval process for natural health products in the United States.

### *Natural Health Product Regulatory System Governing Authority*

According to Ag-West Bio Inc. (2007), in the US, natural health products generally fall into the category of “dietary supplements” and are regulated under the Food and Drug Administration’s *Dietary Supplement Health and Education Act 1994*. However, FDA approval is not required for the marketing of dietary supplements (Centre for Food Safety and Applied Nutrition, 2007).

Alternatively, vitamins and mineral nutrients are regulated under Fortification Policy (CFR, Title 21, Part 104 – Nutritional Quality Guidelines for Food) (Smith, 2007a). However, as mentioned above, food fortification is loosely regulated in the United States.

### *Natural Health Product Regulatory System Structure and Responsibility*

According to the US Food and Drug Administration, the responsibility of ensuring safety of a dietary supplement falls under the manufacturer of the product. The manufacturer is also responsible for accurate (“truthful and not misleading”) labelling of the product. The FDA only steps in to ensure product safety after the product has been marketed by monitoring the dietary supplement market (Centre for Food Safety and Applied Nutrition, 2007).

The post-marketing responsibilities of the FDA include (Centre for Food Safety and Applied Nutrition, 2007):

- Monitoring of voluntary dietary supplement adverse event reporting
- Monitoring of product information (labelling, claims, package inserts and accompanying literature)

The US food supplement regulatory environment has been amended recently. In June 2007, the FDA introduced a final rule related to current good manufacturing practice requirements (CGMPs) for dietary supplements. Under the final rule, manufacturers are additionally responsible for establishing quality of food supplement products, including identity, purity, quality, strength and composition. The FDA will also institute a requirement that industry report “all serious dietary supplement adverse events” starting at the end of 2007 (US Food and Drug Administration, 2007).

### *Natural Health Product Regulatory System Marketing Approval*

Manufacturers of dietary supplements do not have to get approval of products from the FDA. However, they are responsible for submitting “a premarket notice and evidence of safety for any supplements they plan to sell that contain dietary ingredients that were not marketed as dietary supplements before DSHEA was passed—except that the premarket notice is not needed if the new dietary ingredient had previously been used as in ingredient in food” (US Food and Drug Administration, 2007). The FDA uses this information to monitor dietary supplements after they are on the market (US Food and Drug Administration, 2007).

## **A.2 Regulatory System for Functional Foods and Natural Health Products in Australia**

The Australia New Zealand Food Standards Code regulates food according to their intended uses either as part of the general dietary intake for nutritional purposes (i.e., general purpose foods), or for special nutritional purposes such as meal replacement and infant formulae (i.e., special purpose foods) (Australia New Zealand Food Authority, 2002). Functional foods are not defined in food legislation and thus, do not fall into either of the food categories just described.

As such, Food Standards Australia New Zealand (FSANZ) has proposed the following definition for functional foods:

*Functional foods are similar in appearance to conventional foods and are intended to be consumed as part of a usual diet, but have been modified to have psychological roles beyond the provision of simple nutrient requirements (MacDonald, 2004).*

FSANZ does not have a formal definition for functional foods and rather than regulate functional foods as a whole, they regulate the component parts. Thus, they regulate fortification, novel foods, nutrition and health claims (Peachey, 2005).

Natural Health Products are regulated by a different government agency, the Therapeutic Goods Administration (TGA) which is a division of the Department of Health and Ageing (Ghosh et al., 2006). This is the same agency that regulates drugs and pharmaceuticals.

The following is an overview of the regulatory systems that apply to functional foods and natural health products in Australia. Section A.2.1 describes the functional food regulatory background and section A.2.2 describes the NHP regulatory background for Australia.

#### A.2.1 Australian Regulatory System for Health Claims and its Application to Functional Foods

Section A.2.1 is an excerpt from the CANTOX (2007) report “International Comparison on the Management of Health Claims and Novel Foods.” The references used within the text are those cited by CANTOX and can be found in the original report. Note that, since most jurisdictions do not regulate functional foods directly, the regulation of health claims represents the indirect regulatory system for these food products.

##### *Organization and Function of Relevant Regulatory Bodies*

Australia (AU) and New Zealand (NZ) have a unified, bi-national agency - *Food Standards Australia New Zealand (FSANZ)* – that is an independent, expert scientific body. It was established under the *Food Standards Australia New Zealand Act (FSANZ Act)* and is responsible for developing and amending food standards (*i.e.*, food regulations) (FSANZ, 2007a, 2007e).

Food standards are mandatory legal requirements for foods sold in AU and NZ, covering food safety and the content and labelling of foods (FSANZ, 2007e). They are developed by FSANZ either by application from any agency, body, or person, or by a proposal of its own initiative (FSANZ, 2007b). In addition to the best available scientific evidence, legislative requirements of the FSANZ Act, government policies, international treaties, economic and social impacts, and risk analyses are considered in the development or amendment of a food standard (FSANZ, 2007a).

To achieve broad community support for their work and public confidence in regulatory decisions, FSANZ collaborates with various stakeholder groups. Consultation with the community is an essential part of FSANZ's decision-making process (FSANZ, 2007a). FSANZ is comprised of 146 public service employees. Standards or variations to standards are approved by the FSANZ Board which then notifies its decisions to the *Australia and New Zealand Food Regulation Ministerial Council (ANZFRMC)*. If ANZFRMC does not request to review a draft standard within 60 days, it is gazetted by FSANZ and automatically becomes law (FSANZ, 2007a).

### *Relevant Legislation*

Food standards appear in the *Australia New Zealand Food Standards Code* (“the Code”) which came into effect December 2000. The Code covers all foods produced and imported into AU and NZ. It is enforced by Australian State and Territory governments and the New Zealand Government through their Food Acts and Regulations; non-compliance with the Code incurs penalties. The process for amending the Code is prescribed in the FSANZ Act. Any agency, body, or person can make an application to vary the Code (FSANZ, 2007b).

In December 2003, ANZFRMC requested that FSANZ propose a new framework for the regulation of Nutrition, Health and Related Claims (FSANZ, 2007e) and established a policy guideline to guide this process (Australia New Zealand Food Regulation Ministerial Council, 2004). The impetuses for a new management system for claims were three-fold and related to consumers and their value of nutrition, health and choice; industry and their interest in a regulatory landscape that enables product development and marketing opportunities; and inconsistency in the marketplace with claims being managed by various regulations or voluntary codes of practice (established by industry) (FSANZ, 2005a, 2007f).

Three consultations were held on FSANZ’s proposed management system for nutrition, health and related claims – Standard 1.2.7 – occurring in 2004 (Initial Assessment Report), 2005 (Draft Assessment Report), and 2007 (Preliminary Final Assessment Report) (FSANZ, 2004, 2005a, 2007f). FSANZ anticipates that final recommendations on health claims will be ready for consideration by the Ministerial Council in May 2008.

### *Profile and Regulation of Health Claims*

Currently, nutrient content claims (e.g., “this food is high in fibre”) and some function claims (e.g., “calcium is good for healthy bones and teeth”) are allowed, while health claims are prohibited due to Standard 1.1A.2. The prohibition is on statements that imply the food is slimming or has weight-reducing properties; imply the food has therapeutic or prophylactic action; include the word “health” or similar words as part of the name of the food; give advice of a medical nature; or name a disease or physiological condition. Only one claim, relating folic acid to prevention of neural tube defects, is exempt from this prohibition (FSANZ, 2007c, 2007e).

Standard 1.2.7 is being proposed by FSANZ to revoke Standard 1.1A.2 (FSANZ, 2005a, 2007g). As a consequence, a wider range of health claims will be allowed (FSANZ, 2007c), including claims that mention a physiological condition. Unless permitted by the Code, claims will not be allowed to refer to the prevention, diagnosis, cure or alleviation of a disease, ailment, defect or condition, or their symptoms (Australia New Zealand Food Regulation Ministerial Council, 2004). Four claims have been substantiated by FSANZ, relating foods to disease-risk reduction, which will be available for use once Standard 1.2.7 has been approved (FSANZ, 2007e).

Standard 1.2.7 proposes three categories of claims, two of the three categories considered are health claims (nutrition content claims; general level health claims) and high-level health claims (FSANZ, 2007g). Unlike high-level health claims that would require pre-approval by FSANZ with an application to vary the Code, nutrition content claims and general level health claims would not. Rather, evidence to support their truthfulness would have to be produced by the manufacturer upon request by an enforcement agency (FSANZ, 2005a, 2007c,e,f,g).

### *Application of Regulatory System to Functional Foods*

FSANZ's guidance on health claim substantiation applies to functional foods in that the subject of general level or high-level health claims can relate to the "property" of a food. Functional foods would likely classify as "novel foods" - foods that do not have a history of significant human consumption by the broad community in Australia or New Zealand; non-traditional foods that have features or characteristics which raise possible safety concerns (FSANZ, 2005c).

Novel foods and novel food ingredients are regulated by Standard 1.5.1 – Novel Foods – of the Code and must undergo a pre-market safety assessment before sale in Australia or New Zealand (FSANZ, 2005c). For any food or food ingredient deemed to be novel, an application must be made to FSANZ to vary the Code since all novel foods/novel food ingredients are listed in a Table in Standard 1.5.1 (FSANZ, 2005c). Applications on novel foods or novel food ingredients require technical information (e.g., physical and chemical properties; impurity profile; manufacturing process; identity and purity; analytical method for detection); safety information (history of use in other countries; composition; method of preparation and specifications; allergenicity potential; metabolism/toxicokinetic studies; animal toxicity studies; human tolerance studies); dietary exposure to the novel food (including target groups and risk groups); nutritional impact of the novel food; impact on consumer understanding and behaviour; and impact on the food industry (Commonwealth of Australia, 2007).

#### A.2.2 Australian Regulatory System for Natural Health Products

This is an excerpt from similar work the George Morris Centre is conducting on natural health product regulatory systems in various jurisdictions. The section describes the governing authority, structure and responsibility and market approval process for natural health products in Australia.

In Australia and New Zealand, natural health products, also known as traditional or alternative medicines, are classified as complementary medicines (Ghosh et al., 2006) and are defined in the *Therapeutic Goods Act (1989)* – section 52F (Ghosh et al., 2006). However, if they are sold as food they may be classified as caffeinated beverages or food drinks (Ghosh et al., 2006). The category of complementary medicines includes herbs, minerals, nutritional and dietary supplements, homeopathic medicines and aromatherapy oils (Ghosh et al., 2006).

##### *Governing Authority and Structure and Responsibility*

In Australia, complementary medicines are regulated under therapeutic goods/products legislation which is administered by the Therapeutic Goods Administration (TGA) division of the Department of Health and Ageing (Ghosh et al., 2006). The *Therapeutic Goods Act 1989*, which came into effect in 1991, lays out the provisions of complementary medicine registration and use.

In the future, it is intended that a single agency will regulate therapeutic products in place of the Australian TGA and the New Zealand Ministry of Health's Medicines and Medical Devices Safety Authority (Medsafe)<sup>23</sup>. The intended name for this joint "Trans-Tasman" agency is the Australia New Zealand Therapeutic Products Authority (ANZTPA) (Ghosh et al., 2006).

However, according to the Australian Therapeutic Goods Administration (Australian Government, 2007), ANZTPA development has been postponed because "the New Zealand

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<sup>23</sup> Currently, in New Zealand, the Ministry of Health's Medicines and Medical Devices Safety Authority (Medsafe) administers complementary medicines legislation (Ghosh et al., 2006).

Government was unable to secure the support needed to pass their implementing legislation to establish the Australia New Zealand Therapeutic Products Authority (ANZTPA) through its parliament” (Australian Government, 2007). The two countries still plan to amalgamate their therapeutic product regulatory frameworks in the future (Australian Government, 2007). The difficulty of this amalgamation is thought to be because the current NZ regulations are not as stringent as the Australian regulations and through this amalgamation NZ would be acquiring the more stringent regulations of Australia (NBJ, 2007a).

### *Marketing Approval*

The US Commercial Service suggests that the Australian regulations of supplements and natural products are the most stringent in the world because it is regulated under the same authority as pharmaceuticals and prescription drugs. All supplements and natural products must be registered with TGA before sales can occur in Australia and in order to be registered, they must meet the same requirements as pharmaceuticals. In addition, foreign companies need to have an Australian partner who handles the importation and be responsible for the sale of the products in Australia (NBJ, 2007a).

NBJ (2007a) reports that currently, commercialization of a product can be slow if the active ingredient of that product is not already on the “Approved List”. The authors cite the example of a pine needle extract application that took 22 months to receive an approval recommendation from the TGAs expert advisory. Although this is an example of the system working slowly, the authors also discussed the regulators willingness to be flexible with respect to the rules when approving substances that didn’t necessarily fall easily within the current definitions (i.e. the pine needle extract did not fall easily within the definition of “herbal extracts” as pine is not an herb). The authors suggest that the authority is showing a willingness to make the rules, and make them apply rather than simply enforcing the current rules (NBJ, 2007a). If a product is on the approved list the electronic regulatory system that is in place in Australia allows for the launch of a new product within a two-week turnaround (NBJ, 2007a).

It is also noted by NBJ (2007a) that due to local and global pressure on the TGA to be seen as policing the industry the regulator has implemented compliance procedures. One in every four new products is randomly selected for review. There is also pressure to have the evidence of therapeutic claims submitted pre-product launch. The authors suggest that the most likely outcome of these pressures will be for new products to supply a summary of evidence supporting their therapeutic claims; however, these will be evaluated randomly or evaluated due to a complaint (NBJ, 2007a).

### ***A.3 Regulatory System for Functional Foods and Natural Health Products in the United Kingdom***

The following is an overview of the regulatory systems that apply to functional foods and natural health products in the United Kingdom. In the United Kingdom, legislation, including food standards, is made by the national Government(s), in compliance with EU legislation (National Centre of Excellence in Functional Foods, 2004). Therefore, this overview is for the EU health claim regulatory environment. Section A.3.1 describes the functional food regulatory background and section A.3.2 describes the NHP regulatory background for the European Union.

### A.3.1 European Union Regulatory System for Health Claims and Food Fortification

Section A.3.1 is an excerpt from the CANTOX (2007) report “International Comparison on the Management of Health Claims and Novel Foods.” The references used within the text are those cited by CANTOX and can be found in the original report. Note that, since most jurisdictions do not regulate functional foods directly, the regulation of health claims represents the indirect regulatory system for these food products. The section concludes with a description of the food fortification regulatory environment in the European Union, since this system is applicable to some functional foods, as defined in the literature (for example, orange juice fortified with calcium). The food fortification regulatory system overview is an excerpt from similar research that the George Morris Centre is conducting on food regulatory systems in several jurisdictions (and not attributed to CANTOX).

#### *Organization and Function of Relevant Regulatory Bodies*

The *European Food Safety Authority* (EFSA) is an independent European agency funded by the European Union (EU). It operates separately from the *European Commission* (EC) (the executive branch of the European Union), *European Parliament* (EP) (parliamentary body of the European Union), and 27 EU Member states (EFSA, 2007a).

EFSA is committed to providing objective, independent, science-based advice and clear communication on existing and emerging risks; it is a “risk assessor”. Scientific opinions and advice produced by EFSA are initiated by requests from the EC, EP, and Member States, or by EFSA itself. EFSA’s assessments help the “risk managers” (EC, EP, and Member States) manage risk and develop sound European policies and legislation (EFSA, 2007a).

EFSA’s activities are guided by a set of key values: openness and transparency; excellence in science; independence; and, responsiveness. EFSA’s scope of work covers nutrition; food and feed safety; animal health and welfare; and, plant protection and plant health (EFSA, 2007a).

#### *Relevant Legislation*

The European Parliament adopted a new regulation for nutrition and health claims on foods – Regulation (EC) No. 1924/2006 (hereafter referred to as “the regulation”) which became applicable from July 2007 (European Parliament, 2006). The impetuses for the EU regulation were many: to facilitate the free movement of foods; create equal conditions for competition (currently member states differ in their regulations of nutrition and health claims); facilitate consumer choice; and to ensure a high level of consumer protection (European Parliament, 2006). The regulation is intended to harmonize laws and regulations of Member States pertaining to nutrition and health claims (European Parliament, 2006).

#### *Profile and Regulation of Health Claims*

Claims referring to the amount or calories of a nutrient or substance in the food (*i.e.*, nutrition claims) are not considered health claims whilst those referring to health or disease, such as Article 13 and Article 14 claims, respectively, are considered health claims. Article 14 claims make reference to reduction of disease risk or to children’s development and health. Article 13 claims are claims other than those referring to the reduction of disease risk or to children’s development and health and relate to the role or a nutrient/substance in growth, development, and functions of the body; psychological and behavioural functions; slimming or weight control or a reduction in sense of hunger, increase in the sense of satiety or reduction in available energy from the diet (European Parliament, 2006).

Nutrition and health claims are approved by EFSA and their use, if not restricted (due to claim substantiation being based on proprietary data), is available to any food business operator so long as eligibility criteria are met. Evidence requirements for the approval of Article 13 claims are very different from the requirements for Article 14 claims; the latter requires a formal scientific substantiation dossier (European Parliament, 2006).

#### *Application of Regulatory System to Functional Foods*

The subject of nutrition claims in the EU can be an “other substance”; that is, a substance other than a nutrient that has a nutritional or physiological effect (European Parliament, 2006), such as a bioactive. Moreover, the subject of Article 13 and Article 14 claims can be a food constituent (e.g., a bioactive). Functional foods thus fall into the scope of regulation of foods with health claims.

Additionally, within EFSA, there is a Panel which provides independent scientific advice on the safety of food processes excluding cooking (e.g. irradiation) and the safety of substances deliberately added to food or used in contact with food, including “so-called functional ingredients” commonly found in functional foods (EFSA, 2007c).

#### *Regulatory Processes for the Voluntary Fortification of Foods*

This description of the EU regulatory system for food fortification is an excerpt from similar work the Centre is conducting on food regulatory systems in several jurisdictions.

The European General Food Law Regulation, Regulation (EC) No. 178/2002, was established in 2002. The Regulation prescribes the “general principles and requirements of food law...and procedure in matters of food safety” (Coppens et al., 2006). Regulation development also resulted in the establishment of the European Food Safety Authority (EFSA) (Coppens et al., 2006).

The regulation for the fortification of foods, Regulation 1925/2006 was officially adopted in July 2007. This regulation deals only with the voluntary fortification of foods by food manufacturers, and not mandatory fortification of certain foodstuffs. Mandatory fortification rules differ among member states and these rules and regulations will remain within the member states’ jurisdiction.

Regulation 1925/2006 sets out a positive list of vitamins and minerals that can be added to foodstuffs and a positive list of sources of vitamins and minerals that may be used in the Community Register. There will be a transitional phase for products that are on the market that do not meet the requirements, for example the vitamins or minerals are not on the positive list.

The information on the label must comply with article 4(1), group 2, of Directive 90/496/EEC on nutrition labelling (Brans, 2006). Labels can have statements regarding the addition of the vitamins and/or minerals but that these statements must not be misleading. Nutrients added to foods without a desirable nutritional profile (with a high sugar, fat or salt content) will not be able to make a claim as outlined in the new nutrition and health claims regulation (Brans, 2006).

Minimum and maximum amount levels must be met. Minimum and maximum levels are not yet tabled and proposals for these amounts may be submitted to the Commission up to January 19 2009. At which time the Commission will present the proposals, along with scientific advice from EFSA to the Standing Committee on the Food Chain and Animal Health (Brans, 2006).

### A.3.2 European Union Regulatory System for Natural Health Products (Food Supplements)

This is an excerpt from similar work the Centre is conducting on natural health product regulatory systems in several jurisdictions. The section describes the governing authority, structure and responsibility and marketing requirements for natural health products in the European Union.

The European Union has harmonized its regulatory process for food supplements, but not all natural health products. The European Parliament and the Council of the European Union define food supplements as follows (Coppens et al., 2006):

*...foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities.*

According to Coppens (2006), food supplements were nationally regulated in the EU until 2002, when the Food Supplements Directive 2002/46/EC came into effect. Annex I and Annex II of this directive provide a list of the vitamins and minerals that can be used in the manufacture of food supplements. The European Commission is responsible for authorizing the maximum daily recommended amount of the vitamins and minerals listed in Annex I and Annex II. It sets these levels by conducting scientific risk assessment that account for the sensitivity of different consumer groups and the intake of vitamins and minerals from other sources (Article 5). Minimum amounts must also be set, where appropriate, to ensure that a significant amount of the vitamin or mineral is present in the supplement (Article 5).

The label on the food supplement must contain the daily recommended amount for consumption, a warning not to exceed the daily recommended dose, that the supplement should not be used as a substitute for a varied diet, and the word “supplement” must be used (Article 6). The label and any associated advertising must not attribute to the supplement the property of preventing, treating, or curing a disease (Article 6). There must also be no mention that a varied diet cannot provide appropriate quantities of nutrients in general (Article 7). To ensure compliance with the labelling requirements, the manufacturer or importer of the food supplement may be required to submit a draft of the label to each member country of the EU where it plans to market the supplement (Article 10) (Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (Text with EEA relevance), 2002).

If a member country conducts its own research and has detailed grounds for establishing that a food supplement as it is currently marketed poses a human health risk, it can temporarily restrict trade of the supplement (Article 12). The country must then notify the European Commission which will immediately deliver its opinion on the new evidence with the assistance of the Standing Committee on the Food Chain and Animal Health (Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (Text with EEA relevance), 2002).

### **A.4 Regulatory System for Functional Foods and Natural Health Products in Japan**

The following is an overview of the regulatory systems that apply to functional foods and natural health products in Japan.

This section is an excerpt from the CANTOX (2007) report “International Comparison on the Management of Health Claims and Novel Foods.” The references used within the text are those cited by CANTOX and can be found in the original report. Note that it appears in the CANTOX discussion that the terms functional foods and natural health products correspond to the Japanese terms “health foods” and “so-called health foods”, respectively.

### *Organization and Function of Relevant Regulatory Bodies*

Within the Japanese government, the government body that regulates foods and drugs is the *Ministry of Health, Labour and Welfare* (MHLW). MHLW provides standards and regulations pertaining to food. More specifically, within the MHLW exists a *Pharmaceutical and Food Safety Bureau* within which there is a *Department of Food Safety*. The Department of Food Safety has three divisions: *Policy Planning Division*; *Standards and Evaluation Division*; and an *Inspection and Safety Division*. The Standards and Evaluation Division establishes specifications and standards for food, food additives, food labelling, pesticide residues, and animal drug residues. Within the Standards and Evaluation Division is the *Office of Health Policy on Newly Developed Food* which is responsible for nutrition labelling standards, foods with health claims, dietary supplements, and the safety assessment of genetically modified foods (MHLW, 2006d).

### *Relevant Legislation*

In Japan, products are classified as food or drugs; there is no in-between category for products considered as dietary supplements.<sup>24</sup> Thus, relevant legislation is food-related and pharmaceutical-related, to address issues pertaining to conventional foods, and products in non-conventional food form (e.g., tablets, capsules) that are not considered drugs. Relevant legislation includes the *Food Safety Law*, *Food Sanitation Law* and the *Pharmaceutical Affairs Law* (Ohama et al., 2006).

Based on the *Pharmaceutical Affairs Law*, two lists are issued by MHLW that identifies substances as “drugs” or “non-drugs”. Each of these lists is subcategorized into substances of plant origin, animal origin, or others (e.g., food additives). Vitamins, minerals, and 23 amino acids are excluded from the drug category (Ohama et al., 2006).

The *Health Promotion Law* prohibits exaggerated and misleading claims on foods and requires claims to be substantiated by scientific evidence. Non-compliance with the *Health Promotion Law* results in imprisonment for up to six months or a fine (Ohama et al., 2006).

### *Profile and Regulation of Health Claims*

Foods with health claims include “Foods with Nutrient Function Claims” (FNFC) and “Foods for Specified Health Uses” (FOSHU). They are regulated by the *Health Promotion Law* and are thus prohibited from making exaggerated, misleading claims and claims that are not substantiated by

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<sup>24</sup> Japan’s definition of a drug includes (Ohama et al., 2006):

- Items recognized in the Japanese Pharmacopoeia;
- Items (other than quasi-drugs) that are intended for use in the diagnosis, cure, or prevention of disease in man and animal, and which are not equipment or instruments;
- Items (other than quasi-drugs and cosmetics) that are intended to affect the structure or functions of the body of man or animal.

scientific evidence. “Nutrient Function Claims” on FNFC are pre-approved claims by MHLW. “Specific health uses” for FOSHU require approval by MHLW through a standard, qualified, or individual route of approval.

“So-called health foods” are another category of foods that make claims that are exaggerated and misleading and have led to consumer contamination with toxic substances, over-dosing, and contraindicated drug interactions. Reasons for this are twofold: 1. So-called health foods are not regulated by the Health Promotion Law; their regulation depends on various laws; and, 2. So-called health foods do not require approval by MHLW (Ohama *et al.*, 2006).

Japan ranks the scientific evidence to support claims on FNFC or FOSHU according to A, B, or C ranks, in order of decreasing scientific support. Weak science (Rank C) is sufficient to approve FOSHU products through a qualified FOSHU route of approval (Ohama *et al.*, 2006; MHLW, 2006c).

#### *Foods with “Nutrient Function Claims” (FNFC)*

“Nutrient function claims” (NFC) on FNFC are based on rank A (the highest) scientific evidence and are structure/function claims for 17 nutrients, 12 vitamins and 5 minerals. They describe the function of vitamins or minerals in the maintenance of healthy skin and mucosa; vision; utilization of energy from protein or carbohydrates; red cell production; calcium absorption from the gut and growth of bone; protection of body fat from oxidation; cell health; normal foetal growth; maintenance of taste; development of bone and teeth; function of enzymes; bone formation; blood circulation; and energy generation (MHLW, 2006b).

For manufacturers to use NFCs, they must follow specifications regarding levels of the vitamins/minerals to be added in the food and must include warning statements on the foods (MHLW, 2006b).

#### *Foods for “Specified Health Uses” (FOSHU)*

Unlike NFCs, which are claims that refer to the function of nutrients (vitamins and minerals), FOSHU carry claims that refer to the function of nutrients and other food ingredients. Also unlike NFCs, which are structure/function claims, FOSHU includes claims on structure/function or disease-reduction. The claims can be supported by ranks A, B, or C levels of scientific evidence (Ohama *et al.*, 2006).

A product seeking FOSHU status must demonstrate safety, quality and efficacy, although with different rigor depending on whether the product is seeking FOSHU status through “individual”, “standardized”, or “qualified” routes. The “individual” route of approval is for disease-risk reduction claims, of which two have been approved – folic acid and neural tube defects; and calcium and osteoporosis (MHLW, 2006c). Safety, quality, and efficacy are evaluated by different bodies within MHLW (Ohama *et al.*, 2006).

The manufacturers of FOSHU are generally companies with strong research and development that can absorb the costs of demonstrating safety, quality, and efficacy of their products. As of December 2005, approximately 569 products were approved as FOSHU with specified health effects on intestinal conditions; cholesterol/triglycerides; blood sugar; blood pressure; teeth; bone; and iron supply (Ohama *et al.*, 2006). The two most popular health effects are regarding intestinal conditions (approximately 45% of FOSHU claim this effect) and on cholesterol/triglycerides levels (approximately 20.6% of FOSHU claim this effect).

#### *Application of the Regulatory System to Functional Foods*

Although Japan has been credited with coining the term “functional foods” in 1984, the government prohibited the use of this term since it implied “drug-like” effects. As a result, the term “health foods” became widely used. Health foods refer to foods with health claims (FNFC and FOSHU) in addition to “so-called health foods” (Ohama et al., 2006). Japan permits health foods to be sold as tablets, capsules, powders, liquids, etc., although sublingual tablets and sprays into the oral cavity are prohibited. Foods with health claims (i.e., FNFC, FOSHU) are generally functional foods in conventional food form and not in a form typical of dietary supplements (tablets, capsules), whereas “so-called health foods” are generally dietary supplements and mostly include herbal or botanical products (Ohama et al., 2006).

Japan’s regulation of functional foods has been criticized. Although products approved as FOSHU indicate such an approval on the product’s label, the *Japan Health Food and Nutrition Food Association* offers its own “seal of approval” of product, increasing consumer confusion (National Center of Excellence in Functional Foods, 2004).

## Appendix B: Overview of Research and Development by Jurisdiction

This appendix describes literature on research and development in functional foods and natural health products for the four jurisdictions profiled: United States, Australia, United Kingdom and Japan.

### B.1 Research and Development of New Products in the United States

#### Functional Foods

According to Leatherhead Food International (2006), Kellogg's signed an agreement with Martek Biosciences in 2006 to use their omega-3s in new products. Some of these new products have been Nature's Path FlaxPlus and Zoe O's wholegrain flax cereals.

Currently, FDA research is taking place on soya's effect on cholesterol levels. The soya sector has been under scrutiny by the American Heart Association because of its use of the FDA approved claim that soya lowers cholesterol. The American Heart Association reviewed 22 studies that have found a lack of evidence for soya's link on decreasing cholesterol.

According to Leatherhead Food International (2006, p. 153), in the egg sector of the functional food market "price does remain a barrier to further development, as the nutritionally-enhanced eggs are sold at a huge premium over standard lines."

Table B.1 shows the number of new functional beverages, new functional food products and new food or beverage products marketed as added fibre, added calcium or added vitamin/mineral-fortified introduced in the years 2001 to 2006. Product introductions have generally been increasing since 2001 for all three categories of functional products (Mintel, 2006).

**Table B.1 New Product Introductions with a Functional or Fortified Positioning in the United States, 2001-2006**

Year	New Functional Beverage Products	New Functional Food Products	New Food or Beverages Marketed as Added Fibre, Added Calcium, or Vitamin/Mineral Fortified
2001	20	124	282
2002	23	24	567
2003	46	37	866
2004	31	66	1,386
2005	33	106	1,016
2006 <sup>1</sup>	33	147	799

Notes: 1) New introductions through to October 14, 2006.

Source: Mintel, 2006

#### Natural Health Products

No information was found on research and development in the US dietary supplement market.

## B.2 Research and Development of New Products in Australia

### Functional Foods

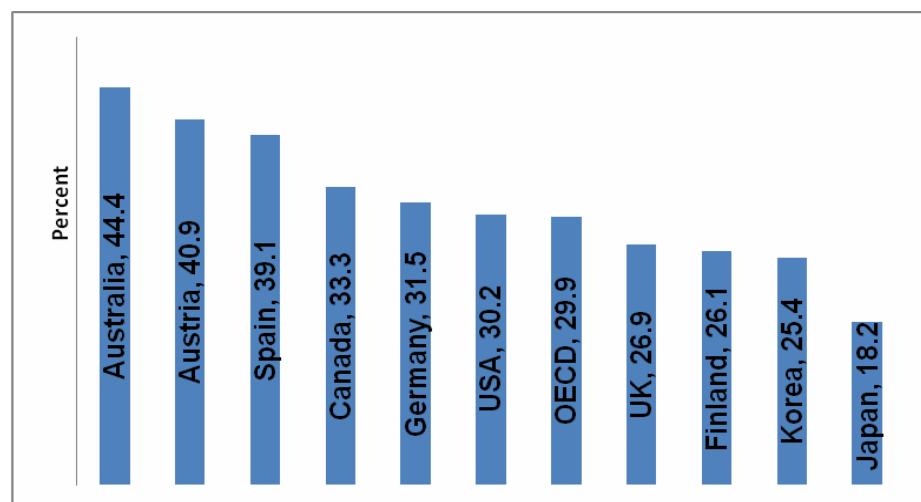
According to the National Centre of Excellence in Functional Foods (2006), the following areas are where there is evidence to support a health claim and thus it is predicted there are new R&D and marketing opportunities:

- Sodium (with or without potassium) and hypertension
- Fruit and vegetables and coronary heart disease
- Whole grains and coronary heart disease
- Saturated and/or trans fat and elevated serum cholesterol or heart disease
- Calcium (with or without vitamin D) and osteoporosis
- Folate and neural tube defects
- Omega-3 fatty acids and coronary heart disease

R&D expenditure in the Australian industry is dominated by large companies. Funding for R&D predominately comes from the industry (95%), with only a small percentage being provided by the government (National Centre of Excellence in Functional Foods, 2006).

Despite it being reported that the majority of funding comes from industry, the same document from the National Centre of Excellence in Functional Foods (2006) reports that Australia's government commitment to R&D outranks Canada, Japan, US and the UK (refer to Figure B.1 below), with 44.4% of gross public expenditure on R&D. The "Backing Australia's Ability" program is an example within this R&D initiative (NCEFF, 2006). Under this program, the Australian Government has committed AU\$8.3 billion (C\$7.95 billion) over the 2001/02- 2010/11 period to promote science and innovation. Functional food R&D falls under this program. The Australian government also offers R&D tax concessions and other incentive support programs to enhance commercialization. Despite this positive environment for R&D, business expenditure on R&D in Australia falls below the OECD average (National Centre of Excellence in Functional Foods, 2006).

**Figure B.1 Percentage of Gross Expenditure on Research and Development Financed by Government, Selected OECD Countries, 2002-03**



Source: (Australian Food Statistics 2005 as cited in National Centre of Excellence in Functional Foods, 2006)

The following organizations in Australia, involved in functional food-related R&D (in some cases not exclusively), demonstrate the focus on and activity in research and development in functional foods in Australia:

1. **The Commonwealth Scientific and Industrial Research Organization (CSIRO)** is Australia's largest research organization, and spends approximately AU\$110 million (C\$101.67 million) each year representing 29% of publicly-funded biotechnology research. Their major areas of focus in functional food R&D are:
  - Bioactive screening and in vivo testing
  - Polyphenol R&D (physiology and pharmacology)
  - Biological assays (biochemical, cellular, tissue and whole animal models)
  - Long term feeding studies (safety, ageing, diet-drug interactions)
  
2. **Food Science Australia** is Australia's largest and most diversified food research organization and a joint venture of CSIRO and the Department of Primary Industries, Victoria. Their major areas of focus in functional food R&D are:
  - Literature reviews, patent searches and opportunity analysis
  - Identification and characterization of bioactive components and functional food ingredients (also includes flavour work)
  - Sensory-consumer interface, Physico-sensory interface
  - Chemical analysis and structural characterization (including LC-MS)
  - Cell based assays
  - Extraction or fractionation of functional food ingredients and bioactive components from
  - Agribusiness raw materials or waste streams
  - Aqueous high power ultrasound as an alternative to organic solvent systems
  - Scalable continuous chromatographic processes
  - Enzymic hydrolysis and peptide fractionation
  - Incorporation of bioactive components, with demonstrated retained efficacy, into ingredients and processed food products. A wide range of pilot scale manufacturing technologies are available.
  - Microencapsulated products, powders, emulsions etc.
  - Emerging processing technologies (low temperature pasteurization etc.) that enhance shelf-life and safety of functional food ingredients and products, e.g., Pulsed Electric Fields, High Pressure Processing, High Power Ultrasonic (National Centre of Excellence in Functional Foods, 2006).
  
3. **Department of Primary Industries (DPI)** - Victoria is made up of four divisions including - Agriculture, Fisheries, Minerals and Petroleum, and Regional Services. The Department of Agriculture has an active R&D interest in the Functional Foods area and is one of the founding partners of the National Centre of Excellence in Functional Food. Their major areas of focus in functional food R&D are:
  - Metabolic health (obesity, diabetes, cardiovascular health)
  - Gut health (colon cancer, inflammation, gut microbiology, probiotics and prebiotics, gut pathogens)
  - Immune Health (immunomodulation, immunoregulation including anti-inflammation, resistance to infectious diseases)
  - Bone health
  - Genome health

In addition to the above industries, universities are also heavily involved in research related to functional foods. Some of these universities include University of Wollongong, Queensland University - Centre for Nutrition and Food Sciences, Curtin University of Technology - School of Public Health, Deakin University - Centre for Physical Activity and Nutrition Research (C-PAN), RMIT University - Food Science Research Group (FSRG) and University of Western Sydney. There are also joint research initiative between universities and the government such as the Cooperative Research Centers (CRC) (National Centre of Excellence in Functional Foods, 2006).

#### *Natural Health Products*

Blackmores, one of Australia's leading complimentary medicine suppliers has been increasing their focus on research and development by partnering with universities and hospitals in product/ingredient trials. They support the Southern Cross University and the University of Queensland in their joint initiative called the Australian Centre for Complementary Medicine Education and Research (ACCMER). They are also supporting a major trial looking at the role of B vitamins in the prevention of secondary stroke, this trial is called VITATOPS and is coordinated by the Royal Perth Hospital (NBJ, 2007a).

### **B.3 Research and Development of New Products in the United Kingdom**

#### *Functional Foods*

According to Mintel (2006b), 130 new functional food products were launched in the UK between January 2005 and January 2006. The largest proportion of these launches was in the functional dairy area (43%), followed by the functional beverage area (41%). Each of these areas experienced over 50 new product launches in the time period.

There has been significant new product development in the yogurt and yogurt drink sector. In 2005, a large number of new functional yogurt products were introduced in the UK market from suppliers such as Muller, Nestle and Yoplait (Mintel, 2006b). Yogurt products for children, especially, have been a focus for new product development. Brand extensions have also contributed to the large number of product introductions in this sector.

The growing functional juice sector is driven by the introduction of new products such as PepsiCo's Tropicana Essentials (to lower cholesterol) in 2006 (Mintel, 2006b).

Although functional foods sectors that are well established in the UK market, such as breakfast cereals, spreads and stimulant drinks, are not experiencing the same growth as the yogurt and drinks and juice sectors, growth may begin to increase again due to industry refocus on research and development in these areas. For example, Kellogg's has been developing a breakfast cereal containing DHA omega-3 oil (Mintel, 2006b).

Research and development in omega-3 containing products has also been the impetus for the growth of the "other" category in the functional food market. This development is a result of the Joint Health Claims Initiative approval of a generic polyunsaturated fatty acids – omega-3 claim. The driving force behind UK market expansion and investment in new product research and development and promotion has been large multinational companies such as Danone and Unilever (Leatherhead Food International, 2006).

#### *Natural Health Products*

No information was found on the research and development of new NHPs in the United Kingdom.

#### **B.4 Research and Development of New Products in Japan**

##### *Functional Foods*

The Japanese Ministry of Agriculture, Forestry and Fisheries (MAFF) provides functional food related cost-share programs for industry. The aim of this funding is to promote development of new technologies for functional food component isolation and purification. Since 1990, MAFF has provided a total of approximately ¥31 million (~C\$403,000) to functional food research and development (Groote, 2002).

The Ministry of Education, Culture, Sports, Science and Technology (MEXT) and the Ministry of Health, Labour & Welfare (MHLW) also contribute funding to functional food related research and development (Groote, 2002). The MEXT provides grants to research universities and their affiliated institutions. For example, between 1996 and 2001, the Ministry funded a total of 27 functional food related research and development projects in the amount of ¥43.3 million (~C\$563,000) (Groote, 2002). Besides establishing and administering the FOSHU approval framework, the MHLW provides financial support for health and safety research. Funding for functional food related research is available under the Environmental Health-Related research programme of MHLW. This programme has provided ¥2.6 million (~C\$33,800) to functional food related research since 1998 (Groote, 2002).

According to a recent Japan Trade and Investment Study assessing Canadian investment opportunities in the Japanese FFNHP market (Bailey, 2007b), “there is no question that almost all of the responsible food and beverage companies in Japan have, or will soon have, established priorities related to the development of health FF & NHP products and/or ingredients.” The study, which involved one-on-one interviews with Japanese companies in this area, revealed that companies are very secretive about their research and development initiatives due to the highly competitive nature of the Japanese FFNHP market (Bailey, 2007b).

The interviewed companies also indicated that they are interested in the development of *Tokuho* (Foods for Specified Health Uses) foods with permitted on-label health claims, but are wary of developing in this area because of “the current high costs and long lead times involved in obtaining government approval for truly new products (with new functional ingredients and new approved health claims)” (Bailey, 2007b). According to the study, these costs and timelines are restricting development of these products for even large companies. For example, according to one interviewed company, “a truly new *Tokuho* product approval (presumably with a new functional ingredient and new health claims) is likely to cost US\$5 million by the time the necessary testing has been done” (Bailey, 2007b).

##### *Functional Foods and Natural Health Products*

Another area of interest for Japanese FFNHP companies is pharmaceutical natural health products. Specifically, this area is a product development focus for companies that are already manufacturing over-the-counter (OTC) and prescriptions drugs (Bailey, 2007b).

The following is an overview of the areas of interest in FFNHP development from the perspective of the interviewed companies in the trade and investment study. Note that this list includes non-food NHPs in addition to functional food and natural health products.

- Examples of specific **health condition technologies** of interest:

- **Obesity-related** ingredients, including clinical trial opportunities in Canada
  - **Metabolic Syndrome** risk factor prevention ingredients clearly separated from directly preventing or curing the disease diabetes
  - **Allergy-related** ingredients
  - **Food Oils** with unique fatty acid and/or protein profiles for various (undefined) health conditions
  - Examples of specific **bioactive technologies** of interest for food:
    - **Lignan enzymes** for use in processing non-GMO grains
    - **Korean ginseng** and **Japanese pumpkins (*kabotcha*)** grown in Canada for processing in Japan
    - **Amino acid** production technologies beyond those currently being used in Japan
    - **Brown seaweed** bioactive extraction procedures
    - **Seaweeds** with skin care efficacy
    - **Collagen peptides** for skin care and cosmeceuticals
    - **New probiotic and enzymes** for R&D collaboration
    - **Peptides** for R&D collaboration
    - **Flax lignans**
    - **Processed starches** from rice, Japanese pumpkin, kudzu, bracken, and lotus root, as well as non-GMO corn and potato starch
  - There is interest in Complimentary and Alternative Medicine (CAM) approaches to the OTC category, subject to the specific regulatory requirements. All of the health related products and ingredients must be “evidence-based” to avoid conflict in Japan with the established pharmaceutical companies.
  - One growing commercial interest in Japan from even the large food and beverage companies is the cosmetics market. Part of the reason is related to the growing complexity and cost of entering the *Tokuho* market for foods with allowed health claims.
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