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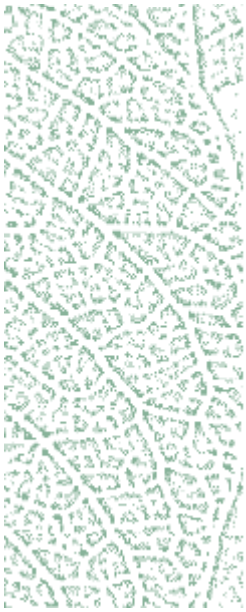
Nutraceutical Market & Industry Information

Natural Health Products (NHP), nutraceuticals and functional foods represent one of the fastest growing markets in the developed world. Increasing consumer expectations that food should provide health benefits beyond simple nutrition is the primary force driving the market. Health Canada (1998) defines a **nutraceutical** as a product that has been isolated or purified from foods and generally sold in medicinal forms not usually associated with food. Nutraceuticals have been shown to exhibit a physiological benefit or provide protection against chronic disease. According to Health Canada (1998), a **functional food** is similar in appearance to a conventional food and is consumed as part of the usual diet. These foods have demonstrated physiological benefits, and/or reduce the risk of chronic disease beyond basic nutritional functions. **Dermaceuticals** are naturally derived plant or animal extracts that are used in skin care products. When applied topically, several natural extracts have medicinal properties such as protecting the skin from water loss as well as reducing redness, irritation and inflammation.

The Canadian Office of Natural Health Products (2000) has proposed that NHPs would include products, which are manufactured, sold, represented for use in humans to maintain or promote health or to treat or prevent disease or conditions. NHP would include products which are comprised of one or more of the following medicinal ingredients: vitamins & minerals; lipids; botanicals; algae and fungus; amino acids; digestive enzymes; micro-organisms (except vaccines and antibiotics); homeopathic preparations and substances used as traditional medicines. This definition would also include nutraceuticals.

The Nutrition Products Market

Current world consumption of natural health products (NHP), nutraceuticals and functional foods is estimated to be between $70



and $250 billion annually depending upon the product categories that are included in the statistics. The U.S. is the largest importer of Canadian NHP, nutraceuticals and functional foods. In the U.S., the sale of nutrition products consisting of natural health products (including dietary supplements and herbs), natural and organic foods, functional foods and natural personal care products, generated $44.5 billion in consumer sales in 1999 (Nutrition Business Journal - NBJ, 2000).

Consumer sales growth in 1999 was approximately 8% or roughly twice that of the U.S. economy (NBJ, 2000). An approximate 10 % annual growth rate over the next three years is anticipated for dietary supplements, functional foods and nutraceuticals with the greatest gains in mass-market sales rather than health food stores. In comparison, the $466 billion conventional food business is growing at a yearly rate of only 2-3% (NBJ, 1998).

According to 1999 statistics published by the NBJ (2000), the supplement market generated $15.4 billion in the U.S. while functional foods amounted to about $16.1 million. NBJ uses a broad definition for functional foods, including "any product with added ingredients or fortification specifically for health or performance purposes". This category includes "designer foods" ranging from cholesterol-lowering spreads such as Benecol and Take Control to ready-to-drink teas with herbs, "performance" foods like sports drinks and bars, hypoallergenic baby foods and soymilk and "enriched" foods like cereal, milk and yogurt.

The Canadian Industry

Canadian market data is difficult to interpret as much of it is extrapolated from U.S. sales and adjusted downwards to take into consideration the belief that U.S. consumers are more ardent users of dietary supplements than are Canadians. According to Dr. Frank Chandler, Past-Chair of the Federal Advisory Panel on Natural Products, annual sales for alternative medicines and natural products in Canada could be as high as $2 billion. However, NBJ (1998) indicated that Canadians purchased approximately $1 billion worth of dietary supplements, nutraceutical and functional food products.

Canadian Nutritional Market Data

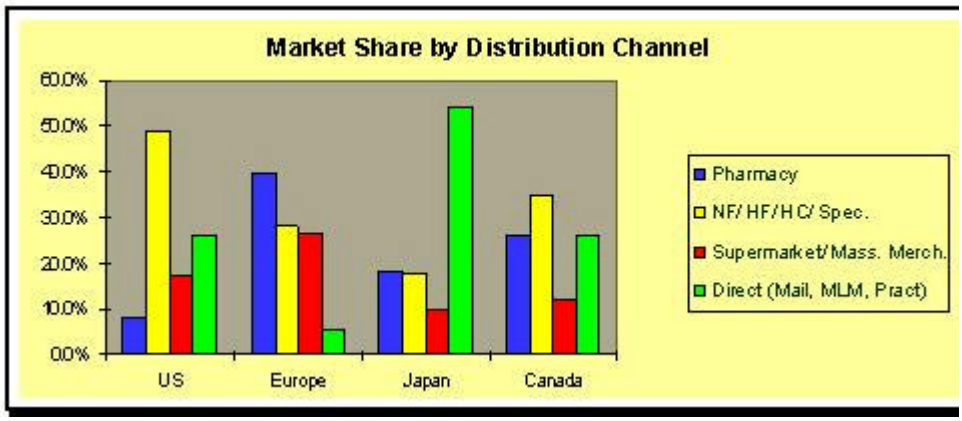
PRODUCT TYPE	**ESTIMATE (U.S. Billion $)**
Nutraceuticals	0.13
Functional Foods	0.50
Vitamins/Minerals	0.04
Dietary Supplements	0.03
Medicinal Herbs	0.28
Sports Beverages	0.05
Total	**$ 1.03**

As in the U.S., the fastest growing market segments in Canada are natural health products, primarily herbal and botanical products. The herbal supplement sector posted a growth rate of 24% between 1996 and 1998 in Canada (Lapsley, 1998). At the 680 Shoppers Drug Marts across Canada, sales of natural health products grew by 14% in 1997 (Canadian Health Food Association, 1997).

Similar to the U.S., there are four main distribution channels for natural health products, nutraceutical and functional foods in Canada:

- Pharmacy: includes sales through traditional pharmacy and drugstore type stores and chains.
- NF/HF/HC/Spec.: Includes sales via Natural Food, Health Food, Health Care, and Specialty Stores.
- Supermarket/Mass Merchandisers: Includes sales from supermarkets and large retail and discount chains.
- Direct: Includes sales from internet, mail order and multi-level marketing companies, as well as direct sales from practitioners.

Market Share by Distribution Channel



NBJ, 1998

This figure demonstrates that there are differences in the distribution channels for these products in different regions. The dominant distribution channels in the U.S. are health food and specialty stores. In Europe, the dominant channel is pharmacies and in Japan the direct sales channel. In Canada, health food and specialty stores dominate but are followed closely by sales in pharmacies and through direct purchase (mail, multi-level marketing or practitioners). Canadians use direct mail purchases for products, principally from the U.S., that are unavailable in the Canadian market.

In an industry survey conducted by KPMG Consultants (1999) for the Saskatchewan Nutraceutical Network, it was predicted that changes in distribution channels in Canada are expected to continue with the following trends:

- Health food stores and dedicated retailers will continue to be the largest distribution channel for a period of time, but will eventually be overtaken by conventional retail outlets, especially as larger manufacturers enter the business.
- On line shopping will continue to grow, especially as Internet providers develop. Traditional mail order will remain a relatively small channel.
- Practitioners and the internet have showed significant growth in sales, and will play an increasing role in early adoption and building image for growth through conventional retailing.

As in the U.S., Canadian market growth in the natural health products, nutraceutical and functional food industry is being driven by demographic, economic and social trends, which indicates that the changes are long term. According to a report published in the Nutrition Business Journal (1998), the key factors driving this growth and changes in the supply chain include:

- Aging populations
- Increasing interest in "healthy living"
- Emphasis on preventative measures to control health care costs
- Increased acceptance and utilization of "alternative" treatments
- 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
- Rising acceptance among doctors, pharmacists and other health professionals
- General consumer dissatisfaction with conventional treatments, therapies and drugs

Overview of the Canadian Industry

There is limited information on the Canadian industry infrastructure in part because of its rapidly evolving nature and due to its relative newness. Furthermore, some of the activities of these companies overlap into the food processing and pharmaceutical industries. The data available for the Canadian industry focuses on a much narrower definition of the nutraceutical industry when compared to the U.S. and was compiled from a draft (unpublished) survey report conducted by Agriculture and Agri-Food Canada (AAFC) based on members of the Canadian Health Food Association and including select larger Canadian companies (Hall, 1998). The results of the survey were disappointing because of a low response rate, and therefore, do not provide a complete picture of the Canadian industry. As indicated earlier, according to the NBJ (1998), Canadian sales of natural health products, nutraceuticals and functional foods were estimated to be $1 B in 1998. However, this study only reported sales at $680 million.

The AAFC survey estimated that the Canadian natural health products, nutraceutical and functional food industry is made up of about 120 companies, many of which are in the processing and retail sectors (Hall, 1998). These companies are distributed widely throughout the country and are located in every province. Approximately 25% of the industry is located in Ontario, with 22% being located in both British Columbia and Quebec. Alberta has the next highest concentration with 14%, Saskatchewan and Nova Scotia each having 6%, with the remaining 3% located in Manitoba, New Brunswick and Newfoundland. This distribution is not surprising in that a greater number of companies are located in the provinces with a fairly large concentration of food and pharmaceutical manufacturers. However, the reader is cautioned that these numbers are conservative and represent primarily those companies that are categorized as "large" in the Canadian context, in size and scope. This survey did not capture the estimated hundreds of small companies across the country that are involved on a limited scale in the production, processing or distribution of natural health products and nutraceuticals (KPMG Consultants, 1999).

For example, in the industry survey conducted by KPMG Consultants (1999), approximately 50 companies in Saskatchewan were identified as being involved in the nutraceutical or functional foods industry. Their estimated total sales in 1998 were between $40 and $50 million. The Saskatchewan nutraceutical industry currently consists mostly of start-up companies. Typically, these new companies are entering the industry as part of a farm diversification strategy to increase farm incomes. The majority of companies have sales of less than one million dollars annually, and many do not have sales estimates. Seventy-five percent of the companies have less than ten employees. Most are either in the research and development phase, or are early in the commercialization phase and are struggling to launch their products. Several of the firms surveyed by KPMG were active in both agricultural production and manufacturing, which suggests that many are entering manufacturing as a way of selling the products they grow. The situation in Saskatchewan is typical of the industries in the Western Canadian and Maritime provinces.

Size of the Canadian Nutraceutical Industry (Based on Dollar Sales)

Size Category	**No. of Companies**	**Avg. Revenue ($)**	**Avg. # of Employees**	**Avg. R&D ($)**	**Tota ($)**
<$1M	20	500,000	20	870,000	10,0
*$1M to $9,999,999	63	3,100,000	50	940,000	197,
*$10M to $49,000,000	20	32,000,000	130	1,200,000	637,
>$50M	17	100,000,000	710	3,300,000	1,66
Total	**120**				**3,34**

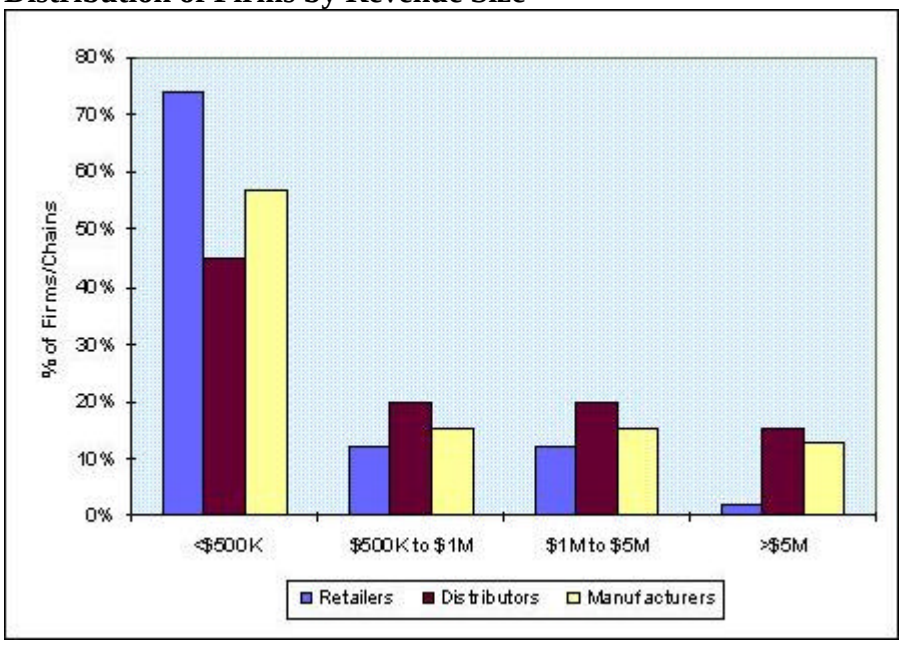
Total	120				3,34

Hall, 1998

As indicated, when compared to the global natural health products, nutraceutical and functional food industry, the Canadian industry is characterized by small and medium sized companies. There are about 20 companies in Canada with less than $1 million in sales, averaging $0.5 million per company. In terms of the number of companies, this is 17% of the market and in terms of sales, approximately 0.5%. The second group has sales in the range of $1 million to $9,999,999 and there are approximately 63 companies in this segment. This group is the largest in terms of number of companies and represents about 53% of the industry, but only $197 million, or 8% of total sales. In the $10 million to $49,999,999 category, there are 20 companies, or 17% of the market. Sales from this group amounted to $637 million, or 25% of total. The average revenue per company for this category is $32 million. Finally, there are 17 companies with sales over $50 million, for a 14% share of the market. In terms of sales, this category is by far the largest, at $1,667 billion, or 66.5% of total market sales. The average sales of these companies is $100 million. Revenues from other activities, including the distribution and sale of other products, manufacturing and sales activity of overseas subsidiaries, etc., may be included in these sales figures.

Another survey conducted by the Canadian Health Food Association (1998), as the non-profit trade association representing 1,100 members of the natural health products industry, showed the same trend reported by Hall (1998) that the industry is dominated by small to mid-size firms. As shown below, there are few firms that have sales greater than $5 million.

Distribution of Firms by Revenue Size



Canadian Health Food Association: Sector Profile, 1998

The size of the company does not appear to have any relationship with the types of products they produce. There are large companies with sales greater than $50 million that handle numerous product lines. These range from nutritional supplements and vitamins and minerals to medicinal products such as herbs. As well, there are medium to large specialized companies that deal only in specific products such as essential fatty acid supplements (gamma-linolenic acid from borage and evening primrose oils and fish oil products). Some of the small companies with sales of less than a million dollars also offer a full range of products.

Employment in the industry varies substantially. Companies with larger revenues generally have more employees, although there is quite a substantial range in the number of employees within size classes. This range suggests that complexity of production and/or marketing is likely the determining factor in the number of employees.

The size of the industry can also be described by categorization into groups based on sales. The following table provides a breakdown of the industry in terms of the number of companies in each size class and the average sales of companies in that group.

The Natural Health Products Industry in Canada

	Sales (million $)	**Employment**	**Sales/empl**
Retailers	$680	10,400	$65,000
Distributor	$203	2,950	$69,000
Manufacturer	$362	5,250	$69,000

Canadian Health Food Association: Sector Profile, 1998

The money spent on R&D by nutraceutical companies is fairly substantial when one considers the relative infancy of the industry. The revenue a company generates is not indicative of the amount of money spent on R&D. In fact, many of the smaller companies have very high R&D budgets, and spend much more money on R&D in comparison to their revenue than do companies with larger revenues. In fact, for companies with revenues of less than a million dollars, the average amount spent on R&D exceeds average revenue. This suggests that smaller companies may be more involved in product development and less focused on commercialization aspects. As well, these companies are likely receiving government funding to supplement their R&D budgets. Larger Canadian companies tend to spend a much smaller percentage of revenue on R&D. This is probably due to the ability to purchase the rights to new products from smaller, more research oriented companies (KPMG Consultants, 1999).

Retail Sector

In 1997, the Canadian Health Food Association completed a sector profile specific to the Canadian natural health products industry that revealed the following:

- In 1997, there were 1,700 health food and supplement store retailers in Canada whose primary business was the sale of natural health products.
- Vitamin, herbal, supplement and homeopathic remedy sales were estimated at $455 million or 67% of total sales. (These retail sales figures do not include sales through pharmacies, grocery stores, or mass merchandising stores.)
- The average increase in sales of natural health products from participating retailers between 1996 and 1998 was 24%.
- Retailers surveyed anticipated a 20% increase in annual sales for each of the years 1999 and 2000.
- 76% of health food and nutritional supplement stores anticipated an increase in employment levels over the next five years.

Pharmaceutical Sector

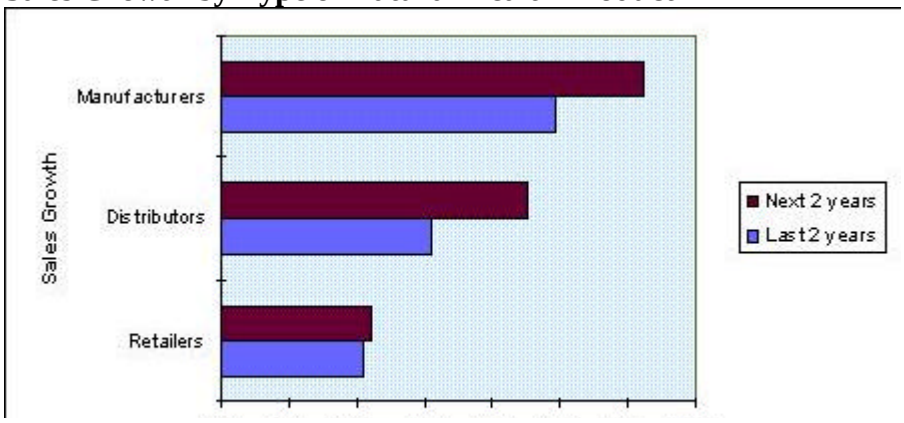
According to Pharmacy Post (1997):

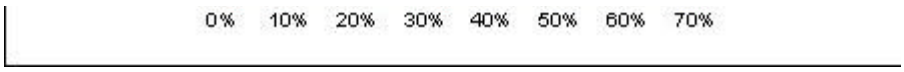
- 9 out of 10 Canadian pharmacists stocked herbal remedies with 63% planning to increase their shelf space in upcoming years.
- 62% of pharmacists stocked homeopathic remedies, with 48% increasing their shelf space in 1996.
- 43% of pharmacists expanded their vitamin section in 1996, with another 30% planning to expand this section in 1997.
- Retail margins on herbal products were reported at 35%, comparing favorably with over-the-counter drugs at 31%.

Manufacturing Sector

The fastest growing segment of the Canadian natural health products, nutraceutical and functional food industry has been the manufacturing segment which also provides the best growth and business opportunities in the Canadian health food sector.

Sales Growth by Type of Natural Health Product Firm





Source: Canadian Health Food Association: Sector Profile, 1998

Approximately 70% of Canadian manufacturers import ingredients or whole nutraceuticals and functional foods, to complement their production (Canadian Health Food Association, 1998). Forty-three percent indicated that 100% of their imports came from the U.S. About 48% of Canadian manufacturers import herbs and 31% import dietary supplements. Nutraceutical and functional food products are exported by approximately 65% of Canadian manufacturers. These companies are primarily exporting dietary supplements (50%) and herbal products (39%).

Classification of Products

a. Natural Health Products

Canada's prairie and forested regions offer an abundant source of wild herbs and large areas of fertile land make the country an ideal location for the cultivation of a wide variety of medicinal plants (KPMG, 1999). The range of herbs produced by Canadian companies is diverse. Saskatchewan growers, for example, reported production of over 70 different herbs and spices (Saskatchewan Agriculture & Food, 1999). The primary herbs grown in Canada include echinacea, ginseng, garlic, milk thistle, feverfew, goldenseal, St. John's wort, valerian, ginseng, astragalus, and cayenne. Other herbs include seabuckthorn, anise, fireweed, senega root, sarsasparilla, milk thistle, chamomile, yarrow, calendula, and stinging nettle. Spice and fruit crops include caraway, coriander, mustard, dill, peppermint, cumin, blueberry, Saskatoon berry, chokecherry, and buffalo berry. In addition, a variety of herbal tinctures are produced. natural health products derived from elk antler such as elk velvet capsules, powders and tinctures are also produced and processed in various parts of Canada.
Producers are looking at alternative crops in order to diversify their production from lower value commodity crops. Recently, more and more of these news crops are medicinal herbs, making the availability of raw materials substantial. The trend towards growing alternative crops has also been fuelled by numerous medicinal plant conferences that have taken place, not only in Canada, but throughout North America.

b. Nutraceuticals

Canadian companies have developed expertise in the formulation and manufacture of an array of nutraceuticals such as essential fatty acid supplements from a variety of sources, including evening primrose, borage, flax seed, hemp and marine animals. Canola phytosterols and flaxseed lignans are also sold into the health food market in the form of capsules or blended with oil.

c. Food and Food Ingredients

The food and food ingredient sector is a very important part of the Canadian nutrition industry. These products are very popular with consumers as they are the easiest to understand in terms of benefit to human health. Researchers, doctors and other health care practitioners are increasingly recommending the consumption of a balanced diet with high consumption of grain products and fruits and vegetables in order to reduce the risk of several diseases. This trend is extremely beneficial to the Canadian industry which is recognized as a leading producer and exporter of high quality agricultural products including grains, oilseeds and dairy.

The types of food and food ingredient products produced by Canadian companies include eggs with increased levels of omega-3 fatty acids, whole grains including wheat, oat and barley products with enhanced amounts of dietary fiber (soluble and insoluble), lactose free and fermented dairy products, green and black tea, modified fatty acid vegetable oils, legumes and fruit products. There are also some specific functional food type products sold in Canada including Kellogg's Bran Buds with Psyllium, Quaker Oatmeal, Ocean Spray Cranberry Juice, Tropicana and Minute Maid calcium enriched orange juices and Soy World Inc.'s So Good (a soy product with isoflavones). Unilever Canada has successfully marketed trans fatty acid free "Becel" margarine to health care professionals and consumers for a number of years.

Canadian Consumer Trends

A series of consumer polls investigating use of alternative therapies amongst Canadians have been conducted recently. The information from these polls indicates that the use of alternative therapies including supplements, botanicals and functional foods is growing amongst Canadian consumers.

According to a national consumer survey conducted by Gallup Canada (1999) for *Traditional Medicinals Inc.* (Sebastopol, California) more than two-thirds of Canadians agree that natural herbal supplements can be as effective as prescriptions or over-the-counter remedies in the maintenance, prevention, and treatment of health problems. Telephone interviews with 1,003 adult Canadians were conducted between September 16 and 23, 1999.

The results indicated that those persons surveyed believed that:

- Herbal supplements are now more accepted by consumers (94%).
- The medical community has become more accepting of herbal supplements (62%).
- Medicinal tea has health benefits (37%), including 44% of the women surveyed.
- They were "very likely" or "somewhat likely" to take an

herbal supplement to treat a cold (51.4%).
- Echinacea is a good way to treat a cold (33%).
- They were "very likely" or somewhat likely" to take an herbal supplement to combat stress or sleeplessness (38%).
- They were more likely to consider buying herbal supplements if labels provided information explaining health benefits (68%).
- Natural herbal supplements can be as effective as prescription or OTC drugs: agreed strongly (20%); agreed somewhat (46.8%); neither agreed nor disagreed (12%); disagreed somewhat (13.6%); disagreed strongly (4.6%).
- 20% of those surveyed have consulted a complementary and alternative medical (CAM) practitioner such as a naturopathic physician, a medical herbalist, or a homeopathic doctor.
- Among the reasons given for not Consultants CAM professionals: person does not get sick (22%); health insurance does not pay for this type of service (17%).

The Nonprescription Drug Manufacturers Association of Canada conducted a survey of 8,000 for the period of 1996-98 to evaluate consumption patterns and health care behavior (Graves, 1999). They found consumption of herbal products rose from 15-35%, with the most users female 45-66 years, highest consumption in western Canada, and garlic and echinacea the most popular herbs. They concluded that natural health products had moved out of "niche" status and into mainstream for self care. According to a 1997 poll conducted by the Canada Health Monitor:

- 56% of Canadians used natural products in the past 6 months.
- 65% of these Canadians made their purchases in a drug store.
- 29% reported purchasing products in a health food store.
- More than 1.5 million Canadians were substituting prescription drugs with lower cost natural health products.

A CTV/Angus Reid Group poll, conducted in 1997, revealed the following information about users of alternative medicines and practices in Canada:

- An 81% growth in the use of alternative medicines and practices over the past 5 years was reported.
- Over 42% of Canadians use alternative medicines and practices with the most popular being:
    1. Chiropractics (25%)
    2. Herbology (10%)
    3. Homeopathy (8%).
    4. Others: massage therapy, aromatherapy, reflexology, hypnosis, vitamin therapy, health foods, energetic healing, reiki, yoga, Native American medicine, osteopathy, and physiotherapy.
- The primary reasons quoted by the consumers surveyed for using alternative medicines and practices were: "Don't hurt you and may help" (48% of the 42% users); "regular medicines on their own aren't working for me" (34%);

"alternative medicines and practices are more natural" (33%).
- 90% of those using alternative medicines or practices reported being satisfied with the results.
- The majority of those surveyed (67%) believed that "the government should regulate alternative medicines and practices in the same way that they regulate other drugs and practices to make sure they are safe and really do what it is they claimed they will do."

In the CTV/Angus Reid Group Poll, of the 42% of Canadians using alternative and practices, the majority of those most likely to report use included:

1. Residents of the province of British Columbia
2. Females
3. Canadians aged 35 to 54
4. More affluent Canadians (52% among those with annual household incomes of $50,000 or more)

The most dramatic growth in the use of alternative medicines and practices (146%) was among Canadians aged 18-34.

Perceptions of Canadian Consumers Regarding Health Claims for Foods

The National Institute of Nutrition conducted 901 face-to-face interviews in English and French over the summer of 1998 to ascertain the opinions of Canadian consumers regarding health claims. (National Institute of Nutrition, 1999a). The objectives of the study were to determine how accurately claims communicate health benefits, their value to consumers, their influence in food selection and the value of third party endorsements. Potential health claims in the areas of fibre and cancer, calcium and osteoporosis, saturated fat and coronary heart disease and folic acid and neural tube disorders were assessed. A number of interesting observations were found. Surprisingly only 15% believed the Canadian government strictly regulated nutritional claims, 57% believed they were not very strictly regulated, and 24% believed they were not regulated at all.

The survey determined that Canadian consumers were familiar with diet and disease relationships for coronary heart disease, cancer, hypertension and diabetes and were most comfortable with a "may reduce" or "helps reduce" rather than a "can reduce" health claim. Canadians appreciate endorsements from Health Canada or agencies such as the Canadian Cancer Society that they considered trustworthy. This finding differs from American consumers who indicate less trust in governmental regulatory bodies. For those concerned about a particular health issue, claims were seen as interesting and relevant, and could influence a decision among purchasers already using similar products, but were not as likely to initiate product use (National Institute of Nutrition, 1999).

Overview of Current Canadian Regulations

The Food and Drugs Act currently regulates the advertising and sale of foods and drugs in Canada. This act does not deal specifically with natural health products, nutraceuticals and functional foods. As a result, these products are considered as either foods or drugs depending on the type and concentration of the active ingredient and whether claims are made on the product.

The definition of food under the Food and Drugs Act includes "… *any article manufactured, sold or represented for use as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatever". Drugs are defined as "… any substance or mixture of substances manufactured, sold or represented for use in: the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, restoring, correcting or modifying organic function*". Section 3 under the Food & Drugs Act prohibits the sale or advertisement of any food, drug, cosmetic or device to the general public represented as a treatment, preventative or cure for any disease, disorder or abnormal physical state included in Schedule A, a lengthy list of disorders.

Most natural health products supplements, nutraceuticals and medicinal herb products marketed in Canada make no claims and are regulated as foods since they do not currently meet Health Canada's rigorous pharmaceutical drug standards. When regulated as a food, there are no provisions in the legislation to make claims of a "health" or "therapeutic" nature regarding the use of, or possible side effects of, the product. Thus, the consumer may be inadequately informed about the use of the product. To protect consumers, Health Canada has banned or restricted the use of certain natural health products because the agency was unsure of the product's safety as a food. According to many industry members, the standards and regulations applied to natural health products in Canada are inappropriate, leading to restricted market entry of many safe and effective products. Research conducted by the Canadian Health Food Association (1998), for example, indicated that 42% of the 858 natural health products sold by a typical large U.S. supplier are prohibited for sale by a Canadian supplier in Canada. For example, U.S. approved products such as melatonin, single amino acids, and DHEA (dehydroepindrosterone) are prohibited for sale in Canada.

As indicated, any natural health products, nutraceutical or functional food that carries a health claim is treated as a drug. This requires a Drug Identification Number (DIN) which is issued by the Therapeutic Products Directorate (TPD) of the Health Protection Branch after it reviews the DIN application. The cost of a review will vary but it is a significant investment for smaller companies. Companies have the choice of obtaining a DIN, manufacturing under Drug Good Manufacturing Practices in many cases and marketing their natural health products, nutraceutical or functional

food product as a drug or selling it without claims. Some traditional North American Indian herbal products have been allowed for sale without a DIN, but this limited number of products is not at all reflective of the large number of European, Chinese, East Indian, and Aboriginal natural health products currently used by contemporary Canadian society (Health Canada, 1998). This regulatory structure has been viewed by industry as causing serious impediments to growth and development because it discourages innovation and marketing of natural health products, nutraceuticals and functional foods. A novel approach to the regulatory quagmire is that Tropicana choose to apply for a DIN number, and provide dosage information on packaging, for their "calcium and vitamin supplement", otherwise known as orange juice in the U.S.

Health Canada has recognized that the current regulatory framework does not support labeling and advertising of the potential health benefits of natural health products, nutraceuticals and functional foods to consumers. Beginning in 1996, Health Canada began a series of regulatory reviews for food labeling, including natural health products, nutraceuticals and functional foods.

A 1996 Health Canada Report "Recommendations for Defining and Dealing with Functional Foods" outlined the key issues related to permitting health claims on food products (Scott and Lee, 1996). In 1997 Health Canada acknowledged in a draft policy document that diet does affect health, with the totality of the diet being most important (Health Canada, 1997). The authors further recognized that scientific research is identifying foods, food groups, and food components that have a potential role in disease prevention and modification of physiological function. They also acknowledged that the Canadian Food and Drugs Act and Regulations of 1964 are perceived as a barrier to allowing health claims for these products.

Natural Health Products Initiative

As indicated earlier, currently under the Canadian Food and Drugs Act, natural health products are regulated as foods, cannot have any pharmacological activity, and, except for those defined as novel foods, require no pre-market notification. Most natural health products without health claims are marketed in Canada as foods. natural health products defined as drugs must meet pharmaceutical profile definitions and processing requirements in addition to undergoing rigorous safety assessments.

In early 1997, the Minister of Health, Honorable Alan Rock, commissioned a public review of natural health products to be conducted over the period fall 1997 to spring 1998. A final report was published in November 1998.

a. Advisory Panel on Natural Health Products 1997-98

In May 1997 the Minister of Health announced the formation of the Advisory Panel on Natural Health Products. Panel members were

assigned the task of reviewing and recommending the most appropriate regulatory framework for herbal remedies including product and establishment licensing, cost recovery, and international harmonization. The chairman of the Panel was Dr. Frank Chandler, Director, College of Pharmacy, Dalhousie University. He also sat on Health Canada's Advisory Panel for Nutraceuticals and Functional Foods. In fall 1997 the mandate of this panel was expanded to include traditional herbal, Chinese Ayurvedic (East Indian), and native North American medicine.

The Advisory Panel on Natural Health Products recommended to the House of Commons Standing Committee on Health, in their final report of May 13, 1998, that the category of "drugs" should be replaced by the term Therapeutic Products in Dosage Form (Health Canada, 1998). An underlying principle for this new term was that the definition would be expanded to incorporate the intended use of the products in the maintenance of human wellness. Dosage forms would include but not be limited to capsules, tablets, injectable substances, oral solutions, topical preparations, suppositories, and inhalants. This regulatory definition would be further sub-divided into two categories: Pharmaceuticals and Natural Health Products. Pharmaceuticals would include some of the products now defined as drugs, whereas Natural Health Products would encompass "*substances or combinations of substances consisting of molecules and elements found in nature as well as homeopathically prepared products, for the purpose of maintaining or improving health and treating or preventing diseases/conditions. natural health productss would include, but would not be limited to, vitamins, minerals, enzymes, co-enzymes, co-factors, herbs or botanicals, and animal source substances, and a variety of molecules extracted from natural substances such as amino acids, polysaccharides, peptides, naturally occurring hormones and precursors as well as naturally occurring molecules and synthesized by chemical or biological means*". All products sold in dosage form, including nutraceuticals, whether produced domestically or imported, would be covered by this definition (Health Canada, 1998).

When the Advisory Panel tabled their preliminary report, they suggested that regulations for all food and health products be viewed as a continuum, as shown in the following Table. Their proposed framework was based on risk management and considered health claims, dosage forms, and the relative risk of products and their ingredients as corner stones, However in their final report they focused upon products in a dosage form only and marketed as natural health products for human use. They have recommended several mechanisms as options to set up a separate agency to govern the natural health products and complementary medicine industry in Canada (Health Canada, 1998).

Proposed Framework for all Health Claims

DOSAGE FORM	HEALTH CLAIMS		
	STRUCTURE FUNCTION	RISK REDUCTION	TREATMENT
Yes	Pharmaceuticals		
Yes	Natural Health Products (Includes Nutraceuticals)		
No	Natural Health Products (Includes Functional Foods)		
No	Conventional Foods		

b. Standing Committee on Health 1997-98

The House of Commons Standing Committee on Health was commissioned by Minister Rock to conduct a public review on natural health products beginning in 1997. Their mandate was to recommend to Parliament a plan of action "on the most effective way to strike for the right balance between freedom of choice and ensuring the safety of consumers". The Standing Committee had an impressive membership, ranging from medical doctors to researchers to consumer advocates. The Committee heard presentations and assimilated information from an equally impressive and diverse group of concerned Canadians and foreigners. Due to extensive submissions to this committee, their final report was delayed until fall 1998. In November 1998, the Standing Committee tabled a report entitled "Natural Health Products: A New Vision" which provided recommendations regarding legislation and regulations governing natural health products including defining natural health products as a separate category from foods and drugs (Health Canada, 1998).

Although in their report, the Standing Committee did not define natural health products specifically they did agree with the definition proposed by the Advisory Panel. The Standing Committee made a total of 53 recommendations covering 16 broad areas. Their recommendations included the establishment of a new regulatory authority that would report directly to the Assistant Deputy Minister of the Health Protection Branch of Health Canada. Once cleared by the new agency, the Standing Committee suggested that a product sponsor could make structure and function, risk reduction, and therapeutic claims provided that sufficient evidence to support the claim was presented. They further indicated that Health Canada should assess these claims in a way that considers several standards

of evidence, such as professional consensus and traditional references, and not only clinical trials. A pre-market approval process for natural health products which would ensure that products are safe was recommended that would be based on a risk management approach that recognizes that natural health products fall along a continuum of relative safety and therefore require different levels of control. This assessment would apply to pre-market licencing and post- market monitoring. Further recommendations included the requirement to establish appropriate Good Manufacturing Practices guidelines covering specific quality control and testing for these products and that manufacturers, importers and distributors of natural health products should be obliged to hold valid establishment licences.

c. Office of Natural Health Products 1999

In March 1999 Minister Rock accepted all 53 recommendations made by the Standing Committee including the creation of a new Office of Natural Health Products (ONHP). Further, he made a 3-year funding commitment of $7 million for the ONHP and $3 million for research in the area of natural health products. There are still issues which need to be addressed including the definition of "natural health products". Until this is done, it is unclear whether these recommendations will cover only traditional medicines, homeopathic preparations, vitamin and mineral supplements, or whether this will also include nutraceuticals and functional foods.

A Transition Team of 17 people was recruited to establish the office. They released their first progress report in late 1998. They established the vision of the ONHP as to be recognized as the national authority for the management of natural health products used in Canada; respected worldwide as a leader in natural health product regulation and a leading national and international partner in the management of natural health products. The Team also indicated their intention to create and maintain an innovative regulatory environment based on a wellness model that will become a global standard in natural health products regulation.

The Mission of the ONHP will be to ensure that all Canadians have ready access to natural health products that are safe, effective and of high quality while respecting freedom of choice and philosophical and cultural diversity. The Team has established linkages with other key Health Canada personnel responsible for food safety and nutrition policies, Health Promotion programs and Health Protection Branch Legislative Renewal. These discussions focused on the importance of incorporating wellness promotion models in new legislation, policies and program initiatives being planned in the Department. The Team has also drafted a definition of natural health products and a system for classifying products for internal review. The Transition Team has recommended to the Canadian Codex contact point that since natural health products are neither foods nor drugs they should be exempt of the considerations of the United Nation's Codex Alimentarius.

d. Office of Natural Health Products 2000 - Present

In February 2000, Health Canada appointed Dr. Philip Waddington as the Executive Director for the Office of Natural Health Products (ONHP). Dr. Waddington has a Doctorate of Naturopathy and an extensive background in natural health care. He will oversee the development of appropriate regulations and definition for natural health products, through the guidance of an Expert Advisory Committee. This Committee would review options for research and laboratory capacities and report these findings to Health Canada.

The ONHP will provide guidance in developing appropriate manufacturing and labelling standards for natural health products. The ONHP will have the authority to approve natural health products for the Canadian market, and will be staffed with a core team of experts providing consultation to stakeholders and linking outside experts in the various fields of natural health products. The establishment of an Expert Advisory Committee is the next step in the process. The committee will provide the ONHP with advice and guidance toward fulfilling the office's mandate, which reads: "To ensure that all Canadians have ready access to natural health products that are safe, effective and of high quality while respecting freedom of choice and philosophical and cultural diversity."

Since the appointment of Dr. Waddington, the Transition Team has recommended that the Health Protection Branch immediately implement an Interim Management Policy for regulating natural health products. The recommendation is intended to ensure that the new OHNP begins to assume authority and primary responsibility for natural health products in partnership with other government agencies. In regard to research activities, the Team recommended a research strategy which incorporates priorities developed by its subcommittee as well as those developed at a multi-stakeholder research conference held in the fall of 1999 by Health Canada. These strategies include:

- development of a repository of current research on natural health products in Canada;
- provision of initial support for research submissions to the new Canadian Institute of Health Research (CIHR) that meet ONHP priorities; and
- establishment of a stable research budget in order to develop a balanced, sustainable research program.

The Transition Team recommended that an arms-length appeals mechanism be put in place to resolve regulatory disputes, once all efforts are exhausted within the working levels of the ONHP. Following a written request by the appellant, an Appeal Committee of 3-5 members would be constituted. The ONHP Executive Director and the appellant would each assign a Committee member and would both agree on either one or three additional members, depending on the size of Committee requested by the appellant.

Neither an appellant's employee or person involved in the dispute, nor a person under the Executive Director's staff reporting structure, could be nominated. The Appeal Committee would be required to deliver its opinion within 60 days.

In order to meet its proposed mission, the new ONHP will need to recognize and respect the traditions and cultural practices of Canada's various ethnic groups. The Transition Team is recommending that the ONHP:

- where circumstances require, give full consideration and provide specific guidelines tailored for culturally-based natural health products;
- recognize the traditional references, terminology and concepts of ethnic minorities as part of the references on Standards of Evidence; and
- ensure proper and thorough consultation with respective cultures by Consultants with the Expert Advisory Committee, special working groups, stakeholders and, as necessary, foreign governments.

Because many natural health products and their excipients may be derivatives of foods, the issue of labeling genetically modified food products is of concern to natural health products according to the Transition Team. They recognized that there is increasing public concern over the prevalence of genetically modified organisms (GMO's) in the Canadian food chain, and that Canadian consumers have expressed their desire to choose whether or not they consume products that have been genetically modified. The Team recommended that consumers be allowed to make an informed choice through mandatory GMO labeling measures. Recognizing that the complexities and time factors needed to achieve such labeling, the Team also recommended that:

- the ONHP work towards creating a framework and standards to allow the labeling of non-GMO natural health products, including both active ingredients and excipients; and
- that the ONHP work with other government departments and agencies to affect the necessary changes to make this possible.

The recommendations made by the Transition Team as well as those of the Standing Committee on Health were used to develop the Guiding Principles for a Proposed Regulatory Framework for NHPs.

An Expert Advisory Committee (EAC) on NHP has been appointed. The proposed mandate of this body is: "The EAC will act as a group to which issues of interest to the Director of the ONHP regarding the regulation of natural health products, can be referred to for advice. Such advice shall be rendered in accordance with the Mission of the ONHP. The EAC may, with the concurrence of the Director, strike sub-committees to provide specialized advice not otherwise available to the Director."

In the spring and summer of 2000, the ONHP conducted Consultation Sessions on their proposed regulatory framework. The consultations were held across Canada and were focused on consumers, health care providers, retailers and other industry members. Areas of discussion included the requirements for product labeling, product quality and health claims for NHP (i.e. vitamins, minerals, herbal remedies, etc.).

Several issues were raised at the consultations and in subsequent communications to the ONHP including concerns with product access and cost, to both the industry and consumers. The establishment of GMPs relevant to NHPs, the ability to make claims recognizing the restrictions imposed by Schedule A and the standards of evidence that will be required to make claims were emphasised as areas where the ONHP will have to focus attention. Other comments received related to appropriate and meaningful labelling, the potential workload for the ONHP and the need to work within international Codex guidelines.

A Workbook, which describes the Guiding Principles for the Proposed Regulatory Framework, is available from the ONHP website - www.hc-sc.gc.ca/hpb/onhp.

Nutraceuticals and Functional Foods

a. Therapeutic Products and Food Directorates Project 1996-98

To develop a policy framework for health claims, the Therapeutic Products Programme and Food Directorate of the Health Protection Branch initiated a joint project in the fall of 1996 with the formation of a government Working Group and the support of an External Advisory Panel (EAP). A consultation workshop was held the spring of 1997 to stimulate stakeholder discussion on the policy and program implications related to functional foods, nutraceuticals and health-related claims. The Workshop was held to discuss the following:

"Products with proven physiological benefits should be available to Canadians. A regulatory environment that is conducive to this aim will fairly and responsibly permit the promotion to consumers of food and drug products that have shown by valid scientific evidence to improve health. It is postulated that health claims benefit consumers provided that the information is substantiated, truthful, not misleading and not likely to lead to harm."

The Working Group and the EAP incorporated discussions from the consultation workshop as well as other written comments into a draft policy document which was issued by Health Canada in October 1997. In it the EAP and stakeholders agreed on the following working definitions:

"*A **nutraceutical** is a product produced from foods but sold in*

powders, pills (potions) and other medicinal forms not generally associated with food and demonstrated to have physiological benefits or provide protection against chronic disease" (Health Canada, 1997)

"*A **functional food** is similar in appearance to conventional foods, is consumed as part of a usual diet, and has demonstrated physiological benefits and/or reduces the risk of chronic disease beyond basic nutritional functions*" (Health Canada, 1997)

The EAP recommended, that the Food and Drugs Act be amended to permit structure/function and risk reduction claims while therapeutic claims would continue to be regulated as drugs as outlined in the following Table.

Analytical Framework for Health Claims for Nutraceuticals/Functional Foods

	STRUCTURE/FUNCTION	**RISK REDUCTION**		**T**
		PRODUCT SPECIFIC	GENERIC	
DEFINITION	Asserts the role of a nutrient or other dietary component intended to affect the structure or physiological function in humans.	Asserts a relationship between a specific food product and reduced risk of a disease or a specific health outcome.	Asserts a relationship between a nutrient in a diet and reduced risk of a disease.	A re be (s tr m di or pl
PRIOR PRESENCE OF RECOGNIZED DISEASE STATE IN TARGET GROUP	No	No	No	Y
TARGET GROUP	General population	General population and sub-groups	General population and sub-groups	S in di m po su (p

In November 1998, a Health Canada internal working group in

conjunction with the External Advisory Panel released a Final Policy Options Analysis paper for nutraceuticals and functional foods. The recommendations of the advisory panel for the definitions were included as well as recommendations were to permit structure/function claims and risk reduction claims and to continue to regulate therapeutic claims as drugs. The structure/function scenario would be similar to the regulatory framework for dietary supplements in the U.S. known as the Dietary Supplement Health and Education Act (DSHEA). Risk reduction claims are currently permitted for certain food and food constituents in the U.S. under the Nutrition Labeling and Education Act (NLEA).

One key difference with the U.S. is that the proposed changes could allow product specific claims whereby a company sponsoring research and development on its product would be allowed an exclusive claim. Another food with the same "active ingredient" would not be able to make the claim unless supported by research.

As the next step towards implementing health claims for foods, Health Canada took a three-part approach:

1. *Consideration of Generic Health Claims that:*

(1) were authorized for use in the U.S. under the standards of evidence in the NLEA (1990), (2) are consistent with current science, and (3) stakeholders agree are appropriate in the Canadian context.

In the U.S., health claims are defined as *"Any claim on the package or label or other labeling (such as an ad) of a food, including fish and game meats, that characterizes the relationship of any nutrient or other substance in the food to a disease or health-related condition"*.

A project was begun in 1999 to evaluate the ten generic health claims authorized in the United States under the standards of evidence in the *Nutrition Labeling and Education Act* (1990) (NLEA). A discussion paper on the U.S. claims, a report from a consultation workshop held in July, 1999 and summary of stakeholder comments are available on the Food Program website.

Health Canada has completed a process to review the science supporting the ten U.S. generic health claims. The process involved having Canadian experts prepare reports updating the science related to the health claims in the time since the U. S. Food and Drug Administration (FDA) finalized its review (i.e., 1993 for most claims). These reports were subsequently peer reviewed. Broad scientific agreement was apparent for five of the claims as follows:

- Sodium and Hypertension,
- Calcium and Osteoporosis,
- Saturated and Trans Fat and Cholesterol and Coronary Heart

Disease,
- Fruits and Vegetables and Cancer, and
- Sugar Alcohols and Dental Caries.

The following claims are being further reviewed and will be resolved by the end of the year:

- Folate and Neural Tube Defects,
- Fibre-Containing Grain Products, Fruits and Vegetables and Cancer,
- Fruits, Vegetables and Grain Products that Contain Fibre, Particularly Soluble Fibre and Risk of Coronary Heart Disease.

Health Canada has developed claim wording that they regard as truthful and not misleading in scientific content. Health Canada has proposed that foods bearing health claims should fall into one of the four food groups of *Canada's Food Guide to Healthy Eating* (CFG) and be consistent with *Nutrition Recommendations for Canadians* and its subsequent update on *Dietary Fat and Children*. Health Canada is also proposing that claims not be permitted for foods that fall into the "Other Foods" category of CFG, including foods that are mostly fats and oils; foods that are mostly sugar; high fat and/or high salt snack foods; beverages such as water, tea, coffee, alcohol, and soft drinks; and herbs, spices, and condiments. Specific nutrition labeling requirements for each claim are presented in the Consultation Document that is available from the Food Program web-site.

2. *Develop Standards of Evidence and a Guidance Document on Data Requirements for Supporting the Validation of New Health Claims for Foods.*

In 1999, Health Canada appointed 23 individuals to serve on an "Expert Advisory Panel for Standards of Evidence for Health Claims for Foods". The mandate of the Panel is to work with Health Canada to assist in the development of standards of evidence to allow structure/function and risk reduction claims for foods. The first assignment of the Panel was to comment on a "*Draft Discussion Paper: Development of Standards of Evidence for Health Claims for Foods*".

According to Health Canada, the proposed standards are intended to reassure consumers that the products carrying the claims are safe, and that the claims are valid. The standards would apply to all food or beverage products that bear direct or indirect claims about their health benefits.

- A **direct health claim** is clearly stated and straightforward. Example: "Calcium reduces the risk of osteoporosis."
- An example of an **indirect or implicit health claim** would be "Contains calcium," thereby relying on consumer awareness of the proposed benefits of the ingredient.

Such food or beverage products would include:

- conventional foods
- foods to which biologically active substances have been added
- foods that have been modified by other means, including foods derived from biotechnology.

The proposed standards do not include nutraceuticals and other natural health products sold in dosage form. Health Canada states, however, that "… if such products are added to foods, the appropriateness of their inclusion would be assessed. If the inclusion is found to be appropriate, the modified food would be evaluated according to the proposed standards".

A Consultation Document on Standards for Evidence for Evaluating Foods with Health Claims has been developed. The Document describes the principles governing the proposed standards, which have three important elements: product safety, claim validity, and quality assurance. The proposed standards would require that, in order to carry health claims, all food products must undergo at least a basic safety evaluation to ensure that the products would not have adverse nutritional or toxicological effects. Further, a health claim for food would have to be proven valid by good, solid science. Under the proposed standards for quality assurance, the manufacturer of a product that may carry a health claim must also demonstrate that the product can be produced on a consistent basis. Health Canada is requesting comments on the proposed standards. A Synopsis providing an overview of the proposals, as well as the Consultation Document are available from the Food Program web-site.

3. *Development of an Appropriate Regulatory Framework to Allow New Health Claims for Foods*

As the final step in the process, new regulations and/or amendments to existing regulations, where required, will be initiated to enable the use of new health claims for foods. The establishment of a regulatory framework for new health claims will take into account other developments in related legislation and regulations.

(These articles were adapted from information that appears on Health Canada's Food Program website: www.hc-sc.gc.ca/food-aliment/english/subjects/health_claims/index.html)

Canadian Nutraceutical & Functional Food initiatives

- B.C. has established the ***B.C. Nutraceutical Network***, an informal organization which encourages networking for individuals interested in research and business opportunities in nutraceuticals.
- The ***Functional Foods Network*** is located at the University of

Alberta.

- The Universities of Toronto, Western Ontario and Guelph have established the ***Ontario Centre Initiative for Functional Foods***. The objectives of the Initiative are to work with industry on new product development, to encourage and support research and educational training opportunities, to enhance consumer awareness and to stimulate changes in government legislation and policy.
- In Quebec, the pharmaceutical sector has a very strong presence and is becoming more interested in the area of natural health products. Agriculture and Agri-Food Canada, Ste. Hyacinthe, McDonald College and the Universities of Laval, McGill and Montreal are undertaking R&D activities in the area.
- No formal nutraceutical initiatives are underway in the Maritimes, although BioAtlantech Inc. has sponsored several events that include nutraceutical presentations. Several companies process and distribute fish and seal oils, seaweed, kelp and shark cartilage as well as evening primrose oil and herbal products.

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