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# Nutraceuticals

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University Honors Thesis

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May 4, 2004

## "Nutraceuticals"

Ever since the beginning of time, humankind has depended on food for their survival. From the days of primitive humans hunting for the bare necessity of food, to the wide selection and abundance that we have today in our supermarkets, the food industry has undergone many modifications. Even with all of these modifications, the vital role that food and nutrition play in the lives of humankind has stayed constant over time. A good example of a present day modification to the food and beverage world is that of the ever-growing nutraceutical industry.

At this point, it will be very helpful to define several terms related to nutraceuticals. The first word that one needs to become familiar with is *nutraceutical*. The United States Food and Drug Administration (FDA) define this as “any food or food ingredient considered to provide medical or health benefits, including the prevention and treatment of disease,” (Altruis Biomedical Network, 2002. pg. 1). Michele Veeman (2002, pg. 528) delivers the Canadian definition of nutraceutical as “anything that is isolated from food and sold in dosage form that have demonstrated physiological benefits or reduce the risk of chronic disease.” It is obvious there is not a universal definition for this term, but these two definitions are very similar to one another because both nations believe that a nutraceutical should provide a health benefit to the consumer that is greater than that of a general food item. The Canadian definition of a *functional food* is very closely related to the U.S. meaning of nutraceutical. Veeman (Canadian Journal of Agricultural Economics, 2002, pg. 528) stated Canada's definition of a functional food which is “similar in appearance to conventional food and consumed as part of a usual

diet.” As in the nutraceutical definition, these foods must “demonstrate physiological benefits or reduce the risk of chronic disease, above and beyond their basic nutritional functions.” To summarize, in Canada, the only difference between a nutraceutical and a functional food is that the nutraceutical is sold in dosage form. A few good examples of nutraceuticals in Canada are vitamins, minerals, amino acids, etc.

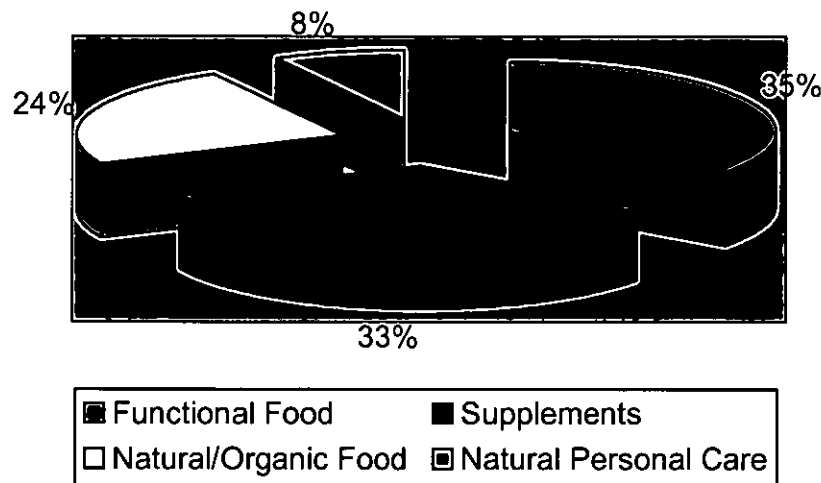
In the United States, the terms functional food and nutraceutical are interchangeable with one another. Examples of these products include fruits, vegetables, and even chocolate. These everyday food items have the potential benefit to their consumers of things such as to reduce the risk of cancer, improve urinary tract health, and reduce the risk of cardiovascular disease (Faye, 2002, pg. 2). These advantages are obtained simply by consuming the food items as part of the consumers’ everyday diets. Being able to gain all of these benefits without taking additional substances is becoming very appealing to many consumers. Also, the ever-growing prices of prescription drugs are another influencing factor for people to try this innovative technique for enhanced health status.

Nutraceuticals are considered to be one of the fastest growing areas of interest for human health and disease prevention according to the College of Agriculture, Food and Natural Resources at the University of Missouri-Columbia (2002, pg.1). The U.S. and Canada are the two nations that are leading the bandwagon of this new, innovative concept of disease prevention. Canada is currently working on the transformation of nutraceuticals from a “niche” market to one of the mainstream food industry (Saskatchewan Nutraceutical Network, 2002, pg.25). Even though Saskatchewan is producing most of these products, their reduced market size forces them to find outside sources of selling the Natural Health Products (NHP). The first area Saskatchewan

producers began to market these goods were in the other Canadian provinces such as Quebec, Manitoba, and British Columbia. Then, they began looking at other developed countries as a source of sales for the new products. The U.S. is doing its part to help the Canadian market grow by being the number one importer of Canadian Natural Health Products, which include functional foods and nutraceuticals (Saskatchewan Nutraceutical Network, 2002, pg. 15).

Figure 1:

### 2001 U.S. Consumer Market



Source: Nutrition Business Journal's Functional Foods Report (2002, pg. 15)

Figure 1 shows the amount of money that consumers spend on Natural Health Products; the highest percentage (35%) is spent on the functional food category. If this trend continues, there will continue to be an increase in the amount of spending on functional food items over the next few years.

The market demand for these products is being shaped by a number of external factors. One is the increase in disposable income. If families have more money to spend on food and food products, they will not be as hesitant to buy a product that costs a little more, especially if that product offers additional health benefits such as those offered by nutraceuticals and functional foods. In a recent survey of 200 college students enrolled in classes within the College of Agricultural Sciences (COAS) at Southern Illinois University Carbondale (SIUC), which was conducted in February 2004, 80 percent of the students indicated they would pay more for a product that either (a) was proven to promote better health, or (b) had a label that described its health benefits. While the majority of students were only willing to spend 10 percent or more on these premiere products, others were willing to give as much as 20 percent more than the current price without an increase in their income. In the United States, the focus of this new industry on disease prevention is growing due to the concern that all age groups are showing towards contracting serious illnesses. Many Americans are becoming increasingly aware of the dangers of chronic illnesses, such as cancer, heart disease, and hypertension, and are willing to take the extra precautions to reduce their chances of contracting one or more including paying a premium for foods that will promote better overall health. The nutraceutical market is already beginning to show the effects of these factors.

In 2001, the sale of functional foods was over \$1 billion higher than that of dietary supplements and over \$5.5 billion higher than the sale of natural and organic foods (Saskatchewan Nutraceutical Network, 2002, pg. 5). This adds up to being 35 percent of the total nutritional industry's sales (Saskatchewan Nutraceutical Network, 2002, pg. 5). The best-selling products within the functional food market are the beverages. These drinks target two of the most important groups of people in the U.S. today, the first of these groups being the super-busy, working American by providing a ready-to-drink beverage. The second group being that of the athletes, by offering sports and energy drinks to the health conscience (Saskatchewan Nutraceutical Network, 2002, pg. 6). All of the functional food products that are being produced today are being done so in response to consumer demand for more health-oriented products. This will generate more sales for the company and in-turn, will increase the shareholders' value. It is easy to see, that everyone wins in this situation.

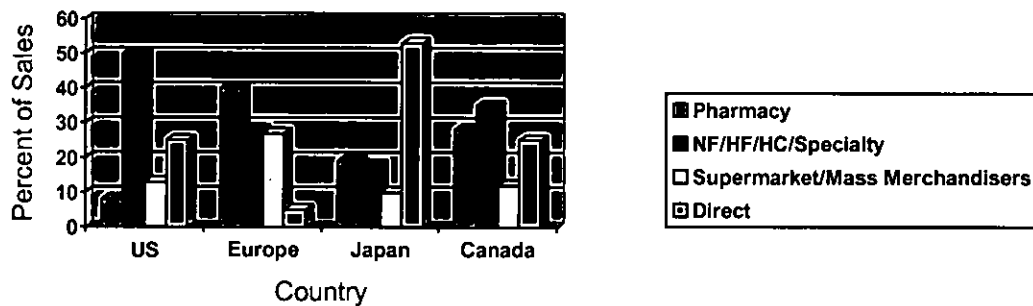
The Canadian Natural Health Product market closely resembles that of the U.S. market in the three major categories of products including vitamins and minerals, natural and organic foods, and herbs and botanicals (Saskatchewan Nutraceutical Network, 2002, pg. 25). One change that the Canada's market is undergoing is the transformation from a niche market to one of the main stream. A big part of this advancement is a consequent of the abundance of distribution options that are available for the health products. These include the four main channels according to the Saskatchewan Nutraceutical Network (2002, pg. 27):

- 1) Sales that are made through traditional pharmacy and drugstore types of businesses.

- 2) Sales that are made through other stores such as Natural Food, Health Food, Health Care, and Specialty Stores.
- 3) Sales that are made through supermarkets and other mass merchandisers.
- 4) Sales that are made directly to the consumer by Internet, mail order, and those made from practitioners.

Figure 2:

### Market Share by Distribution Channel



Source: Saskatchewan Nutraceutical Network, 2002, pg. 27

It is clear from Figure 2 that the dominant source of Natural Health Product Sales in the U.S. and Canada is that of Specialty Stores and other similar businesses. This is due to the advancement in their markets compared to that of other countries being researched. In Europe, the pharmaceutical channel is dominating sales with Specialty Stores and Supermarkets closely following. Japan's market is clearly dominated by the direct sales of their Natural Health Products, which furnishes over half of the total market sales.

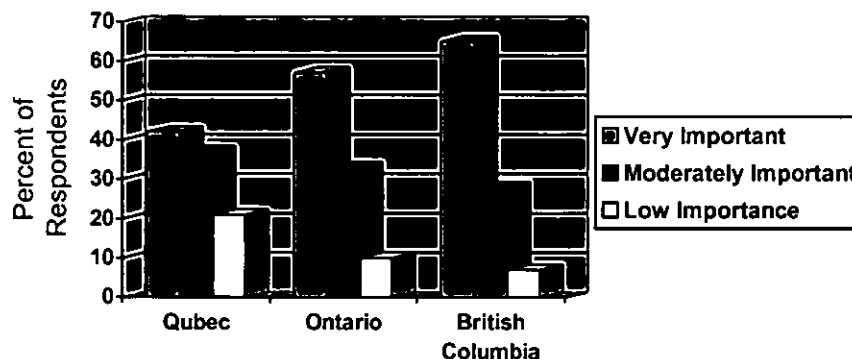


There are several factors that are responsible for the trends in market growth for the functional food industry (Saskatchewan Nutraceutical Network, 2002, pg. 30). The first one is the scientific findings that diet is linked to overall health outcomes. When asked if there was a relationship between one's diet and their overall health, 48 percent of those students surveyed answered that there was a "strong relationship" between the two. Another 34.8 percent believed the relationship was "semi-strong" and the final 13.6 percent took a neutral position on the question. Research has shown that currently 5 of the 10 the leading causes of death are linked to diet in individuals. Examples include certain types of cancer, coronary heart disease, stroke, and two types of diabetes (mellitus and atherosclerosis). The second cause behind market growth is the increase in consumer interest in self-care and alternative medicine. In a recent survey conducted by the International Food Information Council, 95% of those individuals surveyed believed that certain foods could reduce the risk of disease, or at the very least improve health.

Canadian food processors/retailers understand these startling statistics, and are striving to increase expenditures in the nutraceutical and functional food market by "adding value" to their products (Veeman, 2002, pg. 531). They are also employing the idea of "target marketing" in the economy. Target marketing is a way of advertising in which the producers appeal to a specific group of society that they believe will be the largest consumer of the good. Examples of groups of people that they are focusing on are working moms, the baby boomers, and athletes. All of these individuals are concerned about their health and are willing to spend a little more money in order to obtain the results displayed by the Natural Health Products. However, the everyday Canadian does realize the importance of diet in the process of preventing diseases. In a survey

conducted by West (Canadian Journal of Agricultural Economics, 2002, pg. 545) the following results were obtained for the question: Do you think that food choices play a role in preventing chronic illnesses?

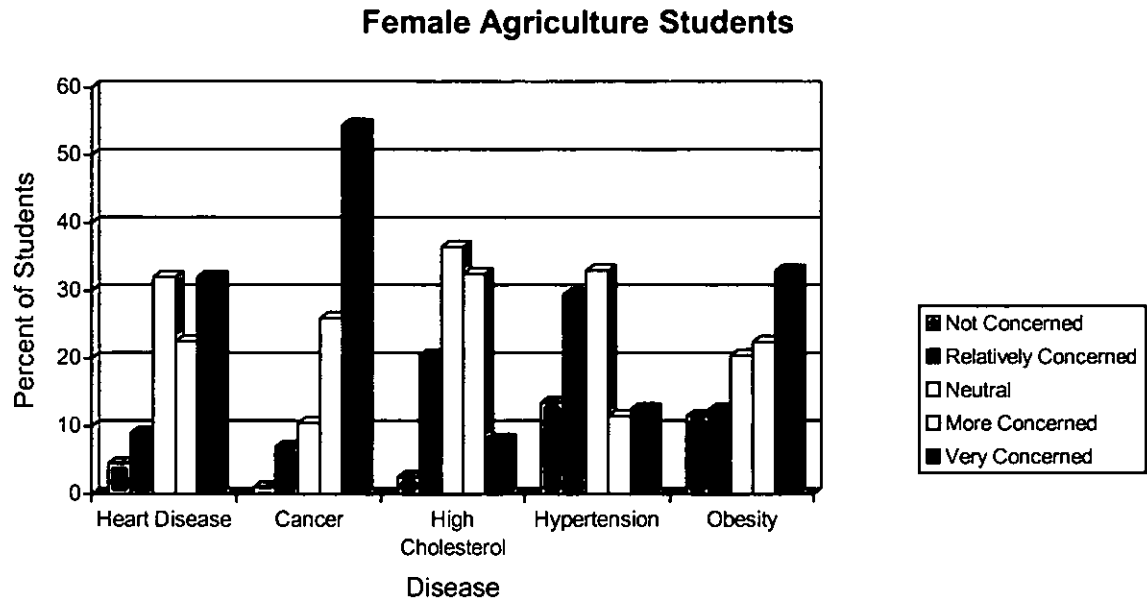
Figure 3:



It is clear in Figure 3 that across Canada, the majority of consumers find diet "very important" to their health.

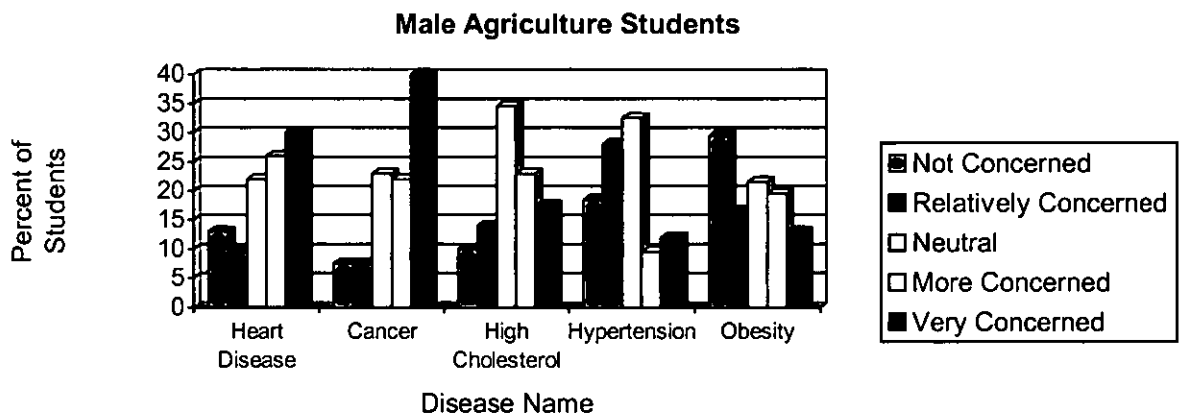
Another factor controlling the demand for these products is aging baby booms. As the members of the baby boom are gradually getting older, their health becomes a major point of interest as it does with most individuals regardless of age. For example, the younger generation of society shows concern with becoming infected with serious diseases as well. In the same survey as mentioned above, the students were asked how concerned they were with five serious diseases: heart disease, cancer, high cholesterol, hypertension, and obesity. After the data source compiled from the participants, the results were then broken down between male and female students. The following illustrates the survey's findings.

Figure 4:



Source: College of Agricultural Sciences Survey, February 2004

Figure 5:



Source: College of Agricultural Sciences Survey, February 2004

As Figures 4 and 5 show, college-age students are most concerned with contacting heart disease or cancer of the five most common illnesses. This is true for the male and female population with 54 percent of the female population showing a “very concerned” attitude towards cancer (Figure 4). Heart disease and obesity were tied for

being the second most feared diseases with just over 30 percent answering “very concerned.” Figure 5 shows that 30 percent of males indicated that they were “very concerned” with heart disease and 40 percent were “very concerned” with obtaining cancer. Only 12.5 percent of the male students surveyed answered “very concerned” to obesity, which is less than half of that suggested by the female participants.

The younger generation shares these concerns with the aging population about long-term, reduction of risks of chronic diseases (Saskatchewan Nutraceutical Network, 2002, pg. 17). These concerns are responsible for the increases the demand for products that will prevent conditions such as heart disease, cancer, obesity, and hypertension just to name a few. This factor influencing demand is closely related to consumer knowledge, which results in an increase in the demand for food products with properties to prevent or reduce the incidents of diseases. The growing price of health care costs associated with the aging population is another factor influencing demand. The number of Americans that are 65 years of age or older grew by an astounding 1100% during the 20<sup>th</sup> century (Saskatchewan Nutraceutical Network, 2002, pg. 29). This trend is expected to continue through the 21<sup>st</sup> century. Seventy-five percent of the individuals in this age group have at least one chronic disease and 50 percent have at least two. These figures are responsible for the ever-growing costs of health care.

As the aging baby booms become aware of the benefits of such products, they will be more likely to consume them in an attempt to reduce their risks of these illnesses. This should result in an increase in demand, i.e. the demand for this functional food shifts right.

The United States has one of the fastest growing nutraceutical and functional food markets of all developed nations. The primary reason for this is because of its consumer's access to have such a mass amount of media coverage. Other, less developed nations are not expanding their health product industry as much because of the lack of publicity about functional foods that the U.S. and similar nations have (Saskatchewan Nutraceutical Network, 2002, pg. 4). As citizens become more aware of the benefits these products have to offer, consumers are going to be much more likely purchasing them. Currently, there are numerous magazines, newsletters, and other sources of information available to consumers in order for them to increase their knowledge of nutraceuticals and related products.

Another reason is the widely used asset of the Internet in the United States (Saskatchewan Nutraceutical Network, 2002, pg. 17). This allows consumers to order products directly and receive them much quicker. It is also responsible for expanding consumer knowledge of newly introduced products such as the largest group of supplements: vitamins and herbs (otherwise known as botanicals). Together, these two categories of functional foods make up 60 percent of the \$17.7 billion of supplement sales (Saskatchewan Nutraceutical Network, 2002, pg. 17). All of these factors will help to keep the natural food sector of the market growing at a steady, rapid pace much like it has been doing since 2001 (Saskatchewan Nutraceutical Network, 2002, pg. 20).

While nutraceuticals are not as closely regulated as prescription drugs are in the United States, there are still a fair number of guidelines that must be followed by functional food companies in order for the product label to make claims of "additional benefits" (Altruis Biomedical Network, 2002, pg. 1). These regulations are designed to

give consumers better information by labeling the products more precisely. By definition in the Saskatchewan Nutraceutical Network (2002, pg. 21), a health claim is a “statement that characterizes the relationship of a substance to a disease or a health-related condition, typically in the context that the regular dietary consumption of a substance ‘may reduce the risk of a specific disease or health condition’”. Examples of claims that are not being allowed include that a functional food can “cure,” “mitigate,” or “prevent” any disease (Saskatchewan Nutraceutical Network, 2002, pg. 22). The following relationships between functional foods and disease are permitted to claim a reduction of risks by consumption by the Food and Drug Administration. These relationships have proven a prevention and/or reduction in the following conditions according to the FDA guidelines.

- Calcium and Osteoporosis
- Dietary Fat and Cancer
- Sodium and Hypertension
- Dietary Saturated Fat and Cholesterol and Risk of Coronary Heart Disease
- Fiber-Containing Grain Products, Fruits and Vegetables and Cancer
- Fruits, Vegetables and Grain Products that contain Fiber, particularly Soluble Fiber and Risk of Coronary Heart Disease
- Fruits and Vegetables and Cancer

Source: Saskatchewan Nutraceutical Network, 2002, pg. 22

In Canada, a more recent correlation has been discovered between soy protein and coronary heart disease (Saskatchewan Nutraceutical Network, 2002, pg. 22).

Law number 105-115 was passed by the 105<sup>th</sup> Congress (1<sup>st</sup> session) and later signed by the President in November of 1997 approving the Food and Drug Administration Modernization and Accountability Act (FDAMA) (The National Academies, 2004, pg. 1). This bill was designed to facilitate the regulatory process of health products including nutraceuticals and functional foods. It calls for the FDA to approve “authoritative statements” that have been made by other U.S. Government agencies, for example the Centers for Disease Control, the National Institutes of Health, and the National Academy of Sciences. Authoritative statements are made “about the relationship between a nutrient and a disease or health-related condition.” Allowing these other organizations to produce these statements will greatly reduce the amount of time it takes for the food and drug review process that the Food and Drug Administration currently uses. Labeling of Natural Health Products in the United States however is not as strict as that in Canada. In fact, the term “natural” can be broadly defined (The Natural/Organic Food Market in the United States, 2000, pp. 5). It was not until May of 2000 that the FDA began requiring that food products that contained genetically altered ingredients list on their label. The following is the most recent criteria that must be included on all food product labels:

- 1) Products labeled as “100% organic” must contain (not including water and salt) not less than 100% organically produced raw or processed agricultural product
- 2) Products that are simply labeled “organic” must contain not less than 95% organically produced raw or processed agricultural product. Any remaining product ingredients must consist of non-agricultural substances or non-organically

produced agricultural products approved in the National List of Allowed and Prohibited Substances

- 3) Products labeled “made with organic (specified ingredients)” must contain at least 70% organically produced agricultural products
- 4) Products with less than 70% organic ingredients may include the work “organic” only in the list of ingredients.

Source: The Natural/Organic Food Market in the United States, 2000, pp. 5

Over the past few years, Canada’s market for Natural Health Products (NHP), nutraceuticals, and functional foods has exploded. In fact, they are leading the research and development of this new industry and have an additional category called dermaceuticals. These products are derived from plant or animal extracts that are used in skin care products (Saskatchewan Nutraceutical Network, 2002, pg. 25). There is such a large amount of research going on right now, that the Directorate of Healthy Canada has proposed to break-up the Natural Health Product category into three subdivision which include:

- 1) Any product that is manufactured, sold, or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder, or abnormal physical state or its symptoms in humans.
- 2) Any product that is manufactured, sold, or represented for use in the resorting or correcting organic functions in humans.
- 3) Any product that is manufactured, sold, or represented for use in maintaining or promoting health or otherwise modifying organic functions in humans.



Source: Saskatchewan Nutraceutical Network, 2002, pg. 9

Technological advances are another driving force in the market for Natural Health Products. These include biotechnology as well as the new studies in “nutrigenomics,” how an individual responds to dietary components based on his/her genetic characteristics. The increasing sales in the health food market are also responsible for the success of the Natural Health Products. This market alone grew between 10 and 20 percent per year in the 1990’s (Saskatchewan Nutraceutical Network, 2002, pg. 29-30). Finally, changes in the governmental regulations of food will ultimately have an effect on the market. Today, Japan is the only country with regulations on functional foods. At the same time, many other countries are discussing what measures to take in the course of regulating their functional foods and how they should go about labeling such products.

Overall, the Canadian industry has been making significant advancements in the nutraceutical world. As these products become more established in the market, it will become easier to educate consumers about them (Saskatchewan Nutraceutical Network, 2002, pg. 29). The companies in this area are working diligently to uncover relationships between plant and animal biomass on the one hand and beneficial health care products on the other. Currently, the industry in Canada is characterized by medium-sized companies which generate sales of \$1 to \$10 billion annually. These sales dollars consist of a variety of products that Canadian firms have to offer. This is due to the great variety and abundance of wild plants that are available to processors from the fertile prairie and forested regions, which are typical of the country. This is not only beneficial, but

promotes diversity to nutraceutical products while opening many doors for expansion of the market (Saskatchewan Nutraceutical Network, 2002, pg. 37).

Statistics show that the U.S. leads Canada in the manufacturing of Natural Health Products (Saskatchewan Nutraceutical Network, 2002, pg. 50). This is accredited to Canada having a much stricter regulatory system than that of the United States. In fact, most of the current nutraceuticals on the market in Canada are included as food items because they are unable to meet the regulations to be included as a pharmaceutical drug. To demonstrate the difference in the regulatory standards between these two countries, the Canadian Health Food Association compared the 858 Natural Health Products that were sold in the U.S. and determined that only 42 percent of those would be available for sale in a Canadian market (Saskatchewan Nutraceutical Network, 2002, pg. 50).

Another barrier to Canadian suppliers in marketing their products as drugs is the investment required to obtain a Drug Identification Number (DIN), which is required for all products marketed as drugs. Many of the smaller companies are unable to come up with the financial resources required to obtain a DIN. As a result of their regulatory system, Canadian suppliers are struggling in terms of growth and development within the industry. Therefore, Canada's regulatory system is considered the largest obstacle in the success of the market for functional foods.

All Natural Health Products (NHP) must include the following information on their product label:

- 1) Brand name
- 2) Product number issued with the product license preceded by the designation of NHP

- 3) The dosage form
- 4) The net amount of NHP
- 5) The name and address of the product license holder
- 6) If the NHP is imported, the name and address of the importer, the proper name and, if any, the common name of each medicinal ingredient
- 7) The strength or potency of each medicinal ingredient
- 8) A qualitative list of all non-medicinal ingredients
- 9) The recommended use or purpose
- 10) The recommended route of administration
- 11) The recommended dosage and, if any, duration of use
- 12) The risk information including any cautions, warnings, contraindications or known adverse reactions associated with its use
- 13) The recommended storage conditions, if any
- 14) The lot number
- 15) The expiration date
- 16) The description of the source material from which the medicinal ingredients are derived or obtained (for example root of plant)
- 17) Notations indicating if the NHP is “sterile” or is available for sale by prescription only

Source: Saskatchewan Nutraceutical Network, 2002, pg. 61

It is obvious that labeling of a Natural Health Product in Canada is a very complicated and difficult task, which requires a significant amount of financial resources

to complete within the regulatory guidelines. To make things even more difficult, in October of 2000, Canada's Health Minister proposed making the labeling of nutritional facts on all pre-packaged foods mandatory (Saskatchewan Nutraceutical Network, 2002, pg. 63).

In 1999, Health Canada began a project to evaluate ten generic health claims that have already been approved in the United States by the guidelines of the Nutrition Labeling and Education Act (1990). Five of the ten claims were agreed upon in both countries. They include:

- Sodium and Hypertension
- Calcium and Osteoporosis
- Saturated, Trans Fat, and Cholesterol and Coronary Heart Disease
- Fruits and Vegetables and Cancer
- Sugar Alcohols and Dental Caries

Source: Saskatchewan Nutraceutical Network, 2002, pg. 66

Three other claims are being reviewed further at the present time,

- Folate and Neural Tube Defects
- Fibre-Containing Grain Products, Fruits, and Vegetables and Cancer
- Fruits, Vegetables, and Grain Products that contain Fibre, and risk of Coronary Heart Disease

Source: Saskatchewan Nutraceutical Network, 2002, pg. 66

According to Health Canada, in order for a functional food to reach its utmost potential, it must be safe and the benefits must be significant. These two requirements

have three important elements, first and foremost is product safety to the consumer. Second, the product must effectively demonstrate the benefits that it claims to. Finally, the product must meet proposed standards of quality assurance. In other words, its benefits must give measurable results while maintaining safety for consumers.

The market for functional foods in Saskatchewan, Canada foreshadows the next generation of agricultural industry growth. The result has the potential to put this province in a leading position as an agricultural producer as well as the home to agricultural processing sector for these foods. According to KPMG Consulting of Saskatchewan, there are currently about 50 companies in Saskatchewan that are involved in the functional food and nutraceutical industries (Saskatchewan Nutraceutical Network, 2002, pg. 72). Several of these firms are involved in not only agricultural production, but also the manufacturing of the products as well. This gives the companies a means of selling the products that they are producing. The products are successful for a variety of reasons including the location of the province. Saskatchewan offers an abundance of plant and animal products that grow in a pollution free environment. They also have a long-time history of producing superior agricultural products as well as resources in technology and scientific research from highly rated universities and colleges (Saskatchewan Nutraceutical Network, 2002, pg. 72).

Saskatchewan companies are looking to Natural Health Products as a way to diversify the agricultural sector, which will hopefully lead to an increase in farm incomes (Saskatchewan Nutraceutical Network, 2002, pg. 73). Agriculture is very important to the Saskatchewan economy not only for production, but also because of manufacturing and research. In fact, they are highly regarded for their crop research institutions as well

as the biotechnology advancements these firms are responsible for. Agricultural biotechnology involves the modification of plants that are consumed as a source of food but the benefits are “substantially equivalent” to existing foods (Veeman, 2002, pg. 535). Activists and other groups that are concerned about the environment and other environmental conditions of such products are reviewing this idea very critically. Saskatchewan has a strong expertise in commodity crops (such as canola and flax), which are being considered as possible nutraceutical and/or focuses as functional foods (Saskatchewan Nutraceutical Network, 2002, pg. 78).

The following is a list of just a few of the products that are currently being produced in Saskatchewan:

<u>Nutraceuticals</u>	<u>Uses</u>
1) Pumpkin Seed oil	Bladder/Prostate health
2) Flaxseed lignans	Reduce Cancer risk/Coronary heart disease
3) Canola phytosterols	Reduce cholesterol absorption
4) Fish oils	Reduce blood clotting
5) Ginseng	Reduce memory loss
<u>Functional Foods</u>	<u>Uses</u>
1) Oat bran	Water-soluble fiber
2) Wheat Bran	Insoluble fiber
3) Flaxseed	Cardiovascular health
4) Hemp Flour	Promotes a balanced diet
5) Lentils	Promotes skin health

<u>Dermaceuticals</u>	<u>Uses</u>
1) Borage Oil	Relieves certain skin conditions and arthritis pain
2) Hemp Oil	Reduces water loss from skin; skin inflammation
3) Canola Phytosterols	Reduces water loss from skin
4) Emu Oil	Anti-inflammatory; anti-aging
5) Willow herb	Promotes prostate and urinary tract health
<u>Natural Health Products</u>	<u>Uses</u>
1) Elk velvet	Anti-inflammatory; anti-aging
2) Bovine Colostrum	Enhances immune system
3) Milk thistle	Anti-depressant; liver protection
4) Cranberry	Remedy for urinary tract infections
5) Caraway	Provide relief from eye infections; toothaches

Source: Saskatchewan Nutraceutical Network, 2002, pg. 74-76

Nutraceuticals are still a relatively new concept within the food sector, however there is potential for enormous market growth by the year 2005 (Functional Foods and Nutraceuticals, 2003, pg. 1). In fact, experts are forecasting the sales of Natural Health Products to surpass that of the processed food market in the future. While this may seem a little extreme, nutraceuticals are the fastest growing field in human health and disease prevention (The Nutraceuticals Webpage, 2002, pg. 1). As the population becomes older on average, they are also becoming more aware of these potential health problems. This, in turn, leads to consumers being more focused on products that are proven to increase their quality of life. As the demand for these goods increases, producers will reap in the

benefits of higher profits for their business. The future of successful agriculture partially lies within the production of nutraceuticals, functional foods, and other Natural Health Products.



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