
National Industrial Hemp Strategy

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Executive Summary

Growth of the Canadian Industrial Hemp Sector

The history of hemp cultivation is as old as the history of civilization. In North America, hemp was a crucial crop during the colonial period, and it continued to be produced right up to and through the Second World War. A combination of regulatory pressures and changing public perceptions around drug use led to the disappearance of domestic hemp cultivation in North America in the years following WW II.

In 1998, Canada joined the large international community of hemp producers by permitting the production of industrial hemp, under a carefully monitored regulatory process. While the growth of the Canadian industrial hemp sector over the past decade has been uneven and at times fraught with challenges, as would be expected from a fledgling industry, there is considerable cause for optimism:

- The market for hemp seed materials for human health, nutrition, and personal care applications is strong and growing. Market price for a drum of conventionally grown hemp oil is approximately \$1600 Cdn, with organic hem oil fetching in the neighbourhood of \$2500 a drum (Spring 2008).
- A favourable court decision in 2004 re-opened the US market, which had been effectively closed in 2000 by the US Drug Enforcement Agency (DEA). This has allowed for substantial and rapid gains in US exports.
- Recently, there has been dramatic growth in Canadian industrial hemp exports, with the US being the primary importer. Hemp seed exports increased 300% from 2006 to 2007. Hemp oil exports were also impressive, increasing 85%. Hemp fibre exports increased 65%.
- The knowledge base being developed by producers and researchers is expanding rapidly, with experienced farmers now consistently producing good yields.
- There is an increasing base of experienced organic producers meeting the strong market pull for organic hemp products, some of whom are now achieving yields that rival conventional farming techniques.
- Acreage under cultivation, while still showing significant annual fluctuations, is now regarded as being on a strong upward trend.

While the growth of the Canadian hemp sector over the past decade has been driven by market demand for hemp seed products, hemp has a broad range of potential product applications. The three primary components of hemp – bast fibres, hurd, and seeds/oil - each have attributes that provide distinct competitive advantages in a multitude of food and health, fibre, oils, and personal care applications. As technologies for hemp processing become commercialized and mature, there is reason to anticipate market penetration by hemp based products in such applications as biocomposites (including bioplastics), textiles, and industrial oils.

The National Industrial Hemp Strategy

Recognizing the need for concerted sector-wide approaches to overcoming roadblocks to expanded commercial production in the Canadian industrial hemp sector, Manitoba Agriculture, Food and Rural Initiatives (MAFRI), the Composites Innovation Centre (CIC) and the Canadian Hemp Trade Alliance (CHTA) have spearheaded the development of the first national industrial hemp strategy for Canada. Working with a broad cross-section of stakeholders representing producers, processors, researchers and research institutions, and the policy community, the goals of this National Industrial Hemp Strategy include:

- Aligning the value chain players towards common goals that will maintain the competing edge of the Canadian industrial hemp sector
- Defining coordinated actions that will open up access to new markets for both seeds and fibres, expanding the sector and increasing the farm gate income of producers
- Attracting more investment into R&D and commercialization in the hemp industry.

The National Industrial Hemp Strategy has defined the following vision and mission for the sector:

Vision	Canada is the global leader with respect to total hemp crop utilization offering solutions along the entire value chain.
Mission	To create an economically sustainable Canadian hemp industry, benefiting all stakeholders along the value chain and enhancing the nation's health and natural environment.

Major Opportunities and Challenges

The process of developing the National Industrial Hemp Strategy, involving comprehensive consultation with Canadian hemp stakeholders, identified major opportunities and challenges for the industry, examining it in terms of three product categories: health and food (including personal care products), fibre and industrial oil applications, and breeding and production.

Health and Food – Opportunities

- Demographic and societal trends leading to increased interest in natural health products and “healthier for you” foods.
- Increasing recognition of the nutritional and health properties of hemp, including the presence of many different bioactive ingredients in hempseed that have shown promise in disease prevention and reduction.
- Emerging markets, such as pet foods and products, and gluten-free products.
- The rapidly expanding market for natural, organic personal care products.

Health and Food – Challenges

- Lack of clinical research specifically on the health benefits of hemp seed and oil.
- The need to educate the public about the reality of THC in hemp products.
- The Canadian regulatory environment for foods with health claims, both for marketing and for product approval, which is not as favorable or transparent as in other global jurisdictions.
- The need for research into hemp food formulations, required for uptake by mid to large size food companies.
- The need to achieve generally recognized as safe (GRAS) status for hemp with the US Federal Department of Agriculture.
- The lack of approval from the Canadian Food Inspection Agency for the use of hemp and hemp products in animal feed.

Fibre and Industrial Oil – Opportunities

- There is a world of new and emerging markets, driven by the increasing viability of substituting hemp-based bioproducts for petroleum-based products, based on emerging technology platforms and the increasing costs of fossil fuels. There are numerous short, medium and long term opportunities for hemp-based products to make significant inroads in these markets.
- Emerging processing technologies are unlocking new industrial applications. With domestic commercial processing of bast fibres expected to come online in 2009, a whole range of natural fibre applications are enabled. Similarly, new product applications are being brought to commercialization.
- There is increasing market demand for environmentally conscious products. Hemp has promising applications in a wide range of green building products, and the substitute of hemp-based products for fossil fuel-based products will deliver significant environmental benefits.
- With the market for hemp seed products expanding, there are increasing amounts of hemp fibre and hurd available for industrial purposes.

Fibre and Industrial Oil – Challenges

- There are a number of challenges relating to the nature and structure of the market for hemp, including EU subsidies. These subsidies distort the real market value and hence the nature of the market opportunity for hemp. Other market challenges include lack of access to risk capital and competition from imports of jute and sisal, and other natural fibres.
- The limited processing facilities in Canada pose a significant threat to the long term growth of the sector.
- Many government stakeholders have not yet demonstrated a significant commitment to hemp as a crop. As such, they are funding other “higher” profile products, and provincial agricultural departments may have other priorities, making funding more difficult to access for hemp.

- Potential issues with production and supply threaten the ability of the sector to grow rapidly in response to potential market demand.

Production and Breeding – Opportunities

- Significant benefits can be realized through modest continued investment in developing best management practices for industrial hemp.
- There are a number of opportunities to breed hemp for specific characteristics such as the introduction of a retting gene, increased water, less lignin, increased pectin and maximizing fibre. These activities will be aided by gene mapping and other activities.
- There are a number of emerging opportunities for Canada to export germplasm, with the international community looking at Canada for our hemp genetics. In the near term, breeding for the US market may afford significant opportunities, if current US prohibitions on industrial hemp cultivation were lifted.
- There is a potential opportunity to create and derive additional revenue for the production of hemp from green markets (e.g. bioremediation, carbon credits).

Production and Breeding – Challenges

- Most manufacturers in North America are moving to use rotary combines. The use of rotary combining damages hemp fibre.
- There are issues in protecting the hemp cultivar, including the potential for cross contamination of cultivars.
- The cost and labour involved in testing and proving seeds.

Strategic Areas for Action

In order to capitalize on identified opportunities for the growth of the Canadian hemp sector, the following strategic areas for action were identified through the extensive stakeholder engagement undertaken in developing the National Industrial Hemp Strategy. Some of these strategic areas for action are common to all of the industrial hemp sub-sectors, while others are specific to a particular industrial hemp industry.

Common to All Platforms

- Work towards improving access to risk capital, including educational efforts targeting the sources of capital, and ensuring that successful projects are well publicized.
- Develop a more detailed understanding of domestic and export hemp markets.
- Continue to work with Health Canada vis-à-vis optimizing the regulatory regime to ensure required oversight while minimizing the cost to producers.
- Support efforts to incorporate sustainability criteria into Canadian policy, with the goal of realizing competitive advantages for hemp and other biomass based products as compared to fossil fuel-based products.

- Work to maintain access to the US markets, including maintaining a close watching brief on the US situation, the forging of alliances with key US industry stakeholders and other industrial hemp proponents
- Continue work on low THC breeding, and broad-based education campaigns as to the benefits and safety of industrial hemp.
- Develop multiple value propositions that make hemp attractive versus competing crops.
- Grow the national industrial hemp network, to establish a strong and unified national industry voice, and a body to act as proponent for many of the actions outlined here.
- Establish increased market stability through improved relationships between producers and processors more closely aligning supply and demand.
- Communication and marketing efforts targeted toward market acceptance from potential end-users of hemp products, including consumer awareness campaigns explaining the benefits, and assuring the public that it is in no way a source of illegal drugs. Industrial end-users will also need targeted campaigns to make them aware of the benefits offered by hemp feedstock.
- Ensure access to highly qualified people for industry stakeholders, involving the identification of required skill sets and collaboration with academia to meet identified industry needs.
- Work with the relevant links in the value chain to ensure required infrastructure (storage, availability of harvesting equipment, pre-processing capacity, and others) keeps pace with the growth of the industry.

Health and Food

- Work with the Canadian Food Inspection Agency (CFIA) to achieve regulatory approval for the incorporation of hemp nutrients into animal feed and treats.
- Research to fill the existing gaps in the knowledge of the health benefits of hemp. Credible evidence of health benefits will be needed to maintain and expand the market for hemp food and health products over the long term.

Fibre and Industrial Oil

- Develop commercial bast fibre processing in Canada. The lack of commercial scale bast fibre processing in Canada is a primary barrier to growth in this sector. Production of sufficient (commercial) quantities of high quality bast fibre and hurd is required to enable the development of downstream applications.
- Identify end-user interest in utilizing hemp as a component of their product. While the broad spectrum of potential industrial hemp products are increasingly understood, there is considerably less understanding of the potential industry receptor capacity interested in commercializing these products.
- Establish test methods of Canadian hemp fibre for specific product applications.
- Develop technologies and methodologies for the increasing variety of market applications.
- Develop fibre grading standards, which are an important component in providing hemp product manufacturers and downstream users of hemp fibre with the stability of supply and quality assurance that they require

- Develop a cost-effective oil processing system.
- Develop market applications for co-products of the hemp decortication process. While much of the attention is focused on hemp oil and bast fibres, it is imperative that valuable markets be developed for all co-products of hemp processing, including short fibres and hurd, hurd only, fines and dust, and seed meal (left after oil extraction).

Breeding and Production

The areas for strategic action in breeding and production are all oriented towards realizing increased yields per acre of hemp crops, optimized for desired applications. These areas include:

- Bioresource engineering, to address properties of hemp such as tough stems and growth that may reach several metres tall.
- Ensure that sufficient supplies of hemp seeds are available for a variety of cultivars, covering the full range of Canadian growing conditions.
- Optimize and develop cultivars for specific Canadian growing conditions.
- Continue the development of best management practices around hemp cultivation, including response of hemp to fertilization, seeding rate, row spacing, harvest management / improved practices, and retting.
- Promote Canadian-bred cultivars internationally to help carve a distinct niche for Canada in the global industrial hemp industry.

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Introduction

Hemp is one of civilization's earliest cultivated crops, with some regions of the world having an unbroken tradition of over 6000 years of hemp cultivation. In North America, industrial hemp was a crucial crop during the colonial period, extending well into the 1800s. Despite the contribution of industrial hemp to the war efforts in both world wars, during the late 1930's legislation was passed in both the US and Canada that made hemp a controlled substance. Regulatory pressures combined with changing public perceptions around drugs led to the disappearance of a domestic North American hemp industry in the years following World War Two. This contraction of the market was mirrored throughout much of the developed world.

However, the fundamental value of hemp as a source of fibre and grains for applications as diverse as functional foods and natural health products, textiles for apparel and industrial applications, biocomposites, insulation, industrial oils, and a host of others, has led to its widespread re-adoption. Canada is a relatively recent entrant into the modern industrial hemp market, with commercial production legalized in 1998.

Despite significant setbacks in 1999-2000, the Canadian industrial hemp sector is showing renewed vigour and widespread optimism. Although there is increasing interest from governments, producers, researchers, and a variety of potential end-users, the sector is clearly still in its infancy, and will need focused and effective action on the part of the entire industrial hemp value chain and support structures to catalyze rapid growth.

Recognizing the need for concerted sector-wide approaches to overcoming roadblocks to expanded commercial production in the Canadian industrial hemp sector, the Composites Innovation Centre (CIC) submitted a program proposal under the Manitoba-Canada Agricultural Policy Framework. This program had several related elements:

1. Assistance with the further development of a national industrial hemp network
2. Evaluation of new hemp fibre decortication technology
3. Development and promotion of the competitive capacity of Canadian industrial hemp production in the international context
4. Development of a national industrial hemp strategy

This document captures the outcomes of the work on developing a National Industrial Hemp Strategy that has been undertaken throughout 2007-2008 by the CIC, the Canadian Hemp Trade Alliance (CHTA), and a broad cross-section of stakeholders representing producers, processors, researchers and research institutions, and the policy community.

The goals of this National Industrial Hemp Strategy are as follows:

“A national strategy for the hemp industry in Canada will align the value chain players towards common goals and maintain the competing edge of Canada through its implementation. By taking coordinated actions identified in the strategy, hemp growers will have access to new markets for both seeds and fibres, and in turn increase their farm gate income. It is also expected that the development of a strategy and the establishment of a national network that will oversee its implementation will attract more

investment into R&D and commercialization in the hemp industry...In summary, the program will help streamline value chains and align resources and actions in the industrial hemp sector in Canada.”¹

This document is structured in three parts. The first section provides an overview of the industrial hemp industry, including the many favourable characteristics of hemp that are driving the growth of the sector, and an overview of the current state of the industry. It also provides a high-level overview of the objectives of the strategy, including vision, goals, and strategic areas of action for the industrial hemp sub-sectors - food and health products (including personal care products), fibre (and co-products), and oil for industrial applications - supported by considerations of breeding and production.

The second section examines each of the industrial hemp sub-sectors (including production and breeding), and their specific strategic components, in more detail. It concludes with a discussion of the communications strategy needed to support the broader Industrial Hemp Strategy.

The third section presents a series of in-depth literature reviews, covering: the nutritional properties of hemp, health and food market considerations, industrial health products, and the agronomics of hemp, focusing on seeding and harvesting. These literature reviews were undertaken as key inputs to the process of developing a National Industrial Hemp Strategy, and are presented as discrete appendices.

Contributions to the development of the National Industrial Hemp Strategy

This National Industrial Hemp Strategy benefited from the contribution of a number of the leading industrial hemp stakeholders in Canada. Direct contributions include:

Kelley Fitzpatrick	NutriTech Consulting	Section on Health and Food (including personal care products), as well as Appendices A & B
Anndrea Schorzman-Hermann		Appendix D and contribution to Section on Breeding and Production
Kristofer Liljefors	The Agricola Group	Appendix C Literature Review of Industrial Hemp Products

In addition, a broad spectrum of stakeholders provided invaluable contributions through participation in workshops, and through direct consultation. Key proponents of this project were the Composites Innovation Centre, Manitoba Agriculture, Food and Rural Initiatives, NutriTech Consulting, and the Canadian Hemp Trade Alliance.

And finally, the input of the Project Steering Committee has been invaluable in pulling the National Industrial Hemp Strategy together. This committee consists of Christine Paquette (Composites Innovation Centre), Kelley Fitzpatrick (Flax Canada 2015), Keith Watson (Manitoba Agriculture, Food and Rural Initiatives), Arthur Hanks (Canadian Hemp Trade Alliance), and Eric Liu (Manitoba Agriculture, Food and Rural Initiatives).

¹ Composites Innovation Centre (July 2007) *Program Proposal under the Agricultural Policy Framework: Industrial Hemp Strategy and Capacity Development Program*.

Why Industrial Hemp?

Industrial hemp provides a true triple bottom-line. The industrial hemp crop sector provides value-added economic benefits through versatile and competitive products, supports sustainable crop production and rural communities, and promises increasing environmental benefits as hemp products are increasingly substituted for fossil fuel derived products. Hemp promises benefits for:

1. Producers (strong farms)
2. Consumers (healthier choices)
3. Business (affordable and versatile biomass with many product outcomes)
4. The environment (non-toxic, organic, biodegradable and sustainable, with the potential to substitute for a broad spectrum of fossil fuel products)

Hemp in North America has frequently been viewed as having limited market applications associated with green, organic or environmentally-aware products. Such a limited niche has supported a small market limited by legislative burdens and unfounded drug-enforcement fears. However, due to such factors as the re-emergence of an industrial hemp crop in Canada, increasingly environmentally-aware consumer preferences and the need for rural diversification, stakeholders - from government to consumers - are becoming aware of industrial hemp's unique value-added profile and the potential to generate economic, social and environmental benefits.

The hemp plant has three primary components: bast fibre, hurd, and seed / oil.

Hemp bast fibres are among the strongest and most durable of natural fibres, with high tensile strength, wet strength, and other characteristics favourable for various industrial products. It has been estimated that hemp produces three to four times as much useable fibre per acre per year as forests, and the bast fibre contains a low amount of lignin (the natural polymer that binds plant cells together), which allows it to be bleached without the use of chlorine. Hemp bast fibre is used in the production of a wide range of products where its strength and durability are advantageous, including cordage (rope, twine, etc.), specialty papers, fabrics for clothing and other applications, and industrial textiles such as geotextiles and carpeting. The strength of hemp fibre also makes it ideal for use in a range of composites for applications such as moulded car parts and fibreboard for construction.

Hemp hurd is composed of cellulose-rich, short fibres, and make up approximately 75% of the hemp stalk. They are spongy and absorbent, ideal characteristics in applications such as animal bedding and industrial absorbents. They may also be used to produce low-quality paper. More recently, hemp hurd has been used to produce a concrete-like substance for use in building applications, as well as for insulation and to produce fibreboard.

The **whole hemp stalk** can also be used to produce various **biofuels** such as bio-oil (or pyrolytic liquid), cellulosic ethanol, syngas (synthetic gas) and methane. Alternatively, the bast fibre can first be removed for use in high-value fibre applications, and the remaining hurd can then be processed into biofuel. The

processes by which hemp is converted to biofuels may also produce valuable chemicals and other materials as bi-products.

Hemp oil is extremely nutritious, and is used in foods and nutraceutical products for humans and animals, as well as in personal care products. Hemp oil is also suitable for use in industrial products such as paints, varnishes, inks and industrial lubricants, and can be used to produce biodiesel. The crushed seed meal left over from oil production is frequently used for animal feed.

The individual properties of these components offer multiple advantages to value-added products. To illustrate, here are few unique properties of hemp that allow it (and its end-products) to compete in food and non-food markets:

- **Fibre Strength:** Hemp fibres are longer, stronger, more durable, and more lustrous than cotton fibres, with added anti-microbial, mildew resistance and absorbency characteristics. In addition, hemp crops grows faster, yields more, and uses far less pesticides, herbicides and water than cotton.
- **Essential Fatty Acids and other ‘heart-healthy’ properties:** Hemp seed oil has higher levels of essential fatty acids (EFAs) than any other crop, is one of only two crops to also have gamma-linolenic acid (GLA), and has the highest complete protein concentration other than soy.
- **Positive agronomics for an organic crop:** Hemp can be grown organically and sustainably with high yields.

Literature on industrial hemp provides abundant descriptions of environmental, social and economic advantages gained through the production of hemp and hemp-based products. These advantages generate positive benefits throughout the hemp value chain for producers, retailers and consumers and are conferred through positive agronomics, environmental benefits and the technical advantages of using hemp components (fibres, hurd, seeds and oil) in various product markets.

There are, however, several current limitations on the adoption of industrial hemp, including:

- Breeding for specific Canadian environments is still at an early stage;
- Production of industrial hemp is still low, limiting availability and distorting pricing;
- technical characteristics are not yet confirmed for use of hemp fibre in many potential product applications, such as a replacement for fibreglass in composites, and;
- The huge US market is perceived as risky, with legislative burdens and elements of the federal government (DEA) that have been overtly hostile to the growth of the industrial hemp market.

The advantages and benefits of hemp can be summarized in two basic “storylines”:

1. Hemp components confer advantages to end-products and consumers
2. Hemp production is supported by positive agronomics, potential environmental benefits, and the need for rural diversification

The four primary markets for hemp components include fibre, industrial oil, food and natural health.

1. Competitive Advantage in Food and Health

Hemp seed and hemp seed oil confer advantages to natural health food products based on three specific properties:

- A high concentration of essential fatty acids (Omegas 6 and 3 are in the optimum ratio of 1:3) and gamma linolenic acid;
- A high concentration of protein, vitamins (e.g. vitamin E) and minerals; and
- A high concentration of nutritional fibre.

The higher concentration and more readily accessible quantities of EFAs, GLA and protein ensure that hemp's natural benefits can be extracted competitively for use as ingredients in health promoting foods. Hemp's agronomic profile, value to producers and its affinity for organic production further increase the marketability and economic value of hemp products.

2. Competitive Advantage in Fibre Markets

Hemp fibres impart specific advantages to a wide variety of products:

1. **Textiles:** Hemp fibre is extremely competitive with cotton and linen due to agronomic advantages, and has further advantages in quality and technical features. Hemp fibres grown using sustainable practices have higher yields and produce fibres that are stronger, longer, more durable and more lustrous than organic cotton. In addition, hemp fibres have anti-microbial, mildew-resistant and excellent absorbent properties. Hemp textiles also have increased breathability, UV resistance and endurance as compared to cotton textiles.
2. **Composites:** Hemp fibres are competitive with natural and synthetic fibres due to specific advantages conferred by its tensile properties, and by its environmental performance as compared to spun glass and other current fibres. These tensile properties give hemp fibres good strength to weight ratio, and combined with their length make them useful in fibreboards and other composites.
3. **Pulp and Paper:** The low lignin content of hemp makes it highly competitive to wood pulp for use in paper production. Hemp bast fibres require less treatment for pulp production, and the strength of hemp fibres makes them ideal for use in high-end paper applications, where durability is an advantage. Paper applications are by far the largest market for hemp fibres in Europe.
4. **Low value markets:** The shorter, lower-value hemp fibres retain anti-microbial, mildew-resistant and absorbency properties which make them useful as animal/horse bedding. The high tensile strength of hemp bast fibre makes it suitable for the production of cordage (rope and twine), hempcrete and lower value composite applications, and its natural insulation properties make it ideal for the production of thermal insulation products.

Hemp's many properties also make it valuable for use in a number of other products and markets, such as industrial textiles and building materials.

3. Competitive Advantage in Industrial Oil applications

Hemp oil is non-toxic and is classified as a semi-drying oil, and can be used in a range of oil-based industrial products including paint, varnish, detergents, solvents, and lubricants for machinery. Paints made from hemp oil have been found to penetrate wood better than other paints and provide high resistance to water. Hemp oil can also be used in non-toxic printing inks.

4. Competitive Advantage in Personal Care markets

The competitive advantage for hemp oil / hemp seed oil for use in personal care products is based on the oil's EFA properties. The personal care industry includes several thousand products, ranging from hand lotions to shampoos.

As polyunsaturated fatty acids, EFAs impart excellent emollient, lubricating and moisturizing properties to a variety of body care products. The external application of these compounds is suggested to alleviate or remedy common skin problems (dry, scaling or cracked skin), and provide 'smoother texture' to lotions and related personal care products.

Summary

The table on the following pages summarizes the many properties and advantages of industrial hemp:

Table 1: Hemp Components, Advantages, Benefits and Applications to the Primary Market

Hemp Component	Component Properties / Advantages	Benefits	Primary Market Applications
<p>Hemp Bast Fibres (Bast, outer or long fibres – 20% of the stalk)</p>	<p><i>Primary Bast Fibres</i> (70% of fibres):</p> <ul style="list-style-type: none"> • High tensile properties make it strong and durable • High wet strength • Length of fibres is useful (up to 7ft) • More lustrous than cotton • Mildew-resistant • Anti-microbial properties • Increased yields (compared to trees) • Low lignin • Lower inputs to pulp (energy and chemicals) • Less bleaching required • Versatile <p><i>Secondary Bast Fibres</i> (30% of fibres): Less valuable, higher in lignin</p>	<ul style="list-style-type: none"> • Superior quality to linen in textiles • Superior paper that lasts longer and is more environmentally friendly • Superior fibreboards • Superior use in automotive panels (stronger and lighter) • Hemp added to concrete increases tensile and compressive strengths, reduces shrinkage and cracking; hemp can reinforce plastics, and substitute mineral fibres • Organic/acid-free textile • Environmental benefits from hemp production • Natural fibre composites are approximately 25 percent stronger than wood fibre reinforced thermoplastics and have none of the negative handling or environmental issues associated with glass fibre • There is increased recycling capacity due to strength. Hemp paper can be recycled upwards of 20 times, as compared to 4-5 times for traditional paper 	<p>Textiles – target for substitution is cotton and linen</p> <p>Fibreboard – targets for substitution are wood-fibres, and straw</p> <p>Pulp & paper - target for substitution is pulp from trees</p> <p>Natural Fibre Markets – targets for substitution include biofibres/composites using flax, and bast fibre to replace glass and carbon fibres</p>
<p>Hemp Hurd (Hurd or inner / short fibres – 70-80% of the stalk)</p>	<ul style="list-style-type: none"> • Hurd is 55-77% cellulose • High in silica • Mildew-resistant • Anti-microbial properties • Twice as absorbent as wood 	<ul style="list-style-type: none"> • Appropriate for low grade paper. • High yield - 1 acre of hemp can replace 4.1 acres of trees for pulp production • Absorbency, anti-mildew and anti-microbial properties are advantageous in animal bedding 	<p>Possible markets: rayon, biomass fuel / energy, cellophane, food additives, industrial fabrication materials and newsprint pulp</p>

Hemp Component	Component Properties / Advantages	Benefits	Primary Market Applications
Hemp Seed Oil	<ul style="list-style-type: none"> Moisture retention qualities High essential fatty acid content; highest proportion (81%) and best balance of total EFAs of any crop plant Hemp seed is second only to soybeans in complete protein One of only two plants that contain both EFAs as well as gamma linolenic acid (GLA) 	<ul style="list-style-type: none"> EFAs and GLA have well-documented food health benefits EFAs and oil content make it suitable for oils and topical treatments; it is an emollient Moisture-retention properties support topical treatments and skin lotions Non-toxic and organic are advantageous for marketing health related products EFAs provide natural moisturizing effect on skin 	<p>Food and Health</p> <p>Natural Health Care</p>
Hemp Oil for Industrial Applications	<ul style="list-style-type: none"> Non-toxic Semi-drying oil Compared to soy oil – faster drying 	<ul style="list-style-type: none"> These attributes allow it to be used in non-toxic applications It can be used in paints, oils, detergents and varnishes Hemp based paints penetrate wood better and are more water-resistant 	<p>Target would be other natural oils in use (including flax)</p>
Agronomics and environmental impacts	<p>Lower inputs since it grows rapidly, is relatively pest/disease resistant and out-competes weeds:</p> <ul style="list-style-type: none"> less fertilizer less herbicides low water requirements less pesticides higher yields <p>Versatile – can grow on marginal land Crop properties – dense foliage, deep root structure</p>	<ul style="list-style-type: none"> Economic advantages for producers Organic growth-conditions Versatile crop Revitalizes soil and utility in crop rotation Can be recycled, can be grown ecologically, biodegradable and has no waste disposal problems Products that integrate are usually non-toxic and treated with less chemicals (e.g. paper, cotton replacements) 	<p>Rural Economy and Agricultural Production</p> <ul style="list-style-type: none"> Numerous market opportunities as a commodity and value-added crop Supports soil remediation Lower costs and inputs to producers <p>Environmentally Friendly Consumer Markets</p> <ul style="list-style-type: none"> Health and environmental preferences Organic markets for food and non-food Green marketing

Profile of the Industry

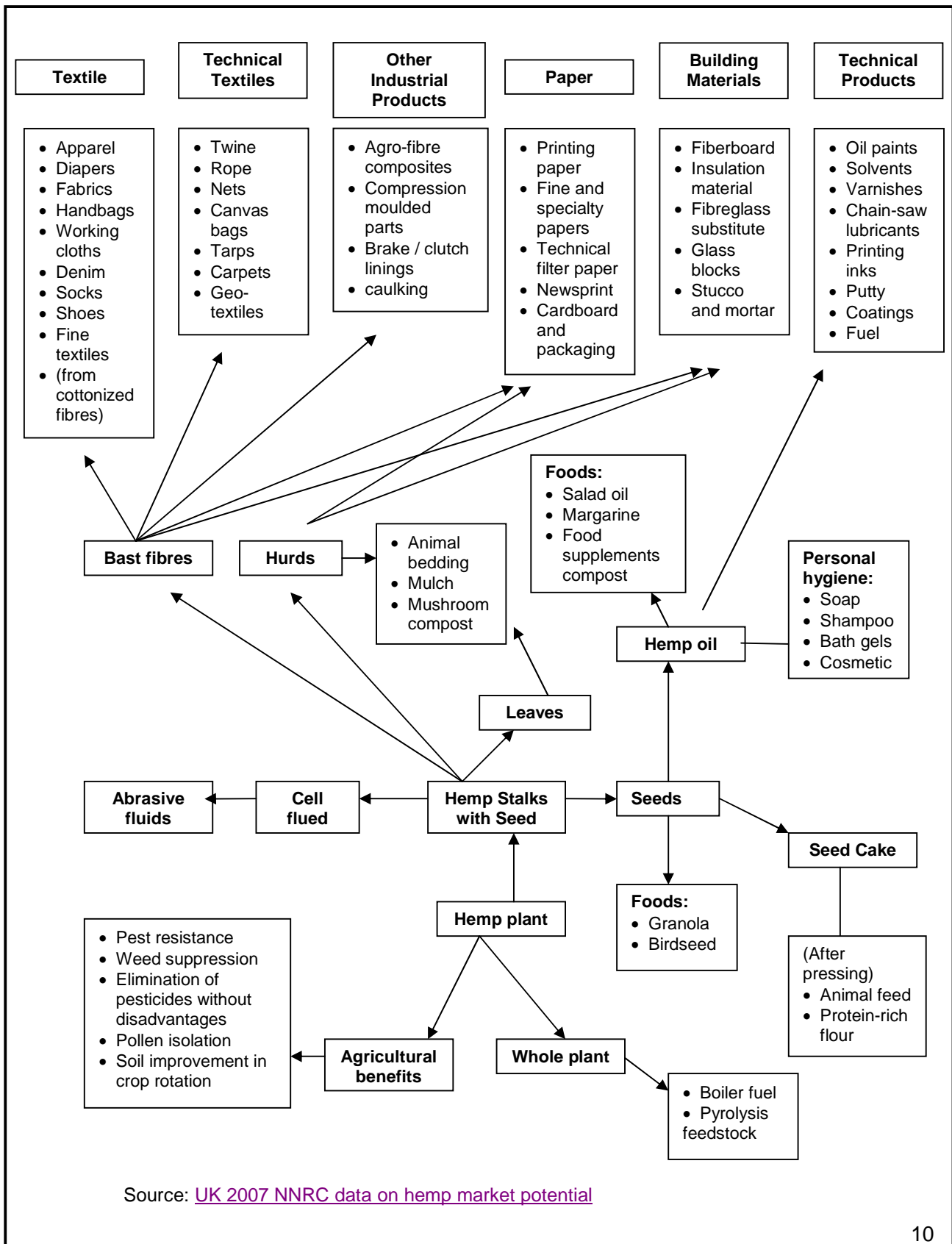
Definition

The term industrial hemp refers to varieties of *Cannabis sativa* characterized by low levels of tetrahydrocannabinol (THC, marijuana's primary psychoactive chemical), grown for specific industrial, health, and food outcomes. The European Union (EU) and the Organization for Economic Cooperation and Development (OECD), which includes Canada, use 0.3% THC as the dividing line between industrial and potentially drug-producing varieties of *C. sativa*.

Industrial Uses for Hemp

For millennia, the plant species *Cannabis sativa* has been a source of fibre and oilseed used worldwide to produce a variety of industrial and consumer products. Hemp fibre is suitable for use in a wide range of products including carpeting, home furnishings, construction materials, automotive parts, textiles, and paper. As an oilseed, hemp seed has many uses, including industrial oils, cosmetics, pharmaceuticals, and food.

In the modern context, the broad spectrum of applications for hemp grain and fibre can be mapped as follows:



History of Hemp Cultivation

Hemp (*Cannabis sativa*) is among the earliest cultivated crops, having been grown for fibre and seed for at least 6,000 years. Hemp was arguably the most important non-food crop during the colonial period, and played a prominent role in the European settlement of North America. The crop was widely grown in North America up until the mid-1800s, and hemp fibre was used primarily in sails, riggings, canvas, ropes, clothing and paper. The seed was also crushed for oil, food and feed. By the turn of the 20th century, the cotton gin (or cotton engine) made cotton the fabric of choice for apparel, and the market for coarse natural fibres was increasingly met by imports. Coupled with advances in synthetic petroleum products throughout the first half of the 20th century, hemp production saw a marked decline.

In 1937, The United States Congress passed the first federal law to discourage *Cannabis* production for marijuana (the Marihuana Tax Act; 50 Stat. 551). Canada followed suit with the Opium and Narcotics Control Act in 1938. However, industrial uses were still permitted, with the government actively encouraging farmers to grow hemp for fibre and oil during World War II. In the years following the war, competition from synthetic fibres, regulatory changes, and mounting public anti-drug sentiment resulted in steady and dramatic reductions in the acres of hemp being planted, with the crop disappearing entirely from production after 1958.

International Context for Industrial Hemp

While industrial hemp production is banned outright in the US and, until recently, was also banned in Canada, it is legal in many parts of the world. Currently, more than 30 countries in Europe, Asia, and North and South America permit farmers to grow industrial hemp as an agricultural commodity, with roughly 14 of these countries selling part of their production on the world market. Recent and reliable data on the size of the global hemp crop is not available, however.

The United States is now the only developed nation in which the production of industrial hemp is prohibited. Great Britain lifted its ban in 1993, followed by Germany in 1996. Despite subsidies in some jurisdictions (the European Union subsidizes hemp fibre production under its Common Agricultural Policy), industrial hemp is generally considered a minor crop in the developed world.

The following provides a snapshot of the state of industrial hemp cultivation internationally:

Table 2: Overview of International Industrial Hemp Cultivation²

Australia	<ul style="list-style-type: none"> • Research trials began in Tasmania in 1995 • Victoria has had commercial production since 1998 • New South Wales has research • Production began in Queensland in 2002 • Industrial hemp crops were licensed in Western Australia in 2004³ • Recent report published: “Creating a Vibrant Fibre Sector in the Future Australian Economy”⁴
Austria	<ul style="list-style-type: none"> • Has a domestic hemp industry, including the production of hemp seed oil and medicinals
Chile	<ul style="list-style-type: none"> • Has grown hemp in the recent past for seed oil production
China	<ul style="list-style-type: none"> • World’s largest exporter of hemp textiles • Medium density fibre board is now becoming available • China has had an uninterrupted hemp trade for approximately 6000 years
Denmark	<ul style="list-style-type: none"> • First modern hemp trials planted in 1997, with a commitment to organic production methods
Finland	<ul style="list-style-type: none"> • Had a resurgence of hemp activity in 1995 with several small test plots • Developed Finola, a cultivar for northern climates (breeder code FIN-314) • In 2003, Finola was accepted to the EU list of subsidized hemp cultivars • Hemp has never been prohibited in Finland
France	<ul style="list-style-type: none"> • Never prohibited industrial hemp • Source of hemp seed for export, as well as high quality hemp oil

² Source: Hemp Industries Association website, at: <http://www.thehia.org/facts.html>, with additional data integrated.

³ See “Creating a Vibrant Fibre Sector in the Future Australian Economy” at:

<http://www.ausbiotech.org/spotlight/details.asp?id=117&returnToUrl=%2Fdefault%2Easp>

⁴ Available at: <http://www.ausbiotech.org/UserFiles/File/future%20is%20fibres%20strategy.pdf>

Germany	<ul style="list-style-type: none"> • Banned hemp in 1982 • Research re-commenced in 1992 • Ban on growing hemp lifted in 1995 • Considerable industrial hemp R&D is ongoing
Great Britain	<ul style="list-style-type: none"> • Lifted hemp prohibition in 1993 • Markets for animal bedding, paper and textiles exist • Subsidies are given to farmers growing hemp
Hungary	<ul style="list-style-type: none"> • Currently rebuilding their hemp industry • Significant exporter of hemp cordage, rugs and fabric to the US • Also export hemp seed, paper, and fibreboard
India	<ul style="list-style-type: none"> • Stands of naturalized Cannabis exist, used for cordage, textiles and seed
Italy	<ul style="list-style-type: none"> • Investing in industrial hemp, especially for textile production
Japan	<ul style="list-style-type: none"> • Possesses a rich religious tradition that includes hemp; custom requires that the Emperor and Shinto priests wear hemp attire for certain ceremonies • Traditional spice mixes include hemp seed • There is a thriving retail market for a variety of hemp products
Netherlands	<ul style="list-style-type: none"> • Involved in a multi-year study to evaluate hemp for paper applications • R&D into specialized processing equipment • Activities in hemp breeding
New Zealand	<ul style="list-style-type: none"> • Hemp trials began in 2001; various cultivars are being planted in the north and south islands

Poland	<ul style="list-style-type: none"> • industrial hemp being grown for fabric, cordage, and hemp particle board • Activities into the use of hemp for phytoremediation (heavy metals)
Romania	<ul style="list-style-type: none"> • Largest commercial producer of industrial hemp in Europe • Hemp exported to Hungary, Western Europe and the US
Russia	<ul style="list-style-type: none"> • Largest hemp germplasm collection in the world is at the N.I. Vavilov Scientific Research Institute of Plant Industry (VIR) in St. Petersburg; funding is needed to maintain and support the collection
Slovenia	<ul style="list-style-type: none"> • Some domestic production • Manufacturing of currency paper
Spain	<ul style="list-style-type: none"> • Production of industrial hemp was never prohibited • Produces rope and textiles • Exports hemp pulp for paper
Switzerland	<ul style="list-style-type: none"> • Producer of hemp
Turkey	<ul style="list-style-type: none"> • Hemp has been grown for at least 2800 years for such applications as rope, caulking, food and feed, paper, and fuel
Ukraine, Egypt, Korea, Portugal, Thailand	<ul style="list-style-type: none"> • Producers of hemp

US Context for Industrial Hemp

The US market for hemp products will be very significant in the development of the Canadian industrial hemp sector. All hemp products sold in the United States are imported or manufactured from imported hemp materials.

As discussed, the US federal government began regulating production of hemp in 1937 due to concerns about the psychoactive properties of some cultivars of *Cannabis sativa*, and production in the United States completely ceased by 1958. Starting in 1970, production of all varieties of *Cannabis* in the US, regardless of THC content and intended use, fell under the umbrella of the Controlled Substances Act. This act adopted the same definition of *Cannabis sativa* that appeared in the 1937 Marihuana Tax Act. The statute thus applies to all varieties of

the *Cannabis* plant, making no distinctions between low and high-THC varieties. Strictly speaking, the CSA does not make *Cannabis* illegal. Rather, it makes it illegal to grow the crop without a DEA permit.

In the early 1990s a renewed interest in the production of industrial hemp emerged in the US, especially in agricultural regions that were highly dependent on a single crop. Reflecting this growing stakeholder interest, more than 25 states have considered hemp legislation, with 15 having passed laws calling for research into industrial hemp during the past decade.⁵ Most state resolutions call for scientific, economic, or environmental studies, and some include laws authorizing the planting of experimental plots under state statutes. The National Conference of State Legislators (NCSL) has endorsed industrial hemp for years.

However, the Drug Enforcement Administration (DEA) currently has ultimate authority as to whether any industrial hemp production authorized under a state statute will in fact be permitted. It further enforces standards governing the security conditions under which the crop must be grown.

The DEA has proved unwilling to grant licenses for growing small plots of hemp for research purposes, as has been authorized by some state laws. It issued a permit for an experimental plot in Hawaii in the 1990s (now expired), but no more since then.

Their rationale involved concerns as to whether commercial cultivation of industrial hemp would increase the likelihood of covert production of high-THC marijuana cultivars, while complicating detection and enforcement activities. There were also concerns that supporting industrial hemp would “send the wrong message to the American public concerning the government’s position on drugs.”⁶

Rather than supporting the growth of an industrial hemp sector, the DEA made a concerted effort beginning in late 1999 to ban exports of hemp food products that might contain even trace amounts of THC. They acted administratively to demand that the US Customs Service enforce a zero-tolerance standard for the THC content of all forms of imported hemp, and hemp foods in particular.

The DEA held that when Congress wrote the statutory definition of marijuana in 1937, it exempted certain portions of the *Cannabis* plant from the definition in the belief that the non-flower (stems and leaves) portion of the plant contained no THC whatsoever. With minute amounts of THC detectable throughout the hemp plant, it felt justified in treating all hemp material as a controlled substance.

A coalition of hemp industry trade groups, retailers, and a major Canadian exporter brought the DEA to court, arguing that Congress clearly intended to allow industrial uses of hemp when the material contained non-psychoactive levels of THC, citing the precedent whereby poppy seeds are permitted, despite trace amounts of naturally occurring opiates.

⁵ See: <http://votehemp.com/state.html>

⁶ Source: Congressional Research Service Report to Congress: Hemp as an Agricultural Commodity, updated March 23, 2007

On February 6, 2004, the US Court of Appeals ruled that “the DEA’s definition of ‘THC’ contravenes the unambiguously expressed intent of Congress in the CSA and cannot be upheld.” This ruling was not appealed, re-opening the market for imported hemp material and products. While ultimately unsuccessful, the DEA’s actions did serve to significantly set back the development of US domestic hemp product processing, and by extension the Canadian industrial hemp sector.

Legislation was introduced to Congress in February of 2007 that would permit the cultivation of industrial hemp in the United States. If enacted, the Industrial Hemp Farming Act of 2007 would amend Section 102 of the Controlled Substances Act (21 USC. 802(16)) to specify that the term “marijuana” does not include industrial hemp.

The bill would permit industrial hemp production based on state law, without preemption by the federal government under the Controlled Substances Act. The measure would grant exclusive authority to any state permitting industrial hemp production and processing to determine whether any such *Cannabis sativa* plants met the limit on THC concentration as set forth in the Controlled Substances Act. In any criminal or civil action or administrative proceeding, the state’s determination would be conclusive and legally binding.

The measure was referred to the House Committee on Energy and Commerce and to the House Committee on the Judiciary.

The Canadian Industrial Hemp Sector

With the disappearance of Canadian hemp production following the Opium and Narcotics Control Act of 1938, there was no commercial industrial hemp activity in Canada for several decades.

Canada began revisiting its regulation of industrial hemp in the early 1990s. Health Canada began issuing licenses for research crops starting in 1994, with increasing acreage planted through to 1997. A number of Canadian companies, universities and provincial governments took advantage of these research licenses to advance research in both production and processing.

Vigorous efforts on the part of these stakeholders convinced the federal government to license commercial industrial hemp production, with the Industrial Hemp Regulations⁷ coming into effect on March 12, 1998. These regulations cover all aspects of hemp cultivation, including processing, transportation, sale, and importing and exporting. The rationale provided by the Health Canada for permitting commercial production of industrial hemp is as follows:

“In recent years, interest in the cultivation of industrial hemp, as a potential source of new jobs, has grown in the agricultural and industrial sectors, as has the need for the development of alternative sources of fibre. In addition, the information gathered as a result of the issuance of research licenses over the past four years has indicated that industrial hemp could be successfully grown in Canada as a separate entity from *Cannabis* (marihuana). With such a demand and the encouraging research findings, Health Canada chose to give the agricultural and

⁷ Industrial Hemp Regulations, available at: <http://laws.justice.gc.ca/en/showtdm/cr/SOR-98-156>

industrial sectors the opportunity to build what is essentially a new industry by changing the laws restricting the cultivation of industrial hemp.”⁸

While enabling the first commercial hemp production in Canada in decades, the regulations around licensing requires a suite of obligations from producers:

- Producers must register the GPS coordinates of their industrial hemp fields
- Only certified, low-THC cultivars are permitted
- The grower must arrange for tissue sampling of the crop by a certified sampler and laboratory THC analysis; the cost of these operations is borne by the grower
- Government must be allowed access to hemp crops for testing of THC levels
- There is a maximum allowed THC level of 10ppm in hemp seed products.
- Thorough cleaning of vehicles and equipment is required
- Industrial hemp licenses are issued for a calendar year only and must be renewed if the product is carried into the new year

Canada has adopted the threshold for allowable THC that was established by the Organization for Economic Cooperation and Development, with a THC level of 0.3% being the maximum for industrial hemp. Many varieties being grown in Canada at present originated in Europe. There is ongoing work on Canadian cultivars, and several varieties adapted to specific Canadian growing conditions are becoming available.

241 licenses for industrial hemp cultivation were issued in 1998. In 1999 this number jumped to 545, with considerable optimism among producers and processors as to the future of the crop. However, the Canadian industrial hemp industry suffered a serious setback in 1999, which significantly challenged growth in the sector until it began to rebound in 2005.

A US company, Consolidated Growers and Processors (CGP) Inc., was a primary contractor of industrial hemp acreage in Canada during the rebirth of the industry in 1998-1999. It was a large contributor to the dramatic growth in acreage seen in 1999, especially in Manitoba, and was responsible for an estimated 40% of all industrial hemp contracted in Canada during that year. Unfortunately, the company went bankrupt, defaulting on its obligations to producers, and leaving them with large quantities of hemp seed and fibre. Much of this material was not sold, with producers absorbing the consequent losses.

The bankruptcy of CGP went hand in hand with the DEA's aggressive efforts to ban the import of all hemp products. The combination sent a profound chill through the Canadian industrial hemp sector. However, with the success of the court case against the DEA in 2004, and continued improvements in breeding, production, and processing, the industry is seeing a strong resurgence, with 2006 marking the first year in which production levels exceed those of 1999. 2007 saw a dramatic reduction in hemp acreage planted, but this is being seen more as a correction of the overproduction in 2006, rather than an indication of a second sustained downturn. Another significant factor in the 2007 downturn was the increasingly positive economics of growing other crops.

⁸ Source: Health Canada website, at: http://www.hc-sc.gc.ca/dhp-mps/pubs/precurs/factsheet_fiche_e.html

With the imminent commercialization of made-in-Canada bast fibre processing technologies, the research and development work under the Biofibres Initiative, and the continued strength and growth of the food and health markets, there is renewed optimism amongst stakeholders from all stages in the industrial hemp value chain as to the future growth of the sector.

Currently, the prairie provinces are the primary hemp producers, as seen in the examination of acreages in Canada which follows later in this section. Manitoba has historically had the largest crops, followed by Saskatchewan and Alberta. Ontario, Quebec and British Columbia have more modest hemp production, although there are strengths in hemp processing, especially in Ontario.

Due to strong demand for organic hempseed, roughly one third of the current Canadian hemp crop is certified organic.⁹

Production

As proven through its cultivation over a large percentage of the planet's arable land, industrial hemp is a hardy, fast growing, resilient and high yield crop. It is an annual broadleaf plant, featuring a taproot. The female flowers and seed set are indeterminate,¹⁰ with both ripe and immature seeds on the same plant during harvest. The typical height of an industrial hemp crop is between 2 to 4.5 metres. Some cultivars that have been optimized for seed grow shorter and stockier, while cultivars optimized for fibre can be taller. Under ideal growing conditions, industrial hemp is capable of very rapid growth.

Industrial hemp is well adapted to temperate regions. In Canada, industrial hemp has shown good potential as an alternative to be included in rotation with other, more traditional crops. Used in rotation, industrial hemp has the potential to disrupt traditional crop disease cycles, while delivering attractive profit margins.

Most cultivars of hemp are photoperiodic, taking their cue to flower (seed) from the shortening days and increasingly red cast of the late summer sun. The period from seeding to harvest is between 70 to 140 days, depending on the cultivar, with most varieties taking somewhere between 85 and 120 days. This relatively short growing season, coupled with its tolerance for a wide variety of growing conditions, makes it a potentially viable crop for many regions in Canada. Hemp grown for fibre-only applications can be harvested during pollination, 60 to 90 days after seeding.

Industrial hemp has a long history of breeding and genetic selection, with a great variety of cultivars in existence. Work on optimizing hemp for specific regions in Canada is well underway, with steady improvements in both genetics and production methodology being realized. Canadian hempseed breeders have been developing unique cultivars targeting such properties as essential fatty acid profiles, seed yield, short stature (more favourable for combining and more energy into seeds), fibre quality, fibre yield, and low THC levels. Dual purpose cultivars, with favourable seed and fibre properties, are also common.

⁹ Source: Don Lotter. (2001) *Hemp Heaven and Hell... a story in two parts*. Newfarm.Org, at: http://www.newfarm.org/international/canada_don/manitoba/index.shtml

¹⁰ The seeds continue to develop and mature over an extended period of time.

Health Canada has approved 27 cultivars of industrial hemp for use in Canada. These cultivars have a proven THC content of under 0.3%, with many of them containing much lower concentrations than this. Health Canada has recently begun exempting certain cultivars of hemp from the full regime of inspection and analysis, due to a solid track record of very low THC. Finola was the most widely planted breed of hemp in 2007, at 5224 acres, followed by USO 14 at 4486 acres and Crag at 1168 acres.

In Ontario, hemp yields average 1250 lbs/acre of grain using the Anka cultivar, and yields as high as 1800 lbs/acre have been achieved on occasion growing Crag.¹¹ Arthur Hanks of the Canadian Hemp Trade Alliance advises farmers to prepare for a low average of 500-700 lbs/acre, and points out that if production costs can be kept to \$300/acre, they can make money on that. However, experienced farmers quite often average 1100-1200 lbs/acre. The top yields that Arthur Hanks has heard of are 2000 lbs, for Finola under irrigation, and he has noticed that experienced hemp farmers tend to average much better yields.¹²

Manitoba's Management Plus Program lists hemp variety yields as follows:¹³

Table 3: Manitoba Hemp Variety Yields

Year	Variety	Acres	Yield per acre (pounds)	# of Producers
2004	FINOLA (FIN 314)	380	551	4
	USO 14	2,559.00	295	19
	USO 31	1,359.00	128	5
2005	FELINA 34	208	183	3
	FINOLA (FIN 314)	1,116.00	163	8
	USO 14	6,841.00	346	40
	USO 31	1,376.00	212	7
2006	ALYSSA	535	406	6
	CRAG	487	476	6
	FINOLA (FIN 314)	2,843.00	639	21
	USO 14	23,338.00	560	83
	USO 31	2,508.00	445	14

When interpreting the chart above, it must be kept in mind that these yields include both conventional and organic farming, and as is discussed further on, inexperienced organic farmers tend to average yields of 50% of what conventional farming would produce.

¹¹ Correspondence with Shep Shepenko

¹² Correspondence with Arthur Hanks, The Canadian Hemp Trade Alliance. www.hemptrade.ca

¹³ http://www.mmpp.com/Home_Page.htm

Agronomics

If hemp is planted at the proper time it reportedly suppresses most weeds. However, some growers feel weed control is still necessary for optimum yield.¹⁴ Insect and disease problems must be managed like any other crop. However: “its rapid growth and vigorous nature allow it to overcome the attack of most diseases and pests.”¹⁵ Hemp has been found to require approximately the same fertility as a high-yielding crop of wheat, with up to 110 kg / ha of nitrogen, depending on soil fertility and past cropping, as well as phosphorous. Roughly 40% of the mass of industrial hemp crops are left in the field in the form of roots, leaves and tops, and this material contains over half of the nutrients applied to the crop. Many of the nutrients will be available to future crops.

The OMAFRA factsheet *Growing Industrial Hemp in Ontario* provides a detailed overview of the agronomics and best practices for hemp cultivation in Ontario, available at: <http://www.omafra.gov.on.ca/english/crops/facts/00-067.htm>.

Similar data is available for Manitoba at: <http://www.gov.mb.ca/agriculture/crops/hemp/bko05s00.html>.

Saskatchewan Agriculture and Food has published a document entitled *Hemp Production in Saskatchewan*, available at: http://www.votehemp.com/PDF/Hemp_Production_SK-2006.pdf.

Alberta Agriculture and Rural Development provides extensive information at: [http://www1.agric.gov.ab.ca/\\$department/deptdocs.nsf/all/agdex126?opendocument](http://www1.agric.gov.ab.ca/$department/deptdocs.nsf/all/agdex126?opendocument).

The British Columbia Ministry of Agriculture and Food has published an *Industrial Hemp Factsheet*, available at: <http://www.agf.gov.bc.ca/speccrop/publications/documents/hempinfo.pdf>.

Other provinces may have similar material available.

Acreage under Cultivation

The following table lists the acres under cultivation since commercial cultivation began in 1998:

¹⁴ Source: Don Lotter. (2001) *Hemp Heaven and Hell... a story in two parts*. Newfarm.Org, at: http://www.newfarm.org/international/canada_don/manitoba/index.shtml

¹⁵ OMAFRA Factsheet: *Growing Industrial Hemp in Ontario*, at: <http://www.omafra.gov.on.ca/english/crops/facts/00-067.htm>

Table 4: Hectares of Hemp under cultivation 1998-2007

	Canada	BC	AB	SK	MB	ON	QC	NB	NS
1998	2400	72	38	263	606	1164	24	214	19
1999	14205	225	754	3093	8887	1023	86	4	126
2000	5485	291	306	1426	2906	217	239	0	102
2001	1312	96	113	392	472	209	30	0	0
2002	1530	200	123	449	597	142	19	0	0
2003	2733	7	153	672	1468	397	13	4	18
2004	3531	18	639	1004	1655	183	10	4	18
2005	9725	0	916	3429	5018	251	74	19	18
2006	19458	111	2103	6154	11726	346	88	8	18
2007	4684	43	605	2078	1728	53	173	4	0

Source: Health Canada, as found at: Alberta Agriculture and Food. (August 2007) Industrial Hemp Production in Canada, @ [http://www1.agric.gov.ab.ca/\\$department/deptdocs.nsf/all/econ9631](http://www1.agric.gov.ab.ca/$department/deptdocs.nsf/all/econ9631)

As can be seen, Canadian hemp production is concentrated in Saskatchewan, Manitoba, Alberta and Ontario. In 2007, for the first time Saskatchewan overtook Manitoba as the largest producer of hemp, followed by Alberta, Quebec, Ontario, British Columbia, and finally New Brunswick. As hemp is a new crop in Canada, no production statistics are currently being collected by Statistics Canada.

In 2007 there were 179 licenses issued by the Industrial Hemp Section of Health Canada's Office of Controlled Substances, with 149 licenses for cultivation, and 30 licenses for breeding.

Economics of Production

Producers tend to be clustered in networks and co-operatives, and / or are located in relatively close proximity to processing facilities in order to minimize transportation costs. A primary challenge for hemp growers is to find a buyer who will contract for the purchase of their harvest. Currently, the only other market for industrial hemp, aside from contracts with known processors, is the supply of local cottage industries.

Costs of production are tied to a number of interrelated variables. Factors such as small acreage, low yields, the age and cost of equipment, the cost of land, and opportunity cost (as determined by competing uses for this agricultural land) will negatively impact the economics of production.

In addition to the typical expenses associated with agricultural production in Canada, growing industrial hemp will entail some additional expenses, including police security checks, considerable regulatory paperwork, GPS requirements, and THC sampling and testing.

Assuming markets for both fibre and grain (hempseed), dual purpose crops currently have an advantage in costs of production against revenue generated. However, the market for fibre remains underdeveloped. As the hemp sector continues to grow and as new technologies are applied to the production, processing and manufacturing of components using hemp fibres, more commercial possibilities will become feasible and market demand will grow, strengthening the farm gate value delivered to farmers.

Fibre

The value of unprocessed hemp fibre (straw) is influenced by such factors as fibre length, fineness, colour and the market demand for a given quality of fibre. The quality of the fibre will be influenced by the maturity of the plants, conditions during field retting (if employed), and issues of storage. Prices paid to producers range considerably, and are hard to pin down due to the absence of reliable price or quality indicators. The North American market for hemp fibre remains underdeveloped, due to the lack of commercial bast fibre processing capacity and specific market pull from end-use companies?

Grain

Grain markets for hemp have been more robust, with prices noted between \$0.45-\$0.55 per pound.¹⁶ The Canadian Hemp Trade Alliance reported a market price of \$0.50 to \$0.60 cents per pound for conventional hemp seed, with an \$0.85-cent/pound market price for certified organic seed in winter 2003-2004. Producers in Manitoba in 2007 reportedly received \$0.40 per pound for conventional hemp seed, and \$0.80 per pound for organic hemp seed.¹⁷ The demand for hemp seed is currently the primary driver of the Canadian industrial hemp industry.

Organics

Producer experience in Manitoba indicates that industrial hemp grown organically initially yields approximately 50% of what would be seen using conventional techniques, primarily due to the inability to get enough nutrients to the crop, and especially nitrogen. However, it has also been noted that, if judged by the experience with organic production in other crops, this yield is expected to catch up to within 10% of conventional techniques after some years of “agronomic fine-tuning”.¹⁸ It is interesting to note that the reported price for organic hemp seed exactly tracks the reduction in yield that is being seen.

Markets

As pointed out by Small and Marcus, it typically takes between 10 to 15 years for the industry associated with a new agricultural crop to mature. While it is true that foreign imports have been the basis for hemp products in North America for upwards of two decades, production is barely a decade old in Canada. The industrial hemp industry is still in its infancy, and as such, is likely to “continue experiencing the risks inherent in a small niche market for some time.” However, Small and Marcus further express that “hemp ... has such a diversity of possible uses, is being

¹⁶ Source: OMAFRA Industrial Hemp Factsheet, at: <http://www.omafra.gov.on.ca/english/crops/facts/00-067.htm>

¹⁷ Source: Don Lotter. (2001) *Hemp Heaven and Hell... a story in two parts*. Newfarm.Org, at: http://www.newfarm.org/international/canada_don/manitoba/index.shtml

¹⁸ *Ibid.* and correspondence with Arthur Hanks, Canadian Hemp Trade Alliance

promoted by extremely enthusiastic market developers, and attracts so much attention” that it is likely to carve out a much larger share of the North American marketplace.”¹⁹

An update in 2007 of a December 2003 report from Agriculture and Agri-Food Canada draws an even more positive conclusion, based on its reading of consumer interest. After listing hemp’s “remarkable advantages”, including its superior agronomic characteristics, its substantial yield of fibre per acre, and the many developing market niches, the report notes that “these advantages are in tune with the environmental and health preferences of today’s North American public.” AAFC concludes by stating that “the growing curiosity of consumers, the interest shown by farmers and processors, and Canada’s excellent growing conditions for industrial hemp allow optimistic views for its future.”²⁰

Fibre and food uses for industrial hemp are growing rapidly and have increased over 300 percent in just the past few years.

Hemp Seed

Much of the growth in hemp production is a result of the increased sales of hemp food products. Between 2005/2006 and 2006/2007, the value of Canadian hemp seed products exported more than doubled, and the quantity of exports increased fourfold (see table page 25). As pointed out by the Canadian Hemp Trade Alliance, the harvesting, shelling, and processing technologies for conventional oilseed crops in Canada are suitable for handling hemp seed. This has enabled acreage to expand as soon as markets are found. Most of the hemp currently grown in Canada is for hempseed for processing into oils and meal.

Hemp Fibre

The Canadian hemp fibre industry is not currently as developed as the grain market, with biomass engineering issues still needing to be optimized, including harvesting and processing, as well as transportation, handling and storage. The Canadian Hemp Trade Alliance has stated that: “The current economic reality of hemp [fibre] is that it cannot compete with waste products (wood, straw, stover, etc.) on price.... Hemp is valued between 4-10 times that of waste fibres, so it must find its way to the right products and markets.” However, these markets are beginning to emerge. The bast fibre processing platform being commercialized by Naturally Advanced Technologies is specifically targeting hemp for advanced textile applications, with the potential to supply superior quality fibre of the correct specifications to a great variety of other applications, including composites. It should be noted that in these early days of the development of markets for hemp fibre, the available supply of fibre is a bi-product of hemp seed crops.

Another competitive pressure on the price for Canadian hemp fibre is international supply, particularly from China. The world hemp fibre market continues to be dominated by low cost producers, with China, South Korea, and the Former Soviet Union producing roughly 70% of the world supply.

¹⁹ Small, Ernest and Marcus, David. (2002). *Hemp: A New Crop with New Uses for North America*. Pp. 284–326. In: J. Janick and A. Whipkey. (Eds.) *Trends in New Crops and New Uses*. ASHS Press, Alexandria, VA., p. 321

²⁰ Agriculture and Agri-Food Canada, *Profile: Canada’s Industrial Hemp Industry*, <http://www4.agr.gc.ca/AAFC-AAC/display-afficher.do?id=1174595656066&lang=e>

To be competitive with low cost, low-quality fibre from China, Canadian processors must produce superior fibre, with advantageous characteristics as compared to imported fibre. The substantial transportation costs associated with the trans-continental shipping of biomass further work in favour of a domestic industry.

Market data for hemp fibre is spotty at best. Estimates for the current US fibre markets for yarn and fabrics are in excess of \$14 million, with the retail clothing market estimated in excess of \$80 million. The industrial fibre market is expected to see double digit gains in sales in North America over the next several years.²¹

Imports and Exports

Approximately 90% of Canadian hemp materials and products are currently exported to the US with some additional exports to Romania and Trinidad-Tobago. Exports are being driven by the rapidly expanding grain market. However, the only industrial trade data collected by Statistics Canada was on hemp fibre until January 1, 2006, when new Harmonized System (HS) export codes for hemp oil and hemp seed (grain) came into effect.

During 2006/2007, the value of Canadian hemp seed / oil exports to the US was \$1,986,668. The USDA trade database shows that the value of Canada's exports of hemp seed to the United States grew from \$0 in 2004 to \$1.2 million in 2006, after the legal dispute over US imports of hemp products ended favourably for Canadian hemp exporters in late 2004.

Canadian industrial hemp fibre exports have been highly variable over the past decade. From the start of commercial production through to 2005, exports ranged from a low of zero tonnes to a high of 389 tonnes. After peaking at 389 tonnes in 2000, exports decreased 46% in 2001 to 212 tonnes and declined further to 88 tonnes in 2004. However, industrial hemp fibre exports did improve by 41% reaching 124 tonnes in 2005, representing a monetary value of \$188,940.²²

Recently, there has been dramatic growth in Canadian industrial hemp exports. Hemp seed exports increased 300% from 2006 to 2007. Hemp oil exports were also impressive, increasing 85%. Hemp fibre exports increased 65%.²³

²¹ Source: Industrial Hemp Profile, from the Agricultural Marketing Resource Centre (last updated December 2006), at:

<http://www.agmrc.org/agmrc/commodity/biomass/industrialhemp/industrialhempprofile.htm>

²² Canadian Industrial Hemp Exports and Imports (2005), at:

http://www4.agr.gc.ca/resources/prod/doc/prod/psc-lcs/pdf/hemp-chanvre_e.pdf

²³ These figures were calculated by comparing the figures from January to June 2006 to the same period in 2007. AAFC and Statistics Canada figures, as quoted at:

<http://alternativeapproaches.com/pnuke1/Article3570.html>

Table 5: Canadian Hemp Seed Export to All Countries (Crop Year – June to July)

	Value (Cdn \$)				Quantity (Kg)			
	2003/ 2004	2004/ 2005	2005/ 2006	2006/ 2007	2003/ 2004	2004/ 2005	2005/ 2006	2006/ 2007
United States	0	0	719 114	1 843 667	0	0	113 328	525 107
Ireland	0	0	23 356	1 843 667	0	0	95 040	294 633
United Kingdom	0	0	53 116	15 809	0	0	2 996	68 718
Japan	0	0	2 406	30 459	0	0	105	59 116
Costa Rica	0	0	0	8 433	0	0	0	20 238
Germany	0	0	0	5 473	0	0	0	9 951
Sweden	0	0	952	4 376	0	0	42	5 206
Australia	0	0	0	2 560	0	0	0	380
South Africa	0	0	0	1 385	0	0	20	701
Neth. Antilles	0	0	340	696	0	0	20	701
Total	0	0	799 284	1 986 668	0	0	113 328	525 107

Source: Agriculture and Agri-Food Canada, @ <http://www.cdnseed.org/pdfs/CSTA%202006%20Stats/Exports/x12079910.pdf>

Table 6: Canadian Industrial Hemp Fibre Imports and Exports, 1996-2005

	Imports		Exports	
	Quantity (tonnes)	Value (Cdn\$)	Quantity (tonnes)	Value (Cdn\$)
1996	53	\$107,177	0	\$0
1997	196	\$271,983	1	\$501
1998	61	\$74,038	17	\$74,949
1999	349	\$351,4\41	187	\$164,183
2000	56	\$235,777	389	\$407,233
2001	88	\$95,395	212	\$238,774
2002	210	\$262,077	230	\$274,099
2003	278	\$274,733	134	\$201,821
2004	210	\$351,385	88	\$142,906
2005	212	\$416,464	124	\$188,940

Source: Statistics Canada, March 2006, <http://www4.agr.gc.ca/AAFC-AAC/display-afficher.do?id=1174495716187&lang=e>

Global imports and exports of hemp seeds

The following countries are listed by the FAOSTAT, the statistical branch of the Food and Agriculture Organization of the United Nations, as being importers of hemp seeds:

Table 7: Hemp Seed Import Quantities by Country (2005)²⁴

Country	1000s of tonnes	Country	1000s of tonnes
Austria	0.47	Luxembourg	0
Bahrain	0.02	Malta	0.01
Barbados	0.01	Netherlands	4.61
Belgium	4.42	Niger	0
Cyprus	0	Philippines	0.01
Czech Republic	0.04	Poland	0.4
Denmark	0.85	Portugal	0.13
Faroe Islands	0	Qatar	0.19
France	0.33	Romania	0.01
Germany	1.63	Serbia and Montenegro	0.02
Greece	0.46	Slovakia	0
Ireland	0.02	Slovenia	0.02
Italy	0.82	Spain	1.39
Japan	1.24	Sweden	0.71
Latvia	0.04	United Kingdom	1.96
Lebanon	0.11	Venezuela, Republic of Bolivar	0.08
Lithuania	0		

Note that both Canada and the US are not included in the UN statistics, reflecting the relatively undeveloped state of data collection on the North American industrial hemp industry.

Supplying this global market for hemp seeds are the following countries:

²⁴ FAOSTAT website, @ <http://faostat.fao.org/site/535/DesktopDefault.aspx?PageID=535>

Table 8: Hemp Seed Export Quantities by Country (1000 tonnes)²⁵

Country	1000s of tonnes	Country	1000s of tonnes
Austria	0.03	Netherlands	1.38
Belgium	1.17	Poland	0.01
China	12.42	Portugal	0
Czech Republic	0	Romania	0
Denmark	0	Slovenia	0
Egypt	0.01	Spain	0.48
France	4.99	Sweden	0.02
Germany	0.24	United Arab Emirates	0
Greece	0	United Kingdom	0.02
Italy	0.01	Unspecified	0.1

Lack of data

It must be noted that overall there is a lack of data on Canadian and North American markets for hemp products, as evidenced by the exclusion from the FAOSTAT figures. Statistics on hemp production are in the early stages of development in North America, and hemp products fall under a great many product categories, with no consistent means of identifying them as having a hemp component.

For example, the USDA trade database shows that the value of US imports under categories actually labeled “hemp” amounted to \$6.3 million in 2006 and \$6.7 million in 2005. However, this is widely acknowledged to significantly under-represent the aggregated size of the domestic industrial hemp product market.

²⁵ FAOSTAT website, @ <http://faostat.fao.org/site/535/DesktopDefault.aspx?PageID=535>

Objectives

If the National Industrial Hemp Strategy is to accomplish its objective of helping streamline value chains and aligning resources and actions in the hemp sector, the industry must define both a clear vision and set of goals, as well as provide a roadmap of concrete actions towards these goals.

This section outlines the central elements of the National Industrial Hemp Strategy. It presents a vision and goal for the sector, and provides a framework for examining strategic initiatives and concrete actions towards realizing the desired outcomes. This framework categorizes the industrial hemp sector in terms of its primary sub-sectors: food and health (including personal care products), and industrial fibres and oils, with breeding and production providing a foundation for both. Collectively, these categories form the three pillars of the National Industrial Hemp Strategy.

After examining the vision and goal of the Strategy, and outlining the three central pillars, attention will be turned to elements of the Strategy that are common to all pillars. This section concludes with a high level overview of the specific strategies and actions that have been identified for the individual pillars, with special attention to the areas of commonality and overlap. This high level overview is expanded upon in subsequent sections, with detailed examinations of the strategic considerations involved in each pillar.

Vision and Goal for the Canadian Industrial Hemp Sector

Vision	Canada is the global leader with respect to total hemp crop utilization offering solutions along the entire value chain.
Goal	To create an economically sustainable Canadian hemp industry, benefiting all stakeholders along the value chain and enhancing the nation's health and natural environment.

Framework for Action

In the process of developing this National Industrial Hemp Strategy, the following framework was adopted for defining discrete market niches, with associated strategic considerations:

- I Health and Food (including Personal Care Products)
- II Fibre and Industrial Oil

And underpinning these two sub-sectors is:

- III Breeding and production

Each of these three pillars is addressed as a discrete unit in the sections that follow.

In the development of the National Industrial Hemp Strategy, there were three elements that underpinned and informed the development of all three pillar-specific strategies:

Whole Crop Utilization

The strategies that have been developed incorporate an integrated co-products approach that derives maximum value from the hemp feedstock. For dual-purpose and seed-only hemp cultivars, this philosophy envisions harvesting and utilizing both seeds and stems. For fibre-only crops, there will be no seed production, as harvesting is done prior to seed production occurs. Pursuing a whole-crop utilization strategy will both maximize the farm gate value of industrial hemp, and will distinguish this crop from most conventional crops that focus on only one element of the entire plant.

Specific Industry Outcomes

The strategies developed under each pillar are tailored to the unique parameters at play in these discrete markets. The focus for the three pillars, both separately and collectively, is on pursuing industry-specific goals, involving the elimination of barriers to value chain development and the maximization of value for each stage in these value chains.

Environmental Sustainability

Industrial hemp is an alternative crop with a significant role in the growth of Canada's bioeconomy. The tremendous potential of this crop will be squandered if value chain development is pursued without attention to the sustainability of the system. The National Industrial Hemp Strategy will incorporate an acknowledgment of the importance of sustainability throughout.

Summary of Key Strategic Areas for Action

In order to capitalize on identified opportunities for the growth of the Canadian hemp sector, the following strategic areas for action were identified through the extensive stakeholder engagement undertaken in developing the National Industrial Hemp Strategy. Some of these strategic areas for action are common to all of the industrial hemp sub-sectors, while others are specific to a particular industrial hemp industry.

Common to all Platforms

Access to capital

Capital is required for product development and the commercialization of emerging processing technologies and products. Risk capital is not naturally attracted to emerging industries with the uncertainties that still characterize the Canadian hemp sector, and the turmoil of 1999 – 2000 is a further challenge in these efforts. Concerted efforts must be made to both educate sources of capital as to the advantages and potential markets for hemp products, and to ensure that commercial hemp ventures are seen to succeed, building a track record of profitability for the sector.

Because of the immaturity of the sector, government support will be essential in securing the necessary capital to move technologies and product platforms from development into

commercial operation. A clearly defined value proposition, a strong, unified industry voice, and a sophisticated and knowledgeable approach to government relations will be necessary to ensure that the Canadian hemp sector delivers the significant triple bottom line benefits to Canada, and specifically to Canadian agricultural value chains, that are promised.

Develop more detailed understandings of domestic and export hemp markets

Knowledge of Canadian and export hemp markets is not readily available, forming a significant barrier to attracting commercial interest in the crop, and to telling the industrial hemp “story” with maximum impact. Generally, research on the economics of the sector has been lacking. Key information includes the current and potential size of various domestic and international markets, the state of global competition, insights as to what various potential industry stakeholders are looking for from hemp biomass and how it could best be provided to them, and an analysis of niche industrial hemp markets where Canadian stakeholders – commercial, research, and policy – can build a world-leading competitive position.

Continue to work with Health Canada around optimizing the regulatory regime

The ideal situation would provide Health Canada with the confidence it requires that no psychoactive cultivars are being grown by licensed producers, while minimizing the costs to producers (time and money). Ongoing work is required to increase the comfort level around the cultivation of industrial hemp, with a steady normalization of the industry.

Similarly, the regulatory process for researchers should be reviewed and streamlined, to encourage long-term research on issues of importance to the industrial hemp industry.

Support efforts to incorporate green credentials in Canadian policy

Policies to begin incorporating environmental performance into regulatory or tax-based systems will serve to provide a distinct competitive advantage for industrial hemp products as compared to equivalent fossil-fuel based products. Two such mechanisms are a cap and trade system (with a domestic market for carbon credits), and a carbon tax. British Columbia has already implemented a carbon tax, and the common perception is that it is only a matter of time until some sort of policy is implemented at the federal level. The Canadian hemp industry should work in concert to promote such measures.

Work to maintain access to the US markets

The closing of the US market to Canadian hemp products in 1999 had a devastating effect on the Canadian hemp industry. Despite the fact that a coalition that included a Canadian processor defeated this market closure in court, the fact remains that powerful elements within the US federal government (the DEA) are hostile to the industrial hemp industry.

Areas for strategic action include maintaining a close watching brief on the US situation, the forging of alliances with key US industry stakeholders and other industrial hemp proponents, continued work on low THC breeding, and broad-based education campaigns as to the benefits and safety of industrial hemp.

Develop multiple value propositions that make hemp attractive versus competing crops

The fewer the viable markets for Canadian hemp crops, the more fragile and vulnerable the Canadian hemp sector will be. Producers need multiple opportunities to sell their crops, including markets for all components of the crop.

Build a national industrial hemp network

In order to build the capacity to capitalize on many of the opportunities and to undertake the strategic initiatives outlined here, a strong and unified industry voice will be necessary. This national industrial hemp network requires strong leadership and a strong cohesive well funded network consortium bringing together stakeholders from all along the value chain to address common problems and barriers. Researchers and industry need to be brought together around solving the barriers to effective commercialization of hemp processing technologies and products.

A national voice for the industrial hemp industry is further needed to ensure that industrial hemp has a voice at relevant regulatory forums, establishing the stability and presence to be recognized as a key stakeholder in policy development.

This national voice will also have a key roll in networking with allied industries and initiatives to advance mutual interests. An obvious target for consortia building would be the growing natural fibres sector in Canada.

Establish a degree of market stability

If the industrial hemp industry is to gain mainstream acceptance among producers and other key links in the value chain, it must fully overcome its turbulent first decade, promoting confidence in producers, processors, and end markets. A degree of market stability will be necessary to catalyze action along the value chain. Achieving such market stability will involve strong relationships between processors and producers.

Consumer Acceptance

A concerted campaign is called for in order to establish consumer acceptance of hemp products, involving marketing, promotion and ongoing public awareness effort, ensuring that the many benefits of hemp are widely understood, and cementing the message that industrial hemp is not a potential source of illegal drugs.

Acceptance from potential end users

Related to this effort is the need to educate potential downstream links in industrial hemp value chains as to the value proposition offered by hemp substitutes.

Access to Highly Qualified People (HQP)

Many industry stakeholders are already encountering challenges in securing personnel with the required skill sets, such as experience in operating and maintaining specialized hemp processing machinery. Industry stakeholders must identify the skill sets that they will

require to execute their growth strategies, and should work with colleges and universities to proactively design programs to meet these market needs.

Infrastructure

If the industrial hemp industry is to expand dramatically, it will rapidly encounter infrastructure issues, such as storage issues, availability of harvesting equipment, and pre-processing (densification) for transportation over longer distances. A concerted effort amongst all involved stakeholders, including strong government involvement, will be necessary to ensure that infrastructure issues are not a limiting factor on the growth of the Canadian hemp industry.

Another infrastructure issue identified frequently in stakeholder consultations was the need for demonstration and R&D facilities, with access to hemp cultivation and processing for research and proof-of-concept purposes.

I - Health and Food

Approval for use in food and feed

Canadian Food Inspection Agency (CFIA) approval has not been granted to incorporate hemp nutrients into animal feed and treats.

Research into health benefits

There are many gaps in research around the health benefits of hemp. Credible evidence of health benefits will be needed to maintain and expand the market for hemp food and health products over the long term. Widespread market acceptance can be greatly accelerated by comprehensive (and successful) clinical trials.

II - Fibre and Industrial Oil

Development of commercial bast fibre processing capacity in Canada

Fibre processing is still in the development stage in Canada. As seen in the section addressing fibre and industrial oil applications, the lack of commercial scale bast fibre processing in Canada is a primary barrier to growth in this sector. Production of sufficient (commercial) quantities of high quality bast fibre and hurd is required to enable the development of downstream applications.

Identification of end-user interest in utilizing hemp as a component of their products

While the broad spectrum of potential industrial hemp products are increasingly understood, there is considerably less understanding of the potential industry receptor capacity interested in commercializing these products. Furthermore, concrete commitments by a number of end-market users is lacking as this sector does not fully understand what hemp products or ingredient are available for incorporation into existing and potential product lines. While there is a fairly good idea of the parameters of the food and health markets for industrial hemp in North America, a similar understanding has not been developed for fibre and oil applications.

Industry testing of Canadian hemp fibre for specific product applications

Similar to the above, industry adoption of hemp biomass for specific product applications will be predicated on extensive testing and validation of the characteristics of this material. As commercial hemp processing technologies and facilities come online, it will be essential to have representative samples analyzed by prospective industry consumers.

Favourable industry testing can become powerful marketing tools, as evidenced by Naturally Advanced Technologies, a Canadian company close to commercializing a bast fibre processing platform. It currently has a market capitalization in the neighbourhood of \$40M, with gross revenues of approximately \$2M in 2007 from sales of hemp clothing in the company's apparel division. This market valuation is in part based on industry interest driven by extremely positive initial test results.

Development of technologies and methodologies for an increasing variety of market applications

Once commercial processing of hemp fibre comes online in Canada, a variety of product applications will become feasible. Ongoing R&D efforts to commercialize the broad spectrum of fibre and industrial oil applications are necessary to drive market pull for the output of these processing facilities. During the stakeholder consultations undertaken in developing this strategy, a strong opinion was expressed that there will be huge demand for industrial research once commercial fibre processing is available. Additionally there is strong transportation industry pull to develop natural fibre mats to replace fibreglass mats. Continued work in this area is key, with Canadian (Manitoba) commercial bus manufacturing representing 60% of the total North American market.

Develop industry standard fibre grading standards

Industry grading standards are an important component in providing hemp product manufacturers with the stability of supply and quality assurance that they require, and in expanding the downstream users of hemp fibre.

Develop a cost-effective oil profiling system

Similar to the above, cost-effective oil profiling de-risks the use of hemp oil for downstream links in the value chain.

Development of markets and applications for co-products

While much of the attention is focused on hemp oil and bast fibres, it is imperative that valuable markets be developed for all co-products of hemp processing, including short fibres and hurd, hurd only, fines and dust, and seed meal (left after oil extraction). If industrial hemp is going to be a viable crop that supports profitable value chains, maximum value must be derived from every unit of hemp biomass.

III - Breeding and Production

The areas for strategic action in breeding and production are all oriented towards realizing increased yields per acre of hemp crops, optimized for desired applications. Advances realized

through efforts in breeding and production are essential if the Canadian industrial hemp industry is to be competitive against other hemp producing nations, particularly China.

Bioresource Engineering

Hemp crops exhibit relatively tough stems, and grow to many metres tall given optimum growing conditions. While functional hemp seed and fibre harvesting equipment is currently being employed by the Canadian hemp producers, there are still many avenues for optimization. In many cases, producers have made the necessary equipment modifications at the farm level to overcome obstacles that are encountered. The ongoing efforts to optimize these systems must be supported and expanded.

Seed Supply

The industry must ensure that sufficient supplies of hemp seeds are available for a variety of cultivars, covering the full range of Canadian growing conditions.

Optimize and Develop Cultivars for Specific Canadian Growing Conditions

This area for strategic action is both obvious and self explanatory. As well as optimizing for regional growing conditions, there is tremendous potential for the breeding of desired characteristics. Longer term goals include the engineering of specific industrial traits such as precisely defined oil or fibre characteristics for specific industrial applications. It is anticipated that there will be ongoing interest in breeding down THC content for the foreseeable future.

Continued Development of Best Management Practices around Hemp Cultivation

Aspects of hemp cultivation that will benefit from continued development of best management practices include:

- Response of hemp to fertilization
- Seeding rate
- Row spacing
- Harvest management / improved practices
- Retting

International Promotion of Canadian-Bred Cultivars

Given Canada's proven strength in the breeding of northern climate agricultural crops, it should be expected that Canadian breeders produce superior cultivars. There is the potential to promote these cultivars on the world stage, helping carve a distinct niche for Canada in the global industrial hemp industry.

This discussion has examined the many strategic areas for action that were identified in the extensive stakeholder consultations undertaken in developing this strategy. The following sections examine each of the industrial hemp sub-sectors in more detail, starting with health and food (including personal care products), fibre and industrial oil, and then production and breeding. The market opportunities for each category are examined, along with the short and

medium to long term actions that are needed to capitalize on identified opportunities, and to meet existing and potential threats and challenges.

I Health and Food (including personal care products)

Overview

Demographic and societal trends have led to increased interest in natural health products (NHP, or dietary supplements) and healthier for you foods (“functional foods”). There are a number of key factors driving this growth in demand, as well as changes in the supply chain. These factors include:

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

There are many different bioactive ingredients in hempseed that have shown promise in disease prevention and reduction. However, clinical research specifically on hempseed and oil is lacking. Research on hempseed and oil is critically needed for industry marketing, for regulators and for health professionals – all groups require data supporting efficacy to ensure consumer confidence in this exciting functional food and natural health product.

Definitions

For the purposes of this report, the definition of functional foods as proposed by Health Canada will be used, that being, a functional food is “... similar in appearance to a conventional food, consumed as part of the usual diet, with demonstrated physiological benefits, and/or to reduce the risk of chronic disease beyond basic nutritional functions”.²⁶ This definition also includes “healthier for you” foods which generally are those foods marketed for their intrinsic health value.

Canada is the only global jurisdiction that has legislation related to “natural health products (NHP)”, also known as dietary supplements in other global areas. These regulations became effective on January 1, 2004.²⁷ The regulations apply to all NHPs including homeopathic preparations, substances used in traditional medicine, a mineral or trace element, a vitamin, an amino acid, an essential fatty acid or other botanical, animal or microorganism-derived substance. These products are generally sold in a medicinal or “dosage” form.

²⁶ Health Canada. Standards of Evidence for Evaluating Foods with Health Claims – Fact Sheet. http://www.hc-sc.gc.ca/food-aliment/ns-sc/ne-en/health_claims-allegations_sante/e_soe_fact_sheet.htm.

²⁷ Government of Canada. Natural Health Products Regulations. Canada Gazette Part 2. June 2003. <http://canadagazette.gc.ca/partII/2003/20030618/html/sor196-e.html>.

Nutritional Properties of Hempseed

Hemp (*Cannabis sativa*) is one of the oldest crops cultivated by man. It has been grown for fibre and seed for the last 5,000 years. Today, hempseed and oil are very popular in food and health products and are found in snacks, nutrition bars, hummus, nondairy milks, breads, cereals, prepared foods and numerous other applications. The oil is available in capsules or bottles. Because of its medicinal benefits, hemp oil is also used as a topical ingredient in natural body care and cosmetic products.

Hemp Oil

Hemp oil is produced by pressing the hemp seed. Hemp has the highest level of the essential fatty acids (EFAs) which are required in the diet as they can not be synthesized by humans (see chart below). The EFAs play critical roles in the reduction of several diseases and chronic conditions and a must for good health. The two foundation EFAs are called linoleic acid (omega 6, LA) and alpha-linolenic acid (omega 3, ALA).

Young animals deprived of dietary LA and ALA rapidly display negative health effects, including diminished growth, liver and kidney damage, and dermatitis; these eventually result in death. LA and ALA are so important because they are components of cell membranes. The proper functioning of all body cells depends upon healthy membranes as they act as “gate-keepers” for substances moving in and out. In the skin and the layer around the nerves, EFAs provide a moisture barrier and an insulating layer.

Hemp oil is also unique in that it is a rare plant source of a vital omega-6 EFA called gamma linolenic acid or GLA. Modern day diets and sluggish enzyme activity in our bodies often impair the synthesis of GLA which may cause deficiency. Hemp oil is also very low in saturated fats which are very detrimental to the heart and circulatory system.

Fatty acids (%)	Hemp	Borage	Blackcurrent	Evening Primrose	Soybean	Canola
Saturated	9	14	10	10	14	7
Linoleic (LA)	57	38	48	73	54	23
Alpha Linolenic (ALA)	20	0	13	0	7	11
Gamma Linolenic (GLA)	3	20	14	10	0	0
Total EFAs	80	58	75	83	61	34

Diet plays an enormous role in the onset of disease. The World Health Organization has found that chronic diseases contribute to approximately 60% of all deaths worldwide and 50% of the total burden of disease.²⁸ Almost half of these deaths are from cardiovascular diseases (CVD),

²⁸ World Health Organization. Diet, Nutrition and the Prevention of Chronic Disease, series 916. 2003.

hypertension, obesity and diabetes. The WHO estimates that these chronic diseases will account for 70% of all deaths worldwide by 2020.

Hemp Oil Aids Circulation

EFA's in particular GLA and ALA, have been shown to reduce the risk of CVD and hypertension by lowering blood cholesterol and blood pressure and reducing blood platelet clotting.²⁹ Several studies have reported the beneficial effects of ALA on reducing the risk of heart disease. One in particular, which began in 1986 and included 51,529 health professionals, demonstrated that a 1% increase in dietary ALA intake was associated with a 40% reduction in the risk of non-fatal heart disease.³⁰ In the Nurse's Health Study, which involved a 10-year follow-up of 76,283 women with no previously diagnosed CVD, a higher intake of ALA was associated with a lower relative risk of both fatal and non-fatal myocardial infarction.³¹ ALA can reduce ventricular fibrillation (rapid and irregular heartbeat) and help normalize heart beats.³² GLA can also reduce the risk of CVD by lowering levels of total and LDL-cholesterol.³³

Hemp benefits the circulatory system through its effects on blood fats. One study has examined the effects of hemp oil in humans and showed significant reductions in total cholesterol and more favorable cholesterol ratios in the blood.³⁴ Recent animal data has also shown that the fatty acids in hemp oil reduce platelet aggregation or clotting. Dr. Grant Pierce and his colleagues at the St Boniface Hospital Research Centre in Winnipeg, Canada supplemented the diets of rats with hempseed for 12 weeks and found a 35% decrease in the blood's tendency to clot.³⁵ Blood clots can cause a heart attack if they occur in the arteries leading to the heart, or a stroke if they occur in the brain.

Hemp Oil May Reduce Inflammation

Inflammation is a controlled, ordered process whereby the body responds to infection or injury. Symptoms include redness, swelling, heat and pain. Chronic inflammation is linked with age-related diseases such as CVD, obesity, diabetes and cancer. ALA can reduce the most damaging inflammatory compound called C reactive protein or CRP as much as 75% when compared to a 'traditional Western style' diet.³⁶ GLA has been studied for decades for its efficacy in arthritis and other inflammatory disorders. In randomized, placebo-controlled clinical

²⁹ Lanzmann-Petithory, D. 2001. Alpha-Linolenic Acid and Cardiovascular Diseases. *Journal of Nutrition, Health and Aging*. 5(3): 79-183.

³⁰ Ascherio A, Rimm EB, Giovannucci EL, et al. 1996. Dietary fat and risk of coronary heart disease in men: Cohort follow up study in the United States. *Br. Med. J*; 313: 84-90.

³¹ Hu FB, Stampfer MJ, Manson JE, et al. 1999. Dietary intake of α -linolenic acid and risk of fatal ischemic heart disease among women. *Am. J. Clin. Nutr.* 69:890-897.

³² Vos E, Cunnane SC. 2003. α -Linolenic acid, linoleic acid, coronary artery disease, and overall mortality (letter). *Am. J. Clin. Nutr*; 77: 521-522.

³³ Laidlaw M, Holub BJ. 2003. Effects of supplementation with fish oil-derived n-3 fatty acids and gamma-linolenic acid on circulating plasma lipids and fatty acid profiles in women. *Am J Clin Nutr.* 77:37-42.

³⁴ Schwab US, Callaway JC, Erkkilä AT, Gynther J, Uusitupa MI, Järvinen T. 2006. Effects of hempseed and flaxseed oils on the profile of serum lipids, serum total and lipoprotein lipid concentrations and haemostatic factors. *Eur J Nutr.* 45(8):470-7.

³⁵ Richard MN, Ganguly R, Steigerwald SN, Al-Khalifa A, Pierce GN. Dietary hempseed reduces platelet aggregation. 2007. *J Thromb Haemost.* 5: 424-5.

³⁶ Zhao, G., Etherton, T.D., Martin, K.R., et al. 2004. Dietary alpha-linolenic acid reduces inflammatory and lipid cardiovascular risk factors in hypercholesterolemic men and women. *J. Nutr.* 134: 2991-2999

trials significant and progressive improvement in patients with active rheumatoid arthritis treated with amounts of GLA from 500 mg to 2.8 g/day have been reported³⁷ and included reductions in swollen and tender joints, duration of morning stiffness and patient's assessment of pain.

Hemp Oil GLA May Reduce Diabetes

Diabetes is a disease in which the body does not properly produce or use insulin. It can lead to neuropathy, a condition where nerves degenerate. Symptoms of pain and numbness follow leading to skin ulceration, amputation and impotence. In over 400 patients, 480 mg/day of GLA continued to improve established diabetic neuropathy symptoms throughout a 3 to 12 month period.³⁸ The positive effects of GLA may be due to a restoration of normal nerve function through improvements in cell membrane function.

Hemp GLA May Aid in Weight Control

GLA supplementation may impede weight regain following major weight loss. Fifty formerly obese humans were randomized into a double-blind study and given either 890 mg/d of GLA or 5 g/d olive oil (control).³⁹ Following one year, weight regain was significantly lower in the GLA group, and continued to be until the conclusion of the study at 50 weeks.

The Importance of EFA Balance

The ratio of the amounts of omega-6 to omega-3 EFAs in vegetable oils is a hotly debated topic among nutritionists. Omega-6 and omega-3 EFAs work synergistically at the cellular level to ensure effective metabolism. An excess of either can cause an imbalance in cell function. Leading experts such as the Scientific Review Committee of Health Canada and the World Health Organization have recommended that the ratio of intake of omega-6 EFAs to omega-3 EFAs should range from 4:1 to 10:1. Hemp oil has a 3:1 ratio – the oil closest to an ideal omega 6:omega 3 range. Put simply, hemp oil contains three omega-6 EFAs for each omega-3 EFA.

So what does this mean for daily intakes? Nutritionists generally recommend that, for EFAs to provide optimal cell function and contribute to overall health, daily requirements should range from 7 to 11 g of LA and from 1.5 to 3.0 g of ALA.⁴⁰ This can be obtained from one tablespoon of hemp oil. People who consume a diet high in saturated fats or trans fatty acids, those who are overweight or under a great deal of stress will require more EFAs.

³⁷ Zurier, R.B., DeLuca, P. and Rothman, D. 1996. Gamma-linolenic acid, inflammation, immune responses and rheumatoid arthritis. In: Gamma-linolenic acid: Metabolism and its roles in nutrition and medicine. Huang, Y-S. and Mills, D.E., Eds., AOCS Press, Champaign, Ill. pp. 129-136

³⁸ Horrobin, D.F. 1997. Essential fatty acids in the management of impaired nerve function in diabetes. Diabetes. 46(2S):S90.

³⁹ Schirmer, MA and Phinney, SD. 2007. Gamma Linolenate Reduces Weight Regain in Formerly Obese Humans. J. Nutr. 137: 1430–1435.

⁴⁰ Albert CM, Oh K, Whang W, et al. 2005. Dietary α -linolenic acid intake and risk of sudden cardiac death and coronary heart disease. Circulation 112: 3232-3238.

Antioxidants

Hemp oil contains a number of antioxidants including natural Vitamin E, at higher levels than other oils. Vitamin E helps to reduce the damage to body cells caused by the constant assault of free radicals which are produced as a result of normal metabolic processes in living systems. Pollution, second hand smoke, many dietary constituents and aging contribute to the production of free radicals often exceeding the protective antioxidant capacity of our bodies leading to oxidative stress. Antioxidants in hemp oil “neutralize” free radicals and offer protection against oxidative damage.

Phytosterols

Phytosterols are found in high levels in hemp oil. Like humans who produce cholesterol for various metabolic functions, plants produce phytosterols. These compounds have similar structure to cholesterol. Phytosterols act to lower cholesterol by competing for absorption in the gastrointestinal tract decreasing the overall amount of cholesterol absorbed and available to the blood stream.⁴¹

Hemp Protein

Proteins are essential to life and participate in every process within cells. Protein is necessary in the diet, since the essential amino acids which make up their structures can not be synthesized in the body and must be obtained from food. Hemp is an exceptionally high quality plant protein in terms of amino acid composition. Only soybeans are higher in total protein, but absorption is much more limited than hemp. Hemp protein contains all 21 amino acids, including the 8 essential amino acids in a ratio that resembles “complete” protein sources such as meat, milk, and eggs.

Dr. Jim House of the Department of Human Nutritional Sciences, University of Manitoba found that the protein digestibility of hemp nuts was over 0.6 closely followed by hempseeds and hemp protein flour.⁴² The standard against which protein digestibility and amino acid quality is assessed is casein which measures 1.0. Most importantly, hemp protein is highly digestible, with >90% digestibility for hemp nuts. Hemp protein is also a valuable source of other non-essential amino acids including arginine which can help to lower blood pressure.

Gluten free Proteins in Hemp

Gluten is a general name given to the storage proteins found in wheat, rye, barley, and oats. Celiac disease occurs when consuming gluten proteins triggers an autoimmune response that damages the lining of the small intestine, which can reduce nutrient absorption and contribute to other ailments of the body and immune system. About one in 133 people or more than 2.5

⁴¹ Lees, A.M., Mok, H.Y., Lees, R.S., McCluskey, M.A. and Grundy, S.M. 1977. Plant sterols as cholesterol-lowering agents: Clinical trials in patients with hypercholesterolemia and studies of sterol balance. *Atherosclerosis*. 28:325-338.

⁴² House, J. 2007. Characterization of Hemp Seeds, Hulled Seeds and Protein Flour for Macronutrients, Protein Composition and Digestibility. Report for the Canadian Hemp Trade Association. *Unpublished results*.

million people in the US suffer from celiac disease and the disease is also increasing in Canada.⁴³ Hempseed and protein contain no detectable gluten proteins.

Hemp Protein Powders

Hempseed protein powder is produced by cold pressing whole hemp seeds to expel the oil, resulting in a dry cake. The cake is then milled at low temperatures to remove a portion of the fibre and produce a concentrated form of protein. The resulting protein powder contains on average 50% protein. Typically, a standard 30g serving of hemp protein powder supplies about 15g of protein.

There are differences between hemp protein and its major competitor, soy protein. Hemp protein does not contain anti-nutritional factors that reduce the absorption of soy protein. Unlike hemp protein powder, many soy isolate powders that are not labeled organic are processed with hexane, a petroleum solvent. The resulting hexane-processed soy is utilized in many soy protein powders, cereals, and bars. In addition, non-organic soybeans used in many soy products are often derived from genetically modified soybeans. Hemp is never genetically modified.

Dietary Fibre

Soluble and insoluble fibre accounts for about 30% of the weight of full-fat hempseeds. Soluble fibres delay transit through the stomach, trapping fat and sugar which aids in the maintenance of blood glucose and cholesterol. Insoluble fibres promote laxation and provide relief from constipation. Recommended levels of fibre for women is 25 grams and for men is 38 grams per day. However, usual intakes for most people average only 14 to 15 g/day.⁴⁴ Hempseeds are an important source of healthy fibres.

Vitamins

Hempseed is a very good source of the important vitamin B complex including Vitamins B1 (thiamine), B2 (riboflavin) and B6 (pyridoxine). The B vitamins play a role in metabolism, enhancing the immune and nervous systems, and supporting cell growth and division. Vitamin B1 is involved in the regulation of carbohydrate metabolism and in the nervous system. Vitamin B2 aids in the metabolism of fats, carbohydrates, and respiratory proteins. A deficiency can result in skin lesions and light sensitivity. Vitamin B6 is involved in the absorption and metabolism of amino acids and fats. Deficiency in these vitamins may result in smooth tongue, skin disorders, dizziness, nausea, anemia, convulsions, and kidney stones. Hempseeds are also rich in folic acid which is very important for all women who may become pregnant. Adequate folate intake during the periconceptual period helps protect against a number of congenital malformations including neural tube defects which can result in malformations of the spine (spina bifida), skull, and brain.

⁴³ Prevalence of Celiac Disease. 2007. <http://www.celiac.com/>

⁴⁴ Alaimo K, McDowell MA, Briefel RR, et al. *Dietary Intake of Vitamins, Minerals and Fiber of Persons Ages 2 Months and Over in the United States: Third National Health and Nutrition Examination Survey, Phase 1, 1988-91*. Hyattsville, Md: National Center for Health Statistics; 1994. Advance data from vital and health statistics: No 258.

Minerals

Hempseeds are rich in the minerals phosphorus, magnesium and manganese. Magnesium, the fourth most abundant mineral in the body, is required for more than 300 biochemical reactions in the body, including the maintenance of muscle and nerve function, heart rhythm and bone strength. These minerals help to regulate blood sugar levels, promote normal blood pressure, and are involved in energy metabolism and protein synthesis.

Hemp Oil and Skin Care

Hemp oil contains important nutritional compounds which are critical for ensuring healthy, soft and vibrant skin as well as to reduce the signs of aging. Hemp body products include shampoos, conditioner, hand & body lotions, bath and massage oil, moisturizing cream, and lip balms.

Diet significantly influences the health and vitality of the skin and hair. Because of their importance in the cell membrane, EFAs protect the skin from moisture loss that can lead to premature sagging and wrinkles. GLA and ALA are preferentially stored in the skin. People who reduce dietary fat, especially EFAs, too drastically will very quickly notice dry, eczema-type skin problems. Loss of skin epidermal barrier function leading to rapid moisture loss is one of the first consequences of EFA deficiency. This is referred to as transepidermal water loss. Long term depletion of dietary EFAs will lead to erythema (abnormal skin redness) with scaling, dermatitis, skin atrophy, edema, hair loss, and itching⁴⁵.

ALA and GLA have been shown to reduce skin inflammation and improve overall skin vitality, such as softer, smoother, healthier skin. The numerous antioxidants especially Vitamin E found in hemp oil can also reduce the damage that free radicals can cause to skin and hair by “quenched” their effects. EFAs and antioxidants are critical to reduce aging and preserve the health of the skin and hair.

Health and Food Market Opportunities for Hemp

There are several Canadian functional foods and natural health product companies focusing on the development and marketing of hemp and hemp products. The majority of the suppliers are located in Western Canada while Eastern Canadian companies are more involved in exporting and direct sales to retailers. The Canadian hemp industry is comprised of innovative, entrepreneurial companies – primarily SMEs (small and medium size companies) that are supplying the global functional food, natural health products and ingredients’ markets. An important characteristic of these companies is their evolution, for the most part, from farm based companies supplying the local market to global businesses. The hemp focused FFNHP industry is one that is truly rural based – the most successful companies in the sector (e.g. Hemp Oil Canada, Mum Original) have a strong working relationship with the local producer community and in fact market hemp products with a guarantee of high quality from the seed to the package.

The hemp industry has received very little government support and has made tremendous market achievements despite this fact. It is an industry that continues to be developed based on

⁴⁵ Callaway J, Schwab U, Harvima I, Halonen P, Mykkänen O, Hyvönen P, Järvinen T. 2005. Efficacy of dietary hempseed oil in patients with atopic dermatitis. *J Dermatolog Treat.* 16(2):87-94.

merit rather than government funding. However in order to experience further success in the global food and health markets and to continue to grow, there are several opportunities and challenges that should be addressed with both industry cash and in-kind support.

The opportunities and challenges that are described here have been identified through a comprehensive nutrition literature review (Appendix A) and a thorough market assessment (Appendix B). Observations were confirmed by several in-person industry stakeholder consultations and interviews that were held throughout this initiative

1.0 Market Opportunities – Short Term

1.1 Promoting the Goodness of Hemp

As is apparent from the literature review (See Appendix A), hempseed, protein oil and nuts have an abundance of healthy constituents that need to be exploited through marketing and communications activities. Effective information dissemination to key target groups such as the food industry, health care professionals, the medical community and consumers should be undertaken.

It is recommended that the industry association, CHTA play a leading role in promoting the health benefits of hemp. At least a part time position should be devoted to this role.

Reaching health professionals with key messages about the health benefits of hemp, and how to incorporate hemp into the diet to achieve these benefits, has been identified by hemp suppliers as a key priority. The initial target for the dissemination of this information is the health care community and dietitians who are consumer's direct links to health and nutrition information.

Depending upon funding availability, several marketing and promotional materials should be developed.

1. Maintenance of current research and food technology database – this unique hemp database provides overview abstracts on scientific and food related publications and is posted on CHTA website.

The CHTA should develop a 'consumer-friendly' website with helpful information on the health aspects of hemp, recipes, commonly asked questions, etc.

2. Development of nutritional and functionality information via newsletters and fact sheets for distribution and posting on the CHTA website.
3. Webcasts – Depending upon funding, at least one 'informational' webcasts should be planned. Web Cast technology provides an opportunity to communicate technical information via a controlled, inter-active and focused educational message to a large targeted audience. The content is to be decided upon but potential areas of interest include technical/formulation issues, regulatory update, supporting consumer research, new products, health claims, etc.

The promotion of hemp as a high quality and safe Canadian crop and Canadian product must resonate throughout all communications.

The Question of THC

In recent years, the presence of trace residual delta-9-tetrahydrocannabinol (THC), the main psychoactive ingredient of marijuana, in food products incorporating hemp seed and seed derivatives (hemp nuts, oil, flour, meal, and protein isolate) has raised concerns over THC's potentially adverse impacts on human health. It has been established over the last decade that the consumption of currently available hemp foods does not pose an unacceptable health risk due to THC.⁴⁶ A hazard assessment for the intake of THC via hemp foods, including the establishment of Lowest Observed Adverse Effects Level (LOAEL) and No Observed Adverse Effect Levels (NOAEL) for oral ingestion of THC, derivation of safety factors, and estimation of the corresponding acceptable daily intake (ADI) has supported this. An exposure assessment for the intake of THC via hemp foods, assuming their extensive daily consumption with trace residual THC levels achieved by Canadian suppliers in hemp seed and seed derivatives has also established that even very extreme consumption of hemp based products would not yield near harmful levels of THC. This message needs to be communicated responsibly and effectively to all stakeholder groups.

The ultimate goals of communication and marketing efforts is to increase the awareness and usage of hemp by the domestic and international food industry and to secure the support of health associations, dieticians, the medical and academic communities and other health professionals regarding the health benefits of hemp. The CHTA should establish itself as the resource for third party, accurate, unbiased and high quality science based information about hemp.

1.2 Hemp Food Formulation Research

Many forms of hemp are commonly used in different types of food products. However most of these products are being developed and marketed by small companies involved in the natural and organic segment of the food sector. Mid to larger size food companies may be interested in using hemp but will require data establishing its health attributes and formulation characteristics. In particular, these companies require technical information about using hemp in foods especially as related to maintaining the quality and the stability of the oil fraction. In order that hemp can be more effectively utilized by the food industry, product development should occur in conjunction with clinical studies. As far as the practicalities of food fortification are concerned, manufacturers must consider their target consumer market, as well as the particular health issue it wishes to address. Hemp, as a vegetarian option, can be added to all types of foods and beverages.

1.3 Clinical Trial to assess the Health Effects of Hemp

Hemp contains a heart healthy fatty acid profile, an array of lipid lowering constituents including soluble fibre, phytosterols and Vitamin E, and highly digestible, high quality protein. The health effects of these ingredients in isolation or from other products are described in the literature review. Well-designed clinical research is needed to determine the significance of these

⁴⁶ Grotenhermen, F., Leson, G. and Pless, P. October 2001. Assessment of exposure to and human health risk from THC and other cannabinoids in hemp foods. Report commissioned for US Hemp Industry.

constituents in terms of health benefits for humans, particularly in regard to cardiovascular diseases such as myocardial infarction and stroke, cardiac arrhythmia, and atherosclerosis.

Inflammation is a key feature of these chronic diseases. Atherosclerosis, for example, is now recognized as an inflammatory disease, and all stages – initiation, growth and complication of the atherosclerotic plaque – are an inflammatory response to injury. Chronic, low-grade inflammation is also associated with insulin resistance, obesity and type 2 diabetes. The inflammatory cytokine tumor necrosis factor- α (TNF- α) is over expressed in obesity and contributes to insulin resistance. Potential markers of inflammation include soluble adhesion molecules (e.g. E-selectin, P-selectin, intracellular adhesion molecule-1, vascular cell adhesion molecule-1) and acute-phase reactants (e.g. fibrinogen, serum amyloid protein, C-reactive protein). Of these, CRP is consistently shown to be a strong predictor of CVD and it is possible that at least some of the known cardiovascular risk factors may affect the risk for CVD by modulating inflammation.

There has been no assessment of the effects of hemp on inflammatory compounds such as TNF- α , interleukin-1 β , and major eicosanoids. No studies have measured the effects of hemp on C-reactive protein (CRP) or the soluble adhesion molecules. No research has been conducted on the effects of hemp protein or fibre on serum lipids or on inflammatory biomarkers.

Positive results from clinical research that assesses the effects of hemp on inflammatory reactions and biomarkers would produce results that could benefit millions of Canadians with chronic disease, including children, many of whom are overweight or obese and at risk of developing diabetes.

- A study population of healthy adults and those with one or more chronic diseases (e.g. cardiovascular symptoms, type 2 diabetes, obesity or metabolic syndrome)
- Five dietary interventions:
 1. Control group (usual diet)
 2. Group consuming usual diet + ground hempseed
 3. Group consuming usual diet + hemp oil
 4. Group consuming usual diet + hemp nut
 5. Group consuming usual diet + hemp protein flour
- A dietary intervention lasting 3-6 months, with clinical assessments made at baseline, 1 month, 3 months and/or 6 months
- Assessment of serum lipids, glucose and insulin, weight loss measurements (DXAE) and a range of inflammatory biomarkers: main eicosanoids, cytokines (e.g. tumor necrosis factor- α , interleukin-1 β), platelet-activating factor (PAF), soluble adhesion molecules (E-selectin, P-selectin, intracellular adhesion molecule-1, vascular cell adhesion molecule-1) and acute-phase reactants (e.g. fibrinogen, serum amyloid protein, C-reactive protein).

1.4 Other Opportunities

As identified in the literature review and the market assessment, there are a number of areas that the hemp industry is currently witnessing success which have the potential to grow even further, including:

- Gluten free

- Natural Personal Care
- Pet food Products

Depending upon resources, these areas could be explored further and direction as to next steps provided by the research community and the industry.

2.0 Medium Term Opportunities

2.1 Hemp Fibre, Diabetes and the Glycemic Index (GI)

Low-glycemic products target the over 20 million diabetics in the United States, in addition to consumers concerned about boosting their energy level and losing weight.

GI represents a potential area for research in hemp seed and hemp seed products, due to the low percentage of non-fibre carbohydrates present. The high proportion of total carbohydrate present as dietary fibre in hemp seed warrants further research to determine if hemp products, especially those containing a significant hull fraction, would provide beneficial effects for humans in relation to the glycemic response.

The GI effects of hemp and hemp products in humans could be economically assessed by the GI Laboratory at the University of Toronto. The standard protocol requires that ten normal subjects are studied on multiple occasions (maximum 3 per week) in the morning after an overnight fast. After a fasting blood sample, subjects eat a test meal containing 50g available carbohydrate and have further blood samples at 15, 30, 45, 60, 90 and 120 minutes after starting to eat. Capillary blood is obtained by finger-prick and whole blood glucose determined with an automatic analyzer using the glucose oxidase method. Each subject conducts one trial of each test food and 3 trials of the reference food. The reference food can be anhydrous glucose or white bread. These results will provide GI numbers that can be used in marketing (in the US) as well as indications of satiety for weight control and weight loss applications.

Parallel to metabolic and clinical research, there will be a need for processing research to determine economical and feasible scale-up technologies for industrial use of extracted and possibly concentrated hemp fibre for use by the dietary supplement and functional food ingredient industries.

2.2 Allergen Testing

Food allergies have become a major public health issue in many countries and government officials are becoming increasingly diligent in their monitoring of incidence. Members of the hemp industry have received questions regarding potential allergens in hemp and hemp protein products. Testing should be done to alleviate any concerns related to the presence of allergenic proteins in hemp.

In the United States, it is estimated that approximately 150 individuals die each year from accidental ingestion of an allergenic food. Food allergy is estimated to be the cause of 33% of emergency visits for treatment of anaphylaxis (severe allergy), and peanuts and tree nuts are the foods most often associated with these severe reactions.⁴⁷ Additionally, in the US, 4% of the

⁴⁷ Food Allergy and Anaphylaxis Network. 2007. <http://www.foodallergy.org>.

general population has a food allergy and 1% a peanut allergy. The incidence is similar in Canada with an estimated 1.2 million Canadians affected by various food allergies.⁴⁸

In the US, allergen labeling requirements cover the eight foods (egg, milk, peanut, tree nuts, fish, shellfish, soy, and wheat) that account for 90% of food allergies. In Canada, the list also includes sesame and in the EU, mustard is part of this list as are celery, sesame, and all cereals containing gluten (i.e. wheat, barley, oats, spelt, kamut, and their hybridized varieties).

Food Allergies

A food intolerance is not an allergy - it is an adverse food-induced reaction that does not involve the immune system. Lactose intolerance is one example of a food intolerance. A person with lactose intolerance lacks an enzyme that is needed to digest milk sugar. When the person eats milk products, symptoms such as gas, bloating, and abdominal pain may occur.

A food allergy occurs when the body's immune system reacts to a certain food, usually a protein. The reaction may result from the ingestion and in some cases skin contact or inhalation of a food or food additive. The most common form of an immune system reaction occurs when the body creates immunoglobulin E (IgE) antibodies to the food. When these IgE antibodies react with the food, histamine and other chemicals (called mediators) cause hives, asthma, abdominal pain and diarrhea, or other symptoms of an allergic reaction.⁴⁹

Hypersensitivity or allergic reactions to milk and egg are often outgrown at an early age, whereas reactions to peanut, tree nuts, fish, and shellfish tend to last a lifetime. Celiac disease, which is not IgE-mediated but nevertheless results in an allergic reaction, is also life long and requires the strict avoidance of gluten-containing grains. There is no definitive treatment for food allergies other than to avoid the offending foods, especially in cases where the reaction is quite severe.

Food allergy testing in a clinical setting is not a simple study. Depending upon funding, a number of subjects allergic to common food allergens are included. Either skin sensitivity or sensitivity to consumption of hemp protein is assessed.⁵⁰ The tests determine the presence of IgE antibody directed to particular foods. Two commonly used tests are blood (IgE RAST) and skin prick tests. The blood tests require a small sample of blood to be sent to a laboratory, where the amount of IgE antibody to the specific food is measured.

Skin tests are performed by exposing a tiny area of scratched skin to the food being evaluated. A positive skin test results in a mosquito-bite-looking reaction at the site of the test within minutes.

IgE RAST tests measure IgE-mediated reactions to a particular food. Oral challenge tests are generally used. These tests are conducted by giving gradually increasing amounts of hemp protein while observing the subject for symptoms. This is followed by laboratory analysis of IgE. Publication in a referred journal will be required so that the results can be used to support the "lack of allergenic potential" of hemp and hemp protein.

⁴⁸ Zarkadas, M, Scott, F, Salminen, and Pong, AH. 1999. Common Allergenic Foods and Their Labelling in Canada - A Review. *Can. J. Allergy Clin. Immunol.* Vol. 4, No 3.

⁴⁹ Food Allergy and Anaphylaxis Network. 2007. <http://www.foodallergy.org>.

⁵⁰ Food Allergy News; April-May 1998: vol. 7 no. 4

3.0 Long Term Opportunities

3.1 GRAS (Generally Recognized as Safe) Affirmation for Hemp Products

In the US, functional/nutraceutical ingredients can be marketed as dietary supplements, food additives, or as generally recognized as safe (GRAS) ingredients. The regulatory requirements to determine safety are different for each of these categories.⁵¹ In 1997, the Food and Drug Administration (FDA) proposed replacing the GRAS affirmation process with a notification procedure whereby any person may notify FDA of a determination that a particular use of a substance is GRAS. Under the notification procedure, the FDA evaluates whether the submitted notice provides a sufficient basis for a GRAS determination and whether information in the notice or otherwise available to FDA raises issues that lead the agency to question whether use of the substance is GRAS. Under this process, the FDA does not make its own determination of the GRAS status of an ingredient but relies on the opinion of an Expert Panel to review a petition and determine GRAS.

A substance is GRAS if its use in food has a proven track record of safety based *either on a history of use before 1958 or on published scientific evidence*. Hemp does not have GRAS status, and two companies using hemp in bread products have expressed some concerns regarding this. As hemp gains popularity and profile in the US market and as larger companies become more interested in hemp as an ingredient, the safety of hemp (i.e. GRAS) will become a great issue and one that the industry will have to address. For example, companies such as Kellogg and General Mills are very reluctant to use food ingredients that do not have official GRAS. In addition, GRAS is a prerequisite for US health claims (Nutrition Labeling Education Act – NLEA) or qualified health claims.

Thus a two stage approach is recommended to deal with the issue of GRAS. Commission a consultant to assess GRAS for hemp oil and seed. A comprehensive assessment should be conducted of published literature for metabolism, toxicology, and human clinical trials that bear on the safety of ingestion of hemp products. Depending upon this assessment, undertake any safety research to address any data gaps that may be found. Once data has been collected and assessed, proceed with GRAS. The GRAS process involves drafting safety documents and convening a GRAS expert panel to review and approve the submission, and dealing with FDA throughout the process.

3.2 Gain CFIA Approval for the use of Hemp in Animal Feeds

The nutritional profile of hemp appears ideal for animals. Currently, the Canadian Food Inspection Agency (CFIA) has not approved hemp or hemp products for use in animal feeds and some in the hemp industry have identified this as a problem. This would require safety testing in regard to THC in various animal models and feeding trials to establish feeding levels. This is a longer term and more costly area and may not be necessary should hemp in higher value human food products continue to gain economic success in the food markets.

⁵¹ Burdock GA., "Dietary supplements and lessons to be learned from GRAS" Regulatory Toxicol. Pharm. 2000, 31:68-76.

The Market

Canada

Statistics Canada estimated the total revenue in Canada from FFNHP at \$2.9 billion in 2004, of which \$823 million came from firms producing functional foods, \$1.6 billion from firms producing NHP and \$442 million from firms producing both.⁵²

For 2003, data from the Nutrition Business Journal (NBJ) indicates that the Canadian nutrition industry including supplements, personal care products, and natural/organic and functional foods was valued at US \$ 4.8B, a steady increase over the last four years.⁵³ While functional food sales in the US represent approximately 4.0% of total food sales, Canada's portion of total food sales is only 2.2%. According to NBJ, the Canadian market is experiencing a respectable 7.8% overall annual growth rate surpassing the 2-3% growth rate of the traditional food industry.

Canada does not currently possess a significant portion of the international health products market. In 2005, Canadians spent US\$36.70 per capita on fortified/functional packaged foods and beverages whereas this figure was US\$68.60 in the US, US\$82.80 in the UK and US\$138.60 per capita in Japan.⁵⁴

However, domestic demand is expected to increase. Research conducted by Leverus Inc revealed that a 0.5% increase in the share of total spending translates to a \$500 million (20%) increase in the size of the NHP sector at the retail level. Lewis (2006) estimates that by 2012 the Canadian functional food market value will be 2.9 billion.⁵⁵

The Global Market

The global market for functional foods, dietary supplements (natural health products, NHP in Canada) and food ingredients is comprised of companies that see the industry as a growth opportunity and the ability to make higher margins. It has attracted players the size of ADM, BASF, DSM, Nestle, Cargill, Bayer, Kellogg, Quaker Oats, Pepsi-Co and Danone as well as many small and medium sized enterprises. It is in this environment that the development of "healthier for you" functional foods, ingredients and NHP (FFNHP) has become a serious focus for the industry as well as the research community in Canada and internationally. The Canadian hemp industry has identified health foods and NHP has a market opportunity over the short to longer terms.

From an industry point of view, FFNHP offer a way to add value to existing products and to innovate with new ones. Such products are being developed to create higher-margin; value-

⁵² Leverus Inc. 2005. *Canada's Natural Health Products Sector in 2005: State of the Industry Report*. Prepared for Canadian Health Food Association, Canadian homeopathic Pharmaceutical Association and Canadian Natural Products Association by Leverus Inc in co-operation with Inter/Sect Alliance Inc.

⁵³ Ferrier, G. 2005. Nutrition Business Journal. NBJ Industry Overview. Webcast. April, 2005. www.nutritionbusiness.com.

⁵⁴ Leverus Inc. 2005. *Canada's Natural Health Products Sector in 2005: State of the Industry Report*. Prepared for Canadian Health Food Association, Canadian homeopathic Pharmaceutical Association and Canadian Natural Products Association by Leverus Inc in co-operation with Inter/Sect Alliance Inc.

⁵⁵ Lewis, H. 2006. *Global Market Review of Functional Foods- Forecasts to 2012*. Just Food. from: <http://www.just-food.com/store/product.aspx?id=44028&lk=pop>.

added lines for manufacturers and inevitably their customers and shareholders. Of extreme importance, FFNHP offer the opportunity to positively impact health care costs which are becoming an increasingly significant burden to governments world-wide.

In 2006 world consumption of NHP (supplements), natural and organic foods, natural personal care and functional foods was approximately \$ 228 billion US.⁵⁶ This market is dominated by the functional foods sector at \$85 billion US, with the primary markets being the United States, Europe, Japan and Asia⁵⁷. Current and projected growth rates are more than triple that of conventional foods and pharmaceuticals, at ~9% to 12% per annum. It is anticipated that, based upon past data, the industry will witness steady and continued growth to 2012 when projections of global sales for functional foods alone near \$95 billion dollars.

The global supplement industry reached sales of \$68 billion in 2006 on growth of 5%, according to NBJ.⁵⁸ The US market contributed one-third or \$22 billion to the total, followed by Europe at 23% and \$16 billion. Japan was the third largest regional market with declining sales of \$11 billion in 2006.

Macro Trends

Several macro trends are driving the global growth of the functional food and NHP industries and the interest in the area by the research community, governments and consumers. Global macro trends include the increasing prevalence of chronic disease and rising obesity rates, the increasing cost of health care, changes in public policy and the role that science will play in the development of functional foods.

Rising Disease

The World Health Organization's 2003 report on diet, nutrition and the prevention of chronic disease noted that, "the burden of chronic disease is rapidly increasing worldwide."⁵⁹ In 2001, chronic diseases contributed to approximately 60% of all deaths worldwide and 46% of the total burden of disease. Almost half of these deaths were from cardiovascular diseases, obesity and diabetes." The WHO estimates that chronic disease will account for 70% of all deaths worldwide by 2020 in comparison to statistics for 2000.

Obesity

Obesity is a problem of growing concern and according to the WHO,⁶⁰ it has reached epidemic proportions globally, with more than 1 billion adults overweight and at least 300 million obese. In the US approximately 129.6 million Americans, or 64% of the population, are overweight or obese.⁶¹ The latest data from the National Center for Health Statistics of the CDC show that 30

⁵⁶ Nutrition Business Journal. May/June 2007. The Global Nutrition Market. www.nutritionbusiness.com.

⁵⁷ Ferrier, G. 2005. Nutrition Business Journal. 2005. Functional Foods VIII. The Emergence of Healthy Foods. Vol. X. 10/11.

⁵⁸ Ferrier, G. 2005. Nutrition Business Journal. 2005. Functional Foods VIII. The Emergence of Healthy Foods. Vol. X. 10/11.

⁵⁹ WHO Technical Report Series #916, 2003. "Diet, Nutrition and the Prevention of Chronic Diseases".

⁶⁰ World Health Organization. February 2003. Global Strategy on Diet, Physical Activity and Health. <http://www.who.int/dietphysicalactivity/publications/facts/obesity/en/>

⁶¹ Statistics. 2004. Center for Disease Control and Prevention. <http://www.cdc.gov/nchs/fastats/>.

percent of US adults 20 years of age and older—over 60 million people - are obese. The percentage of young people who are overweight has more than tripled since 1980. The CDC estimates that 400,000 American deaths in 2000 (that is 1 out of every 700) were related to poor diet and physical inactivity. Canadian obesity rates too have increased over the past 25 years, with nearly one-quarter of all Canadian adults (up from 14 per cent in 1978-79) now considered seriously overweight, according to Statistics Canada.⁶²

Cardiovascular disease (CVD)

CVD accounts for the death of more Canadians than any other disease. In 2002 (the latest year for which Statistics Canada has data), cardiovascular disease accounted for 78,942 Canadian deaths.⁶³ 35% of all male deaths in Canada in 2002 were due to heart diseases, diseases of the blood vessels and stroke. For women, 37% of all deaths in 2002 were due to CVD.

The US has the highest prevalence of cardiovascular diseases among global nations.⁶⁴ One in 3 adult men and women has some form of CVD which has been the primary killer in the US every year but 1918.⁶⁵ Nearly 2500 Americans die of CVD each day, an average of 1 death every 35 seconds. CVD claims more lives each year than the next 4 leading causes of death combined, which are cancer, chronic lower respiratory diseases, accidents, and diabetes mellitus. Of the over 71 million American adults with 1 or more types of CVD, close to 28 million are estimated to be age 65 or older.

Diabetes

There are currently more than 246 million people with diabetes worldwide and at least 50% of all people with diabetes are unaware of their condition. By 2025, it is estimated that this number will rise to over 380 million. Diabetes is the fourth main cause of death in most developed countries and is the leading cause of blindness and visual impairment in adults.⁶⁶

The number of Americans with diabetes had risen to 20.8 million in 2005 or 7% of the US population, 1.5 million new cases from 2004.⁶⁷ Individuals with metabolic syndrome (obesity, CVD and/or diabetes symptoms) are estimated to number over 50 million.⁶⁸ The prevalence of adult obesity increased 57% in the brief period between 1991 and 1999, and currently over 60% of US adults are overweight.⁶⁹ These increases cannot be explained by the aging of the

⁶² Statistics Canada. July 2005. Canadian Community Health Survey: Obesity among children and adults 2004. <http://www.statcan.ca/english/research/82-620-MIE/82-620-MIE2005001.htm>.

⁶³ Statistics Canada, Causes of Death 2002. Released 2004.

⁶⁴ Heart Association Statistics Committee and Stroke Statistics Subcommittee Heart Disease and Stroke Statistics--2006 Update. A Report From the American Members of the Statistics Committee and Stroke Statistics Subcommittee. 2006. *Circulation*. February. <http://circ.ahajournals.org>

⁶⁵ NHANES 1999–02. Center for Disease Control. American Heart Association. www.aha.org.

⁶⁶ International Diabetes Federation. 2007 Facts and Figures. <http://www.idf.org/>.

⁶⁷ American Diabetes Association. 2005 statistics: Total Prevalence of Diabetes & Pre-diabetes. <http://www.diabetes.org/diabetes-statistics/prevalence.jsp>

⁶⁸ Ford, E.S., Giles, H.W., and Dietz, W.H. 2002. Prevalence of the metabolic syndrome among US adults: findings from the Third National Health and Nutrition Examination Survey. *JAMA*; 287:356-9.

⁶⁹ Mokdad, A.H., Serdula, M.K., Deitz, W.H., et al. 1999. The spread of the obesity epidemic in the United States, 1991-1998. *JAMA*; 282:1519-22.

population alone, as similar increases are also being seen in US children.⁷⁰ Currently in Canada, over 2 million Canadians have diabetes, up from 722,491 in 1995.⁷¹ Approximately 80% of people with diabetes will die as a result of heart disease or stroke. Diabetes is a contributing factor in the deaths of approximately 41,500 Canadians each year.

Aging Demographic

The increase in disease burden being experienced worldwide is related not only to obesity, poor diet and lifestyle, but also to an aging population. During the 20th century, the number of Americans age 65 years and above increased 1100%. By 2010, the number of people over 50 years of age will increase by 48% from early 2000 numbers; in contrast, the group aged 13-24 years will grow by only 16%. By the year 2035, it is estimated that 70 million people will over the age of 50.⁷² A similar situation is occurring in Canada. According to Statistics Canada and reported by Agriculture and Agri-Food Canada, by 2016, about 44% of the Canadian population will be 45 years of age or more.⁷³ In North America, currently, more than 75% of individuals who are 65 years of age or older suffer at least one chronic disease, whereas 50% have at least 2, a situation that imposes a tremendous burden on the health care system.

Rising Health Care Costs

An increase in disease incidence leads to overall increases in the cost of health care. In the US, healthcare costs were \$1.9 trillion in 2004, a 7% increase from 2003, and are projected to reach \$3.1 trillion by 2012 – or 17.7% of GDP.⁷⁴ Spending by private health insurance has increased 10 fold since 1987. Costs increased from \$3.6 billion in 1987 to \$36.5 billion on obesity-linked illnesses in 2002. Total health care spending on obesity in 1987 was 2% compared to 11.6% in 2002.

Canada continues to rank among the world's top ten health spenders when compared to other countries in the Organization for Economic Co-operation and Development (OECD) and ranked eighth in per capita spending (US \$3,326).⁷⁵ Total health expenditure in Canada, in current dollars, was estimated at \$141.2 billion in 2005, and is forecast to have reached \$150.3 billion in 2006 and \$160.1 billion in 2007.

Chronic disease accounts for a significant portion of health care costs and this is growing. In Canada, cardiovascular diseases, diabetes and cancer combined cost the Canadian economy close to \$60B annually.⁷⁶ The direct cost of obesity to Canada's health care system is estimated to be \$1.8B.⁷⁷

⁷⁰ American Diabetes Association. Consensus Statement. 2000. Type 2 diabetes in children and adolescents. *Diabetes Care*. 23:381-9.

⁷¹ Canadian Diabetes Association. 2005 statistics. The prevalence and costs of diabetes. http://www.diabetes.ca/Section_About/prevalence.asp

⁷² United States Census Bureau. 2005. Population Estimate. <http://factfinder.census.gov/>

⁷³ Agriculture and Agri-Food Canada. 2005. Canadian Consumer Trends. Food Value Chain Bureau. http://www.agr.gc.ca/misb/fb-ba/index_e.php?s1=cons&page=intro.

⁷⁴ *Health, United States*. 2007 annual report on trends in health statistics. <http://www.cdc.gov/nchs/fastats/>

⁷⁵ Canadian Institute for health Information. 2007. National Health Expenditure Trends – 1975 – 2007.

⁷⁶ Canadian Institute for health Information. 2007. National Health Expenditure Trends – 1975 – 2007.

⁷⁷ <http://www.medicalnewstoday.com/medicalnews.php?newsid=10170> [sourced: January 26, 2007]

Food Product Trends

Multinationals Shift Focus to Health and Wellness

The formulation of foods for health is one of the leading focuses of the food industry. Foods that deliver a well-recognized health benefit to consumers have been a significant market opportunity for many years, as supported by the fact that during the early 2000s the market for healthy foods grew by 10 - 20%.⁷⁸

Surveys of top global food executives confirm an industry focus on healthier foods.⁷⁹ The “better for you” category was the food group that offered the most potential for revenue growth, reported by 54 percent of firms (up from 42 percent in last year’s survey). Organic foods were cited by 44 percent of firms (up from 15 percent in the previous survey) and high-end/premium foods (a new category on this year’s survey) were reported by 43 percent. Health is truly the future of foods and in fact many believe that all foods are fast becoming functional.

“All Natural”

The terms “all-natural” and “naturally healthy” are popular among marketers to describe a food’s health benefits. To some consumers the word “natural” is synonymous with “healthy”. The term also implies that the health benefit is intrinsic to the product and not the result of added ingredients. The reformulation of foods so that they can be described as “all natural”, and the marketing of natural health benefits, has accelerated rapidly over the last two years and today these are the most commonly adopted strategies in the business of food and health worldwide.

Of relevance to hemp, the following types of brand communications are used to identify “health” to consumers:

- Free-from wheat/gluten/soy/dairy/lactose
- Free-from artificial additives/preservatives/colors/ trans fats
- Organic
- All-natural
- Contains only natural ingredients
- No unnatural ingredients
- Naturally high in fibre/ antioxidants
- Non GMO

Heart Healthy Ingredients

Although obesity and related health conditions are causing concern on a global scale, many consumers are looking at dietary changes in an effort to prevent disease and obesity in the first place. According to a 2005 survey by HealthFocus International, cardiovascular disease is one of consumers’ top three health concerns--not only in the US--but also in regions from India and China to France and the U.K. to Latin America.

⁷⁸ Nutrition Business Journal. 2004. Annual Industry Overview 2005. Vol. X, No. 5/6.

⁷⁹ Grant Thornton 2007 Survey of US Food & Beverage Companies. 2007. Food Processing Magazine. www.foodprocessing.com

In 2007, Mintel International's Global New Products Database identified close to 560 new products from around the world that referenced cardiovascular and/or heart health. 2008 information from the group's Global New Products Database reveals a massive 244 percent increase in new introductions in the heart health category - from 43 products in 2006 to 148 in 2007. In 2003, only 22 new products were launched in this category, followed by 19 in 2004 and 54 in 2005.

Of relevance to hemp ingredients, the heart health trend is currently the most important for new product development and is projected to be so for at least the next 5 years with omega 3 fatty acids, phytosterols, fibre and whole grain being top of the list ingredients.⁸⁰

Fibre

Concerns with growing incidence of diabetes and obesity have led to increasing interest by food developers, in soluble fibre and in particular the glycemic index. This is an opportunity area for hemp as it is rich in soluble fibre.

Food companies are increasingly extending brand labels and/or developing new food products containing fibre. The reasons are numerous including the acceptance by the health care community regarding the established health benefits of fibre, label regulations especially in the US that allow positive health statements related to fibre content and steadily increasing consumer awareness of fibre and recognition of its health advantages.

Researcher Frost & Sullivan notes that fibre is an ingredient market worth \$200 million in the US alone in 2004, predicting it will double to \$400 million by 2011, a conservative figure compared to some other market estimates. Euromonitor International puts the global market for foods marketing high-fibre claims including packaged foods, baked goods, bread, biscuits and cereals at about \$80 billion globally, rising to \$95 billion by 2011. In the US, ACNielsen found sales with fibre label claims rose 15.5% to \$1.6 billion in the year ended August 2005 compared to 11.4% in 2004, 2% in 2003 and 4% in 2002.⁸¹

Glycemic Index (GI)

There is strong scientific evidence that supporting low GI diets and weight loss as well as diabetic control. 44% of the North American population is actively trying to lose weight. Almost one in four shoppers in both Canada and the US has decreased their consumption of high-glycemic carbohydrates within the past two years, and one in three has decreased their consumption of carbohydrates, according to the 2005 HealthFocus Trend Report.⁸² At the same time, approximately one in ten are increasing their consumption of low-glycemic carbohydrates and "better-for-you" carbohydrates.

In early 2007, the market research firm Packaged Facts reported that sales of low-glycemic foods and beverages reached \$350 million in 2006, and predict that sales will keep increasing at a compound annual growth rate of over 45 percent from 2007 to 2011, with sales projected to reach \$1.8 billion in 2011.⁸³ In a *Wall Street Journal* article, it was reported that the growth in

⁸⁰ Sadler, J. 2005. Future Health Food and Drink Trends. 2005. Business Insights Ltd.

⁸¹ ACNielsen. 2005. Facts on Fibre. www.acneilsen.com.

⁸² HealthFocus. 2005. The 2005 HealthFocus Trend Report: The national study of public attitudes and actions toward shopping and eating. HealthFocus International, Fla.

⁸³ Packaged Facts. 2007. "Low Glycemic Index Food and Beverages in the US"

total food and beverage sales in 2005 increased by 3%.⁸⁴ Low fat, reduced fat and fat-free foods increased in sales by just over 2%, low carbohydrate food sales declined by over 10%, and low glycemic foods grew 412%.

Gluten Free

The US market for gluten-free foods and beverages is currently estimated at \$696 million US, and is anticipated to grow to \$1.7 billion US by 2010.⁸⁵ The same report found that since 2001, the market for gluten-free products has grown at a compound annual rate of 27%, and is anticipated to grow 25% per year until the year 2010.

According to information published by SPINS, more than 3,150 products with gluten-free label claims are currently on the market in the US. An 86% increase in new product launches in the “gluten-free” category was observed in 2006.⁸⁶ In 2006, 40% of gluten-free products on the market were sold in health and natural food stores, 20% through specialty food websites and catalogue purchases, and 14% via mainstream supermarkets.⁸⁷

Emerging Markets for Natural Ingredients

Pet Foods and Products

With the “humanization” of pets, many owners are taking as much care of the health of their pets as they do their own. A recent survey conducted for Purina Pro Plan Selects indicated that 90% of respondents “always try to purchase foods with the most health benefits for themselves and 82% look for foods with the most wholesome ingredients for their pets.”⁸⁸ Industry analysts have observed that trends in the pet food market not only mirror human food trends; they often do so at an accelerated rate.⁸⁹

In 2005, an American Pet Products Manufacturers Association survey reported that 63% of households in the United States owned a pet, which equates to over 69 million homes.⁹⁰ Consumers spent over \$14 billion on pet food during 2005 in the United States alone. And pet food manufacturers released 175 new dog and cat food products during the first six months of 2006. Euromonitor predicts that the global pet food and pet care products market will increase by 15.1%, from 58.2 billion US in 2005 to 67.0 billion US in 2010.⁹¹

High quality protein remains the most important characteristic of pet food for both consumers and pet food manufacturers. The highest quality proteins are animal sources as they are both digestible and highly available. However, there may be an opportunity for hemp protein because of its excellent amino acid profile and high digestibility. Pets are increasingly viewed as

⁸⁴ Ellison and Ball, 2006. *Wall Street Journal*.

⁸⁵ Packaged Facts. 2006. Gluten Free Foods and Beverages in the US www.marketresearch.com

⁸⁶ Gluten-free knocks low-carb fad off the shelf. February 2, 2007. www.money.cnn

⁸⁷ Gluten free market set to boom. 2007. www.foodnavigator-usa.com

⁸⁸ Nutraceuticals World. 2007. New Ipsos poll shows consumers equally concerned about their health and their pets' health. http://www.nutraceuticalsworld.com/news/2007/07/24/new_ipsos_poll_shows_consumers_equally_concerned_about_their_health_and_their_pets%92_health.

⁸⁹ Industry Statistics & Trends - American Pet Products Manufacturing Association. www.appma.org.

⁹⁰ 2005-2006 National Pet Owner's Survey. American Pet Products Manufacturers Association survey.

⁹¹ Pet Food and Pet Care Products globally. www.euromonitor.com.

a part of the family and this has led to a recent expansion of health and wellness pet foods and products.

Natural Personal Care

The natural, organic and cosmeceutical segments of the personal care market have experienced significant growth in recent years, and are expected to continue to expand in the foreseeable future as Natural Products Companies (NPC) and large consumer marketers increase their investments into this segment of the Health and Beauty Care (HBC) market. Retail sales of natural and organic personal care products, which represented over 10% of the HBC market in 2005, exceeded \$5.5 billion in 2005 growing at 14.6% (\$12 billion globally). In comparison, the overall US cosmetics and toiletries market grew by a 3.5% in 2005.⁹²

The Consumer

Consumers are a critical driving force behind the development of healthier for you foods and NHP. As they strive to maintain good health into old age, they are attempting to take greater control over their health care needs. With the rising incidence of obesity and the significant increases in the rates of chronic disease, consumers are becoming increasingly aware of the link between diet and medical disorders. Consumers are seeking alternatives to conventional medicine which has been dominated for decades by an attitude of “treat” rather than “prevent” illness.

A number of consumer surveys have indicated that increasingly consumers believe that eating healthy is a better way to manage illness than through medication. The most common reasons that appear to motivate food purchase decisions are ensuring overall good health, reducing fat intake, following a physician's advice, and to control weight and cholesterol.⁹³ Since 1996, taste, nutrition, cost and convenience have been the key drivers of food choices for Canadians.⁹⁴ It is forecast that food and supplements will continue to be seen by consumers as a solution to present and pending health problems.⁹⁵

Princeton Survey Research Associates recently reported that 76% of consumers feel that eating healthfully is a better way to manage illness than medication. The top five factors motivating food purchase decisions, according to the results of this survey, are ensuring overall good health, reducing fat intake, following a physician's advice, and to control weight and cholesterol intake.⁹⁶ In 2002, the annual "Shopping for Health" study, a joint survey between the Food Marketing Institute and Prevention Magazine, noted that 68% of shoppers are more likely to treat themselves before seeing a physician, up from 31% in 1998.⁹⁷

⁹² Natural Personal Care Overview. August 2006. Nutrition Business Journal.

⁹³ Princeton Survey Research Associates. 2004. Consumers attitudes: Food and Health. <http://www.psrai.com/news.jsp>

⁹⁴ Canadian Council of Food and Nutrition. October 2006. “Tracking Nutrition Trends VI report”. www.ccfnc.ca/events.

⁹⁵ Canadian Council of Food and Nutrition. October 2006. “Tracking Nutrition Trends VI report”. www.ccfnc.ca/events.

⁹⁶ Princeton Survey Research Associates. 2004. Consumers attitudes: Food and Health. <http://www.psrai.com/news.jsp>

⁹⁷ Shopping for Health. Self Care perspectives. 2002. Food Marketing Institute. <http://www.fmi.org/>

Regulatory Issues

Crucial to tapping into the potential for functional foods and NHPs is establishing a market-friendly regulatory framework. Japan was the first global jurisdiction to institute regulatory reforms that encourage companies to utilize health claims to develop healthier foods and to communicate such messages to consumers. Part of the reason this system developed in Japan was due to that country's concern over a rapidly aging population. Europe is another leader in functional food development, not due to favorable regulations but more so to excellent public awareness of the health benefits of foods and natural medicines as well as a significant focus upon research. The EU is moving ahead with harmonization across nations of regulations for health claims and for scientific substantiation of FF efficacy. Due in part to industry lobbying as well as consumer interest, the US established health-claim environments for both food and dietary supplement products in the mid 1990's.

In Canada, health products are either foods or drugs. A Natural Health Product (NHP), as defined by Health Canada, is "any plant or plant material, a bacterium, fungus, alga, non-human plant material, or an extract or isolate of these materials." This includes vitamins and minerals, herbal remedies, homeopathic medicines, traditional medicines such as Traditional Chinese Medicine (TCM), probiotics and other ingredients such as amino acids and essential fatty acids. It is essentially equivalent to the US "dietary supplement" regulatory definition.

The NHP regulations were implemented in January 2004 by Health Canada through its newly formed Natural Health Products Directorate (NHPD). As an addition to the scheme of the Canadian Food and Drug Act and Regulations, NHPs are considered a subset of drugs, in which health claims such as disease treatment or prevention, as well as structure/function claims, are allowed. The regulations include product licenses, labeling requirements, evidence summary reporting, safety summary reporting, quality summary reporting, clinical trial guidance and procedures, GMP and site licenses.

The regulations require pre-market approval from NHPD for all NHPs that are new to the Canadian market, as well as re-approval of all existing NHPs in a six-year transition period. In addition, site licenses are required for Canadian companies that manufacture, package, label or import NHPs.

In Canada, the current regulatory environment for foods with health claims, both for marketing and for product approval, is not as favorable or transparent as in other global jurisdictions. Canada has three categories of health claims and two categories of claims not considered health claims. Health claims include structure/function claims, risk-reduction claims and therapeutic claims – all are claims related to the definition of a drug by claiming uses related to the prevention or management of a disease or abnormal physical state, including their symptoms (applies to risk-reduction claims and therapeutic claims) or the modification of organic functions beyond what is considered normal and required for the maintenance of good health (applies to structure/function claims).⁹⁸ Because such claims bring food under the definition of a drug, regulatory amendments are required to approve the use of these claims.

⁹⁸ Government of Canada (2002). B.01.603 of Food and Drugs Act: Regulations Amending the Food and Drugs Regulations (Nutrition Labelling, Nutrient Content Claims and Health claim). Canada Gazette <http://canadagazette.gc.ca/partII/2003/20030101/html/sor11-e.html> .

Nutrient content claims and biological role claims are not considered health claims since they do not bring food under the definition of a drug. As such, no regulatory amendments are required for their use. Nutrient content claims describe or imply levels of a nutrient in a food while biological role claims describe the function of nutrients or energy in the body for normal growth and development or health maintenance.

Canada's definition of biological role claims (generally recognized nutritional function of energy or nutrients in maintaining good health and normal growth and development) is comparable to the US definition of structure/function claims (intended to affect normal structures or functions in humans or describe general well-being) and therefore the two countries' definitions of structure/function claims are not comparable.

Regulations for "functional" foods in Canada are described in this report as outdated, overly stringent and time consuming, and have forced the marketing of Canadian bioactive innovation to occur outside of Canada, for the most part in the United States.

November 2007 Consultations

In November 2007, Health Canada announced a review of the current framework for the management of health claims for foods. This review is part of the *Blueprint for Renewal*, a major Health Canada initiative aimed at modernizing the oversight for health products and food. In particular, the health claim framework is a component of the *Regulatory Modernization Strategy for Food and Nutrition*.⁹⁹

An Inter-departmental Policy Team has been established to advise and help guide the development of this discussion document. The objective is an effective framework that will:

- support informed consumer choice by allowing foods with health benefits to be marketed with substantiated claims;
- continue to protect consumers from misleading and unsubstantiated health claims on foods; and
- support conditions for a fair and competitive market environment that will allow for more consumer choice of food products.

The four main themes for consultation and the specific issues of interest in each include:

Theme 1: Efficient and transparent processes

- modernize or improve processes used to approve claims
- develop a more transparent and open approach

Theme 2: Sound evidence for consistent, credible claims

- the nature of the evidence needed to substantiate a health claim and how to interpret it for decision making
- the capacity of petitioners to provide the evidence

⁹⁹ Health Canada 2005. Regulatory Modernization Strategy for Food and Nutrition.http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/blueprint-plan/index_e.html

Theme 3: Clear policies for today and tomorrow

- functional foods and foods at the food/natural health product interface
- managing a broader range of function claims
- managing diverse front-of-package claims
- eligibility criteria for foods to carry claims

Theme 4: Supporting informed consumer choice

- improving consumer understanding of health claims
- monitoring the impact of health claims on the food supply and on consumer choice

Themes 2 and 3 involve the classification of claims within a new proposed system that separates health claims into a “general” and “specific” category. The “specific” health claims are further categorized into disease risk-reduction claims and function claims. As with the current system, when food relates to the definition of a drug, regulatory amendments would be required to authorize use of the claim on foods. Disease risk-reduction claims and one of the three categories of function claims will bring food under the definition of a drug, requiring regulatory amendments. This process is laborious, and can take upwards of three years to complete the regulatory process.¹⁰⁰

¹⁰⁰ Health Canada. November 2007. Managing Health Claims for Foods in Canada: Towards a Modernized Framework. http://www.hc-sc.gc.ca/fn-an/consultation/init/man-gest_health_claims-allegations_sante_2_e.html

Table 9 : Canada’s Proposed New System for Categorizing Health Claims

Canada’s Proposed New System for Categorizing Health Claims ¹⁰¹					
	General health claims	Specific health claims			
General Feature	Do not refer to a specific health effect, disease, or health condition	Refer to a specific health effect, disease, or health condition			
Type of claim	General health claim	Disease risk-reduction claim	Function claims		
Specific feature	Promote overall health, healthy eating or provide dietary guidance e.g. “good for you”; “healthy choice”	Link consumption of food/food constituents to a reduced risk of disease in context of total diet ¹	About restoring, correcting or modifying body functions ¹	About maintenance of body functions necessary for maintenance of good health and normal growth and development	About maintenance or support of body functions associated with maintenance of good health or performance
¹ Will require regulatory amendments since would be considered drug claims under <i>Food and Drug Regulations</i>					

For all global jurisdictions, the need to ensure strong and robust data for safety is critical for any new ingredient for foods or supplements.

Hemp Oil and Skin Care

The health industry is being increasingly driven by aging demographics in industrialized nations. With the global population having more than tripled since the 1950s, more people than ever before are reaching the age of 50. Demand for anti-aging solutions is therefore increasing. Younger consumers too are increasingly conscious of ways to ensure health and wellness and are seeking ways to delay aging and maintain soft and vibrant skin. While it is still not possible to reverse the effects of ageing, its mechanisms have been identified by scientific studies, together with various active biological compounds that interact with such mechanisms.

Hemp oil contains important nutritional compounds which are critical for ensuring healthy, soft and vibrant skin as well as to reduce the signs of aging. Based on hemp oil, natural cosmetics and body care items were among the first grown-in-Canada products to be made widely available to the North American public. Hemp body products include shampoos, conditioner, hand and body lotions, bath and massage oil, moisturizing cream, and lip balms. Although early cosmeceutical uses of hemp oil were based primarily on testimonials, there is growing scientific evidence to demonstrate the efficacy of the unique fatty acid profile of hemp in personal care products.

¹⁰¹ Health Canada. November 2007. Managing Health Claims for Foods in Canada: Towards a Modernized Framework. http://www.hc-sc.gc.ca/fn-an/consultation/init/manage_health_claims-allegations_sante_2_e.html

The skin is the largest organ of the body. The functions of the skin include protection of the body against injury, heat and light radiation, regulation of body temperature, elimination of waste products, and secretion of hormones and enzymes. The skin also acts as an external sensory organ and plays an immunological role. The surface of the skin is made up of mostly of dead cells. Underneath the surface, there are three thin distinct layers, including the epidermis, the dermis and hypodermis.

The epidermis is responsible for the look and the health of the skin. It protects the skin from moisture loss and the penetration of chemical products and bacteria. It is also the initial barrier to oxidant assault. The epidermis holds a large amount of water. The skin's capacity to retain water decreases with age, making it more vulnerable to dehydration and wrinkles. It is in this layer that the consumption of hempseed and hemp oil will have its greatest effects.

Aging of the Skin

The most important environmental factor that contributes to ageing is the oxidation of bio-molecules by free radicals, which causes, among other things, ageing of the skin. UV radiation is the main factor. Other oxidative processes cause ageing at the cellular level, which damages many organs in the body and enhances age-related diseases such as arteriosclerosis. Cellular oxidation leads to collagen breakdown, chronic skin inflammation and the accumulation of abnormal elastin in the superficial dermis lead to wrinkles, mottled coloration and skin laxity.

The Influence of Diet

Diet significantly influences the health and vitality of the skin. Of particular importance are the EFAs and antioxidants. EFAs are critical components of the membranes of all cells including of the skin, where they ensure “fluidity” and stability. The proper functioning of all body cells depends upon healthy membranes as they act as “gate-keepers” in the cells.

Antioxidants help reduce the damage to body cells caused by the constant assault of free radicals (reactive oxygen species or ROS) such as generated through UV radiation. Free radicals are produced as a result of normal metabolic processes in living systems. Pollution, second hand smoke, many dietary constituents and aging contribute to the production of free radicals often exceeding the protective antioxidant capacity of our bodies leading to oxidative stress. Antioxidants such as compounds known as lignans, flavonoids and phenols “neutralize” free radicals and offer protection against oxidative damage.¹⁰²

The Importance of the EFAs for Skin health

Both families of omega 6 and omega 3 EFA are necessary for overall skin health – but a balance between the two is important for vibrant skin. EFAs are critical for maintaining the integrity of the skin and the structure of its cell membranes. In fact, when consumed, ALA will accumulate and be preferentially stored in the skin as well as the adipose tissue.¹⁰³ People who reduce dietary fat, especially EFAs, too drastically will very quickly notice dry, eczema-type skin problems. Loss of epidermal barrier function leading to rapid water (moisture) loss is one of the first consequences of EFA deficiency. This is referred to as transepidermal water loss (TEWL).

¹⁰² Balentine, D.A., Albano, M.C. and Nair, M.G. 1999. Role of medicinal plants, herbs, and spices in protecting human health. *Nutrition Rev.* 57 (9 Pt. 2):S41 – S45.

¹⁰³ Sinclair, A.J., Attar-Bashi, N.M., and Li, D. 2002. What Is the Role of α -Linolenic Acid for Mammals? *Lipids.* 37:1113-1123.

Long term depletion of dietary EFAs will lead to erythema (abnormal skin redness) with scaling, dermatitis, skin atrophy, edema, hair loss, itching, poor wound healing and a tendency to cutaneous infection.

ALA and GLA have been shown to reduce skin inflammation and improve overall skin vitality, such as softer, smoother, healthier skin. These benefits are attributed to enhanced blood flow to the skin, maintenance of epidermal integrity (and therefore protection from water loss) and decreased inflammatory eicosanoid synthesis.

In a study of 40 people with psoriasis, those who were treated with medications and omega 3 supplements showed improvements in skin health that were more significant than those treated with medications alone.¹⁰⁴

GLA is particularly important to skin health and in fact has been studied extensively as a treatment option for various skin disorders. Atopic dermatitis is a chronic inflammatory disease that causes eczema, rashes and itching. It is most common in younger people and usually is resolved during adolescence. Low levels of GLA and DGLA believed to be due to reduced activity of the delta 6 desaturase enzyme is thought to play a role in the etiology of the condition.¹⁰⁵ The skin is particularly sensitive to sub-optimal GLA formation as it lacks the delta 6 desaturase enzyme and therefore depends on a supply of pre-formed GLA.

PGE1 acts to enhance moisture levels in the skin, to protect the epidermis from water loss and to reduce inflammation. High levels of LA and correspondingly reduced levels of GLA, DGLA and AA have been found in patients with atopic dermatitis. In such conditions, a defect in the enzymatic conversion of LA to GLA might be responsible for defects in the lipid barrier of the skin and a decrease in the production of the anti-inflammatory DGLA metabolites PGE1 and 15-HETE.

Similar observations have been reported for breast milk of mothers of children with atopic eczema,¹⁰⁶ in which abnormal levels of the n-6 and n-3 PUFA families in colostrum and mature milk have been observed as well as in children with atopic dermatitis.¹⁰⁷ In both situations, GLA supplementation significantly improves epidermal health.

There are many anecdotal reports on the value of hempseed and oil for maintaining healthy, younger looking skin and for the treatment of skin disorders. Clinical studies in humans are limited. Callaway and coworkers have recently compared the effects of either 30 ml (2 Tb.) of either hempseed oil or olive oil in a 20-week randomized, single-blind crossover study with atopic patients (more commonly known as eczema).¹⁰⁸ Levels of LA and ALA, and GLA increased in all lipid fractions after hempseed oil, with no significant increases of AA in any lipid fractions after either oil. Significant reductions in TEWL values, skin dryness and itchiness

¹⁰⁴ [Meschino, James](#). 2003. Essential fatty acid supplementation improves skin texture and overall health. [Dynamic Chiropractic](#), Sep 24.

¹⁰⁵ Henz, B.M., Jablonska, S., Van de Kerkhof, et al. 1999. Double-blind, multicentre analysis of the efficacy of borage oil in patients with atopic eczema. *Brit. J. Dermatol*; 140(4): 685 - 688.

¹⁰⁶ Duchen, K., Yu, G. and Bjorksten, B. 1998. Atopic Sensitization during the First Year of Life in Relation to Long Chain Polyunsaturated Fatty Acid Levels in Human Milk. *Pediatr. Res.* 44(4):478.

¹⁰⁷ Borrek, S., Hildebrandt, A. and Forster, J. 1997. Gamma-linolenic-acid-rich borage seed oil capsules in children with atopic dermatitis. A placebo-controlled double-blind study. *Klin Padiatr.* 209(3):100

¹⁰⁸ Callaway J, Schwab U, Harvima I, Halonen P, Mykkänen O, Hyvönen P, Järvinen T. 2005. Efficacy of dietary hempseed oil in patients with atopic dermatitis. *J Dermatolog Treat.* 16(2):87-94.

improved and dermal medication followed the hempseed oil intervention. This study supports that hempseed oil improves clinical symptoms of atopic dermatitis. It is suggested that these improvements resulted from the balanced and abundant supply of PUFAs in this hempseed oil.

In their paper, Calloway et al. also speculate that hempseed oil may also increase finger nail strength and thicken hair. The cell lines prevalent in the skin, hair and nails are constructed by dermal stem cells from fatty acids that are available in the diet at the time of their formation. Thus adequate amounts of EFAs and GLA will help to replenish cellular growth and aid in healthier skin, hair and nails.

Skin Conditions in Pets

Allergic reactions and inflammation are common in canines and felines. Causes of dermatological disorders include sensitivity to allergens either related to inhalants or fleas; poor diet and/or malabsorption of dietary fats. Cats possess active D5-desaturase activity, but are deficient in the delta 6 desaturase enzyme which makes them more dependent upon GLA and EPA supplementation than dogs. In addition, the cat has a requirement for both LA and AA. Essential fatty acid deficiency in growing cats is characterized by a dry, scaly coat associated with increased TEWL.

Cats often exhibit "miliary" or "crusting" dermatitis characterized by raised, dry, scalelike bumps (papules). Diets in which the only EFA provided is LA are insufficient for normal metabolism leading to retarded growth, and alterations in skin and reproductive function. Cumulative results over two decades suggest that GLA and EPA are useful in the treatment of feline dermatoses with an inflammatory etiology.¹⁰⁹ Dogs also benefit from GLA and EPA as anti-inflammatory agents in the management of canine atopy.¹¹⁰

¹⁰⁹ Harvey, R. G. 1993. Essential fatty acids and the cat. *Vet. Dermatol.* 4(4):175.

¹¹⁰ Harvey, R.G., 1999. A blinded, placebo-controlled study of the efficacy of borage seed oil and fish oil in the management of canine atopy. *Veterinary Record* 144 (15): 405-407.

II Fibre and Oil for Industrial Applications

Overview

This section provides a structured discussion and analysis of the opportunities and challenges associated with the development of industrial hemp fibre and oil products. It is divided into the following key sections:

1. Opportunities for the use of fibre and oil
2. SWOT analysis (Strengths, Weaknesses, Opportunities and Threats)
3. Specific activities to address the opportunities and challenges

Opportunities for the Use of Fibre and Oil

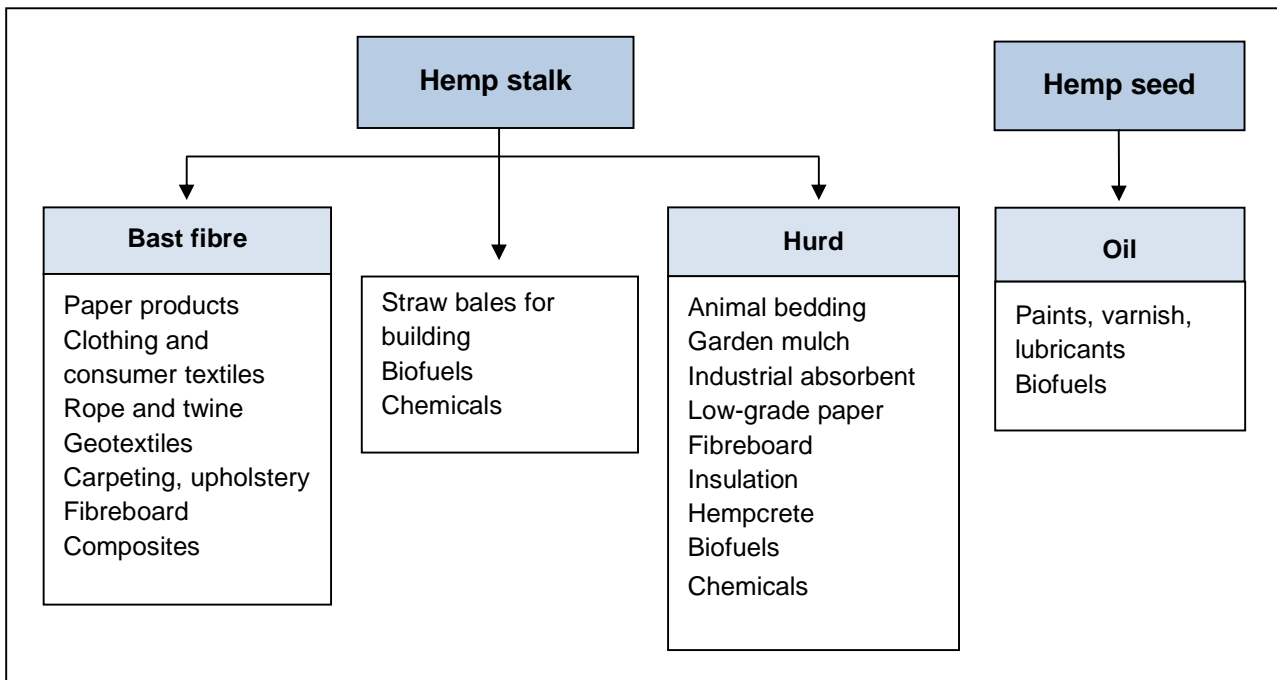
The hemp plant has been used to make useful products for thousands of years. Hemp cord was used 12,000 years ago, and hemp fabrics were used in ancient Mesopotamia and Southeast Asia during the Stone Age. The Vikings produced rope, sailcloth, caulking, fishing line and nets from hemp, and for many centuries, woven hemp fibre was the primary fabric from which clothing was made in Southeast Asia, Europe and North America. Today, hemp can be used to produce over 25,000 different products. Diagram 1: Sources of Industrial Hemp Products (over) provides an overview of the range of products that can be produced from hemp.

Industrial hemp is an emerging industry in Canada, and as such the infrastructure required for processing hemp into a range of valuable products does not currently exist. Because of the limited supply of domestically-grown hemp and its associated high price, it is not economically feasible to produce many hemp products from it at the present time.

However, it should be emphasized that this is only the *current* economic reality of hemp in Canada. The number of hectares licensed for hemp farming in Canada has grown substantially in the decade since commercial cultivation was authorized, from 2,400 in 1998 to 20,554 in 2006 – and this despite serious setbacks in 1999-2000. It is generally accepted that production costs can be lowered by exploiting hemp as a dual-purpose crop, with viable end markets for both the grain and fibre.

There is a critical difference, however, between a potential application or product and a viable opportunity – the ability to match the supply of a product to a specific (current or potential) market demand. This section examines the potential industrial opportunities for hemp oil and fibre in more detail, in terms of the short, medium and longer term opportunities.

Diagram 1: Sources of Industrial Hemp Products



Short Term Opportunities

One of the most immediate short term opportunities is the use of hemp hurd in a number of lower value, higher quantity applications including:

- **animal bedding**
- **garden mulch**
- **oil and waste absorbent**

These applications are particularly promising in that they lend themselves to a whole crop utilization approach. Approximately 75-80% of the hemp stalk is hurd. With such proportions, the economics of fibre utilization necessitates the development of profitable markets for this material. The potential exists over time to move from these lower value applications to higher value composite applications such as hempcrete (the use of hemp hurd as aggregate in a form of concrete). Establishing viable markets for hurd will be essential in enabling commercial scale bast fibre processing.

A second short term application is in the utilization of hemp fibres in **clothing and textiles**. Canada currently has a world leading bast fibre processing platform that is being commercialized by Naturally Advanced Technologies. The company has received very promising feedback on the test fibres that have been provided to a number of the leading global apparel companies.

A third short term opportunity is the use of hemp fibres in a range of **biocomposites** (including bioplastics). Canada is a world leader in both the research and development of technologies in this field. The primary challenges revolve around the production of sufficient quantities and

quality of bast fibre to enable production of the proposed biocomposite products. If reliable supplies of bast fibre become available in Canada at a competitive price point, a host of biocomposite and bioplastics opportunities will become available. Some applications, such as the substitution of hemp fibres for E-glass, can be realized as soon as fibre is available. Other more advanced applications are currently the subject of significant R&D efforts within Canada, including the multi-faceted work of the Composites Innovation Centre and its industry, research and government partners, tackling issues such as the processing of hemp fibre into viable fibre mats for composite applications.

Medium Term Opportunities

A first medium term opportunity is the use of hemp fibre in the **pulp and paper** sector. Currently, this is the most significant use for hemp in Europe. Because of the prevalence and cost competitiveness of wood fibre in North America it is likely that this application will take longer to develop at a commercial scale and that it will build from niche applications for specialty paper and expand over time into more general applications.

A second medium term application is the use of hemp fibres in **industrial textiles** including carpeting and upholstery. There are several companies working on this type of application in North America.

A third medium term application is the use of fibres in green **building materials**. Although many of these applications are well understood, they are only now beginning to achieve market penetration. As market penetration increases, the cost competitiveness of hemp-based green building products will improve, driven by economies of scale in production.

A final medium term application is the use of hemp in **phytoremediation** applications. Hemp has been used successfully to remove heavy metals such as copper, lead, zinc and cadmium from contaminated soils, eliminating the threat of their introduction into the food chain through livestock, for example. More research is required, however, before this emerges as a commercial application.

Longer Term Opportunities

There are two primary longer term opportunities for hemp. The first is in the production of **paints, varnishes, inks and industrial lubricants**. Although hemp oil is well suited to these applications, it is currently far too expensive to use in any but the smallest and highest-value applications. The price of hemp oil will need to decrease significantly before it becomes cost competitive for use in these applications.

A final medium to longer term application is the use of hemp in the production of **biofuels**. The prevailing view is that the current limited supply of hemp, coupled with the high price for hemp oil for functional foods and other health product applications and the high prices for hemp fibre for paper and composites, eliminate hemp for serious consideration as a biofuel crop. It is possible that by-products from primary and secondary hemp processing will be processed through thermal processes to produce process heat and energy, but large scale biofuel applications does not seem probable in the foreseeable future.

However, hemp has several advantages compared with other energy crops used for biofuel production:

- It can be grown on marginal land
- It is resistant to pests and disease
- It is one of the fastest-growing crops
- It exhibits high energy yield per acre

There are a number of potential conversion pathways to transform hemp biomass into biofuels, as illustrated in the following table. However, much research and development will be needed to convert any of these applications to a commercial scale, and hemp biomass will need to be produced in far larger volumes before it can be considered.

Table 10: Summary of Conversion Pathways for Biofuels from Industrial Hemp

Source	Primary Process	Secondary Process	End Product
Seed Oil	Oil extraction	n/a	Use of hemp oil as plant oil fuel
		Transesterification ¹¹¹	Biodiesel
Stalk	Direct combustion	n/a	Heat or combined heat and power (CHP) generation
	Direct fermentation	n/a	Hydrogen or other products
	Hydrolysis	Fermentation	Ethanol or other fermentation products such as butanol
	Gasification	Combustion of syngas	Heat or CHP
		Purification of syngas	Hydrogen
		Catalytic reforming of syngas	Fischer Tropsch (FT) fuels ¹¹²
	Pyrolysis	Combustion of bio-oil	Heat or CHP
		n/a ¹¹³	Use of bio-oil as diesel fuel
		Gasification of bio-oil and combustion of resulting syngas	Heat or CHP
		Gasification of bio-oil and catalytic reforming of resulting syngas	Methanol or FT fuels
	Anaerobic digestion	Combustion of biogas	Heat or CHP
		Purification of biogas	Methane
		Catalytic reforming of biogas	Methanol or FT fuel

¹¹¹ With methanol and a catalyst.

¹¹² The Fischer-Tropsch process is a catalyzed chemical reaction in which carbon monoxide and hydrogen are converted into liquid hydrocarbons.

¹¹³ The extraction of valuable chemicals from the bio-oil (pyrolytic liquid) improves its quality as a fuel. The phenolic fraction of this bio-oil may contain valuable nutraceutical compounds. In the case of flax straw, for example, recent analysis by the Canadian Forest Service of the pyrolytic liquid from pyrolyzed flax straw found high levels of molecules and compounds beneficial to human health (Goodfellow Agricola Consultants Inc., 2007).

SWOT Analysis

The following section is a SWOT (Strengths, Weaknesses, Opportunities and Threats) analysis for the use of hemp fibre and oil in industrial applications. The section begins with a chart summarizing the SWOT analysis and continues with a more in-depth discussion of each of the sub-components of the analysis. The section concludes with a discussion of some of the potential short-term activities that can be undertaken to take advantage of the opportunities that have been identified and to anticipate and bypass or overcome the threats.

Table 11: SWOT Analysis - Hemp fibre and oil for industrial applications

<p>Strengths</p> <ol style="list-style-type: none"> 1. Superior performance characteristics 2. Positive environmental impact 3. Strong market potential 4. Canadian experience and research capacity 5. Rural development 6. Established infrastructure 7. Supportive regulatory environment 8. Growing demand for bioenergy 9. Superior growth characteristics 	<p>Weaknesses</p> <ol style="list-style-type: none"> 1. Inefficient / ineffective processing technologies 2. Lack of supply 3. Transportation and storage 4. Environmental factors 5. Market imbalances 6. Infancy of the value chain 7. Standards and regulatory issues 8. Marketing and communications 9. Limited capacity to produce bioenergy 10. Growing hemp
<p>Opportunities</p> <ol style="list-style-type: none"> 1. New and emerging markets 2. Emerging processing technologies 3. Emerging emphasis on environmental considerations 4. Research, Development & Deployment 5. International Opportunities 	<p>Threats</p> <ol style="list-style-type: none"> 1. Markets and strategic considerations 2. Processing 3. Government regulations and planning 4. Growth and supply

Before engaging in the broader SWOT analysis it is important to note that the discussion relating to the production of industrial oil is limited. For the time being, the value of hemp oil for use in natural health products and functional foods is such (\$1600 for a 200 litre drum of conventional oil, up to \$2500 per drum for certified organic) that it is extremely unlikely that a competitive industrial use will emerge in the short or medium term that is price competitive with these applications.¹¹⁴

¹¹⁴ Figures provided by Mike Fata of Manitoba Harvest Hemp Foods & Oils, and Shaun Crew of Hemp Oil Canada Inc.

Strengths

1. Superior Performance Characteristics

The hemp plant has many properties that make it ideal for use in a variety of product applications including:

Fibre

- *Length* - Bast fibres from hemp are very long, making them well suited for use in products such as paper, twine, and textiles, to name a few.
- *Strength* - Bast fibres also have high tensile strength, which is beneficial in many product applications including composites, paper, twine, textiles (e.g. clothing) and fibreboard.
- *Insulation* - Hemp has strong thermal and acoustic insulation properties (evidence for this is provided by products established in the EU, such as thermal insulation).
- *Breathability, water resistance, etc.* - Hemp fibre is breathable, antimicrobial, water resistant and resistant to UV light; qualities that make it suitable for use in products such as clothing and building products.
- *Lightweight* - Hemp fibres are lightweight, an advantage for products such as composites, clothing, building materials, and paper products.
- *High in Alpha Cellulose* - Hemp fibre has low lignin content and 85-95% alpha cellulose content, making it good for paper applications.
- *Substitutability* - Strength, length, and other properties of hemp bast fibre make it possible for it to move into the existing e-glass market (it has advantages over other sources of natural fibre such as wood and wheat straw).
- *Other Unique Properties* - Hemp also has other unique properties
 - Hemp hurd is high in silica, which when combined with lime reacts to form a lightweight cement-like substance with high strength, high insulation value, etc.
 - Hurd is two to three times more absorbent than wood chips, making them ideal for use as animal bedding (equine, small animals, etc.).

2. Positive Environmental Impact

Hemp is a natural and renewable resource that could help meet Canada's increasing demand both for renewable energy and for other sustainable and environmentally friendly products. The use of hemp in a number of industrial applications and products could significantly improve the environmental performance of these products, by decreasing their greenhouse gas footprint, by reducing the use of non-renewable resources such as fossil fuels, and by increasing their potential to be recycled and their biodegradability (addressing end of life issues).

3. Strong Market Potential

Currently, the price for hemp oil is exceedingly high (\$1600 to \$2500 per drum) for use in food and natural health applications. Hemp fibre and hurd are a bi-product of grain production and, as such, are currently an underutilized resource with much potential for use in a diverse array of products.

At the present time, there is more of a market for hurd than fibre (as mentioned, hemp hurd is very absorbent and can be used as horse bedding with little processing required). Research is

underway in Canada to develop a concrete block with hemp hurd and small fibres as an ingredient. This research and development effort is being pursued with the involvement of an industry partner, to ensure immediate market pull upon successful commercialization.

The straw bale industry is another potential market for hemp bi-products since hemp straw is strong, lightweight, and resistant to mold. While straw bale buildings have existed in Canada for a number of years, extensive and specific technical testing has not been conducted nor comprehensive structural data documented. This work is to be undertaken over the next few years in Canada. One drawback to using hemp straw in straw bale building is that, due to the toughness of the fibre, there are difficulties in cutting bales to size using existing equipment.

4. Canadian Experience and Research Capacity

There is a broad and long term interest in industrial hemp in Canada, and Canadian growers have over ten years of experience in growing hemp for industrial applications. There is also significant Canadian technical and scientific expertise relating to industrial hemp products and applications, with concentrations at the Composites Innovation Centre, the University of Toronto, Queens University, the Alberta Research Council (ARC), and Tekle Technical Services (TTS), a company in Edmonton with a biofibre business incubation centre.

5. Rural Development

Processing of hemp fibre can take place at smaller facilities located in rural areas, thereby stimulating economic activity and benefiting rural communities. This potential for rural development could be enhanced by current efforts to develop zero-waste water-free processing technologies for hemp fibres.

6. Established Infrastructure

Industrial hemp is grown all across the prairies, with production currently concentrated in the prairies. There is a growing base of infrastructure in Manitoba, Saskatchewan and Alberta, along with developing capacity in Ontario, British Columbia, and Quebec.

7. Supportive Regulatory Environment

In comparison with other jurisdictions, Canada offers a supportive regulatory environment for industrial hemp. The restrictive nature of some international regulatory bodies, however, presents a significant barrier to development of hemp as an export crop.

8. Growing Demand for Bioenergy

The demand for bioenergy is increasing rapidly due both to environmental concerns relating to traditional energy sources and the high cost of oil (\$110/bbl) and other fossil fuels. Biomass has an excellent opportunity to serve as a significant feedstock in the production of renewable, 'green' bioenergy.

Hemp produces the highest annual yield of biomass of any Canadian crop (6-10T/acre), and could therefore supply a significant portion of the demand for biomass both in Canada and abroad. In addition, hemp hurd has a high energy content (BTU value), and is a potentially valuable material for solid fuel applications.

The production of bioenergy from industrial hemp could also yield a broad range of by-products. In turn, these by-products could be used in a broad range of industrial applications including for substitution in glues, resins and plastics.

There is the potential to produce a broad range of fuels from hemp, such as hydrogen gas for fuel applications. A longer term opportunity is the conversion of cellulose (sugars) from hemp (including from its fibres) to cellulosic ethanol.

The Manitoba government is currently working on biomass energy initiatives relating to hemp.

9. Superior Growth Characteristics

Hemp offers a number of superior growth characteristics in comparison with other similar crop species including:

- Higher productivity per hectare (compared to poplar and aspen);
- More weed competitive;
- Lower chemical inputs to produce fibre;
- Lower energy input to process fibre;
- Root mass is beneficial to soil and prevents erosion; and
- The crop can be self seeding.

Weaknesses

1. Inefficient/Ineffective Processing Technologies

There are a number of challenges currently associated with the processing of industrial hemp fibre, including:

- Existing retting and decortication processes weaken the hemp fibre. There are superior decortication processes under commercial development.
- Research is still needed into best management practices for fibre production;
- Research is still needed into fibre separation technologies to optimize the fibre processing of different varieties of hemp (e.g. fibre varieties versus dual purpose varieties).

2. Lack of Supply

The primary issue facing the development of hemp fibre applications in Canada is the lack of domestic commercial processing of bast fibres. Until one or more reliable sources of high quality processed fibres are available, the ability of downstream manufacturers to incorporate hemp fibres into their product lines will be extremely limited, as it is uneconomical to source commercial quantities of fibres from overseas.

3. Transportation and Storage

There is currently an insufficient supply of industrial hemp near processing plants and manufacturers to meet the needs of many commercial scale industrial applications. The distance of producers from markets and manufacturers may present a logistical challenge

associated with high transportation costs due to low density of the biomass (\$1/km truckload; 10-12/700 lbs bales).

Since industrial hemp is harvested annually, storage costs are another issue to consider, as well as degradation of fibre during storage.

4. Environmental Factors

Like all crops, hemp is susceptible to environmental factors affecting yield and quality. Further, there may be an inherent variability and inconsistent quality of fibre in natural hemp. These factors can lead to challenges in providing the consistent, high-quality supply of industrial hemp fibre that would be needed to enter into large industrial markets such as automotive parts. Entry into these markets is predicated on the ability to meet market specifications such as purity and fibre length.

5. Market Imbalances

There are a number of market related challenges that impact on the industrial hemp fibre and oil sectors. Ideally, the sector would need to have a good balance in terms of the demand for oil and the demand for fibre. Currently, the higher percentage of hurd than fibre in the hemp plant, coupled with the strong market for the hurd has led to an oversupply of fibre.

In addition, the potential market for fibre is poorly understood. The economics for hemp oil are obvious (with a current market price as high as \$2500 a drum).¹¹⁵ To date, however, there has been no economic or price point analysis to provide a quantitative basis for moving forward with the development of industrial fibre.

There may also be significant barriers to market entry for hemp products including industrial fibre. The automobile market, for instance, requires a steady stream of a high quality, consistent product that can be delivered 'just in time' at a competitive cost. While several European automobile manufacturers are beginning to adopt natural fibre composites, driven in large part by increasingly stringent regulations around end of life issues, there have only been very preliminary movements towards biocomposites in North American auto manufacturing.

There are also challenges in relation to financial markets. The hemp industry is still too new for capital markets to understand the risks associated with the sector, making it very difficult for companies to access growth capital. In addition, the turmoil in the North American hemp market in 1999-2000 has served to chill potential interest from risk capital.

In terms of our ability to learn from other jurisdictions, there are significant differences between European and Canadian production, shipping, and market strategies and regulations; therefore, although the EU can serve as an example for development of the Canadian industrial hemp industry, it is not a 'straight fit'.

¹¹⁵ From correspondence with Mike Fata from Manitoba Harvest Hemp Food and Oils and Shaun Crew from Hemp Oil Canada, the current (March 2008) market price for hemp seed oil can range from \$1600 for a 200 litre drum of conventional oil to \$2500 per drum of certified organic.

Finally, there is what is known as the “scale problem”. It is difficult to know at what size and scope to start establishing the industry, since problems (such as insufficient return on investment) may arise from either starting too big or starting too small.

6. Infancy of the Value Chain

The development of the industrial hemp fibre value chain presents a ‘chicken and egg dilemma’. The fact that the entire value chain for industrial hemp is in its infancy in Canada leads to a number of interrelated issues and challenges, including:

- To date, there has been limited product development using hemp fibres for building and other products, in part because of limited supply.
- Existing markets for hemp products are often small or niche markets, such as the straw bale and equine bedding markets.
- Because of the limited extent of current markets for hemp fibre, there is a lack of demand for processing facilities for industrial hemp which hinders the growth in the industry.
- Fibre-only hemp varieties are not yet economical to grow, because of the low demand for fibre relative to other crops and to hemp seed varieties.
- It is important to consider the price farmers must receive in order to make it worthwhile for them to bale their straw and sell it, rather than burning it.
- Although there is considerable enthusiasm regarding the potential of industrial hemp, extensive development work must be conducted in order to demonstrate business opportunities for producers.
- There is a lack of incubation centres to develop commercial opportunities for hemp.
- There is also a lack of marketing information available on how to access existing markets such as the equine bedding market, which is a strong market for hemp hurd.
- There is a lack of technical data on both hurd and fibre, especially as the fibres relate to composite and building product applications. This technical data includes chemical composition and its application to end-use, mechanical properties of the fibre, compatibility of the fibre with existing commercially used resin systems and mechanical properties of the end-product that contains hemp fibres.
- There are no commercially available “green” building prototypes or composite parts that include hemp fibre products.

Currently, those working on hemp industry development are often operating in isolation, with some collaboration through the Canadian Hemp Trade Alliance (although this is limited in nature), rather than working together in a coordinated effort. It is hoped that the development of the National Industrial Hemp Strategy, with the extensive stakeholder engagement that was undertaken, has served as a significant catalyst for hemp stakeholder networking.

7. Standards and Regulatory Issues

There are a number of regulatory challenges currently facing the hemp industry, including:

- Health Canada has placed a regulatory burden on all producers who wish to grow hemp, involving significant additional investments of time and money.
- There are no herbicides registered for use with hemp.
- Currently, there is a lack of standards on grading for hemp fibre, and no green building prototypes that include hemp fibre products.
- There is some question as to whether hemp-based products can meet building code regulations, as there are no building product prototypes that include hemp that have gone through the rigorous evaluation process at the Canadian Construction Materials Centre (National Research Council's Institute for Research in Construction). Additionally, this process is lengthy and costly, creating an obstacle for manufacturers of hemp-based building products.
- While preliminary work is being done to test composite parts that include both hemp and flax mats as a replacement for fibreglass, there is not enough data to move this area forward quickly towards the commercial manufacture and use of a natural fibre composite products (e.g. bus and automotive components).
- Consideration of the CO₂ that is captured and sequestered in a building product is not included in the LEED® Green Building Rating System used in Canada and the United States.¹¹⁶

8. Marketing and Communications

There is a perception in some circles that the hemp industry lacks professionalism and rigour in advancing its economic and environmental claims. Information and technology communicating the value of hemp are available from the EU, but they have not yet been adapted to the Canadian context.

Further, there is a lack of available information for producers about opportunities for industrial hemp, a lack of information on how to meet large industry opportunities (e.g. automotive), and a lack of technical information (e.g. information on material handling issues).

Strategies to address these weaknesses are explored in the Communications Strategy section of this report.

9. Limited Capacity to Produce Bioenergy

Although there is great potential to produce sustainable bioenergy from hemp, there are some significant challenges currently impeding this opportunity:

- There is a limited supply of hemp biomass, since hemp straw is generally produced only as a co-product or bi-product of the production of hempseed. It is likely that if hemp is to become a source of biomass for energy production this will be enabled by greatly increased hemp production, driven by the success of hemp in other markets such as natural health products.

¹¹⁶ See: <http://www.cagbc.org>

- Bioenergy is a very cost-driven market and currently the costs of hemp oil are prohibitive for any biofuel or bioenergy application.
- Given the utility of hemp for a variety of industrial applications, it is unlikely that it will be a feedstock of choice for lower value bioenergy applications for the foreseeable future.

8. Growing Hemp

There are a number of weaknesses relating to the growth and breeding of hemp. These weaknesses are addressed in greater length in the section on Production and Breeding.

Opportunities

There are a number of interesting opportunities emerging in relation to the production of industrial hemp products.

1. New and Emerging Markets

There is an opportunity to substitute bioproducts for petroleum-based products, based on emerging technology platforms and the increasing costs of fossil fuels. The supply of wood fibre is also decreasing, offering an opportunity for other natural fibres to fill in this gap in supply. Some potential markets include:

Hurd

- Hemp hurd is superior in equine bedding applications – it is antimicrobial, has very high absorbency, and therefore does not need to be changed as often as other bedding fibres, with correspondent savings in labour. Equine bedding is a strong Canadian and US market for hemp hurd, and it can also be used for livestock such as cows and pigs. Since veterinarian research has shown that wood shavings are not recommended for small animals, this may be a possible market as well.
- Absorbent for oil or chemical spills
- Thermal insulation product

Fibres

- Building products
 - Insulation board
 - Insulated wall panel boards
- Automotive, ground transportation and aerospace
 - Automotive parts (i.e. headliners)
 - Interior bus panel
 - Composite part using hemp mat
- Other applications
 - Lightweight cement
 - Recycled plastics

- Furniture industry
 - hemp fibreboard can be manufactured for use in furniture construction
 - hemp fibre may be used as furniture stuffing, where its resiliency is an advantage
 - hemp mat may be used in place of other non-natural fibre mats in furniture manufacture
- Cellulosic ethanol production or other bioenergy/biofuel applications. Hemp has a very high yield of biomass per acre.

2. Emerging Processing Technologies

There are a number of emerging processing technologies for hemp that are available in the EU and in China that have improved requirements for length (50-80cm) and purity (>80%). Future technologies also present an opportunity for on-farm processing.

3. Emerging Emphasis on Environmental Considerations

A number of Canadian municipalities and provinces are moving toward policy that dictates and/or encourages buildings to have a silver or better rating using the LEED® rating system. Natural fibres are environmentally friendly, and therefore may have an opportunity to break into more mature construction materials markets that are not currently using natural fibres. For example, concrete produces significant amounts of CO₂, and hemp can be used to make a concrete-like product (“hempcrete”) that could be substituted for traditional concrete in many applications. Hempcrete products have been developed in the UK and are currently under development for the Canadian environment, with a focus on building products and acoustic block applications. Commercial companies are also moving toward a more “green” story.

4. Research, Development & Deployment

There are multiple product development research opportunities, including opportunities for the development of co-products from hemp. There is a need for demonstration buildings and projects to showcase product opportunities, and to promote the work that is currently ongoing.

One of the most significant opportunities is the development of a ‘one-stop biorefinery model’ for fibre products and food.

5. International Opportunities

There is a significant opportunity for Canada to tap into international knowledge and best practices, and learn what other nations are doing in the area of industrial hemp fibre.

Threats

The key threats that could impact the industrial hemp sector in the future are as follows:

1. Markets and Strategic Considerations

There are a number of challenges relating to the nature and structure of the market for hemp:

- EU subsidies distort the real market value and hence the nature of the market opportunity for hemp.
- Investment capital is readily available in the US to move into the market quickly but this is not currently the case in Canada.
- Imports of jute and sisal compete for market share with hemp fibre.
- Most competitive industries are more mature than the industrial hemp sector and receptor industries such as manufacturers are not necessarily receptive to the introduction of natural fibre sources.
- There is a lack of fully-developed construction products containing industrial hemp products because of a lack of focus on product development for natural fibre-based products.
- There may be a limited window of opportunity for hemp fibres to establish markets, before other natural fibres enter the market.

2. Processing

The limited processing facilities available in the sector pose a significant threat to the long term growth of the sector.

3. Government Regulations and Planning

To date, governments have not demonstrated a significant commitment to hemp as a crop. As such, they are funding other “higher” profile products, and provincial agricultural departments may have other priorities, making funding more difficult to access for hemp. Further, both government and industry may be reticent to be pioneers in this emerging industry.

This limited interest and investment is demonstrated in the lack of planning for an agronomic program for seed production for fibre (seed multiplication program). Potentially, a change in public policy will be necessary to support the growth of the emerging industry. At a minimum, the sector must become better at communicating its associated opportunities and potential.

4. Growth and Supply

There are a number of threats relating to the growth and supply of industrial hemp fibre and oil. These challenges will be discussed at greater length in the section on production and breeding.

Specific activities to address the opportunities/challenges

There are a number of specific short and medium term activities that can be undertaken to take advantage of the opportunities identified through the SWOT analysis. Because of the infancy of the industry, it is not as useful to identify longer activities at this point since these activities will almost undoubtedly build from the short and medium term activities identified below. In some ways, the most important medium and longer term activities will be to build from the momentum generated by the shorter term activities to generate a broader and more comprehensive activity plan.

Table 12: Key Short Term Activities

Short-term activities to address the opportunities/challenges (1-2 years)	<ul style="list-style-type: none"> • Development of commercial bast fibre processing capacity • Marketing • Best Management Practices • Standards and Regulations • Research, Development and Deployment • Bioenergy
Medium-term activities to address the opportunities/challenges (3-5 years)	<ul style="list-style-type: none"> • Breeding for specific properties • Development of Bioenergy • New markets/materials

Most critical short term activities (1-2 years)

Over the short term there will be five critical activities that should be undertaken to help take advantage of the opportunities that were identified.

1. Development of Bast Fibre Processing Capacity

The primary challenge to the growth of the Canadian hemp fibre sector that was identified by the stakeholders who participated in the development of this strategy, and through research undertaken for this process, was the lack of commercial scale bast fibre processing in Canada:

“...area under hemp has decreased more than four-folds in 2007, primarily due to lack of processing facilities for hemp fibre and stock.”¹¹⁷

“The hemp plant stems are usually baled for sale to various industrial users. However, lack of a market has caused bales to back up on Paul’s land. He and other hempseed farmers are awaiting the construction of a fibre processing plant. Until then, Paul is not baling the stems, as it costs \$10 a bale. This year Peder will roll down the five-foot long stems and in the spring will burn them. “Not the best solution, but lacking a market for the stems, it’s all we can do,” says Peder.”¹¹⁸

“I am convinced we need to see 3-4 plants built immediately. With the best technology available....Right now we are all spinning our wheels. Everything is just burning up – people, ideas, opportunities”.¹¹⁹

The broad spectrum of potential markets for industrial hemp fibre will simply not materialize until such time as a reliable supply of high quality fibre is available.

¹¹⁷ Source: Alberta Agriculture and Food, Industrial Hemp Production in Canada, at: [http://www1.agric.gov.ab.ca/\\$department/deptdocs.nsf/all/econ9631](http://www1.agric.gov.ab.ca/$department/deptdocs.nsf/all/econ9631)

¹¹⁸ Don Lotter, writing for Newfarm.Org, at: http://www.newfarm.org/international/canada_don/manitoba/index.shtml

¹¹⁹ Respondent to the Canadian Hemp Industry Questionnaire (conducted as an input to the process of developing this Canadian Industrial Hemp Strategy)

Current efforts in bringing commercial bast fibre facilities online must be actively supported, along with ongoing R&D to optimize the many stages involved in transforming growing hemp fibre into processed fibre and hurd.

2. Marketing

One of the critical opportunities and hence key activities in the short term will be to market hemp as a safe, effective and environmentally friendly product. This can be accomplished through demonstrations such as the development of the “hemp bus”, “hemp board”, “bio-house” (portable) and other industrial hemp products.

These industry marketing efforts should be supported by an industry survey such as that being undertaken by the CHTA and by a concerted public relations campaign. For more information on marketing and communications please see the Communications Strategy section of this document.

3. Best Management Practices

It will be critical, as the hemp sector matures, to disseminate best management practices in relation to the production and harvesting of the crop. Other areas of focus should include lessons learned in dealing with post-harvest processing, regional issues and the use of dual versus single purpose crops (oil versus oil and fibre). It could be useful in the short term to understand and apply best practices that have emerged from the flax sector.

4. Standards and Regulations

There are a number of very specific standards and regulatory issues that should be addressed in the short term including:

- The need for standards to enable reliable and replicable fibre grading
- ASTM testing for hemp
- Registering separate varieties of hemp in order to understand the fibre characterization

5. Research, Development & Deployment

R&D efforts that will be major contributors to the growth of the Canadian industrial hemp sector include:

- fibre processing trials – products/mats
- pulp trial with fibre
- improvements to retting
- develop uses for hemp oil as high value bio-lubricant
- economic models – value chain analysis/case studies – real companies/market analysis
- study of the international influences on the Canadian hemp industry (outside influences, threats, opportunities) fibre processing infrastructure
- cement with hurd for construction application
- research on fibre and recycled plastic
- ASTM test methods
- dual and long fibre-crop harvesting equipment

- absorbency and ammonia issues for hurd in equine bedding and small animal bedding markets, and the compostability of this material

6. Bioenergy

Bioenergy is and will continue to be a critical activity in the short and over the longer terms. Some of the short term activities that should be undertaken include:

- Characterization of burn properties/energy (pelletted / bulk);
- The use of solid biomass for residual heat;
- Exploring the role of bioenergy from hemp biomass in meeting renewable portfolio standards.

Most critical medium activities (2-5 years)

1. Breeding for Specific Properties

An activity that spans the short to long term is the development of specific hemp breeds to deliver desirable characteristics such as increased oil or fibre yield (with results taking upwards of eight years to realize). Work by various breeders is well underway. The utility of new breeds will be enhanced by the development of improved harvesting technologies such as the one pass harvester being investigated by harvesting equipment manufacturers.

2. Development of Biofuel Platforms

Continuous advances in processing technology, coupled with a significant expansion in hectares of hemp under cultivation in Canada with resulting increase in supply, will move the Canadian hemp sector that much closer to the commercial production of second and third generation biofuels from hemp biomass.

3. New Markets and Products

A final medium term activity will be to continue to develop and explore the range of potential markets and products that could take advantage of the properties of industrial hemp products, for instance:

- Develop “green” construction products (insulation, boards)
 - ensure that new products are approved for building codes
 - actively promote awareness and acceptance among end users
- Pulp and paper opportunities (fibre and hurd)
 - packaging industry (cardboard, egg cartons)
- Recycled plastics and hemp fibre opportunities
 - product development is ongoing

III Production and Breeding

Overview

Historically, industrial hemp was one of the most important dual purpose crops. Hemp provided raw material for cordage, fabric and fuel from its premier bast and hurd fibres. In addition to being a fibre source, hemp was also an important oilseed. Despite the valuable characteristics hemp, cultivation began to fade from North American farms in the mid 1930s. After 50 years of hemp probation, Canada became the first North American country to re-legalize hemp cultivation. Today, hemp is grown across Canada, adding to the overall agricultural, economic and production diversity. The renewed interest in hemp has been partially based on increased demand for hemp blended clothing and properties of the high quality omega rich seed oil. Hemp is currently grown in many countries worldwide, with the majority of production in Europe for fibre based products, while in Canada production has been mainly for hempseed. Hemp acreage for both grain and fibre is gradually increasing in Canada as markets are established and products are developed and tested.

SWOT Analysis

The following section is a SWOT (Strengths, Weaknesses, Opportunities and Threats) analysis for the production and breeding of hemp crops. The section begins with a chart summarizing the SWOT analysis and continues with a more in-depth discussion of each of the sub-components of the analysis. The section concludes with a discussion of some of the potential short, medium and longer term activities that can be undertaken to take advantage of the opportunities that have been identified and to anticipate and avoid identified threats.

Table 13: SWOT Analysis - Production and Breeding of Industrial Hemp

<p>Strengths</p> <ol style="list-style-type: none"> 1. Superior performance characteristics 2. Canadian context 3. Regional capabilities 4. Canadian breeders and producers 5. Canadian cultivars 	<p>Weaknesses</p> <ol style="list-style-type: none"> 1. Legal and/or regulatory issues 2. Agronomic challenges 3. The 'straw problem' 4. Challenges in farming methodologies and practices 5. Infancy of value chain
<p>Opportunities</p> <ol style="list-style-type: none"> 1. Best Management Practices 2. Breeding opportunities/Canadian cultivars 3. Export opportunities 4. Green/emerging markets 	<p>Threats</p> <ol style="list-style-type: none"> 1. International competition 2. Regulatory issues 3. The 'THC/marijuana' problem 4. Commodity price instability 5. Increasing use of rotary combines 6. Protecting the cultivar

Strengths

1. Superior Performance Characteristics

The hemp crop has a number of characteristics that offer superior performance or economics to other comparable crops. The most significant characteristics are:

1. Hemp can be grown with relatively modest inputs, and grows quickly and vigorously.
2. Hemp's extensive root structure is beneficial in preventing erosion, aids in the removal of toxins and improves soil structure by aerating the soil for future crops. Hemp is an ideal rotation crop.
3. Industrial hemp is a hardy plant.
 - a. Hemp's rapid growth rate and vigorous nature make it highly disease and pest resistant. Hemp is naturally competitive with weeds, and therefore requires moderate-to-no herbicides.
 - b. Minimal pesticide use is required for industrial hemp, and it is impervious to animals.
4. Hemp is easy to grow for an experienced farmer.
5. Hemp harvesting occurs during the window between the harvests of wheat and soy.

2. Canadian Context

The Canadian context provides some significant advantages for the production of industrial hemp crops, including:

Legal

- It has been legal to grow industrial hemp for over ten years. Canadian producers have over 10 years of experience growing hemp in specific regional conditions.

Public

- Canada has a large group of breeders and many resources, including key genetics.
- There is a general understanding of the value of and respect for intellectual property (although one respondent to the Canadian Hemp Industry Questionnaire felt that IP issues were a major barrier to the development of the industry).
- The Cash Advance Program is available to help farmers fund their operations.
- Canada has a reasonably efficient bureaucratic system and a streamlined application process for licensing of hemp production.

Climate

- Because of its varied climatic zones, Canada offers a range of different growing opportunities.

Structure

- Canada has many large farms, and the largest modern production area for hemp in the Organization for Economic Co-operation and Development.

3. Regional Capabilities

There are a number of important differences between different production regions in Canada that offer a number of unique opportunities:

Western Canada

- It is possible to grow industrial hemp in the northern prairies, which offer long days and cool nights,
- Western Canada has particular strengths in growing and processing oilseeds.
- Hemp is a good fit with existing equipment in Western Canada.

Ontario

- Ontario has unique varieties of hemp.
- There is a longer growing season in Ontario.

4. Canadian Breeders and Producers

Canada has a strong community of breeders and producers who have a number of collective and individual strengths, including:

- There is sharing and cooperation between Canadian breeders.
- There is privately-funded breeding in Canada.
- There are six different programs (Alberta Research Council, Vandenberg/Meier, Parkland Industrial Hemp Growers, Ontario Hemp Association, McElroy, Stonehedge, Callaway-International) involved in breeding and producing hemp.
- Canadian hemp farmers have a high willingness to innovate and apply new technology.
- Historically, there has been significant farmer commitment to the production of industrial hemp.

5. Canadian Cultivars

Canada has access to good hemp genetics, including traditional cultivars. Some of the more prevalent Canadian cultivars that are emerging include: Crag, ANKA, Alyssa, ESTA-1, Carmen, Delores, and Petera. Some of the strengths of these cultivars include:

- They are drought tolerant.
- They include low THC varieties, and varieties that have been THC tested.
- Yields are increasing, and are well suited to the Canadian environment.
- All hemp in Canada is non-genetically modified.
- Canada has been very forward thinking *vis-à-vis* breeding for the US market, and in developing varieties that are appropriate to specific regions or climatic zones.

Weaknesses

1. Legal and/or Regulatory Issues

There are a number of regulatory and/or legal issues that are impacting on the industrial hemp sector including:

- There are no registered herbicides for hemp in Canada.
- Some stakeholders have had issues with respect and payment for intellectual property.
- There is no official standard for the quality of seeds that are produced, and the Grain Commission is not currently working on this, as the industry is perceived as being too small at present to warrant the effort.
- The training and timing of crop inspectors. There was initially a lack of experience and information within Health Canada's Industrial Hemp Regulations Program. There is reportedly now much more experience within the Program.
- There are various regional regulatory issues. For example, an overly-generous insurance system in Manitoba which encourages production where there is no demand was cited as an issue in the regional workshops that were held in developing this strategy.

2. Agronomic Challenges

There are agronomic challenges that are associated with growing hemp, including:

- Hemp is not a crop for first time or “neophyte” farmer.
- There is a high level of potential liability on farmers – for example cross-contamination.
- Areas with clay soils may not be suitable for hemp cultivation, since clay soil is easily compacted and hemp is very sensitive to soil compaction. Young plants are also very sensitive to wet soils or flooding during the first 3 weeks, and water-damaged plants will remain stunted, resulting in a poor crop.
- Pollen contamination leading to breeding weakness is also a challenge

3. The ‘Straw Problem’

Because of the limited markets for hemp straw, producers often encounter the ‘straw problem’ – they produce hemp for the seed but are then left with large amounts of unwanted straw, which often ends up being burned or otherwise disposed of, costing farmers time and expense. Further, there is a lack of harvesting equipment designed to harvest fibre from hemp crops and the processing of the fibre that is collected can be impacted by the environmental conditions in which that crop was produced.

4. Challenges in Farming Methodologies and Practices

Unlike other more mature sectors, there is a great deal of variability in the quality of agricultural practices in the hemp sector. Specific challenges include:

- A lack of peer reviewed agronomy.
- Inconsistency in farming methods that can vary the quality of the hempseed that is produced.
- Handling of grain post-harvest can pose a challenge, and new farmers may be uneducated about appropriate handling practices.
- A general lack of information and a need for 'grower education'.
- Overly high expectations from producers.
- Reliance on other jurisdictions for seed production.

5. Infancy of Value Chain

A final weakness is the overall weakness of the value chain for industrial hemp which leads to a number of specific challenges including:

- A lack of government and industry funding for plant breeding due to the infancy of the market.
- A lack of information regarding the needs of end processors and manufacturers, coupled with a lack of experience in predicting market needs
- There are long storage times involved in the current market situation.
- There is a lack of confidence on the part of farmers and contractors in the final prices for hemp products and plants.
- Seed costs may be too high.
- There is a lack of liquidity in the marketplace.

Opportunities

1. Best Management Practices

A key opportunity is to identify best practices associated with the production and breeding of hemp.

2. Breeding Opportunities / Canadian Cultivars

There are a number of opportunities to breed hemp for specific characteristics such as the introduction of a retting gene, increased water, less lignin, increased pectin, maximizing fibre etc. These activities will be aided by gene mapping and other activities.

3. Export Opportunities

There are a number of emerging opportunities for Canada to export germplasm, with the international community looking at Canada for our hemp genetics. In the near term, breeding for the US market may afford significant opportunities, if current US prohibitions on industrial hemp cultivation were lifted. The legalization by the US of hemp could create easier exports into US and open up larger potential markets.

4. Green / Emerging Markets

A final significant opportunity is the potential to create and derive additional revenue from green markets (through bioremediation) and carbon credits.

Threats / Challenges

1. International Competition

Sources of international competition include:

- Competition from other imported fibres.
- US legalization of production would create competition for market share.
- The potential for over supply: because of limits on production in the US there is a strong market for some products, but production at any scale could lead to significant potential losses of existing US customers.
- Inexpensive Chinese hempseed imports also compete with Canadian-grown hempseed.

2. Regulatory Issues

Ongoing regulatory challenges pose a long term threat:

- The export of whole straw/bale is illegal.
- Regulations being re-visited from both sides may open issues the hemp industry does not want to open.

3. The 'THC / Marijuana' Problem

One ongoing issue is the need to test for THC contamination. Some current challenges include:

- The analytical procedures that are currently in place are variable in terms of their capacities to detect THC.
- The potential exists for marijuana farmers' seed to spread to breeding plots.

4. Commodity Price Instability

Because of the restrictions on supply in some countries and artificial demand in others there are challenges with the price of hemp on an ongoing basis, including:

- Stability of supply.
- Opportunity cost, as determined by the farm gate value that could be earned from competing crops.

5. Increasing Use of Rotary Combines

Most manufacturers in North American are moving to use rotary combines. However, the use of rotary combining damages hemp fibre.

6. Protecting the Cultivar

A final set of challenges involve the hemp cultivars, and potential difficulties with:

- Cross contamination of cultivars
- Plants with novel traits that are found in certain streams within the variety process. The process for testing and proving seeds is very labour intensive.

Specific Activities to Address these Opportunities / Challenges

Many short term production opportunities exist within the Canadian hemp industry. The quality of Canada's arable lands and diverse production regimes can provide a wide range of quality hemp raw seed and fibres. An acreage forecasting system coordinated by processors and contractors will need to be developed as a management tool. Currently, Canada has the ability to supply not only quality hemp seed but retted and baled hemp fibre that could be made available to the market immediately. In addition, opportunities exist to develop best management practices, equipment modification protocols, conduct agronomic research trials and develop new products which could improve existing production. There is a need for advanced grower and producer education opportunities via production seminars which would increase access to information. The hemp re-legalization efforts in the United States could open larger markets to the Canadian hemp industry as a whole. Since hemp can be grown in many different soil zones and in a variety of regions, it represents an opportunity for many communities across Canada.

Research opportunities exist in the areas of phytoremediation and carbon sequestration. These areas of improvement based on agronomic needs could be initiated and delivered via university graduate student projects. This would open many opportunities for academic advancement of the hemp industry. Project goals for research must be developed in order to streamline efforts and increase bilateral communication.

The short and medium to long term activities that can be undertaken to take advantage of the opportunities identified through the SWOT analysis are as follows:

Table 14: Key Short and Medium to Long Term Activities

<p>Short-term activities to address the opportunities/challenges (1-2 years)</p>	<ol style="list-style-type: none"> 1. Strategic breeding to increase/modify production 2. Development of improved harvesting system 3. Storage and drying 4. Soil remediation 5. Industry and economic modeling 6. THC testing 7. Education of growers and producers 8. Other opportunities
<p>Medium to Long-term activities to address the opportunities/challenges (3-5 years)</p>	<ol style="list-style-type: none"> 1. Agronomic studies 2. Breeding studies 3. Research into carbon sequestration

Short term (1-2 years)

Over the short term, there will be eight critical activities that should be undertaken to take advantage of the opportunities that were identified.

1. Strategic Breeding to Increase / Modify Production

Specific activities could include:

- Breeding to reduce lignin and pectin in fibre.
- Breeding of hybrids.
- Field evaluations.
- Short stature varieties.
- Reliable germination test for seed (address dormancy issue).

Fibre

- Fibre-only trials to increase fibre yields in relation to variety (currently there are fibre trials underway at a number of locations).
- Fibre characterization of registered varieties.

2. Development of Improved Harvesting Systems

A key opportunity is to develop improved harvesting systems, including:

- Fibre harvesting processes to minimize damage to fibre/optimize collection of fibre.
- Dual crop harvesting equipment.
- BMP for production and harvesting.

3. Storage and Drying

There is an opportunity to look at best practices in relation to the storage and drying of hemp. Key issues include moisture control and product handling to reduce losses using existing farming systems.

4. Soil Remediation

An additional opportunity involves the characterization of the potential for hemp to be used in soil remediation, including an analysis of phosphorous, nitrogen and heavy metals absorbed by hemp.

5. Industry and Economic Modeling

A fifth opportunity is to explore the econometric model of the industry and sector. Contributing to this work will be:

- An industry survey undertaken by the Canadian Hemp Trade Alliance.
- The development of effective economic models including value chain analysis/case studies of real companies.

6. THC testing

A significant challenge relating to hemp cultivation is the need for accurate and effective THC testing. One short term opportunity is to look at the development of an in-field THC test kit.

7. Education for growers and producers

There is a need for advanced grower and producer education opportunities via production seminars which would increase access to information.

8. Other Opportunities

Other potential opportunities that have been identified include:

- The need to develop and implement quality grading standards
- To develop a set of best practices and lessons learned from flax

Medium to Longer term (3-5+ years)

1. Agronomic Studies

This would include studies such as the long term agronomic national variety evaluation program (testing, characterization) that is being led by Gordon Scheifele.

2. Breeding Studies

This includes looking at the use of breeding techniques leading to increased oil yield. This could also include continued varietal trials looking at optimizing food, fibre, soil fertility, agronomic traits, and an analysis of the potential economics of these improved varieties. A third type of longer term study involves an examination of dioecious and monoecious fibre quality and quantity comparison and productivity analysis.

3. Research into Carbon Sequestration

While it would be valuable to thoroughly understand the carbon sequestration of hemp production and the manufacturing of hemp products, it will likely be several years before this

data would result in direct monetary advantages for the hemp industry, as would be the case if an effective carbon credit trading system was implemented in Canada.

Communications Strategy

Elements of a Successful Communications Strategy

There are a number of core elements to a successful Communication Strategy (CS), including:

1. Objectives and Messaging
2. Core Audiences
3. Core Communications Activities and Tools
4. Optional Communications Activities and Tools
5. Public Engagement

These components must be oriented to the specific needs of the organization or organizations for which it is developed. This section of the Strategy looks at each of these elements in greater detail.

A successful communications strategy must do more than simply lay out a theoretical path to engage stakeholders and partners. It must also reflect the material realities of the organization or organizations it is serving. To this end, this section concludes with a discussion of a range of potential options to move forward – ranging from a small set of core activities which are critical to the integrity of the communications strategy to a broader set of optional activities which would add value but are not essential to the overall success of the strategy.

Objectives and Messaging

The ultimate objectives of the communication strategy:

1. Increase awareness of the potential uses and benefits of hemp;
2. Dispel myths surrounding the safety and efficacy of hemp products; and
3. Increase the utilization of hemp products by domestic and international industries (such as food processing, natural health products, fibres, and composites).

There are three core messages that should be communicated as part of this strategy:

1. Hemp is a high quality Canadian crop with many potential high-value applications in the bioeconomy;
2. The science to date clearly shows that hemp is safe, and that there are no potential health issues relating to the consumption or utilization of hemp-based products, and;
3. Hemp products offer significant health and performance benefits in relation to other existing crops and agricultural products.

These core messages can be supported by providing third party, accurate, unbiased and high quality science-based information about hemp.

Core Audiences

The National Industrial Hemp Strategy (NIHS) has two core audiences:

1. **External** – The network of external stakeholders who need to be engaged to ensure the success of the Industrial Hemp Strategy include all orders of government (federal, provincial, municipal), organizations and agencies within governments (funders, policy and programs, regulators, researchers, others), primary consumers of industrial hemp products, and representatives from the end markets that will be served by these consumers.

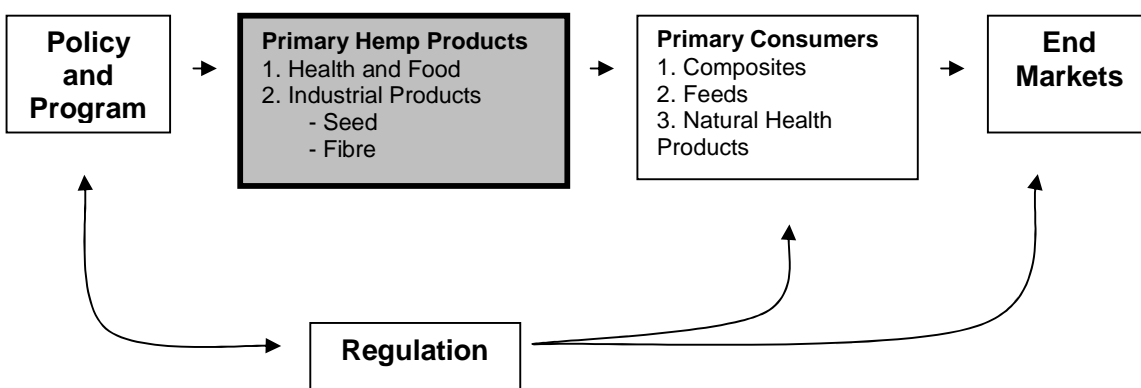
A separate but equally important external audience are the external validators who can provide unbiased evidenced-based support for the health and other beneficial characteristics of hemp and hemp products. This group could include health associations, dieticians, the medical and academic communities, standards organizations and other health professionals regarding the health benefits of hemp, and architect and professional engineers associations regarding the benefits of hemp fibre products.

2. **Internal** – To build a constituency within the industrial hemp community. This community would include farmers (current and potential), breeders, researchers and scientists, primary processors, industrial partners and representatives from the upstream primary consumers for industrial hemp products.

It is important to understand each of these core audiences in detail and to discuss the particular strategies that would be appropriate to engage each stakeholder group within these core audiences.

It can be daunting to consider engaging the full range of potential partners and stakeholders in the National Industrial Hemp Strategy. One way to simplify this process is to articulate a framework which captures the key relationships between these stakeholders and partners. Diagram 3 (below) outlines the core stakeholder groups that are engaged in the National Industrial Hemp Strategy. External stakeholders are captured in the white boxes while the core internal stakeholder groups are captured in the grey box.

Diagram 2: Key Stakeholders in the National Industrial Hemp Strategy



External Audiences

Policy and Program includes elements in the federal and provincial governments that impact on the industrial hemp sector. Key departments and agencies include:

Federal – Agriculture, Industry, Finance, Health Canada, Canadian Food Inspection Agency, National Research Council, Foreign Affairs and International Trade, and other federal research bodies

Provincial – Provincial departments of Agriculture, Industry, Economic Development and Health, and research agencies and bodies

Policy makers should be engaged at both the political and bureaucratic levels. The communications strategy would identify a limited number of core strategic goals that the National Industrial Hemp Strategy is aiming to achieve that would be communicated to policymakers at the appropriate level. Undoubtedly, the broad range of internal stakeholders engaged will generate a diverse list of strategic goals and policy needs and objectives.

It is critical, however, that priorities are established with policy objectives articulated in a coherent and integrated fashion. If fourteen policy priorities are set they are all unlikely to be realized. If two or three well crafted and coherent policy objectives which will lead to demonstrable real world outcomes are articulated, there is a much better chance of achieving these objectives.

Regulation would be active at the international, national and provincial levels. Ideally, the communications strategy would include activities such as:

1. Identifying key regulatory barriers;
2. Developing and communicating strategies to address these challenges, and;
3. Regulatory foresighting - identifying and anticipating likely future regulatory requirements and challenges and engaging regulators at the appropriate levels to address these challenges.

There is a strong linkage between the regulatory and policy and program components of the external audience. While regulatory and policy functions are separated within departments, they are often part of a single overarching departmental or government strategy.

Regulation can also play a key role in the types of primary consumers who will utilize hemp products (for instance, regulatory requirements for fibres that are used in composite materials, health regulations relating to the development and use of natural products) and the end markets into which these primary consumers can market the end products that are produced. Given that many of the hemp products that are produced will be substitutes for existing materials it will be critical for these substitutes to demonstrate that they are of comparable or better quality, performance and price.

Primary Consumers include the broad range of manufacturers and producers who will utilize industrial hemp in the products that they create. There are a broad range of primary consumers who could be engaged through a comprehensive communication plan. Some of the larger potential consumer groups include producers and manufacturers of:

1. Composite Materials
2. Textiles
3. Advanced Fibres
4. Animal Feed
5. Functional Foods
6. Natural and Medicinal Products

Some hemp processors will market their products directly to end consumers. Most, however, will market their products to a range of intermediary manufacturers.

Understanding the needs and requirements of **end markets** will be a critical element of the communications strategy. In essence, the potential range of hemp products that are produced will determine the supply of the industrial hemp market. The needs and requirements of end market consumers represents the ultimate demand.

A range of communications activities will be required to engage end market consumers. One component will be to develop a strategic brand for hemp products and components. As a developing sector, it will be critical to establish a **brand image** (and reality) for performance and reliability that will enable end market consumers to make the choice to purchase products that contain hemp components.

One existing challenge which the hemp industry must work to overcome is the stigma associated with hemp and its linkage to marijuana. This is particularly significant in relation to the natural health products component of the industrial hemp sector, where there are often lingering doubts about the potential presence of THC in hemp food products.

An important communications activity will be to increase the awareness of the health benefits and potential usage of hemp within the domestic and international food and natural health products industries and to secure the endorsement of health associations, dieticians, the medical and academic communities and other health professionals in communicating the health benefits of hemp to key stakeholder groups. It will be critical to provide these stakeholders with independent, accurate, unbiased and high quality science-based information about hemp.

An equally important communications activity will be to identify the key needs and requirements of both end market and primary consumers in order to communicate these requirements back to researchers and scientists, hemp processors and, eventually, breeders and farmers. The market dynamics for industrial hemp products will be dominated by the ability of the sector to understand the core end market needs, to communicate these needs to its key stakeholders, and to develop a range of products that address these needs in an economically viable manner.

Internal Audiences

The second primary audiences are the internal stakeholders who will support the development of and benefit from the implementation of the National Industrial Hemp Strategy. This audience will, at least initially, be of a limited size and scope and would encompass key participants and

the stakeholder engagement sessions that have been undertaken to-date along with other key stakeholders who have been identified as part of the process of developing the National Industrial Hemp Strategy.

The full range of internal stakeholders within the industrial hemp sector is almost as diverse as those that are engaged as external stakeholders and customers. The key internal audiences include:

Farmers, including those that are already engaged in growing industrial hemp and the broader group of farmers for whom hemp could represent an economically viable alternative crop. The core messaging for this stakeholder group will include:

1. The economic potential of continuing to produce or switching to the production of industrial hemp
2. Dissemination of knowledge that will enable success in the industrial hemp sector:
 - a. What kinds of crops will be most desirable?
 - b. What techniques and/or technologies are most effective for hemp growth and harvesting?
 - c. What are the key dynamics/aspects of marketing industrial hemp in Canada and internationally?

Breeders and Agronomic Scientists who will contribute to the development of hemp varieties that are specifically tailored to the requirements of primary and end market consumers, hemp processors, and to the farmers who will grow the hemp for the industrial hemp sector.

Communication foci for this group will include:

1. Market demand (primary and end market consumers)
2. How to increase market supply (farmers and processors)

Perhaps the most significant emerging internal stakeholder group is **Processors**. Processors are those industries who convert raw hemp plants into primary and secondary hemp products including fibres, seeds, oils, functional foods and other high value substances. One of the primary communication challenges within the industrial hemp sector will be to link processors with:

1. *Farmers* – so that they can identify high quality sources of hemp and provide critical guidance and the varieties and characteristics of the hemp plants that they require for their processing applications.
2. *Researchers and Scientists* – to articulate the key challenges and barriers that are hindering the economics of the industrial hemp sector so that the researchers and scientists can develop results-oriented solutions to these challenges.
3. *Regulators* – to ensure that the products that are produced will be acceptable in key primary and secondary market applications.
4. *Primary and End Market Consumers* – to identify those primary hemp products that have the highest current and potential future values and the largest end markets.

Ultimately, the success of the National Industrial Hemp Strategy will depend on the ability to link processors with each of these key constituent groups. In many ways the processors will be the critical link between each of the other internal and external stakeholder groups.

Researchers and Scientists from a variety of additional disciplines who will help to overcome the inherent challenges in the hemp sector by working with the other key internal stakeholders to overcome existing and emerging barriers.

Core Communications Activities and Tools

There are a number of tools that can be employed to engage core audiences. The most basic tool for both internal and external audiences is a **website**. This website should articulate the industrial hemp industry's:

1. Purpose and Mandate
2. Membership and Leaders (Staff and Board)
3. Key Policies
4. Positions on Critical Issues
5. Additional Resources

A website can also serve as a critical media for two-way communication both in the internal and external stakeholder communities. A password-protected member's area with discussion boards and forums can serve as a virtual market or meeting place for members of the Network. A strategically constructed community site can also enable the interaction of key scientific, entrepreneurial and producer resources. At the time of the writing of this document, the CHTA is in the process of re-designing their website to enhance access to information, offer easier access to information and offer a venue to further develop communication tools for the hemp industry and its stakeholders.

A second communications vehicle for policy makers at the federal and provincial levels is a **newsletter** or occasional update. These publications would bring together current data and information in an attractive and informative format, highlighting potential areas for government action (policy) and/or support (programs).

The Hemp Industry would benefit from implementing a series of **face-to-face and virtual events** to bring together key stakeholders from across the sector and from across the country. These events could coincide with the CHTA's annual national conference, as well as special interest group meetings to be coordinated by the CHTA. A special event to showcase the NIHS with strong industry, government and producer involvement could serve as a platform to launch the National Industrial Hemp Strategy. Additionally, conducting a series of bi-annual workshops or knowledge seminars could be simulcast on the web and recorded to ensure the deepest level of penetration within the sector. The hemp industry would also benefit from looking at marketing and communications activities at other national and international conferences and events.

Optional Communications Activities and Tools

In addition to the communications activities identified in the previous section, there are a number of additional activities and tools that could be developed as part of a broader communications strategy.

Expansion of the Trade Organization/Association (CHTA)

The longer term success of a sector communications strategy depends on more than the identification of a single champion or champions. As the sector grows and matures it should

consider further developing its trade association, as well as expanding the breadth and scope of this organization's activities.

Initially the CHTA could be co-resident within one or several of its primary members with guidance from a board of directors drawn from the key representatives from within the stakeholder community. Communications-related activities of an expanded CHTA could include:

1. Engaging with key policymakers and decision makers at the provincial and national levels of government;
2. Disseminating information about the Network and the industrial hemp sector to key sectors both inside and external to the sector;
3. Working with regulators to ensure that Canada's relevant regulatory frameworks are both relevant to the current needs of the industrial hemp sector and are aware of and working to address potential future needs;
4. Marketing and branding of both the industry and of hemp products;
5. Monitoring scientific and research and development progress relating to the sector and to identify key gaps, barriers and emerging opportunities;
6. Bringing together and connect key stakeholders across the entire industrial hemp value chain to share ideas and information;

Many of these activities are already included within the corporate mission of the CHTA, which involves:

1. The promotion of the best interests of Canada's industrial hemp industry
2. The development and execution of marketing and export promotion programs
3. Facilitating research needed to advance the sector
4. Public education of hemp's benefits and potential
5. Helping to develop policy in support of the Canadian hemp industry
6. To serve as a representative to all levels of governments in Canada as well as abroad¹²⁰

The CHTA is run by a single part-time president/executive director associated with an existing bioproducts advocacy group or network. Over time, however, as the sector matures it will become increasingly desirable to move towards a full-time, administratively supported president/executive director with a strong working board that will assist the network and fully represent the needs and requirements of the sector.

Lobbying and Advocacy

As an adjunct to the ongoing core activities of the CHTA, there is a need for ongoing lobbying and advocacy. The purpose of these activities is threefold:

1. To raise awareness of the sector and its primary opportunities and barriers with key decision makers (politicians and senior bureaucrats);
2. To communicate key sectoral challenges and to articulate concrete and viable actions that can be taken by decision makers to address these challenges (for example, the creation of a new policy, to mobilize additional resources for research in the sector, etc);

¹²⁰ <http://www.hemptrade.ca/en/public/about-chta-accs.html>

3. To work with decision makers to implement specific, concrete actions to address the needs of the sector.

Responsibility for lobbying and advocacy activities are fairly clear in the context of a trade organization or association – that organization would be responsible for identifying key lobbying and advocacy opportunities and requirements and mobilizing appropriate advocates from within the sector.

In the absence of a paid lobby position it is key that the hemp industry identify specific champions for individual issues who can be mobilized to meet with and address decision makers relevant to their areas of concern.

Potential Lobbying and Advocacy Activities

Lobbying and advocacy activities can range from single consultations or information days (where the sector hosts a reception for key decision makers), to individual consultations and meetings with key decision makers, to the production of thematic marketing and branding materials that are broadly distributed.

At least initially, the CHTA needs to work to identify and engage with a small range of strategically chosen stakeholders. Given its likely limitations in terms of resourcing, it will be important to identify the one or two primary decision makers in key jurisdictions. Lobbying and advocacy activities can be undertaken either by individuals from the industrial hemp sector who have a high degree of public and/or scientific credibility. Such individuals might include the heads of relevant industrial hemp processors, scientists and researchers from leading institutions and representatives from the farming community.

Public Engagement

A final component of the communications strategy involves public communications. At least initially this will not likely be a high priority for the Canadian Hemp Trade Alliance / Industrial Hemp Industry. It may, however, become a higher priority depending upon the level of consumer uptake and support for consumer products containing hemp products.

There are several forms of public engagement:

1. **Polling** – in order to identify public opinion on key questions such as the acceptance of hemp based products and materials. Polling can be useful in support of other communications activities such as lobbying and advocacy work.
2. **Branding/Marketing** – there are several reasons why public branding and marketing could be of interest as part of a national industrial hemp network. First off, a well executed branding exercise can help to increase the level of latent demand for hemp products in the population. Such activities would focus on addressing and overcoming myths relating to hemp products including linkages to marijuana and other potentially negative associations. Marketing can also be an effective strategy to raise the awareness of a product such as industrial hemp with key decision makers. The downside of branding and marketing efforts is that they can be quite costly and time consuming so is not necessarily resource effective for emerging sectors and/or trade associations.

3. **Media** – A final component of public engagement is working with the media. In general there are two forms of media engagement:

- a. *Earned Media* – Working to engage reporters in key newspapers and in other key media to ensure that they include industrial hemp in appropriate general interest stories and to encourage the development of specific stories and articles relating to industrial hemp sector and/or specific companies or institutions.
- b. *Purchased Media* – Any form of purchased advertisement in print, radio, television or, increasingly, online.

Earned media offers some significant advantages over purchased media: it is much less expensive, it is often seen as having more credibility and it can reach a broader audience. With purchased media, however, there is a much greater degree of control over content and positioning of the product.

Initial work to be undertaken to move towards a comprehensive media plan needs to focus on developing earned media contacts, and connecting key stakeholders with interested representatives from relevant media sources such as agricultural magazines and websites. Over time, as the sector develops, the use of purchased media may become more feasible both on the basis on an increased resource base and broader group of stakeholders to share the cost.

Over time, the Canadian Hemp Trade Alliance may wish to employ some or all of these forms of public engagement as it continues to work towards achieving its goals and objectives.

Appendix A – Literature Review of Nutritional Properties of Hemp

LITERATURE REVIEW NUTRITIONAL PROPERTIES OF HEMP

March, 2008

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LITERATURE REVIEW: NUTRITIONAL PROPERTIES OF HEMP

There are different bioactive ingredients in hemp that have shown promise in disease prevention and reduction. From this literature review, clinical research on hemp is needed for industry marketing, for regulators and for health professionals – all groups require data supporting efficacy to ensure consumer confidence in new functional foods and natural health products.

1.0 HEMP IN FOODS

Hemp (*Cannabis sativa*) is one of the oldest crops cultivated by man. It has been grown for fibre and seed for the last 5,000 years, however there are indications that it was cultivated 20,000 years ago in China. Hemp was produced in North America until 1937 when the Marijuana Tax Act made it a forbidden crop, although the import of hemp seeds for use in bird feed was permitted. During the Second World War hemp production was revitalized as access to imported fibre had been curtailed. Prior to 1937, an active seed breeding program was on-going at the USDA. After this point, such programs continued in only a few European countries. Only China continued the production of hemp seed to any extent.

Over the past decade, hempseed and oil have experienced a revival especially in the food and health area! Hemp seed and oil are increasingly used in natural food products, such as snacks, nutrition bars, hummus, nondairy milks, breads, cereals, prepared foods and numerous other applications. The oil is available in capsules or bottles. The market for hemp oil as a topical ingredient in natural body care and cosmetic products is also growing.

Statistics available from Agriculture and Agri-Food Canada and provided by the Canadian Hemp Trade Association confirm that exports are indeed increasing for hemp seed and oil. As is clear from Tables 1 and 2, seed and oil exports for the six month period ending June 2007 were higher than in total for 2006¹²¹, in fact the dollar value of hempseed exports were up 50% from the previous year and are showing a 300% growth in quantity from 2004.

¹²¹ Agriculture and Agri-Food Canada. September 2007. Hemp Statistics.

Table 1: Hemp Seed Exports to All Countries				
	VALUE (\$ Can)		QUANTITY (TNE)	
	2006	Jun-07	2006	Jun-07
TOTAL:	1,555,430	1,230,522	256	382
United States	1,415,659	1,147,122	211	179
Ireland	57,248	39,918	7	65
United Kingdom	56,861	12,064	22	57
Japan	14,402	18,463	1	58
Costa Rica	5,405	3,028	15	6
Germany	0	5,473	0	10
Sweden	2,630	2,698	0	5
Australia	2,560	0	0	0
South Africa	0	1,385	0	3
Neth. Antilles	665	371	0	1

Between 2006 to June 2007, hemp oil exports showed an 80% growth. The U.S. is the largest export market for both seed and oil where the industry and consumers continue to show a great deal of interest in hemp for food, supplement and cosmetic applications.

Table 2: Hemp Oil Exports to All Countries				
	VALUE (\$ Can)		QUANTITY (TNE)	
	2006	Jun-07	2006	Jun-07
TOTAL:	455,771	375,257	42	36
United States	417,354	315,433	38	31
Korea, South	5,040	19,390	1	2
Japan	7,285	14,172	0	1
United Kingdom	13,831	0	2	0
Ireland	0	13,444	0	2
Germany	0	6,368	0	1
Sweden	2,676	3,370	0	0
Australia	6,000	0	0	0
New Zealand	1,800	2,000	0	0
Finland	1,785	0	0	0
South Africa	0	1,080	0	0

Manitoba followed by Saskatchewan dominate the Canadian provinces with regard to hemp seed (Chart 1) and hemp oil (Chart 2) exports. This is due primary production of hemp in these provinces as well as the presence of strong hemp oil crushing and food companies.

Chart 1: Hemp Seed Exports by Province

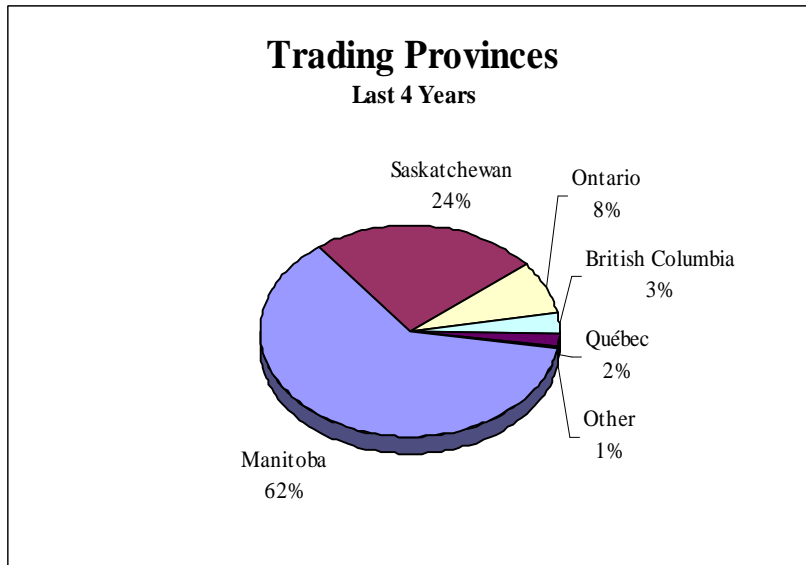
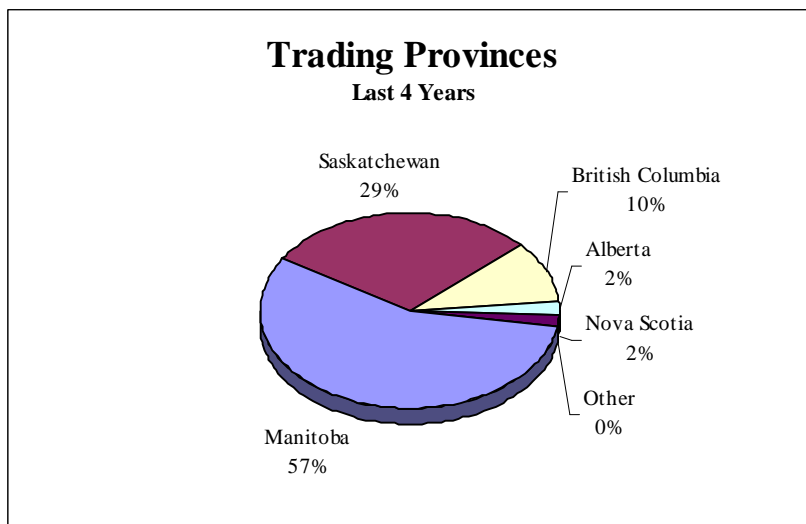


Chart 2: Hemp Oil Exports by Province



Growth in hemp food products is strong. According to the natural products statistic company, SPINS, hemp non-dairy milks, packaged hemp protein, bottled hemp oil and packaged hemp seed/nut are increasing in the US market at a steady pace. Other hemp food products including cereals, breads, snack bars, etc. that contain hemp seed but not as the primary ingredient, are also seeing strong growth. The natural personal care including soaps, shampoos, lotions, and products that contain hemp seed oil continue to gain market presence.

As shown in the following figure, growth rates for these products for the 52 week period ending August 2007 are between 10% and 62%!

HEMP INDUSTRIES ASSOCIATION
8/25/07

Hemp Sales in SPINS - Natural Channel Without Whole Foods

	Current 24 Weeks End Aug. 11, 2007				Current 52 Weeks End Aug. 11, 2007			
	Current \$ Sales	Prior \$ Sales	Dollar % Change	Dollar Change	Current \$ Sales	Prior \$ Sales	Dollar % Change	Dollar Change
<u>Hemp Food Categories</u>								
Hemp Non-Dairy Milks	\$1,117,276	na	na	\$1,117,276	\$1,174,449	na	na	\$1,174,449
Packaged Hemp Protein	\$990,110	\$826,848	58.0%	\$363,262	\$1,840,188	\$1,135,057	62.1%	\$705,131
Bottled Hemp Supplement Oil	\$346,380	\$327,923	5.6%	\$18,457	\$720,802	\$648,032	11.2%	\$72,570
Packaged Hemp Seed/Nut	\$305,344	\$275,951	10.7%	\$29,393	\$590,066	\$534,780	10.3%	\$55,286
All Other Hemp Food*	\$1,625,615	\$1,536,230	5.8%	\$89,385	\$3,373,927	\$3,228,985	4.5%	\$144,942
Total Hemp Foods	\$4,384,725	\$2,766,952	58.5%	\$1,617,773	\$7,699,232	\$5,546,854	38.8%	\$2,152,378
Total Hemp Bodycare**	\$5,876,930	\$5,296,197	11.0%	\$580,733	\$12,148,542	\$10,959,986	10.8%	\$1,188,556
Total Hemp Food/Bodycare	\$10,261,655	\$8,063,149	27.3%	\$2,198,506	\$19,847,774	\$16,506,840	20.2%	\$3,340,934

* Other Hemp Food Products are cereals, breads, snack bars, etc. that contain hemp seed but not as the main/primary ingredient.

** Hemp Bodycare are soaps, shampoos, lotions and other personal care products that contain hemp seed oil.

NOTE: This report does NOT include sales from Whole Foods or conventional sales channels. Nor does it represent all stores which sell hemp foods. This report primarily demonstrates the growth rate of hemp food sales in Natural food stores.

1.1 Nutrient Composition of Hemp Seed

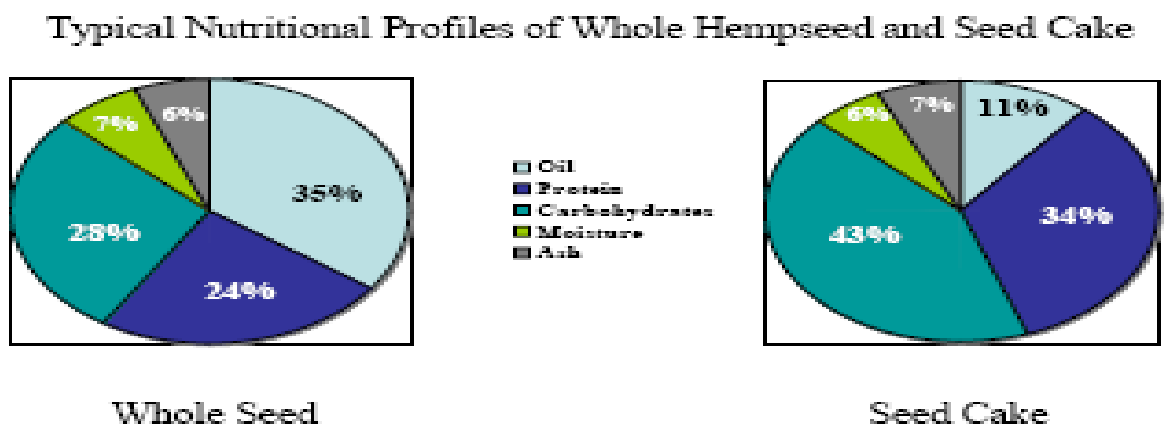
Hemp seed composition is quite interesting in that unlike other oilseeds, it has near equivalent levels of oil, protein and carbohydrates (Table 3 and Figure 1). All three compounds have relevance in the reduction of chronic disease as well as for overall health and wellness.

Table 3: Composition of Industrial Hemp Seed (%)

Component		
	Whole Seed	Dehulled Seed
Hull*	20 - 35	-
Protein	20 - 25	30 - 35
Oil	25 - 34	42 - 47
Carbohydrates	32 - 36	10 - 12
Dietary Fibre	30 - 34	3 - 10
Soluble Fibre	5 - 15	3 - 7
Ash	6	6

* Seed cover, husk, external part of the seed.

Figure 1: Composition of Industrial Hemp Seed (%)



Llaway SC. 2004. Hempseed as a nutritional resource: an overview. Euphytica 140: 65-75
Free PDF available on www.finola.com

2.0 OIL

Hempseed oil is very unique as its fatty acid profile differs from any known vegetable oil. It is over 90% polyunsaturated fatty acids (PUFA), which play very important roles in the reduction of several diseases and chronic conditions and contribute to overall health and wellness in a number of ways. An overview of the importance of dietary fatty acids is provided followed by a description of the fatty acid profile of hempseed.

2.1 Dietary Fats

Dietary fat fulfills certain roles in the body including as a concentrated source of energy. In North America, dietary fat accounts for approximately 33-40% of total caloric intake. It serves as a source of essential fatty acids and as a carrier of fat soluble vitamins. Fat contributes to the palatability of foods and to overall feeling of satiety.

Fatty acids are the nutritional components found in dietary fats and oils. PUFAs are categorized as either omega-6 or omega-3 depending upon the position of their first double bond from the terminal end of the fatty acid. The most important PUFAs for human nutrition in each omega series are:

Omega-6 (n-6) Fatty Acids

Linoleic Acid	C18:2n-6	LA
Gamma Linolenic Acid	C18:3n-6	GLA
Dihomogamma Linolenic Acid	C20:3n-6	DGLA
Arachidonic Acid	C20:4n-6	AA

Omega -3 (n-3) Fatty Acids

Alpha Linolenic Acid	C18:3n-3	ALA
Stearidonic Acid	C18:4n-3	SDA
Eicosapentaenoic Acid	C20:5n-3	EPA
Docosahexaenoic Acid	C22:6n-3	DHA

2.2 Essential Fatty Acids

Essential fatty acids (EFAs) are required in the diet as they can not be synthesized by humans from the shorter chain fatty acid, oleic acid (C18:1n-9). The two foundation EFAs are linoleic acid (C18:2n-6, LA) and alpha-linolenic acid (C18:3n-3, ALA).

Young animals deprived of LA and ALA in the diet rapidly display negative health effects, including diminished growth, liver and kidney damage, and dermatitis; these eventually result in death. It takes longer for the effects to become apparent in older animals, which may have substantial stores of essential fatty acids in their body fats, but symptoms will appear eventually.

The effects of EFA deficiency have been seen in human infants, in adults on parenteral nutrition, or with certain genetic disorders. The absolute requirements for EFAs in humans and livestock depend on a number of factors, including species and sex, but are usually considered to be 1-2% of dietary fat for both LA and ALA.

LA and ALA are components of cellular membranes and act to increase membrane fluidity. The proper functioning of all body cells depends upon healthy membranes as they act as

“gate-keepers” in the cells. The physical properties of the cell including its contents; the shape and “fluidity” of the membrane; and the permeability of substances into and out of the cell are greatly influenced by the EFA. In some membranes, such as in the skin and the layer around the nerves, specific PUFAs provide a moisture barrier and an insulating layer, respectively.

2.3 Metabolism of Polyunsaturated Fatty Acids

LA and ALA are synthesized in plant tissues from oleic acid by the introduction of double bonds between the existing double bond and the terminal methyl group by the sequential enzymatic action of $\Delta 12$ and $\Delta 15$ desaturases as shown in the following Figure.

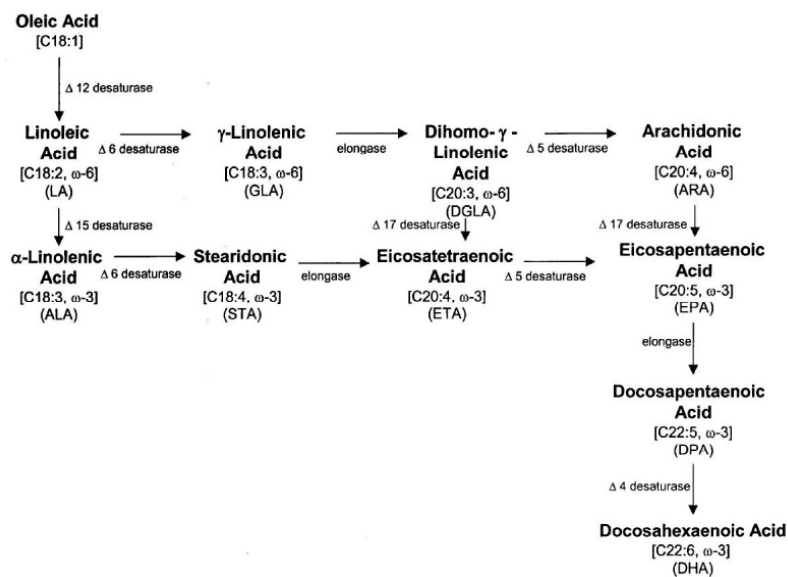


Figure 2: Pathway for Synthesis of Long-chain Polyunsaturated Fatty Acids¹²²

In animal tissues, additional double bonds can only be inserted between an existing double bond and the carboxyl group. Biosynthesis of PUFAs requires a sequence of chain elongation and desaturation steps. The first step of desaturation at the six carbon position is believed to be rate limiting and involves the introduction of a double bond to form GLA and SDA of the omega-6 and omega-3 families, respectively. Genetic, dietary and environmental factors are believed to impair the human Δ -6 desaturase enzyme including aging, stress, diabetes, alcohol, smoking, cholesterol, *trans*- and saturated fatty acid consumption, n-3 fatty acid deficiency and vitamin and mineral deficiencies.

LA in the PUFA Pathway

In human and plant metabolism, LA is converted by alternating series of enzymatic desaturations and elongations to the long-chain omega-6 fatty acids. GLA is the initial metabolite produced in this process. Once GLA has been synthesized, it is elongated to dihomogamma-linolenic acid (C20:3n-6), also known as DGLA.

¹²² DuPont. Production of Polyunsaturated Fatty Acids in Oleaginous Yeasts. US 2005/0136519 A1.

DGLA is a precursor to the 'Series 1' eicosanoids. By the action of human Δ -5 desaturase, DGLA is converted to arachidonic acid (C20:4n-6 or AA). Although DGLA is the precursor for ARA production, consumption of high levels of GLA does not result in the accumulation of high levels of ARA. Like human Δ -6 desaturase, human Δ -5 desaturase has limited activity and it appears that the production of PGE1 and 15-OH-DGLA from DGLA is preferred over AA production.

GLA intakes apparently can increase to quite high levels before AA would be expected to rise – dietary levels that would be near impossible to achieve consuming hemp oil alone. Previous studies have shown that the FA composition of plasma lipids, platelets, erythrocytes and adipose tissue is actually quite resistant to supplementation with AA or DGLA, its direct precursor¹²³. It has been speculated that increased levels of GLA in the diet are diverted to produce series 1 prostaglandins from DGLA and, thus, may not contribute substantially to AA levels in the human matrix¹²⁴.

ALA in the PUFA pathway

ALA is converted by a series of alternating desaturations and elongations to the long-chain omega-3 fatty acids, eicosapentaenoic acid (C20:5n-3, EPA) and docosahexaenoic acid (C22:6n-3, DHA). Stearidonic acid (C18:4n-3 SDA) represents the Δ 6 desaturation product of ALA. It is elongated to 8,11,14,17-eicosatetraenoic acid (C20:4n-3, EA) which is further desaturated to EPA.

The conversion of ALA to EPA is usually described as limited and somewhat slow in humans and is the subject of a great deal of controversy. There is great variability in the conversion rate with estimates as high as 6% converted to EPA and as low as 0.2% converted. The 30-fold difference between these conversion rates may reflect key differences in the study protocols.

ALA conversion is also affected by diet. A diet rich in LA can reduce ALA conversion by as much as 40%. Other factors that interfere with ALA conversion include the intake of dietary cholesterol, saturated fat, oleic acid and *trans* fatty acids and the ratio of polyunsaturated to saturated fats in the diet. High intakes of omega-3 fatty acids can also block ALA conversion.

The relative effectiveness with which dietary LA and ALA are bioconverted to DGLA and AA, and to EPA, respectively, is thus dependent upon regulation of the subsequent desaturation and elongation reactions.

2.4 The Importance of the Eicosanoids

LA and ALA through their conversion to the longer chain PUFAs are the dietary starting point for the production of a number of important, very active, hormone-like compounds called "eicosanoids" (Figure 3).

¹²³ Nelson GJ, Schmidt PC, Bartolini G, Kelley DS, Kyle D. 1997. The effect of dietary arachidonic acid on platelet function, platelet composition, and blood coagulation in humans. *Lipids* 32:421–425; Nelson GJ, Schmidt PC, Bartolini G, Kelley DS, Phinney SD, Kyle D, Silbermann S, Schaefer EJ. 1997. The effect of dietary arachidonic acid on plasma lipoprotein distributions, apoproteins, blood lipid levels, and tissue composition in humans. *Lipids* 32:427–433

¹²⁴ Okuyama H, Kobayashi T, Watanabe. 1997. Dietary fatty acids - the N-6/N-3 balance and chronic elderly diseases. Excess linoleic acid and relative N-3 deficiency syndrome seen in Japan. *Prog Lipid Res* 3:409–457

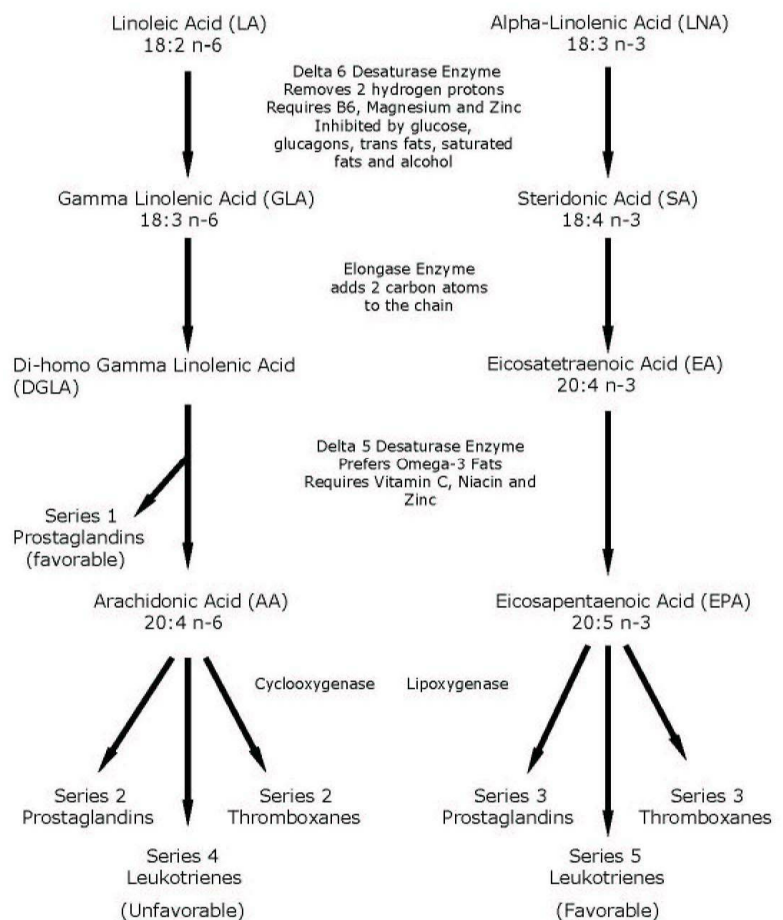
Cyclooxygenase and lipoxygenase are the enzymes responsible for these conversions. Eicosanoids contain twenty carbons and include compounds called prostaglandins (PGE), prostacyclins (PGI), thromboxanes (TXB) and leukotrienes (LTB).

The omega-6 and the omega-3 fatty acid families form different eicosanoids with very different activities. The different eicosanoids compete with one another for cyclooxygenase and lipoxygenase which catalyze the release of the EFA from the cell membranes. An excess of one family of fatty acids can interfere with the metabolism of the other, reducing its incorporation into tissue lipids and altering biological effects. A proper balance of the EFAs in the diet is important for the maintenance of good health.

Omega 6 DGLA is the precursor of the physiologically important 'Series 1' eicosanoids, Prostaglandin 1 (PGE1) and 15 hydroxy-DGLA (15-OH-DGLA).

- PGE1 inhibits platelet aggregation and inflammation, produces vasodilation, inhibits cholesterol biosynthesis, regulates immune responses and reduces blood pressure.
- 15-OH-DGLA inhibits 5- and 12-lipoxygenases, therefore inhibiting the formation of proinflammatory compounds from arachidonic acid (C20:4n-6 or ARA) such as PGE2 and 4-series leukotrienes.

Omega 3 EPA is converted to chemical messengers known as eicosanoids (specifically of the 'Series 3') including prostaglandin 3 (PGE3); thromboxane B3 (TXB3), prostacyclin I3 (PGI3) and leukotriene B5 (LTB5).



- TXA3 is a weak platelet aggregator and vasoconstrictor.
- PGI3 stimulates vasodilation and inhibits platelet aggregation.
- LTB5 is a weak inducer of inflammation and a weak chemotaxic agent.

Omega 6 AA is the substrate for the "Series 2" prostaglandin, prostacyclin and thromboxane and the "Series 4" leukotrienes, including prostaglandin 2 (PGE2); prostacyclin I2 (PGI2); thromboxane B2 (TXB2) and leukotriene B4 (LTB4).

- PGE2 exhibits pro-inflammatory and vasoconstrictive properties. It also induces inflammation, which includes redness and heat due to arteriolar vasodilation as well as swelling and localized edema resulting from increased capillary permeability.
- PGI2 acts a potent platelet anti-aggregatory agent and vasodilator.
- TXB2 causes vasoconstriction and platelet aggregation.
- LTB4 is a potent pro-inflammatory agent and a powerful inducer of neutrophil chemotaxis and adherence.

When diets are too high in omega-6 fatty acids, AA and its potent eicosanoids are produced in abundance, resulting in an over-active immune system that may contribute to chronic diseases like cancer, stroke, diabetes and coronary heart disease.

When humans consume DGLA (from GLA), ALA, SDA, EPA and/or DHA, these fatty acids are incorporated into the cell membranes within and around the cells of the body. They partially replace AA and also compete with AA for cyclooxygenase and lipoxygenase activities. Hence the ingestion of these fatty acids can result in decreased production of PGE2, TXB2 and LTB4. Counteracting these decreases in AA derived eicosanoids are increases in the eicosanoids produced from DGLA and EPA. These alterations in the levels of eicosanoids influence the metabolic processes involved in a number of metabolic functions.

To conclude, the omega 6 and the omega 3 fatty acid families form different eicosanoids with very different activities. A proper balance of the EFAs in the diet is critical for good health and to reduce disease. The omega 6 AA produces eicosanoids that stimulate pro-inflammatory; vasoconstrictive (blood vessel narrowing) and pro-thrombotic (blood clotting) reactions in the body. When diets are high in omega 6 fatty acids, AA and its potent eicosanoids are produced in abundance, resulting in an over-active immune system that may contribute to chronic diseases like cancer, stroke, diabetes and coronary heart disease.

In contrast, the omega 6, DGLA and the omega 3, EPA form eicosanoids that counteract those of AA and cause vasodilation, anti-thrombotic and anti-inflammatory reactions in the body.

2.5 Fatty Acid Profile of Hempseed Oil

Hempseed oil is produced by pressing the hemp seed. The oil can be eaten on its own, blended into other food or used in body care products.

As shown in Table 4, hempseed oil has a unique fatty acid profile especially when compared to other oils. Hempseed oil contains over 90% PUFAs of which 80% of the oil is comprised of the EFA, LA and ALA. Hemp oil is rich in LA (over 55%) and contains, depending on plant variety, 15-20% ALA. Hempseed oil is low in saturated fat (SAT), which constitutes only 8% of total fatty acids.

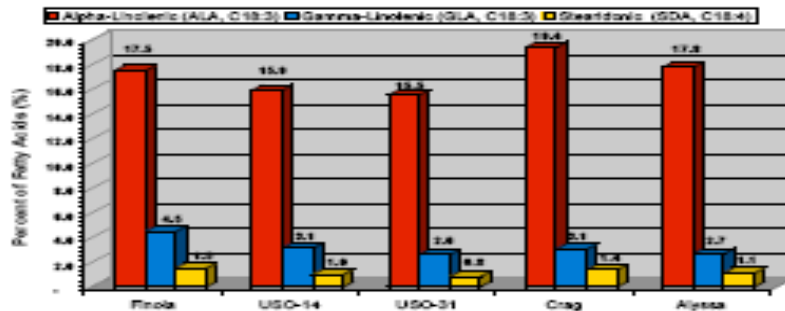
Also unique to hemp oil is the presence of GLA and SDA as shown in Figure 5. GLA may be as high as 5%, but is usually between 2 – 3%. The presence of upwards of 3% of SDA is another distinctive property of the oil. Never varieties of hemp designed for oil production have fatty acid compositions that are skewed towards higher levels of GLA, ALA and SDA.

Table 4. Composition of Hemp and Selected Oils

Fatty acids (%)	Hemp	Borage	Black- <i>Current</i>	Evening Primrose	Soybean	Canola
C16:0	4 - 9	9 - 12	6 - 8	6 - 10	10 - 13	3 - 6
C18:0	2 - 4	3 - 5	1 - 2	1 - 4	3 - 5	1 - 2
Total Saturated	8 - 13	12-18	7-14	8-16	14-18	4-9
C18:1	8 - 15	10 - 15	9 - 13	5 - 12	18 - 28	52 - 68
Total Monounsaturated	7 - 16	12-18	10-16	7-18	18-30	52-70
C18:2	53 - 60	35 - 40	45 - 50	65 - 80	50 - 58	16 - 25
C18:3 alpha	15 - 25	0.2	12 - 15	8 - 14	6 - 13	16 - 25
C18:3 gamma	0 - 5	15 - 25	14 - 20	0.2	-	-
C18:4	0 - 3	0.2	2 - 4	-	-	-
Total Polyunsaturated	68 - 85	50-68	70-86	70-95	50-75	30-52



Typical Levels of Key Fatty Acids
in Hemp Seed Oil

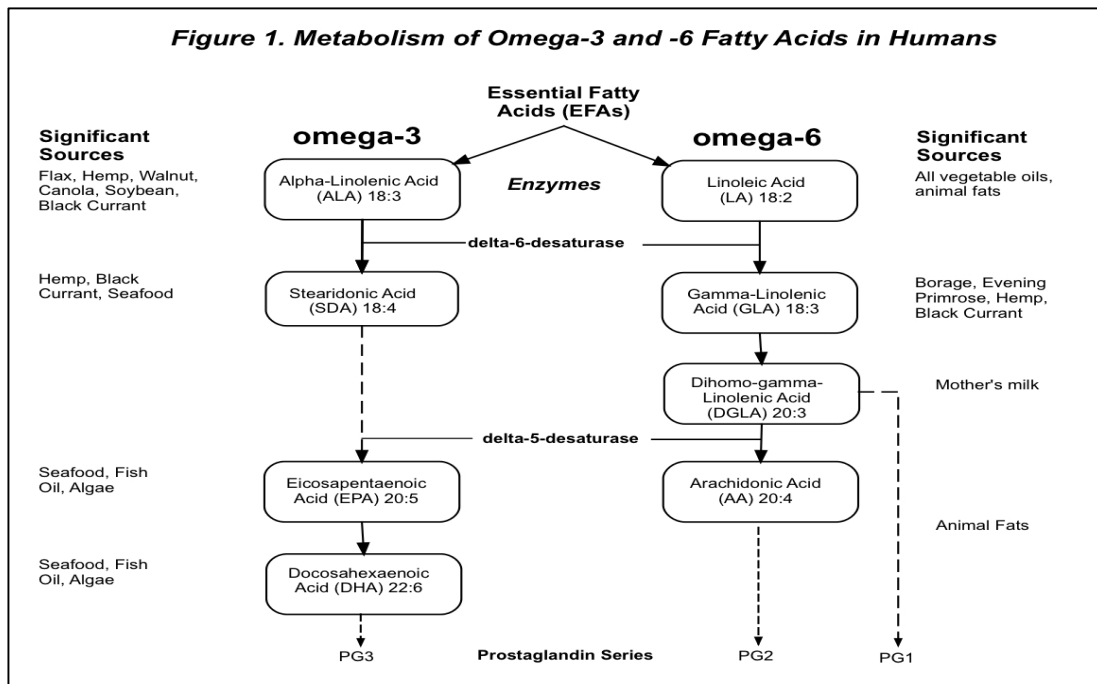


Average 2003/2004 crops

- Alpha-linolenic acid (ALA)
- Gamma-linolenic acid (GLA)
- Stearidonic acid (SDA)

This figure clearly identifies the limited dietary sources of ALA, GLA and SDA. Hempseed oil is more readily available than many of the specialty oils and is much more versatile for home and institutional food use.

Figure 1. Metabolism of Omega-3 and -6 Fatty Acids in Humans



2.6 Health Benefits of Omega 6 and Omega 3 Fatty acids

Diet plays an enormous role in the onset of disease. The burden of chronic disease is increasing worldwide, and is no longer an issue of importance only in developed countries. The World Health Organization's 2003 report¹²⁵ on diet, nutrition, and the prevention of chronic disease reported that in 2001, chronic diseases contributed approximately 60% of all deaths worldwide and 46% of the total burden of disease. Almost half of these deaths are from cardiovascular diseases, obesity and diabetes. The WHO estimates that chronic disease will account for 70% of all deaths worldwide by 2020.

Certain fats and oils can significantly reduce the risk of several diseases and even contribute to the treatment of chronic conditions. Clinical research suggests that the PUFAs GLA (omega 6), ALA (omega 3) and to a limited extent SDA, show varying levels of promise in the prevention of cardiovascular disease, inflammation, diabetes and hypertension. This research is reviewed in the following sections.

2.6.1 Dietary Fatty Acids and Cardiovascular Disease

Omega 3 - Alpha Linolenic Acid

The populations of Japan and Crete have the greatest life expectancy in the industrialized world and also consume the highest levels of ALA in the diet in addition to low intakes of saturated fat¹²⁶. Four case-control studies, one cross-sectional study, three prevention trials and three cohort studies have found a benefit of ALA-rich diets in lowering the risk of CHD, ischemic heart disease (IHD), nonfatal myocardial infarction (MI) and stroke. One prevention trial found no change in the estimated 10-year IHD risk but reported a significant decrease in fibrinogen and CRP levels (inflammatory biomarkers) on ALA-rich diets^{127, 128}. The number of participants in the studies ranged from 233 to 76,283.

Numerous intervention studies have established the beneficial effects of ALA on reducing the risk of adverse cardiac events. The Health Professional Follow-up Study, which began in 1986 with a cohort of 51,529 health professionals, demonstrated that a 1% increase in ALA intake was associated with a 40% reduction in the risk of non-fatal CHD¹²⁹. The Lyon Diet Heart Study included participants who had previously survived a myocardial infarction compared to an experimental group who consumed a typical Mediterranean style diet rich in ALA. The control group consumed a typical Western-type diet low in ALA. The results were impressive with a

¹²⁵ World Health Organization. Diet, Nutrition and the Prevention of Chronic Disease, series 916. 2003.

¹²⁶ Lanzmann-Petithory, D. 2001. Alpha-Linolenic Acid and Cardiovascular Diseases. Journal of Nutrition, Health and Aging. 5(3): 79-183.

¹²⁷ Bemelmans, W.J.E., Lefrandt, J.D., Feskens, E.J.M. et al. 2004. Increased alpha-linolenic acid intake lowers C-reactive protein, but has no effect on markers of atherosclerosis. Eur J Clin Nutr. 58:1083-89.

¹²⁸ Bemelmans WJE, Broer J, Feskens EJM, et al. 2002. Effect of an increased intake of α -linolenic acid and group nutritional education on cardiovascular risk factors: the Mediterranean Alpha-linolenic Enriched Groningen Dietary Intervention (MARGARIN) study. Am. J. Clin. Nutr. 75: 221-227.

¹²⁹ Ascherio A, Rimm EB, Giovannucci EL, et al. 1996. Dietary fat and risk of coronary heart disease in men: Cohort follow up study in the United States. Br. Med. J; 313: 84-90.

75% reduction in non-fatal myocardial infarctions, and a 70% reduction in total death noted amongst the ALA group in comparison to the control group¹³⁰.

In the Nurse's Health Study, which involved a 10-year follow-up of 76,283 women with no previously diagnosed CVD, a higher intake of ALA was associated with a lower relative risk of fatal and non-fatal myocardial infarction¹³¹. ALA can reduce ventricular fibrillation (rapid and irregular heartbeat), and may be more effective in this regard than EPA. The cardio-protective effects of ALA have also been attributed to improvements in arrhythmia (abnormal heart rhythms) and to reductions in platelet aggregation (blood platelet stickiness)¹³².

ALA and stroke risk

Two population studies found a benefit of ALA in reducing stroke risk. In the Edinburgh Artery Study, significantly lower levels of ALA were found in the red blood cell phospholipids of men and women who had had a stroke compared with participants who had no evidence of disease¹³³. In the Multiple Risk Factor Intervention Trial (MRFIT), 96 men who had had a stroke were compared with 96 men without stroke who were matched for age. In the multivariate model, each increase of 0.13% in the serum ALA level was associated with a 37% decrease in risk of stroke¹³⁴. After controlling for risk factors of stroke like smoking and blood pressure, ALA emerged as an independent predictor of stroke risk – that is, men with higher levels of ALA in their serum phospholipids had a lower stroke risk.

ALA and cardiac rhythm (arrhythmia)

The rhythmic pumping action of the heart is controlled by the heart's electrical system. Arrhythmias are abnormal rhythms of the heart muscle and are a risk factor for MI. In humans, the ALA content of adipose tissue was inversely related to risk of MI in one case-control study conducted in Europe and Israel¹³⁵ and with nonfatal acute MI in another study carried out in Costa Rica¹³⁶. In the Nurses' Health Study, a prospective cohort study involving 76,763 women, the dietary intake of ALA was inversely associated with the risk of sudden cardiac death, but not with other fatal CHD or nonfatal MI¹⁵⁶.

¹³⁰ de Lorgeril M, Renaud S, Mamelle N, et al. 1994. Mediterranean alpha-linolenic acid-rich diet in secondary prevention of coronary heart disease. *Lancet*; 343: 1454-1459.

¹³¹ Hu FB, Stampfer MJ, Manson JE, et al. 1999. Dietary intake of α -linolenic acid and risk of fatal ischemic heart disease among women. *Am. J. Clin. Nutr.* 69:890-897. and Albert CM, Oh K, Whang W, et al. 2005. Dietary α -linolenic acid intake and risk of sudden cardiac death and coronary heart disease. *Circulation* 112: 3232-3238.

¹³² Vos E, Cunnane SC. 2003. α -Linolenic acid, linoleic acid, coronary artery disease, and overall mortality (letter). *Am. J. Clin. Nutr.* 77: 521-522.

¹³³ Leng GC, Taylor GS, Lee AJ, et al. 1999. Essential fatty acids and cardiovascular disease: the Edinburgh Artery Study. *Vasc. Med.* 4: 219-226.

¹³⁴ Simon JA, Fong J, Bernert Jr JT, Browner WS. 1995. Serum fatty acids and the risk of stroke. *Stroke* 26: 778-782.

¹³⁵ Guallar E, Aro A, Jiménez FJ, et al. 1999. Omega-3 fatty acids in adipose tissue and risk of myocardial infarction: the EURAMIC study. *Arterioscler. Thromb. Vasc. Biol.* 19: 1111-1118.

¹³⁶ Baylin A, Kabagambe EK, Ascherio A, et al. 2003. Adipose tissue α -linolenic acid and nonfatal acute myocardial infarction in Costa Rica. *Circulation* 107: 1586-1591.

The mechanism by which ALA helps lower the risk of fatal or nonfatal MI appears to involve its effect on cardiac rhythm. In the Family Heart Study, Djoussé and colleagues found that the higher the dietary ALA intake, the lower the risk of abnormally prolonged repolarization of the heart muscle – an indicator of cardiac arrhythmia¹³⁷. ALA content of adipose tissue is positively correlated with 24-hour heart rate variability. That is, women with a higher content of ALA in their adipose tissue had better heart rate variability scores which made them less likely to develop ventricular arrhythmias. Taken together, these findings suggest that ALA helps maintain the heart's normal rhythm, thus partly explaining how ALA helps reduce CVD risk.

Clinical studies as well as small and large-scale population studies indicate that the consumption of ALA-rich diets lower the risk of CVD. In epidemiological research, overall cardioprotective effects of ALA were seen despite differences in study populations, length of follow-up, outcomes and method of analyzing the study data statistically. Diets high in ALA elicit heart health effects through numerous mechanisms and evidence suggests that total intakes of approximately 1.5 to 3 g/d ALA are very beneficial¹⁵⁵⁻¹⁶².

Omega 3 - Stearidonic Acid

SDA has been the subject of recent, although limited, clinical assessment. In a double-blind, parallel design, encapsulated SDA (from modified canola oil), ALA, or EPA was ingested daily in doses of 0.75 g and then 1.5 g for periods of 3 weeks each by healthy male and postmenopausal female subjects ($n = 15/\text{group}$)¹³⁸. Dietary SDA increased EPA and docosapentaenoic acid (DPA) concentrations but not DHA concentrations in erythrocyte and in plasma phospholipids.

Increases in tissue EPA in erythrocyte and plasma phospholipids were measured. At the 0.75-g daily dose (0–3 wk), the effectiveness of SDA was 3.1- to 5.0-fold that of ALA, and the effectiveness of EPA was 3.1- to 3.9-fold that of SDA. At the 1.5-g daily dose (3–6 wk), the effectiveness of SDA was 3.7- to 4.1-fold that of ALA, and the effectiveness of EPA was 3.1- to 3.6-fold that of SDA.

The effects of echium oil which contains about 13% SDA (up to 1g/day for 12 weeks) on blood lipids and mononuclear cells were assessed in healthy young men¹³⁹. In this study, SDA was readily metabolized to EPA. The authors conclude the SDA may offer a plant oil-based option to efficiently increase the EPA status of such cells. SDA bypasses the need for the activity of the delta 6 desaturase enzyme, which is believed to be low in many conditions.

¹³⁷ Djoussé L, Rautaharju PM, Hopkins PN, et al. 2005. Dietary linolenic acid and adjusted QT and JT intervals in the National Heart, Lung, and Blood Institute Family Heart Study. *J. Am. Coll. Cardiol.* 45: 1716-1722.

¹³⁸ James, M.J., Ursin, V.M. and Cleland, L.G. 2003. Metabolism of stearidonic acid in human subjects: comparison with the metabolism of other n-3 fatty acids. *Amer. J. Clin. Nutr.* 77:1140-5.

¹³⁹ Miles EA, Banerjee T and Calder PC. 2004. The influence of different combinations of gamma-linolenic, stearidonic and eicosapentaenoic acids on the fatty acid composition of blood lipids and mononuclear cells in human volunteers. [Prostaglandins Leukot Essent Fatty Acids](#). 70(6):529-38.

Echium oil has also been investigated to determine effects of SDA on tissue fatty acid content and serum triacylglycerol concentrations in hypertriglyceridemic humans¹⁴⁰. Eleven subjects consumed 15 g of echium oil daily for 4 wk. During the treatment period, serum triacylglycerol concentrations decreased by 21%, hypotriglyceridemic properties similar to fish oils. EPA levels increased significantly in plasma and neutrophils. In addition to SDA, echium oil contains LA, GLA, and ALA so SDA and conversion to EPA may not be fully responsible for the results noted.

Omega 6 - Gamma Linolenic Acid

The physiological and clinical effects of GLA have been studied for several decades. In general, healthy individuals are able to synthesize GLA from dietary LA. The conversion of LA to GLA, however is a slow step. It can be further inhibited by a variety of factors including diabetes, aging, zinc deficiency, excess alcohol consumption, high levels of cholesterol, certain viral infections and catecholamines released during stress. People who have inherited an atopic disposition (atopies), which makes them liable to develop eczema, asthma, allergic rhinitis or other allergies, are less able to convert LA to GLA than other people. Thus, insufficient amounts of GLA may be produced by the body even in the presence of adequate LA.

The role of dietary GLA in reducing CVD risk was first investigated nearly 30 years ago¹⁴¹, but it has been relatively understudied compared to other fatty acids in this respect. Dietary GLA has been shown to reduce the proliferation of smooth muscle cells, a pivotal event in the etiology of atherosclerosis, in mice¹⁴².

Few clinical trials in humans, however, have investigated the role of GLA in cardiovascular health. One study by Laidlaw and Holub¹⁴³ determined the effects of different levels of GLA supplementation together with a constant intake of EPA plus DHA on the triacylglycerol-lowering effect of EPA plus DHA alone and on the fatty acid patterns (eicosanoid precursors) of serum phospholipids. Thirty-one women were assigned to 1 of 4 groups, equalized on the basis of their fasting triacylglycerol concentrations. They received supplements providing 4 g EPA+DHA (4:0, EPA+DHA:GLA; control group), 4 g EPA+DHA plus 1 g GLA (4:1), 2 g GLA (4:2), or 4 g GLA (4:4) daily for 28 d. Plasma triacylglycerol concentrations were significantly lower on day 28 than on day 0 in the 4:0, 4:1, and 4:2 groups. LDL cholesterol decreased significantly (by 11.3%) in the 4:2 group. Based upon these limited results, further research appears warranted.

¹⁴⁰ Surette, ME, Edens, M., Chilton, F.H. and Tramposch, M. 2004. Dietary Echium Oil Increases Plasma and Neutrophil Long-Chain (n-3) Fatty Acids and Lowers Serum Triacylglycerols in Hypertriglyceridemic Humans. *J. Nutr.* 134:1406-1411.

¹⁴¹ Kernoff PBA, Willis AL, Stone KJ, et al. 1977. Antithrombotic potential of dihomo-gamma-linolenic acid in man. *Br. Med. J.* 1977; 2:1441-1444.

¹⁴² Fan Y-Y, Ramos KS, Chapkin RS. 1997. Dietary gamma-linolenic acid enhances mouse macrophage-derived prostaglandin E₁ which inhibits vascular smooth muscle cell proliferation. *J. Nutr.* 127:1765-1771.

¹⁴³ Laidlaw M, Holub BJ. 2003. Effects of supplementation with fish oil-derived n-3 fatty acids and gamma-linolenic acid on circulating plasma lipids and fatty acid profiles in women. *Am J Clin Nutr.* 77:37-42.

Summary - Omega 6 and 3 Fatty acids and the Heart

The mechanisms by which omega 6 (GLA) and omega 3 (ALA, SDA , EPA and DHA) fatty acids reduce CVD risk remain under investigation. However, research to date suggests that these fatty acids can:

- **Lower risk of mortality from heart disease.** The EFAs noted above can reduce the chance of uncontrolled heart rhythms and developing fatal blood clots, two major causes of heart disease deaths. EFAs, therefore, lower the chances that heart attacks will be fatal.
- **Improved heart rhythms.** Dangerously fast heartbeats or disordered heart rhythms can be fatal. EFAs help maintain stable heart rhythms by affecting the electrical activity of the heart. Thus, it is more difficult for uncontrolled heart rhythms to develop. Unstable and uncontrolled heart rhythms underlie sudden death, the cause of nearly half of all cardiac mortality. By stabilizing heart rhythms, omega 3s reduce the chance of dying suddenly.
- **Improved heart rate.** Heart rate is the number of beats a minute that the heart pumps at rest. It accelerates to increase the amount of blood ejected by the heart. Heart rate is lower in people who are physically fit and higher in the obese. Usual heart rate is between 60 and 80 beats per minute and usually increases with age. Heart rate adapts to changing conditions and generally speaking, the greater adaptability of the heart, the better its condition. Consumption of EFAs is associated with lower heart rate and with greater heart rate variability, conditions that reflect better heart health and lower the chance of heart attack.
- **Less chance of having a first heart attack.** There is evidence that people who do not have signs of heart disease may be able to avoid having a first heart attack if they consume EFAs often. For people who have had a heart attack, risk of another is also substantially reduced. Consuming these fatty acids regularly improves heart rhythms, reduces the likelihood of blood clots forming, reduces the low-grade inflammation that accompanies heart disease, and improves blood lipid patterns - all effects that discourage heart failure.
- **Less chance of stroke.** A stroke results from a blood clot blocking an artery in the brain. Clots may develop there or be carried to the brain from elsewhere. Non-fatal strokes can cause serious disability. In most western countries, ischemic strokes, the kind caused by blood clots or lack of oxygen, are the most common type. EFAs have been shown to lower the chance of having a stroke.
- **Improving blood lipids.** The blood carries different types of lipids, including fats and cholesterol, throughout the body. High levels of blood lipids lead to deposit in the walls of arteries called plaques. These reduce blood flow and supply of oxygen to the heart. ALA, EPA and DHA improve blood lipids by lowering the amount of LDL-cholesterol and triglycerides, respectively, in the blood, these improvements in blood lipids are especially important in people with type 2 diabetes who have high triglycerides and low HDL.
- **Reduced blood clotting.** Some blood clotting is essential for life, but an excessive tendency towards clotting increases the risk of blocked arteries. These can be fatal when a clot completely closes a blood vessel in the heart, lungs, or brain. EFAs reduce platelet clumping and affect certain clotting factors reducing the tendency for blood to clot. EFAs

also improve blood flow and make red blood cells more flexible so they pass through tiny blood vessels more easily.

2.6.2 Hemp Oil and Cardiovascular Disease

In one of the few studies performed on the hypocholesterolemic effects of hemp oil (HO)¹⁴⁴, Schwab and colleagues provided a comparison of HO and flax oil (FO) on several biomarkers of lipid function in healthy humans. Fourteen subjects consumed HO and FO (30 ml/day) for 4 weeks each in a randomized, double-blind crossover design. The periods were separated by a 4-week washout period. The HO period resulted in higher proportions of both LA and GLA in serum cholesterol esters (CE) and triglycerides (TG) as compared with the FO period, whereas the FO period resulted in a higher proportion of ALA in both serum CE and TG as compared with the HO period. Serum total TG concentration decreased significantly during the FO period. Reduction in serum total TG during the HO period approached statistical significance. The total-to-HDL cholesterol ratio, which has been suggested to better predict the risk of coronary heart disease than LDL cholesterol concentration alone decreased significantly during the HO period compared with the FO period.

Recent animal data suggests that hemp oil can impact CVD through reductions in thrombosis (lowering of platelet aggregation or clotting)¹⁴⁵. Dr. Grant Pierce and his colleagues at the Canadian Centre for Agri-food Research in Health and Medicine, St Boniface Hospital Research Centre in Winnipeg have recently reported that the supplementation for 12 weeks, of either 5% or 10% (wt/wt) hempseed in the diets of male rats significantly inhibited platelet aggregation in comparison to a control chow or palm oil rich diet. Platelet aggregation was approximately 35% lower following the hempseed diets. The results were attributed to the specific fatty acid composition of the hempseed – in particular the high ALA levels. This data also suggests that the delivery of both omega-6 and omega-3 PUFAs together in the diet in foods induces different effects than when studied in isolation.

Further research by the same group has demonstrated that hempseed can significantly alter the levels of ALA in the heart and leads to beneficial cardioprotective effects in hearts subjected to ischemia-reperfusion challenge¹⁴⁶. In this study, a group of 40 male Sprague-Dawley rats were distributed evenly into four groups that were fed for 12 weeks; a normal rat chow supplemented with hempseed (5% and 10%), palm oil (1%), or a 10% partially delipidated hempseed that served as a control.

Plasma ALA and GLA levels were significantly elevated in the rats that were fed a 5% or 10% hempseed-supplemented diet. Only ALA levels were significantly elevated in the hearts of rats fed these diets compared with control. Hearts from hempseed fed rats exhibited significantly better post-ischemic recovery of maximal contractile function and enhanced rates of tension

¹⁴⁴ Schwab US, Callaway JC, Erkkilä AT, Gynther J, Uusitupa MI, Järvinen T. 2006. Effects of hempseed and flaxseed oils on the profile of serum lipids, serum total and lipoprotein lipid concentrations and haemostatic factors. *Eur J Nutr.* 45(8):470-7.

¹⁴⁵ Richard MN, Ganguly R, Steigerwald SN, Al-Khalifa A, Pierce GN. Dietary hempseed reduces platelet aggregation. 2007. *J Thromb Haemost.* 5: 424–5

¹⁴⁶ Al-Khalifa A, Maddaford TG, Chahine MN, et al. 2007. Effect of dietary hempseed intake on cardiac ischemia-reperfusion injury. *Am J Physiol Regul Integr Comp Physiol.* 292(3):R1198-203.

development and relaxation during reperfusion than hearts from the other groups. The investigators suggest that dietary hempseed appears to provide significant cardioprotective effects during post-ischemic reperfusion due to its highly enriched PUFA content.

2.7 Dietary Fatty acids and Inflammation

In recent years, medical research has moved toward almost a unifying theory – of chronic disease as a consequence of low-grade, chronic inflammation. Inflammation is a controlled, ordered process whereby the body responds to infection or injury. Symptoms of inflammation include redness, swelling, heat and pain. Chronic inflammation is linked with age-related diseases such as CVD, obesity, diabetes and cancer. Therefore, agents that exert anti-inflammatory actions are likely to be important in both prevention and therapy of a wide range of human diseases and conditions.

Omega 3 - Alpha Linolenic Acid

Studies have shown that ALA lowers C-reactive protein (CRP)—an inflammatory compound produced in the body¹⁴⁷. Lowering blood levels of CRP may be as important as reducing LDL or “bad” cholesterol for the prevention of heart attacks and strokes. Half of all heart attacks and strokes in Canada and the United States occur in people with normal cholesterol levels, and 20% of all events occur in people with no major risk factors (such as smoking and obesity).

ALA can reduce the inflammatory compound, CRP as much as 75% when compared to a ‘traditional Western style’ diet¹⁴⁸. The addition of a margarine rich in ALA (2.3% energy) to the diet for a period of two years significantly decreased CRP. These results and others suggest that dietary ALA intake is associated with lower levels of inflammation which may also explain the effect of ALA in preventing CVD.

Omega 6 - Gamma Linolenic Acid

GLA has been studied for many years for its efficacy in arthritis and other inflammatory disorders. In rheumatoid arthritis (RA) with active joint inflammation, tumour-like cells known as T lymphocytes invade the synovial joints of the bone leading to severe inflammation. Current treatments used in RA inhibit the cyclooxygenase pathway and therefore reduce the synthesis of the eicosanoids, PGE₂ and TXB₂. These treatments have no effect on levels of LTB₄ which is the most potent pro-inflammatory eicosanoid synthesized through an alternative pathway.

Joint tissue injury and inflammation in RA are also the result of the production of two cytokines from human monocytes - Interleukin-1B (Il-1β) and Tumor Necrosis Factor-α (TNF-α). Both are important polypeptide mediators of inflammation. Agents such as NSAIDs and corticosteroids that interfere with the actions of Il-1β and TNF-α are currently being used to treat RA; however, both may result in undesirable side effects. Administration of 2.4 g GLA/d to RA patients

¹⁴⁷ Lopez-Garcia, E, Schulze, MB, Manson, JE, et al. 2004. Consumption of n3 fatty acids is related to plasma biomarkers of inflammation and endothelial activation in women. *J. Nutr.* 134:1806; and American Heart Association. Inflammation, Heart Disease and Stroke: The Role of C-Reactive Protein. <http://www.americanheart.org/presenter>. Accessed October 26, 2007

¹⁴⁸ Zhao, G., Etherton, T.D., Martin, K.R., et al. 2004. Dietary alpha-linolenic acid reduces inflammatory and lipid cardiovascular risk factors in hypercholesterolemic men and women. *J. Nutr.* 134: 2991-2999

reduces gene expression of $\text{IL-1}\beta$ and $\text{TNF}\alpha$ ¹⁴⁹ apparently through generation of DGLA. DGLA also reduces $\text{IL-1}\beta$ production by peripheral blood mononuclear monocytes (PBMC) *in vitro*^{150, 151}.

Over a twelve week period, in healthy subjects ages 55-75 years, lymphocyte proliferation was significantly decreased (up to 65%) with the consumption of encapsulated 770 mg of GLA or 1 g of EPA plus DHA (720 mg of EPA + 280 mg of DHA). DHA alone (720 mg) had no effect¹⁵². Cell proliferation in inflamed synovial tissue is also reduced following GLA supplementation¹⁵³.

Several randomized, placebo-controlled clinical trials have demonstrated progressive improvement in patients with active RA treated with 1.4 to 2.8 g/day of GLA from borage oil or in free fatty acid form^{154, 155}. Statistically significant and clinically relevant reductions in swollen joint count and score, tender joint count and score, duration of morning stiffness and patient's global assessment of pain. Platelet counts which are elevated during inflammation were also reduced following the GLA supplementation. Joint tenderness was reduced by upwards of 40% after 6 months of treatment and 60% after 12 months of treatment. GLA significantly suppresses the production of PGE_2 , TXB_2 and LTB_4 . T lymphocyte activity and cell proliferation in inflamed synovial tissue is also reduced following GLA supplementation. GLA at doses used in these studies is a well-tolerated and effective treatment for active RA and could be considered an NSAID substitute for some patients.

The mechanism(s) responsible for the anti-inflammatory effects of GLA appear related to the ability of DGLA to suppress human synovial cell proliferation through increases PGE_1 levels, which in turn, increase cAMP levels that suppress tumor necrosis factor- α ¹⁵⁶. The significant suppression of the production of PGE_2 , TXB_2 , LTB_4 and activation of $\text{IL-1}\beta$ and T-lymphocytes reduces the propagation of joint tissue injury in patients with RA. EPA and AA display modest effects on proliferation and are substantially less active than GLA or DGLA.

¹⁴⁹Zurier, R.B., Rossetti, R.G., DeLuca, P., et al. 1998. Modification of human lymphocyte and monocyte function by gamma-linolenic acid (GLA), an unsaturated fatty acid. Studies in vitro and in vivo. Proc. Annual Meeting of the Amer. Oil Chemists' Soc. p. 24.

¹⁵⁰Rothman, D., Allen, H., Herzog, L., et al. 1997. Effects of unsaturated fatty acids on Interleukin-1 \square production by human monocytes. Cytokine. 9(12):1008.

¹⁵¹DeLuca, P., Rossetti, R.G., Alavian, C., et al. 1999. Effects of Gamma linolenic Acid on Interleukin-1B and Tumor Necrosis Factor- α Secretion by Stimulated Human Peripheral Blood Monocytes: Studies In Vitro and In Vivo. J Investig. Med. 47(5): 246 - 250.

¹⁵²Thies F, Nebe-von-Caron G, Powell JR, et al. 2001. Dietary supplementation with gamma-linolenic acid or fish oil decreases T lymphocyte proliferation in healthy older humans. J. Nutr. 131(7):1918-27.

¹⁵³Zurier, R.B., Rossetti, R.G., Seiler, C.M., Laposata, M. 1999. Human Peripheral Blood T-Lymphocyte Proliferation after activation of the T-cell Receptor: Effects of Unsaturated Fatty Acids. Prostaglandins, Leukotrienes and Essential Fatty Acids. 60 (5&6): 371 - 375.

¹⁵⁴Zurier, R.B., DeLuca, P. and Rothman, D. 1996. Gamma-linolenic acid, inflammation, immune responses and rheumatoid arthritis. In: Gamma-linolenic acid: Metabolism and its roles in nutrition and medicine. Huang, Y-S. and Mills, D.E., Eds., AOCS Press, Champaign, Ill. pp. 129-136 and

¹⁵⁵Mangge, H., Hermann, J. And Schauenstein, K. 1999. Diet and Rheumatoid Arthritis - A Review. Scand J Rheumatol. 28(4): 201 - 209.

¹⁵⁶Kast RE. 2001. Borage oil reduction of rheumatoid arthritis activity may be mediated by increased cAMP that suppresses tumor necrosis factor- α . Int Immunopharmacol. 12:2197-2199.

2.8 Diabetes

Omega 6 - Gamma Linolenic Acid

Diabetics require higher amounts of EFA because of impairments in both D6D and delta 5 desaturation. Insulin stimulates the activity of the D6D enzyme and therefore, this enzyme's activity is much reduced in diabetes. Reduced D6D activity affects the omega-6 products significantly more than the omega-3 products. Fatty acid abnormalities have been demonstrated in diabetics, particularly low DGLA and ARA in nerve membranes and red blood cell membranes. Low DGLA levels result in reduced levels of PGE1 which impairs circulation and also increases phospholipase A2 (PLA2) activity, resulting in the release of ARA from membranes and increasing membrane stiffness. Free AA forms vasoconstrictors, restricting circulation and, over time, a deterioration of motor and sensory nerves results.

Insulin dependent diabetes may have its origins in the womb. The availability of GLA and DGLA during foetal life, as indicated by the fatty acid composition of cord blood samples, appears related to childhood glycaemic control and the development of diabetes¹⁵⁷. In close to 300 children, relationships between cord (blood samples collected at birth) plasma fatty acid concentrations and insulin resistance were studied at seven years of age. Cord plasma phospholipid GLA and DGLA concentrations were negatively related to insulin concentrations and calculated insulin resistance, body fatness and proinsulin and leptin concentrations. Thus the foetal availability or metabolism of GLA could be involved in the early origins of insulin resistance.

Neuropathy is a condition where nerves degenerate and symptoms of pain and numbness follows and can lead to skin ulceration, amputation and impotence¹⁵⁸. Diabetic neuropathy develops over time as a result of abnormally high levels of blood glucose and consists of several clinical syndromes affecting motor, sensory and autonomic nerves¹⁵⁹. Neuronal conditions result from reduced nerve Na⁺, K⁺ ATPase activity, which may be caused by a lack of incorporation of n-6 fatty acids in membrane phospholipids. Because the Na⁺, K⁺ ATPase enzyme maintains the membrane electrical potential and allows repolarization, disturbances in activity can alter the process of nerve conduction velocity (NCV).

In a number of diabetic rat studies reviewed for this report¹⁶⁰, GLA supplementation prevented abnormal NCV, reversed the diabetes-induced decrease in NCV and improved Na⁺, K⁺ ATPase activity. These effects are associated with a normalization of n-6 fatty acids incorporated into phospholipid membranes. In addition, it has been hypothesized that through its conversion from DGLA, PGE1 can prevent and reverse deficits in nerve conduction velocity (NCV) and blood

¹⁵⁷ [Rump P](#), [Popp-Snijders C](#), [Heine RJ](#) and [Hornstra G](#). 2002. Components of the insulin resistance syndrome in seven-year-old children: relations with birth weight and the polyunsaturated fatty acid content of umbilical cord plasma phospholipids. *Diabetologia*. 45(3):349-55.

¹⁵⁸ Cameron, N.E. and Cotter, M.A. 1997. Metabolic and vascular factors in the pathogenesis of diabetic neuropathy. *Diabetes*. 46(2S):S90.

¹⁵⁹ Sima, A.A.F. and SugimotoJauy, K., 1999. Experimental diabetic neuropathy: an update. *Diabetologia*. 42(7): 773-788.

¹⁶⁰ Coste, T., Pierlovisi, M., Leonardi, J., et. Al. 1999. Beneficial effects of gamma linolenic acid supplementation on nerve conduction velocity, Na⁺, K⁺, ATPase activity, and membrane fatty acid composition in sciatic nerve of diabetic rats. *J. Nutr. Biochem.* 10: 411 - 420.

flow¹⁶¹. Following GLA treatment, although diabetes develops in alloxan induced diabetic animals, the severity is much less. GLA also restores the antioxidant status to normal range in various tissues and thus can attenuate the oxidant stress prevalent in diabetic tissues¹⁶².

In humans, GLA improves established diabetic neuropathy symptoms through an improvement in nerve flow¹⁶³. The results of a large scale trial involving 400 patients supplemented with 480 mg/day GLA increased phospholipid GLA and DGLA in cholesterol esters; plasma and red blood cells. GLA supplementation improved a number of parameters of neuropathophysiology and clinical measurements of thermal threshold. These improvements increased over time from 3 to 12 months. In contrast, in the placebo treated group, all parameters were negatively affected. After treatment was continued for a second year, further improvements were noted in the GLA treated patients. The mechanism responsible for the positive effects of GLA may be due to a restoration of normal sciatic nerve conduction velocity.

As the symptoms of diabetes and diabetic neuropathy are complex, treatment encompasses a range of options in which GLA is suggested as an important component¹⁶⁴.

2.9 Obesity

Omega 6 - Gamma Linolenic Acid and Weight control

Recent research with GLA may have potential significance for hempseed oil in applications focused on weight control and reduction. GLA supplementation appears to have promise in suppressing weight regain following major weight loss. In one of the first studies in the area of weight control, fifty formerly obese humans were randomized into a double-blind study and given either 890 mg/d of GLA (5 g/d borage oil) or 5 g/d olive oil (controls) for 1 year¹⁶⁵. Body weight and composition and adipose fatty acids of fasting subjects were assessed at 0, 3, 12, and 33 months. After 12 subjects in each group had completed 1 year of supplementation, weight regain differed significantly between the GLA (2.17 ± 1.78 kg) and control (8.78 ± 2.78 kg) groups. The initial study was terminated. Monitoring revealed weight regains of 1.8 ± 1.6 kg in the GLA group and 7.6 ± 2.1 kg in controls for the 13 and 17 subjects, respectively, who completed a minimum of 50 weeks in the study.

In a follow-up study, a subgroup from both the original GLA (GLA-GLA, n=9) and the original control (Control-GLA, n=14) populations either continued or crossed over to GLA supplementation for an additional 21 months. Interim weight regains between 15 and 33 months were 6.48 ± 1.79 kg and 6.04 ± 2.52 kg for the GLA-GLA and Control-GLA groups, respectively. In conclusion, GLA reduced weight regain in humans following major weight loss, suggesting a role for essential fatty acids in fuel partitioning in humans prone to obesity.

¹⁶¹ Head, R.J., McLennan, P.L., Raederstorff, D., et al., 2000. Prevention of nerve conduction deficit in diabetic rats by polyunsaturated fatty acids. *Am. J. Clin. Nutr.* 71(Suppl.):386S-392S.

¹⁶² Suresh Y. and Das UN. 2003. Long-chain polyunsaturated fatty acids and chemically induced diabetes mellitus: effect of omega-6 fatty acids. *Nutrition.* 19(2):93-114.

¹⁶³ Horrobin, D.F. 1997. Essential fatty acids in the management of impaired nerve function in diabetes. *Diabetes.* 46(2S):S90.

¹⁶⁴ Vinik AI. 1999. Diabetic neuropathy: pathogenesis and therapy. *Am J Med.* 30;107(2B):17S-26S.

¹⁶⁵ Schirmer, MA and Phinney, SD. 2007. Gamma-Linolenate Reduces Weight Regain in Formerly Obese Humans. *J. Nutr.* 137: 1430-1435.

The primary observation of this study is that GLA reduces weight regain in formerly obese humans. The .9-mo delay in onset for this effect in this group of subjects is consistent with the movement of GLA into adipose triglycerides. The precise mechanism by which GLA suppresses weight regain is not known. The researchers postulate that potential pathways which may be influenced include improved peripheral glucose disposal via enhanced insulin sensitivity, down-regulation of lipogenesis and up regulation of lipid oxidation.

What is equally interesting to its potential therapeutic value, the fact that GLA supplementation effectively suppressed weight regain in this human study is consistent with abnormal EFA metabolism being a common problem among severely obese humans. This study supports the need for further evaluation of abnormalities in EFA metabolism and obesity in humans. Hempseed oil with its unique fatty acid profile may have specific relevance in correcting EFA status in the obese and aid in eventual weight control.

2.10 The Importance of Dietary EFA Balance

Many countries and international organizations have made formal population-based dietary recommendations for omega 6 and omega 3 fatty acids. Recommendations have typically been between 0.8 to 1.1 g/day of ALA¹⁶⁶.

1. Canada was one of the first global jurisdictions to make specific recommendations for n-3 fatty acid intake as 1.1 – 1.6 g / day of total n-3 PUFA (ALA, EPA, and DHA)¹⁶⁷.
2. In 2002, the American Heart Association revised its recommendations for dietary intake of n-3 fatty acids as follows: 1) Individuals without documented coronary heart disease were advised to eat fish (preferably oily) twice per week plus oils and foods rich in ALA¹⁶⁸.
3. A joint Food and Agriculture Organization/World Health Organization (FAO/WHO) committee recommends an n-6/n-3 ratio of between 5:1 and 10:1 and advises individuals consuming diets with a higher ratio, to consume more foods containing omega 3 fatty acids such as green leafy vegetables, legumes and fish and other seafood⁴⁴. The Japanese Ministry of Health, Labor and Welfare has made a similar recommendation of a dietary ratio of n-6:n-3 PUFAs as 4:1¹⁶⁹.
4. The U.S. Institute of Medicine (IOM) published recommended essential fatty acids in September 2002 that were developed in cooperation with Health Canada and replace the Canadian Recommended Nutrient Intakes (RNIs). An Adequate Intake (AI) for ALA is provided as 1.6 g ALA per day for men and 1.1 g ALA per day for women¹⁷⁰.

Omega-6 and omega-3 EFAs work synergistically at the cellular level and an excess of either can cause an imbalance in metabolism. Currently, the average North American diet skews heavily toward omega 6 intakes. Although a 1:1 to 5:1 ratio of omega 6 to omega 3 in the diet is

¹⁶⁶ Health and Welfare Canada. Nutrition Recommendations: The Report of the Scientific Review Committee. 1990. Cat.No.H49-42/1990E. Ottawa, Ontario.

¹⁶⁷ Ibid.

¹⁶⁸ Kris-Etherton PM, Harris WS, Appel LJ for the Nutrition Committee. 2002. Fish consumption, fish oil, omega-3 fatty acids, and cardiovascular disease. *Circ.* 106:2747-2757.

¹⁶⁹ Ministry of Health Labor and Welfare, Japan. Nutrition Requirements for Japanese. 6th Edition, 1999.

¹⁷⁰ Institute of Medicine. 2002. Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids. Washington, D.C.: The National Academies Press, pp. 8-1 – 8-97.

generally considered to be optimum⁴⁶, most literature cites actual dietary ratios of 10:1 or even 20:1⁴⁸. Hempseed oil with its 3:1 ratio is the closest naturally-occurring oil to this ideal range.

Nutritionists generally recommend that, for EFAs to provide optimal cell function, daily requirements should range from 7 to 11 g of LA and from 2 to 3.5 g of ALA. This can be obtained from one to two tablespoons of hempseed oil. However, individuals who consume a diet high in SFAs or *trans* fatty acids will require more, as will people who are overweight or under a great deal of stress.

3.0 ANTIOXIDANTS

Hempseed oil contains tocopherols (natural Vitamin E) at higher levels than other oils containing GLA, such as borage, blackcurrant and evening primrose (Table 5)¹⁷¹. Vitamin E is a fat-soluble vitamin that exists in eight different forms. Each form has its own biological activity, which is the measure of potency or functional use in the body. Alpha-tocopherol (α -tocopherol) is the name of the most active form of vitamin E in humans. It is also a powerful biological antioxidant¹⁷². The composition of tocopherols in hemp oil is similar to soybean oil where the gamma isomer is dominant with smaller levels of the alpha form. Gamma tocopherol has the strongest antioxidant capacity in food systems such as oils.

Table 5: Tocopherol Content in Hempseed and other Oils

Tocopherols (%)	Hemp	Borage	Black-Current	Evening Primrose	Soybean	Canola
Alpha	10	10	10	40	10	30
Beta	1	-	2	-	5	6
Gamma	85	20	80	55	65	60
Delta	4	70	8	5	20	4
Total Tocopherols(ppm)	600-1200	500-800	400-800	200-600	1200-2200	500-1200

Antioxidants such as tocopherols help reduce the damage to body cells caused by the constant assault of free radicals (reactive oxygen species or ROS) such as generated through UV radiation. Free radicals are produced as a result of normal metabolic processes in living systems. Pollution, second hand smoke, many dietary constituents and aging contribute to the production of free radicals often exceeding the protective antioxidant capacity of our bodies leading to oxidative stress. Antioxidants “neutralize” free radicals and offer protection against oxidative damage¹⁷³.

Preliminary research has led to a widely held belief that vitamin E may help prevent or delay coronary heart disease. Oxidative modification of LDL-cholesterol promotes blockages in coronary arteries that may lead to [atherosclerosis](#) and [heart attacks](#)¹⁷⁴. Vitamin E may help prevent or delay coronary heart disease by limiting the [oxidation of LDL-cholesterol](#). Vitamin E also may help prevent the formation of blood clots, which could lead to a heart attack. Observational studies have associated lower rates of heart disease with higher vitamin E intake. A study of approximately 90,000 nurses suggested that the incidence of heart disease was 30% to 40% lower among nurses with the highest intake of vitamin E from diet and supplements. The range of intakes from both diet and supplements in this group was 21.6 to 1,000 IU (32 to 1,500 mg), with the median intake being 208 IU (139 mg)¹⁷⁵. A 1994 review of 5,133 Finnish men and

¹⁷¹ R. Przybylski. 2005. Hemp as Source of Nutraceutical Oil. Abstract LOQ 3/SOA 3.1. 96th AOCS Annual Meeting. Salt Lake City, Utah.

¹⁷² Traber MG and Packer L. Vitamin E: Beyond antioxidant function. Am J Clin Nutr 1995;62:1501S-9S.

¹⁷³ Balentine, D.A., Albano, M.C. and Nair, M.G. 1999. Role of medicinal plants, herbs, and spices in protecting human health. Nutrition Rev. 57 (9 Pt. 2):S41 – S45.

¹⁷⁴ Jialal I and Fuller CJ. Effect of vitamin E, vitamin C and beta-carotene on LDL oxidation and atherosclerosis. Can J Cardiol 1995;11 Suppl G:97G-103G.

¹⁷⁵ Stampfer MJ, Hennekens CH, Manson JE, Colditz GA, Rosner B, Willett WC. Vitamin E consumption and the risk of coronary disease in women. N Engl J Med 1993;328:1444-9.

women aged 30 - 69 years suggested that increased dietary intake of vitamin E was associated with decreased mortality (death) from heart disease¹⁷⁶.

[Antioxidants](#) such as vitamin E help protect against the damaging effects of free radicals, which may contribute to the development of cancer. Vitamin E also may block the formation of [nitrosamines](#), which are [carcinogens](#) formed in the stomach from [nitrites](#) consumed in the diet. It also may protect against the development of cancers by enhancing immune function¹⁷⁷.

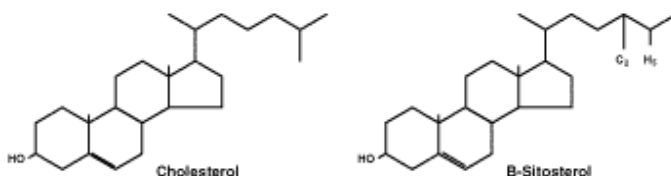
Results of two national surveys, the National Health and Nutrition Examination Survey (NHANES III 1988-94)¹⁷⁸ and the Continuing Survey of Food Intakes by Individuals (1994-96 CSFII)¹⁷⁹ indicated that diets of most Americans do not provide the recommended intake for vitamin E. Caution was noted that low fat diets can result in a significant decrease in vitamin E intake if food choices are not carefully made to enhance α -tocopherol intakes.

4.0 PHYTOSTEROLS

Phytosterols, also known as plant sterols, are a naturally occurring class of compounds found in the cells and membranes of plants. These plant lipid-like compounds are present at low levels in grains, fruits and vegetables. There are approximately 250 different sterols and related compounds in plant and marine materials with the most common ones beta-sitosterol, stigmasterol, and campesterol.

A large body of scientific research dating back to the 1950s has documented the ability of phytosterols to block the absorption of cholesterol and reduce blood cholesterol levels.

Phytosterols have a similar molecular structure to dietary and endogenously secreted cholesterol. The most abundant phytosterols (sitosterol, campesterol, and stigmasterol) differ from cholesterol only in the identity of one side chain or the presence of an extra double bond.



Because cholesterol and phytosterol molecules are similar, phytosterols can compete with cholesterol for absorption in the small intestine. Phytosterols block the absorption of dietary

¹⁷⁶ Knekt P, Reunanen A, Jarvinen R, Seppanen R, Heliovaara M, Aromaa A. Antioxidant vitamin intake and coronary mortality in a longitudinal population study. *Am J Epidemiol* 1994;139:1180-9.

¹⁷⁷ Waters DD, Alderman EL, Hsia J, Howard BV, Cobb FR, Rogers WJ, Ouyang P, Thompson P, Tardif JC, Higginson L, Bittner V, Steffes M, Gordon DJ, Proschan M, Younes N, Verter JI. Effects of hormone replacement therapy and antioxidant vitamin supplements on coronary atherosclerosis in postmenopausal women: a randomized controlled trial. *J Am Med Assoc* 2002;288:2432-40.

¹⁷⁸ Bialostosky K et al. Dietary intake of macronutrients, micronutrients and other dietary constituents: United States 1988-94. National Center for Health Statistics. *Vital Health Stat* 11(245). 2002.

¹⁷⁹ Interagency Board for Nutrition Monitoring and Related Research. Third Report on Nutrition Monitoring in the United States. Washington, DC: U.S. Government Printing Office, 1995.

cholesterol into the bloodstream and inhibit the re-absorption of cholesterol from bile acids in the digestive process, thus reducing the amount of cholesterol entering the bloodstream.

Phytosterols have cholesterol-lowering properties in human subjects by up to 15%. Nutritional studies have reported hypo-cholesterolemic efficacy of phytosterols at levels of 1.5-3.0 g/d administered as a capsule, in a suspension, or as a mixture with margarines or other oils¹⁸⁰.

Phytosterols and phytostanols were approved as GRAS by FDA for the USA market in May 1999. In September, 2000, the FDA issued an interim final rule on plant stanol/sterol esters, allowing labelling on food to state that they have been proven to lower cholesterol and may lower the risk of heart disease when part of a diet low in saturated fat and cholesterol. Scientific studies conducted proved to the FDA that 1.3 grams per day of plant sterol esters or 3.4 g per day of plant stanol esters in the diet are needed to show a significant cholesterol lowering effect. In order to qualify for this health claim, a food must contain at least 0.65 g of plant sterol esters per serving or at least 1.7 g of plant stanol esters per serving.

In addition to receiving approval by the FDA, phytosterol products have been endorsed by a coalition of major health organizations in the US. In 2001, the NCEP (National Cholesterol Education Program), a multidisciplinary coalition of over 40 major medical and health organizations (including the American Medical Association), voluntary health organizations, community programs, and government agencies (including the National Heart, Lung and Blood Institute at the National Institute of Health) published a major report (the Adult Treatment Panel III, ATP III), that recommended the use of phytosterols for the treatment of elevated cholesterol with phytosterols¹⁸¹. The guidelines recommend plant sterols and stanols as “therapeutic dietary options to enhance lowering of LDL (low density lipoprotein) cholesterol”; 2 grams of phytosterols or phytostanols per day, along with 10-25 grams of soluble fiber, was recommended for significant cholesterol reduction.

The American Heart Association has published a “statement” on phytosterols that acknowledged their cholesterol-lowering efficacy, but the conclusion fell short of a recommendation, “Thus although foods containing plant sterols are a promising addition to dietary interventions aimed at improving cardiac risk profiles, more information is required before their routine ingestion is recommended in the general population as a step toward dietary prevention of coronary heart disease”¹⁸².

The levels of sterols in hempseed oil are high in comparison to other oils (Table 6)¹⁸³.

¹⁸⁰ Onge, M and Jones, P. 2003. Phytosterols and human lipid metabolism: efficacy, safety, and novel foods. *Lipids*. 38(4):367-75.

¹⁸¹ JI Cleeman. 2001. Executive summary of the third report of the National Cholesterol Education Program (NCEP) Expert panel on detection, evaluation, and treatment of high blood cholesterol in adults (Adult Treatment Plan III). *J Am Med Assoc* 285:2486-2497.

¹⁸² AH Lichtenstein, RJ Deckelbaum. 2001. Stanol/Sterol Ester-containing foods and blood cholesterol levels - A statement for healthcare professionals from the Nutrition Committee of the Council on Nutrition, Physical Activity, and Metabolism of the American Heart Association, *Circulation* 103:1177-1179

¹⁸³ R. Przybylski. 2005. Hemp as Source of Nutraceutical Oil. Abstract LOQ 3/SOA 3.1. 96th AOCS Annual Meeting. Salt Lake City, Utah.

Table 6: Phytosterol Content in Hempseed and other Oils

Phytosterols (%)	Hemp	Borage	Black-Current	Evening Primrose	Soybean	Canola
Brassicasterol	-	-	-	-	-	10
Sitosterol	55	50	75	90	56	50
Campesterol	15	40	8	8	18	30
Stigmasterol	15	-	10	-	16	1
Total Sterols (ppm)	800-1200	600-800	500-900	600-800	600-1400	800-2600

In early clinical studies, the plant sterol, β -sitosterol and its derivatives such as sitostanol or acylated derivatives, all of which are natural components of vegetable oils and fats, were proved to lower by 10-15% total as well as LDL-cholesterol levels in patients¹⁸⁴. Subsequent research confirmed these initial results and showed that both plant sterol and stanol esters can effectively lower cholesterol levels in humans¹⁸⁵. Phytosterols act to lower cholesterol by competing for absorption in the gastrointestinal tract decreasing the overall amount of cholesterol absorbed.

¹⁸⁴ Lees, A.M., Mok, H.Y., Lees, R.S., McCluskey, M.A. and Grundy, S.M. 1977. Plant sterols as cholesterol-lowering agents: Clinical trials in patients with hypercholesterolemia and studies of sterol balance. *Atherosclerosis*. 28:325-338.

¹⁸⁵ Miettinen, T.A., Puska, P., Gylling, H., Vanhannen, H., and Vartiainen, E. 1995. Reduction of serum cholesterol with sitostanol-ester margarine in a mildly hypercholesterolemic population. *N. Engl. J. Med.* 333: 1308-1312 and Hallikainen, M.A. and Uusitupa, M.I.J. 1999. Effects of 2 low-fat stanol ester-containing margarines on serum cholesterol concentrations as part of a low-fat diet in hypercholesterolemic subjects. *Amer. J. Clin. Nutr.* 69:403-410.

5.0 PROTEIN

Proteins are large [organic compounds](#) made of [amino acids](#) arranged in a linear chain and joined by [peptide bonds](#) between the [carboxyl](#) and [amino](#) groups of adjacent amino acid [residues](#). In the body, proteins serve such functions as acting as enzymes, antibodies, and the structural components of tissues, hormones, and blood protein.

Protein is necessary in [the](#) diet, since [essential amino acids](#) can not be synthesized in the body and must be obtained from food. Through the process of [digestion](#), animals break down ingested protein into free amino acids that are then used in [metabolism](#).

An essential amino acid or indispensable amino acid is an [amino acid](#) that cannot be synthesized [de novo](#) by the organism (usually referring to humans), and therefore must be supplied in the diet. Nine amino acids are generally regarded as essential for humans: [isoleucine](#), [leucine](#), [lysine](#), [threonine](#), [tryptophan](#), [methionine](#), [histidine](#), [valine](#) and [phenylalanine](#).

The following table lists the recommended daily amounts for essential amino acids in humans, together with their standard one-letter abbreviations¹⁸⁶. In some cases, humans can use either of two amino acids, so only the total matters. Hemp protein is of exceptional high quality in terms of amino acid composition and protein structure. A comparison of hemp protein to other common dietary sources is given in Table 7 and clearly shows the high levels of protein available in hemp. Only soybeans are higher in total protein, but absorption of this protein is more limited than in hemp.

Table 7: Comparison of Hemp and other Protein sources

Soybeans	35.0%
Hemp seed shelled	31.0%
Hamburger beef	27.1%
Blue fish	26.0%
Cheddar cheese	23.5%
Chicken	23.5%
Hempseed -- whole	23.0%
Almonds	18.3%
Wheat flour	13.3%
Egg	12.0%

Hemp protein contains all 21 amino acids, including the 8 essential amino acids in a ratio that resembles “complete” protein sources such as meat, milk, and eggs. The typical amino acid

¹⁸⁶ FAO/WHO/UNO (United Nations Organization). Energy and protein requirements. WHO Tech. Rep. ser. no. 724, 1985

profile of hemp is shown in Table 8. On the basis of the amino acid composition of hemp seed and hemp protein products, lysine is the first limiting amino acid in all hemp protein sources, and the amino acid scores for hemp seed, hemp nuts, hemp protein flour and hemp hulls are 0.62, 0.61, 0.58, and 0.50, respectively. Depending on the source, leucine or tryptophan will be the second or third limiting amino acid. All other amino acids yield scores greater than 1.0¹⁸⁷.

Hemp protein is a quality source of the amino acids arginine and histidine, both important for growth during childhood. Hemp protein is also a good source of sulphur containing amino acids methionine and cysteine which are required for the production of vital enzymes and for the repair and growth of lean body tissue. Relatively high levels of the branched chain amino acids leucine, isoleucine and valine which are deemed crucial in the repair and growth of lean body mass are also present.

Table 8: Hempseed Protein - Typical Amino Acid Profile (g/100g)

Aspartic Acid	4.36
Glutamic Acid	7.10
Serine	2.14
Glycine	1.34
Histidine	1.24
Arginine	6.15
Threonine*	1.65
Alanine	1.39
Proline	1.53
Tyrosine	1.00
Valine*	1.64
Methionine*	0.79
Cysteine	0.60
Isoleucine*	1.22
Leucine*	2.02
Phenylalanine*	1.29
Lysine*	0.96
Tryptophan*	0.38

* *Essential Amino Acids*

Proteins are often classified as structural (fibrous) or biologically active (globular). Structural proteins include collagen, keratin, and fibrinogen, which are the main constituents of bones, skin, hair and ligaments. Biologically active proteins are mainly globulins and include hormones, hemoglobin, antibodies (immunoglobulins), and enzymes. It is much more efficient for the body to make globulins out of globular starting material¹⁸⁸. Globular proteins are precursors to many vital compounds in the body:

- hormones (which regulate all the body processes);
- hemoglobin (which transports oxygen, carbon dioxide, and nitric oxide);
- enzymes (which catalyze and control biochemical reactions);

¹⁸⁷ House, J. 2007. Characterization of Hemp Seeds, Hulled Seeds and Protein Flour for Macronutrients, Protein Composition and Digestibility. Report completed for the CHTA.

¹⁸⁸ <http://www.innvista.com/health/foods/hemp/seedprot.htm>

- antibodies (immunoglobulins which protect against bacteria, viruses, and other pathogens)

The total protein content of hemp seed is about 65% of the globular protein edestin, which closely resembles the globulin found in human blood plasma. It is easily digested, absorbed, and utilized by humans and vital to maintaining a healthy immune system. Edestin has the unique ability to stimulate the manufacture of antibodies against invasive agents and is nearly phosphorus-free, which is important for kidney ailments. The other important protein (35%) in hemp seed is albumin, which is also a highly digestible protein because of its globular shape. Albumin is a major free radical scavenger and is similar to the high quality protein found in egg whites.

5.1 Hemp Protein – Nutritional properties

Research by Dr. Jim House of the Department of Human Nutritional Sciences, University of Manitoba¹⁸⁹, has investigated the protein digestibility of hemp products using the Protein Digestibility Corrected Amino Acid Score (PDCAAS), a method of evaluating the protein quality based on the [amino acid](#) requirements of humans. The PDCAAS allows evaluation of food protein quality for humans as it measures the quality of a protein based on the amino acid requirements (adjusted for digestibility) of a 2- to 5-year old child (considered the most nutritionally-demanding age group). Using the PCDAAS method, the protein quality rankings are determined by comparing the amino acid profile of the specific food protein against a standard [amino acid](#) profile with the highest possible score being a 1.0. This score means that after [digestion](#) of the [protein](#), it provides per unit of protein, 100% or more of the indispensable amino acids required¹⁹⁰.

Rats were fed hempseed, hemp nut, hemp protein and hemp hulls. The results shown in Figure 4 identify the primary limiting amino acid in hempseed as lysine, followed by leucine and tryptophan. All plant proteins have limiting essential amino acids and the key to using them in a vegan diet is to complement protein sources so as to achieve a complete balance.

¹⁸⁹ House, J. 2007. Characterization of Hemp Seeds, Hulled Seeds and Protein Flour for Macronutrients, Protein Composition and Digestibility. Report completed for the CHTA.

¹⁹⁰ [Srikantia, S. G. 1981. The Use Of Biological Value Of A Protein In Evaluating Its Quality For Human Requirements. *Joint FAO/WHO/UNU Expert Consultation on Energy and Protein Requirements EPR 81 291*](#)

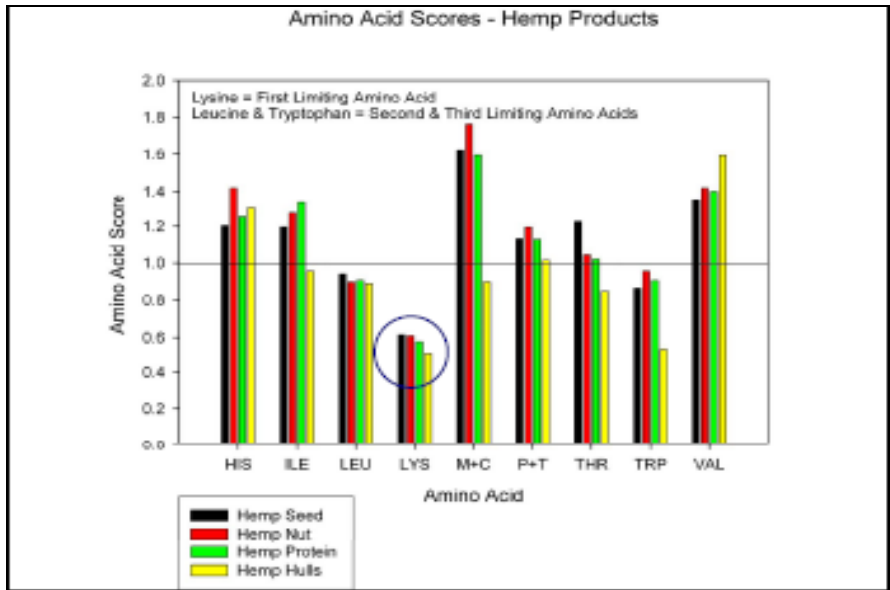


Figure 4: Amino acid scores for Hemp Products

Dr. House further identified a high PDCAAS of over 0.6 for hemp nuts with hempseeds, hemp protein flour having values equivalent or slightly higher than other nuts (see Figure 5).

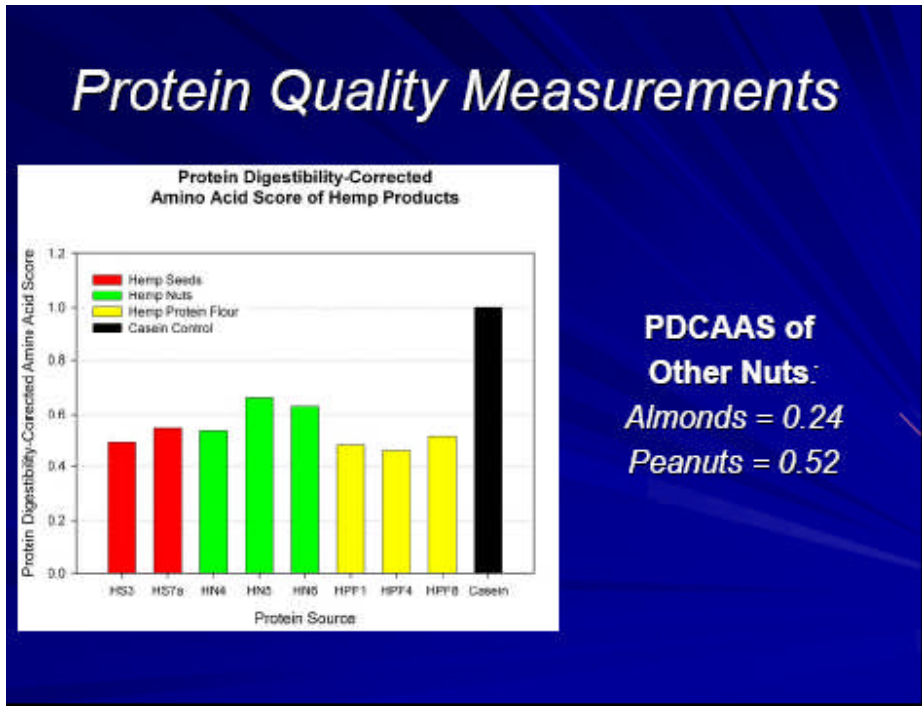


Figure 5: PDCAAS for Hemp Products in comparison to Casein

Data for hemp products is summarized in the following Table as compared to standard case in

protein.

Table 9. Protein digestibility-corrected amino acid score - hemp protein products

	Protein Digestibility %	Amino Acid Score¹	PDCAAS²	Net Protein Efficiency Ratio³
Casein	97.6	1.19	1.00	1.00
Hemp Seed	85.2	0.60	0.51	0.65
Hemp Nuts	94.9	0.64	0.61	0.75
Hemp Protein Flour	86.7	0.56	0.48	0.66

Notes:

¹ Lysine the first limiting amino acid, using the FAO/WHO amino acid requirement pattern for school children

² Protein digestibility-corrected amino acid score, calculated as the product of protein digestibility and the amino acid score

³ Surrogate measure – Determined as the ratio of feed conversion efficiency (FCE) in rats consuming test article divided by FCE of rats consuming casein

Both protein digestibility and Net PER (Protein Efficiency Ratio) are relatively high for hemp nuts and protein flour.

Hempseed is a relatively rich source of the non-essential amino acid arginine as shown in Figure 6. Arginine is important physiologically as the immediate precursor of nitric oxide which relaxes blood vessels. In this respect, arginine is used in many conditions where [vasodilation](#) is required. Research in fact is underway at Agriculture and Agri-food Canada to development bioactive peptides enriched with arginine for blood pressing lowering¹⁹¹. Through its conversion to nitric oxide, arginine also lowers the levels of homocysteine a protein that is associated with heart disease and stroke. Nitric oxide reacts with homocysteine to form the non-toxic compound S-nitroso- homocysteine. Thus there may be potential applications for hempseed amino acids in specialty supplements geared toward blood pressure lowering and CVD.

¹⁹¹ Dr. Alister Muir, 2007. Personal communication.

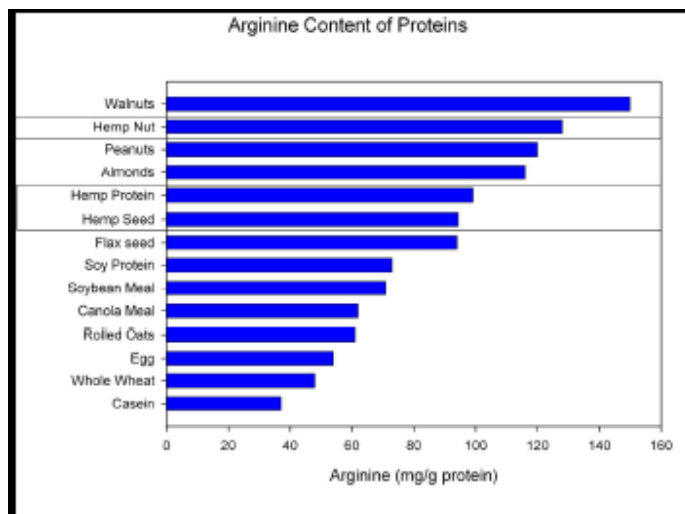


Figure 6: Arginine Content of various protein sources

House concluded that hempseed and protein products contain a balance of the essential amino acids similar to those of other plant and nut protein sources. The limitation in lysine content should be considered for protein complementation. Additionally, and most importantly, hemp protein is highly digestible, with >90% digestibility for hemp nuts. Hemp protein is also a valuable source of other non-essential amino acids including arginine.

Removal of the hull fraction from the hull improves the digestibility of the protein and the corresponding PDCAAS, due to the removal of significant fibre components which limit protein digestion. Improvements in the protein quality of hemp will be geared to the lysine content of hemp proteins, as this amino acid is the limiting amino acid in current protein quality evaluation techniques. The potential exists to include lysine content in future hemp breeding programs in order to enhance the content of this amino acid in hemp proteins.

5.2 Gluten Free Proteins in Hemp

Gluten is a general name given to the storage proteins (prolamins) present in wheat, rye, barley, and oats. Celiac disease occurs when consuming gluten proteins triggers an autoimmune response that damages the lining of the small intestine, which can reduce nutrient absorption and contribute to other ailments of the body and immune system. There is no known cure for celiac disease, but it can be successfully managed with a lifelong commitment to a gluten free diet. All foods containing wheat, rye, barley, and most commercial oats must be eliminated from the diet, as well as many lesser known grains such as bulgur and triticale.

According to WHO/FAO guidelines, a gluten-free food may contain no more than 200 ppm prolamins on a dry weight basis. Foods labeled as gluten-free in Canada and the U.S. does not allow the presence of any gluten-containing ingredients, such as wheat starch.

Celiac disease is far more prevalent than previously estimated, mainly because it remains misdiagnosed in many cases. Celiac is a multi-system, multi-symptom disease, and that makes it difficult to diagnose. Approximately one in 133 people or more than 2.5 million people in the

U.S. are believed to suffer from celiac disease¹⁹². Estimates as to how many people remain undiagnosed run as high as 97 per cent and thus the demand for gluten-free products is in its infancy, and is growing exponentially.

According to the CHTA, analysis has confirmed that hempseed and protein contain no detectable gluten proteins at a detection level of 10 ppm. The maximum level for a product to declare gluten-free is <15 ppm. Both hempseed and proteins are currently used in gluten-free foods and this market offers significant opportunities for food companies for the industry.

5.3 Hemp Protein Powders

Hempseed protein (powder) is produced by cold pressing whole hemp seeds to expel a large percentage of the oil, resulting in a dry cake. The cake is then milled at low temperatures to remove a portion of the fibre and produce a concentrated form of protein. The resulting protein powder contains on average 50% protein. Typically, a standard 30g serving of hemp protein powder supplies about 15g of protein.

There are differences between hemp protein and its major competitor, soy protein. Hemp protein does not contain the trypsin inhibiting factors that reduce the nutritional absorption of soy protein. Unlike hemp protein powder, many soy isolate powders that are not labeled organic are often processed with hexane, a petroleum solvent. The resulting hexane-processed soy is utilized in many soy protein powders, cereals, and bars. Hemp protein powder is produced using only cold-pressed techniques and does not involve the use of hexane in the production process. In addition, non-organic soybeans used in many soy products are often derived from genetically modified soybeans. Hemp is never genetically modified.

6.0 CARBOHYDRATE

The most significant component of hemp carbohydrate is fibre (both water soluble and insoluble) which has positive attributes for food functionality as well as for human and animal nutrition. Soluble fibre in the form of gums has numerous food applications, including thickening, gelling, stabilization, mouth feel, suspending and emulsification. As consumers learn about the need for soluble dietary fibre, gums are also being added to boost the fibre content of finished foods. Gums are of increasing interest when formulating foods with lower carbohydrate and trans fatty acid levels, in these types of formulations gums can contribute to texture when the carbohydrates and/or fats are reduced.

The following sections will describe the nutritional aspects of fibre in detail.

6.1 Dietary Fibre

Fibre as a functional ingredient will never fall out of favour. Consumers are increasingly aware of fibre's health benefits, which have expanded in recent years from gut, digestive health and heart health to energy sustenance, weight management, diabetes, and skin and bone health (via improved calcium absorption).

¹⁹² Prevalence of Celiac Disease. 2007. <http://www.celiac.com/>

Dietary fibre is defined as “endogenous components of plant material in the diet which are resistant to digestion by enzymes produced by man. They are predominantly non-starch polysaccharides and lignin and may include associated substances.”

Total fibre accounts for 13-19% of the weight of full-fat hemp depending upon variety. Hemp flour is lower and hulls are higher, approximately 3.5 % and 15%, respectively, in total fibre. The American Dietetic Association has cited the “significant impact” that fibre can have on the prevention of obesity, cardiovascular disease and type 2 diabetes¹⁹³.

Based on water solubility, dietary fibre is classified as either soluble (pectins, gums, mucilage, and some hemicelluloses), or insoluble (celluloses, some hemicelluloses, and lignin)¹⁹⁴. Hemp contains both water soluble and insoluble forms of fibre. The primary action of fibre in the body is in the gastrointestinal tract, but not all fibre sources have the same physiological effects.

Generally, concentrates of water-soluble fibres delay transit through the stomach and small intestine¹⁹⁵. Soluble fibre in hemp is found primarily as beta-glucan and mucilage. These fibres are rapidly broken down (fermented) by bacteria in the large intestine and do not promote laxation. Fibres that are predominantly water insoluble promote laxation and are either slowly or not fermented¹⁹⁶.

Insoluble dietary fibre plays an important role in the relief of constipation, a common problem among many individuals who consume low fibre diets, are inactive, or are using certain medications for other conditions that may promote constipation as a side effect. Diets high in insoluble fibre result in good colon health, which may have protective effects against colon cancer.

Daily recommended intakes target amounts of 25 grams for women and 38 grams for men¹⁹⁷. However, intake continues to be at less-than-recommended in the US population, with usual intakes averaging only 14 to 15 g/day¹⁹⁸. Most popular North American foods are not high in dietary fibre - servings of commonly consumed grains, fruits, and vegetables contain only 1 to 3 grams of dietary fibre.

¹⁹³ ADA Reports. 2002. Position of the American Dietetic Association: Health implications of dietary fiber. J Am Diet Assoc; 102(7): 993-1000.

¹⁹⁴ Brown, L., Rosner, B., Willett, W.W., Sacks, F.M. 1999. Cholesterol-lowering effects of dietary fiber: a meta-analysis. Am J Clin Nutr; 69(1): 30-42.

¹⁹⁵ Wolever TMS, Jenkins DJA. 1993. Effect of dietary fiber and foods on carbohydrate metabolism. In: Spiller GA, ed. CRC Handbook of Dietary Fiber in Human Nutrition. 2nd ed. Boca Raton, FL: CRC Press; 111-152.

¹⁹⁶ Physiological Effects and Health Consequences of Dietary Fiber. Bethesda, MD: Life Sciences Research Office, Federation of American Societies for Experimental Biology. 1987.

¹⁹⁷ Institute of Medicine. 2002. Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids. Washington, D.C.: The National Academies Press, pp. 8-1 – 8-97.

¹⁹⁸ Alaimo K, McDowell MA, Briefel RR, et al. *Dietary Intake of Vitamins, Minerals and Fiber of Persons Ages 2 Months and Over in the United States: Third National Health and Nutrition Examination Survey, Phase 1, 1988-91*. Hyattsville, Md: National Center for Health Statistics; 1994. Advance data from vital and health statistics: No 258.

Extensive research has been performed on the physiological effects of dietary fibre and risk of numerous chronic diseases – most notably cardiovascular disease (CVD), certain cancers, and diabetes.

Fibre and Cardiovascular Disease

High intake of dietary fibre has been linked to a lower risk of heart disease in a number of large long term studies.¹⁹⁹ In Harvard research involving over 40,000 male health professionals, a high total dietary fibre intake was linked to a 40 percent lower risk of coronary heart disease, compared to a low fibre intake.²⁰⁰ A related Harvard study of female nurses produced quite similar findings.²⁰¹

Fibre intake has also been linked with the metabolic syndrome, a series of factors that increases the chances of developing heart disease and diabetes, including high blood pressure, high insulin levels, excess weight (especially around the abdomen), high levels of triglycerides, and low levels of HDL cholesterol. Several studies suggest that higher intake of fibre may help to reduce this increasingly common syndrome.²⁰²

Dietary fibre, particularly soluble fibre, decreases blood cholesterol concentrations thereby favourably influencing risk of coronary artery disease²⁰³. Increasing soluble fibre intake by 6 g/day, with no other dietary changes, has been shown to decrease LDL-cholesterol by 10-20%²⁰⁴. Additional research has shown that daily intake of 3 g soluble fibre can reduce total cholesterol by approximately 2%, ultimately lowering incidence of coronary artery disease by an estimated 4%²⁰⁵.

Fibre and type 2 diabetes

Diets low in fibre and rich in high glycemic index foods (which cause large spikes in blood sugar) are significant risk factors in the development of diabetes. In the studies on nurses and of male health professionals referenced earlier diets with these characteristics more than doubled the risk of type 2 diabetes when compared to a diet high in fibre and low in high glycemic index foods.¹¹⁻¹⁴

¹⁹⁹ Pereira MA, O'Reilly E, Augustsson K, et al. 2004. Dietary fiber and risk of coronary heart disease: a pooled analysis of cohort studies. [Arch Intern Med](#) 164:370-6.

²⁰⁰ Rimm EB, Ascherio A, Giovannucci E, Spiegelman D, Stampfer MJ, Willett WC. 1996. Vegetable, fruit, and cereal fiber intake and risk of coronary heart disease among men. [JAMA](#) 275:447-51.

²⁰¹ Brown L, Rosner B, Willett WW, Sacks FM. 1999. Cholesterol-lowering effects of dietary fiber: a meta-analysis. [Am J Clin Nutr](#) 69:30-42.

²⁰² McKeown NM, Meigs JB, Liu S, Saltzman E, Wilson PW, Jacques PF. 2004. Carbohydrate nutrition, insulin resistance, and the prevalence of the metabolic syndrome in the Framingham Offspring Cohort. [Diabetes Care](#) 27:538-46.

²⁰³ ADA Reports. 2002. Position of the American Dietetic Association: Health implications of dietary fiber. [J Am Diet Assoc](#); 102(7): 993-1000.

²⁰⁴ Brown, L., Rosner, B., Willett, W.W., Sacks, F.M. 1999. Cholesterol-lowering effects of dietary fiber: a meta-analysis. [Am J Clin Nutr](#); 69(1): 30-42.

²⁰⁵ As reviewed in: ADA Reports. 2002. Position of the American Dietetic Association: Health implications of dietary fiber. [J Am Diet Assoc](#); 102(7): 993-1000.

6.2 Fibre, Diabetes and the Glycemic Index (GI)

The nutritional value of carbohydrates has become a major issue within the food industry. With the recent marketing buzz around 'low carb', consumers are no longer considering carbohydrates just as a source of calories but are now actively selecting specific types of carbohydrates for exclusion or inclusion in their diets.

Upon digestion, carbohydrates produce glucose, which is rapidly absorbed and utilized within the body. Blood sugar (glucose) levels impact the risk of developing diabetes or cardiovascular disease, weight gain, energy levels, as well as mood and concentration. Glycemic response, or glycemic impact, is an indication of how rapidly carbohydrates are digested. The rate and peak of the increase in blood glucose from a particular food is measured by comparing it to the glycemic response of another food (typically, pure glucose). High-glycemic carbohydrates produce a fast and high increase in blood glucose level (similar to that of glucose), while low-glycemic carbohydrates produce a smaller increase relative to glucose. Higher glycemic index foods produce larger fluctuations in blood glucose, and thus may confer a greater risk to individuals for developing diabetes and other co-morbidities.

Low-glycemic products target the over 20 million diabetics in the United States, in addition to consumers concerned about boosting their energy level and losing weight.

Glycemic Index was first defined by David Jenkins and his colleagues at the University of Toronto in 1981 (Jenkins et al., 1981), as the area under the curve for the increase in blood glucose after the ingestion of 50 g of "available" or "glycemic" carbohydrate in a food during the 2-hr postprandial period, relative to the same amount of carbohydrate from a reference food (white bread or glucose) tested in the same individual under the same conditions and using the initial blood glucose concentration as a baseline.

The average GI value is calculated from data collected in 10 human subjects. Both the standard and the test material must contain an equal amount of carbohydrate. The area of the test food divided by the area of the standard expressed as a percentage is the GI value for that food. The glycemic index separates carbohydrate-containing foods into three general categories: (1) High Glycemic Index Foods (GI 70+), which cause a rapid rise in blood-glucose levels; (2) Intermediate Glycemic Index Foods (GI 55-69) causing a medium rise in blood-glucose; and (3) Low Glycemic Index Foods (GI 54 or less), causing a slower rise in blood-sugar.

The advantages of following a low GI diet are reported to be lower risks of developing cardiovascular and type 2 diabetes related complications. According to a recent critical review, "Several health benefits exist for reducing the rate of carbohydrate absorption by means of a low GI diet. These include: reduced insulin demand, improved blood glucose control and reduced blood lipid levels, all factors that may play important roles in the prevention or management of several chronic Western diseases like diabetes, coronary heart disease and possibly certain cancers"²⁰⁶.

²⁰⁶ Augustin LS, Franceschi S, Jenkins DJ, Kendall CW, La Vecchia C. 2002. Glycemic index in chronic disease: a review. *Eur J Clin Nutr.* 56(11):1049-71.

Following a low glycemic diet has been shown to prevent type 2 diabetes and coronary artery disease, including atherosclerosis²⁰⁷. High blood glucose levels or repeated glycemic "spikes" following a meal may promote these diseases by increasing oxidative damage to the vasculature and also by the direct increase in insulin levels²⁰⁸. In the past, post-meal [hyperglycemia](#) has been a risk factor mainly associated with diabetes, however more recent evidence shows that [postprandial](#) hyperglycemia presents an increased risk for [atherosclerosis](#) in the non-diabetic population²⁰⁹. The GI is supported by leading international health organizations including the American Diabetes Association²¹⁰.

In animal studies, weight control was also achieved by feeding animals low GI carbohydrates²¹¹. In a very recent clinical trial²¹², 129 overweight or obese young adults were assigned to 1 of 4 reduced-fat, high-fibre diets for 12 weeks. Diets 1 and 2 were high carbohydrate (55% of total energy intake), with high and low GIs, respectively; diets 3 and 4 were high protein (25% of total energy intake), with high and low GIs, respectively. While all groups lost a similar percentage of weight, the proportion of subjects in each group who lost 5% or more of body weight varied significantly by diet (diet 1, 31%; diet 2, 56%; diet 3, 66%; and diet 4, 33%). Women on diets 2 and 3 lost approximately 80% more fat mass than those on diet 1. LDL cholesterol levels declined significantly in the diet 2 group and increased in the diet 3 group. Both high-protein and low-GI regimens increased body fat loss in this trial, but cardiovascular risk reduction was optimized by a high-carbohydrate, low-GI diet.

According to researchers from Boston Children's Hospital, following a low-GI diet appears to be more beneficial than a traditional low-fat diet in reducing cardiovascular disease risk factors in obese youth²¹³.

A low-GI diet may reduce systemic inflammation among women with type 2 diabetes²¹⁴. In the cohort examined, dietary GI was positively associated with the inflammatory proteins CRP and tumour necrosis factor (TNF-R2) levels. The concentrations of CRP and TNF-R2 were 32 and 11% higher, respectively, in the highest quintile of dietary GI as compared with the lowest quintile.

²⁰⁷ Willett W, Manson J, Liu S. 2002. Glycemic index, glycemic load, and risk of type 2 diabetes. *Am J Clin Nutr.* 76(1):274S-80S.

²⁰⁸ Temelkova-Kurktschiev et al. 2000. Postchallenge plasma glucose and glycemic spikes are more strongly associated with atherosclerosis than fasting glucose or HbA1c level. *Diabetes Care.* 23(12):1830-4.

²⁰⁹ Balkau et al. 1998. High blood glucose concentration is a risk factor for mortality in middle-aged nondiabetic men. 20-year follow-up in the Whitehall Study, the Paris Prospective Study, and the Helsinki Policemen Study. *Diabetes Care.* 21(3):360-7

²¹⁰ Sheard et al. 2004. Dietary carbohydrate (amount and type) in the prevention and management of diabetes: a statement by the American Diabetes Association. *Diabetes Care.* 27(9):2266-71

²¹¹ Pawlak DB, Ebbeling CB, Ludwig DS. Should obese patients be counselled to follow a low-glycaemic index diet? Yes. 2002. *Obes Rev.* 3(4):235-43

²¹² McMillan-Price, J., Petocz, P; Atkinson, F., O'Neill, K., et al. 2006. Comparison of 4 Diets of Varying Glycemic Load on Weight Loss and Cardiovascular Risk Reduction in Overweight and Obese Young Adults: A Randomized Controlled Trial. *Arch Intern Med.* 166:1466-1475.

²¹³ Ebbeling, C.B., Leidig, M.M., Sinclair, K.B., Seger-Shippe, L.G., Feldman, H.A., and Ludwig, D.S. 2005. Effects of an ad libitum low-glycemic load diet on cardiovascular disease risk factors in obese young adults. *Am. J. Clin. Nutr.* 81: 976-982.

²¹⁴ Qi et al. 2006. Whole-grain, bran, and cereal fiber intakes and markers of systemic inflammation in diabetic women. *Diabetes Care.* 29(2):207-211.

In a recent review article, part of the success of low-GI diets is attributed to a focus on the type of carbohydrate consumed, as opposed to the amount²¹⁵. By not restricting the amounts of major nutrients, low-GI diets are more practical and sustainable in everyday life conditions. Low-GI diets may achieve long term success because they focus on controlling blood glucose fluctuations, an underlying cause of disease. GI appears to be related to levels and type of soluble fibre in a food – the more viscous the fibre; the lower will be the GI. Whole-grain intake is generally inversely associated with BMI; refined grain intake is not²¹⁶. Because hempseed is a high source of both insoluble and soluble fibres, it presents an interesting food source for low GI applications.

6.3 Hemp Fibre and the Glycemic Index (GI)

GI represents a potential area for research in hemp seed and hemp seed products, due to the low percentage of non-fibre carbohydrates present²¹⁷. The high proportion of total carbohydrate present as dietary fibre in hemp seed warrants further research to determine if hemp products, especially those containing a significant hull fraction, would provide beneficial effects for humans in relation to the glycemic response.

²¹⁵ Ludwig, D. 2007. *The Lancet*. 369:890-892

²¹⁶ Gaesser, GA. 2007. Carbohydrate Quantity and Quality in Relation to Body Mass Index. *J Am Diet Assoc*. 107:1768-1780.

²¹⁷ House, J. 2007. Characterization of Hemp Seeds, Hulled Seeds and Protein Flour for Macronutrients, Protein Composition and Digestibility. Report completed for the CHTA.

7.0 VITAMINS

As shown in the following figure from the CHTA, hempseed is a very good source of the important vitamin B complex including Vitamins B1 (thiamine), B2 (riboflavin) and B6 (pyroxidine). The B vitamins play a role in metabolism, enhancing the immune system and nervous system, and supporting cell growth and division. Vitamin B1 serves as a catalyst in carbohydrate metabolism and is important in the regulation of the nervous system. Deficiency can cause heart swelling, leg cramps, and muscular weakness.



Intake of Essential Nutrients via Hempnuts

	Daily Value (DV) (mg/day)	mg/100 g	35 g Nuts = % RDI
Energy		5.6 kCal/g	200 kCal
Phosphorus	1000	1200	42%
Potassium	2000	1040	18%
Magnesium	400	570	50%
Calcium	1000	190	7%
Iron	18	18	35%
Manganese	5	10	70%
Zinc	15	10	23%
Copper	2	0.5	9%
Thiamine (B1)	1.5	1.3	30%
Riboflavin (B2)	1.7	1.2	25%
Pyroxidine (B6)	2	1	18%
Folic Acid	0.4	0.7	61%
Vitamin E	30	8	9%

Vitamin B2 aids in the metabolism of fats, carbohydrates, and respiratory proteins. A deficiency can result in skin lesions and light sensitivity. [Vitamin B6](#) is involved in the absorption and metabolism of amino acids and fats. Deficiency in the vitamin may result in smooth tongue, skin disorders, dizziness, nausea, anemia, convulsions, and kidney stones. Overall B vitamins have been shown to:

- Support and increase the rate of [metabolism](#)
- Maintain healthy skin and muscle tone
- Enhance [immune](#) and [nervous system](#) function
- Promote [cell growth](#) and [division](#) — including that of the [red blood cells](#) that help prevent [anemia](#).
- Help combat the symptoms and causes of [stress](#), [depression](#), and [cardiovascular disease](#).

Hempseed is also a rich source of folic acid which is very important for all women who may become [pregnant](#). Adequate folate intake during the periconceptual period, helps protect

against a number of congenital malformations including [neural tube defects](#)²¹⁸. Neural tube defects result in malformations of the spine ([spina bifida](#)), skull, and brain ([anencephaly](#)). The risk of neural tube defects is significantly reduced when supplemental folic acid is consumed in addition to a healthy diet prior to and during the first month following conception²¹⁹. Women who could become pregnant are advised to eat foods fortified with folic acid or take supplements in addition to eating folate-rich foods such as hempseed, to reduce the risk of some serious birth defects.

8.0 MINERALS

Data available from the CHTA indicates that hempseeds are rich in the minerals phosphorus, magnesium and manganese. Of particular importance is magnesium, the fourth most abundant mineral in the body. Approximately 50% of total body magnesium is found in bone. Magnesium is needed for more than 300 biochemical reactions in the body. It helps maintain normal muscle and nerve function, keeps heart rhythm steady, supports a healthy immune system, and keeps bones strong. Magnesium also helps regulate blood sugar levels, promotes normal blood pressure, and is known to be involved in energy metabolism and protein synthesis²²⁰. There is an increased interest in the role of magnesium in preventing and managing disorders such as hypertension, cardiovascular disease, and diabetes²²¹.

²¹⁸ Shaw GM, Schaffer D, Velie EM, Morland K, Harris JA .1995. Periconceptional vitamin use, dietary folate, and the occurrence of neural tube defects. *Epidemiology* 6 (3): 219-226.

²¹⁹ Milunsky A, Jick H, Jick SS, Bruell CL, MacLaughlin DS, Rothman KJ, Willett W. 1989. Multivitamin/folic acid supplementation in early pregnancy reduces the prevalence of neural tube defects. *J Amer Med Assoc* 262 (20): 2847-2852.

²²⁰ Dietary Supplement Fact Sheet: Magnesium. [Office of Dietary Supplements](#). [National Institutes of Health](#). <http://dietary-supplements.info.nih.gov/factsheets/magnesium.asp>

²²¹ Ibid.

9.0 HEMP OIL AND SKIN CARE

The health industry is being increasingly driven by aging demographics in industrialized nations. With the global population having more than tripled since the 1950s, more people than ever before are reaching the age of 50. Demand for anti-aging solutions is therefore increasing. Younger consumers too are increasingly conscious of ways to ensure health and wellness and are seeking ways to delay aging and maintain soft and vibrant skin. While it is still not possible to reverse the effects of ageing, its mechanisms have been identified by scientific studies, together with various active biological compounds that interact with such mechanisms.

Hemp oil contains important nutritional compounds which are critical for ensuring healthy, soft and vibrant skin as well as to reduce the signs of aging. Based on hemp oil, natural cosmetics and body care items were among the first grown-in-Canada products to be made widely available to the North American public. Hemp body products include shampoos, conditioner, hand and body lotions, bath and massage oil, moisturizing cream, and lip balms. Although early cosmeceutical uses of hemp oil were based primarily on testimonials, there is growing scientific evidence to demonstrate the efficacy of the unique fatty acid profile of hemp in personal care products.

The skin is the largest organ of the body. The functions of the skin include protection of the body against injury, heat and light radiation, regulation of body temperature, elimination of waste products, and secretion of hormones and enzymes. The skin also acts as an external sensory organ and plays an immunological role. The surface of the skin is made up of mostly of dead cells. Underneath the surface, there are three thin distinct layers, including the epidermis, the dermis and hypodermis.

The epidermis is responsible for the look and the health of the skin. It protects the skin from moisture loss and the penetration of chemical products and bacteria. It is also the initial barrier to oxidant assault. The epidermis holds a large amount of water. The skin's capacity to retain water decreases with age, making it more vulnerable to dehydration and wrinkles. It is in this layer that the consumption of hempseed and hemp oil will have its greatest effects.

Aging of the Skin

The most important environmental factor that contributes to ageing is the oxidation of bio-molecules by free radicals, which causes, among other things, ageing of the skin. UV radiation is the main factor. Other oxidative processes cause ageing at the cellular level, which damages many organs in the body and enhances age-related diseases such as arteriosclerosis. Cellular oxidation leads to collagen breakdown, chronic skin inflammation and the accumulation of abnormal elastin in the superficial dermis lead to wrinkles, mottled coloration and skin laxity.

The Influence of Diet

Diet significantly influences the health and vitality of the skin. Of particular importance are the EFAs and antioxidants. EFAs are critical components of the membranes of all cells including of the skin, where they ensure “fluidity” and stability. The proper functioning of all body cells depends upon healthy membranes as they act as “gate-keepers” in the cells.

Antioxidants help reduce the damage to body cells caused by the constant assault of free radicals (reactive oxygen species or ROS) such as generated through UV radiation. Free radicals are produced as a result of normal metabolic processes in living systems. Pollution, second hand smoke, many dietary constituents and aging contribute to the production of free radicals often exceeding the protective antioxidant capacity of our bodies leading to oxidative stress. Antioxidants such as compounds known as lignans, flavonoids and phenols “neutralize” free radicals and offer protection against oxidative damage²²².

The Importance of the EFAs for Skin health

Both families of omega 6 and omega 3 EFA are necessary for overall skin health – but a balance between the two is important for vibrant skin. EFAs are critical for maintaining the integrity of the skin and the structure of its cell membranes. In fact, when consumed, ALA will accumulate and be preferentially stored in the skin as well as the adipose tissue²²³. People who reduce dietary fat, especially EFAs, too drastically will very quickly notice dry, eczema-type skin problems. Loss of epidermal barrier function leading to rapid water (moisture) loss is one of the first consequences of EFA deficiency. This is referred to as transepidermal water loss (TEWL). Long term depletion of dietary EFAs will lead to erythema (abnormal skin redness) with scaling, dermatitis, skin atrophy, edema, hair loss, itching, poor wound healing and a tendency to cutaneous infection.

ALA and GLA have been shown to reduce skin inflammation and improve overall skin vitality, such as softer, smoother, healthier skin. These benefits are attributed to enhanced blood flow to the skin, maintenance of epidermal integrity (and therefore protection from water loss) and decreased inflammatory eicosanoid synthesis.

In a study of 40 people with psoriasis, those who were treated with medications and omega 3 supplements showed improvements in skin health that were more significant than those treated with medications alone²²⁴.

GLA is particularly important to skin health and in fact has been studied extensively as a treatment option for various skin disorders. Atopic dermatitis is a chronic inflammatory disease that causes eczema, rashes and itching. It is most common in younger people and usually is resolved during adolescence. Low levels of GLA and DGLA believed to be due to reduced activity of the delta 6 desaturase enzyme is thought to play a role in the etiology of the condition²²⁵. The skin is particularly sensitive to sub-optimal GLA formation as it lacks the delta 6 desaturase enzyme and therefore depends on a supply of pre-formed GLA.

PGE1 acts to enhance moisture levels in the skin, to protect the epidermis from water loss and to reduce inflammation. High levels of LA and correspondingly reduced levels of GLA, DGLA and AA have been found in patients with atopic dermatitis. In such conditions, a defect in the enzymatic conversion of LA to GLA might be responsible for defects in the lipid

²²² Balentine, D.A., Albano, M.C. and Nair, M.G. 1999. Role of medicinal plants, herbs, and spices in protecting human health. *Nutrition Rev.* 57 (9 Pt. 2):S41 – S45.

²²³ Sinclair, A.J., Attar-Bashi, N.M., and Li, D. 2002. What Is the Role of α -Linolenic Acid for Mammals? *Lipids.* 37:1113-1123.

²²⁴ [Meschino, James](#). 2003. Essential fatty acid supplementation improves skin texture and overall health. *Dynamic Chiropractic*, Sep 24.

²²⁵ Henz, B.M., Jablonska, S., Van de Kerkhof, et al. 1999. Double-blind, multicentre analysis of the efficacy of borage oil in patients with atopic eczema. *Brit. J. Dermatol*; 140(4): 685 - 688.

barrier of the skin and a decrease in the production of the anti-inflammatory DGLA metabolites PGE1 and 15-HETE.

Similar observations have been reported for breast milk of mothers of children with atopic eczema²²⁶, in which abnormal levels of the n-6 and n-3 PUFA families in colostrum and mature milk have been observed as well as in children with atopic dermatitis²²⁷. In both situations, GLA supplementation significantly improves epidermal health.

There are many anecdotal reports on the value of hempseed and oil for maintaining healthy, younger looking skin and for the treatment of skin disorders. Clinical studies in humans are limited. Calloway and coworkers have recently compared the effects of either 30 ml (2 Tb.) of either hempseed oil or olive oil in a 20-week randomized, single-blind crossover study with atopic patients (more commonly known as eczema)²²⁸. Levels of LA and ALA, and GLA increased in all lipid fractions after hempseed oil, with no significant increases of AA in any lipid fractions after either oil. Significant reductions in TEWL values, skin dryness and itchiness improved and dermal medication followed the hempseed oil intervention. This study supports that hempseed oil improves clinical symptoms of atopic dermatitis. It is suggested that these improvements resulted from the balanced and abundant supply of PUFAs in this hempseed oil.

In their paper, Calloway et al. also speculate that hempseed oil may also increase finger nail strength and thicken hair. The cell lines prevalent in the skin, hair and nails are constructed by dermal stem cells from fatty acids that are available in the diet at the time of their formation. Thus adequate amounts of EFAs and GLA will help to replenish cellular growth and aid in healthier skin, hair and nails.

9.1 Skin Conditions in Pets

Allergic reactions and inflammation are common in canines and felines. Causes of dermatological disorders include sensitivity to allergens either related to inhalants or fleas; poor diet and/or malabsorption of dietary fats. Cats possess active D5-desaturase activity, but are deficient in the delta 6 desaturase enzyme which makes them more dependent upon GLA and EPA supplementation than dogs. In addition, the cat has a requirement for both LA and AA. Essential fatty acid deficiency in growing cats is characterized by a dry, scaly coat associated with increased TEWL.

Cats often exhibit "miliary" or "crusting" dermatitis characterized by raised, dry, scalelike bumps (papules). Diets in which the only EFA provided is LA are insufficient for normal metabolism leading to retarded growth, and alterations in skin and reproductive function. Cumulative results over two decades suggest that GLA and EPA are useful in the

²²⁶ Duchon, K., Yu, G. and Bjorksten, B. 1998. Atopic Sensitization during the First Year of Life in Relation to Long Chain Polyunsaturated Fatty Acid Levels in Human Milk. *Pediatr. Res.* 44(4):478.

²²⁷ Borrek, S., Hildebrandt, A. and Forster, J. 1997. Gamma-linolenic-acid-rich borage seed oil capsules in children with atopic dermatitis. A placebo-controlled double-blind study. *Klin Padiatr.* 209(3):100

²²⁸ Callaway J, Schwab U, Harvima I, Halonen P, Mykkänen O, Hyvönen P, Järvinen T. 2005. Efficacy of dietary hempseed oil in patients with atopic dermatitis. *J Dermatolog Treat.* 16(2):87-94.

treatment of feline dermatoses with an inflammatory etiology²²⁹. Dogs also benefit from GLA and EPA as anti-inflammatory agents in the management of canine atopy²³⁰.

²²⁹ Harvey, R. G. 1993. Essential fatty acids and the cat. *Vet. Dermatol.* 4(4):175.

²³⁰ Harvey, R.G., 1999. A blinded, placebo-controlled study of the efficacy of borage seed oil and fish oil in the management of canine atopy. *Veterinary Record* 144 (15): 405-407.

Appendix B – Health and Food Market Assessment

HEALTH AND FOOD MARKET ASSESSMENT

March, 2008

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1.0 INTRODUCTION

*“Wellness will be for the next fifteen years...
what convenience was for the last fifteen”*

Brock Leach, chief innovations officer, PepsiCo²³¹

*“It is imperative that the food industry continues to respond
with efficacious products
that have credible benefits, and sophisticated 'natural' solutions that taste good.”*

Ted Ziemann, President, Cargill Health & Food Technologies²³²

***“We, Canadians will pay the health bill, \$1.4 Trillion over the next 10 years.
It means that 7 out of 10 provinces in Canada will essentially reallocate
public dollar expenditures to health care delivery only...”***

Agriculture can be a fundamental pillar for a healthy Canada.”

Gaetan Lussier, Chair, Canadian Agri- Food Policy Research Institute²³³

In the essence of these three quotes we can recognize the opportunities and challenges that lie ahead for the Canadian agricultural and food sector as it attempts to position itself to take advantage of market opportunities in health and wellness. It has become increasingly apparent that health and wellness are becoming fundamental concerns of consumers and helping to mitigate these concerns through healthier food choices can be pivotal to business success in agriculture, food and health. There is an increasing recognition by both the agriculture and health sectors of the ability of agricultural bioactives to improve the health of Canadians and an industry to create new product opportunities for agricultural producers and processors.

In Canada as elsewhere, healthier-for-you foods, natural health products (NHP) and ‘functional’ foods have garnered a great deal of attention in recent years. A driving force behind this opportunity is an increase in nutritional knowledge and the expectations of consumers that food should provide health benefits beyond simple nutrition. The interest in, and market growth of, NHP and functional foods is also being facilitated by dietary concerns of an aging population that have moved from preventing deficiency diseases to longer-term prevention of chronic disease. It has been established that diet

²³¹ Interview. October 2004. New Nutrition Business. London.

²³² Ted Ziemann. October 2005. "Health through Foods - an Economic Solution". Presented at the Robert Mondavi Institute for Wine and Food Science Ground-breaking, University of California-Davis

²³³ Lussier, G. 2005. *Agriculture: A Fundamental Pillar For A Healthy Canada*. Presented at the Agri-Food Innovation Forum. Toronto, June 20th, 2005

plays a role in 5 of 10 of the leading causes of death. Cancer, diabetes and cardiovascular disease (CVD), in particular, are closely linked to dietary patterns.

The global market for functional foods, dietary supplements (NHP in Canada) and food ingredients is comprised of companies that see the industry as a growth opportunity and the ability to make higher margins. It has attracted players the size of ADM, BASF, DSM, Nestle, Cargill, Bayer, Kellogg, Quaker Oats, Pepsi-Co and Danone as well as many small and medium sized enterprises. It is in this environment that the development of “healthier for you” functional foods, ingredients and NHP has become a serious focus for the industry as well as the research community in Canada and internationally. The Canadian hemp industry has identified health foods and NHP has a market opportunity over the short to longer terms.

2.0 DEFINITIONS OF HEALTH PRODUCTS

The health products sector is generally accepted to include “healthier for you foods “or functional foods, dietary supplement (or natural health products – NHP – in Canada) and natural personal care products.

2.1 Functional Foods

“Functional food” is essentially a marketers’ or analysts’ term and is not recognized in law or defined in the dictionary. As such, companies and market researchers use the term inconsistently and there are many variations of the definition. In general, functional foods can be described as “foods that have a potentially beneficial effect on health when consumed as a part of a varied diet”.²³⁴

For the purposes of this report, the definition of functional foods as proposed by Health Canada will be used, that being, a functional food is “... similar in appearance to a conventional food, consumed as part of the usual diet, with demonstrated physiological benefits, and/or to reduce the risk of chronic disease beyond basic nutritional functions”²³⁵. This definition also includes “healthier for you” foods which generally are those foods marketed for their intrinsic health value.

As a category, functional foods include:

- **conventional** foods containing naturally occurring bioactive substances (such as dietary fibre in wheat bran to promote digestive regularity, or beta-glucan in oat bran to lower blood cholesterol)
- foods that have been **modified**, by enrichment or other means, in terms of the amount, type or nature of their bioactive substances. An example is margarine that contains added phytosterol, an extract from plant sources that is known to interfere with cholesterol absorption, thereby lowering serum cholesterol levels
- **synthesized** food ingredients, such as some specialized carbohydrates intended to feed micro-organisms in the gut.

Examples of some common functional foods and food ingredients and their proposed health benefit follow²³⁶.

²³⁴ J Am Diet Assoc., “Position of the American Dietetic Association on Functional Foods” 1999;99: pp1278.

²³⁵ Health Canada. Standards of Evidence for Evaluating Foods with Health Claims – Fact Sheet. http://www.hc-sc.gc.ca/food-aliment/ns-sc/ne-en/health_claims-allegations_sante/e_soe_fact_sheet.htm.

²³⁶ Adapted from: Palou, A, Oliver, P, Rodríguez, A. and Caimari, A. 2005. Functional Foods in the European Union. In: Regulation of Functional Foods and Nutraceuticals: A Global Perspective. ed. C. Hasler. Iowa State Press/IFT Press. ISBN: 0813811775

FUNCTIONAL FOOD	ACTIVE FOOD COMPONENT	TARGET FUNCTION
Dairy products Yoghurts Milks Fats Margarines	Calcium	Prevention of osteoporosis
	Cereals	Control of glycaemia Reduce risk of cancer
	Folic acid	Reduce risk of neural tube defects in the newborn Reduce risk of cancer and CVD
	Oleic acid	Decrease LDL and total cholesterol Increase HDL-cholesterol Decrease risk of CVD
	Omega-3 fatty acids	Control of lipid profile and hypertension Decrease risk of CVD
	Plant sterols	Decrease LDL and total cholesterol Decrease risk of CVD
	Probiotics (<i>Lactobacillus</i> sp., <i>Bifidobacteria</i> sp.) Prebiotics (non-digestible oligosaccharides)	Optimal intestinal function and intestinal microbial balance
	Soy and isoflavones	Reduce risk of breast and prostate cancer Improve the symptoms associated with menopause
	Plant sterols	Decreased LDL and total cholesterol Decreased risk of CVD

Edible oils	Diacylglycerols	Reduce serum triacylglycerol Increase degradation of free fatty acids and reduce fat deposition
Eggs	Omega-3 fatty acids	Control of lipid profile and hypertension Decrease risk of CVD
Meat and derivatives	Less saturated fat	Reduce risk of CVD
	Conjugated linoleic acid	Reduce risk of cancer Reduce serum lipid levels and control of insulinemia Weight loss
Cereals Breakfast enriched cereals Cereal bars	Fibre	Beneficial effects in the digestive process Reduce risk of developing cancer Reduce serum lipid levels and control of insulinemia
	Folic acid	Reduce risk of neural tube defects in the newborn Reduce risk of cancer and CVD
Drinks Juices and enriched drinks	Calcium	Prevention of osteoporosis
	Fibre	Beneficial effects in the digestive process Reduce risk of developing cancer Reduce serum lipid levels and control of insulinemia
	Omega-3 fatty acids	Control of lipidic profile and hypertension Decrease risk of CVD
	Probiotics (<i>Lactobacillus</i> sp., <i>Bifidobacteria</i> sp.) Prebiotics (non-digestible oligosaccharides)	Optimal intestinal function and intestinal microbial balance

	Soy and isoflavones	Reduce risk of breast and prostate cancer Improve the symptoms associated with menopause
	Vitamin C	Antioxidant effects and cancer prevention Enhancement of the immune system
Bread and Bakery products	Cereals	Control of glycaemia Reduce risk of cancer
	Fibre	Beneficial effects in the digestive process Reduce risk of developing cancer Reduce serum lipid levels and control of insulinemia
	Folic acid	Reduce risk of neural tube defects in the newborn Reduce risk of cancer and CVD
	Omega-3 fatty acids	Control of lipid profile and hypertension Decrease risk of CVD
	Prebiotics	Intestinal function and intestinal microbial balance
	Selenium	Increase antioxidant protection Reduce risk of cancer

United States - The most commonly referenced definition for a functional food in the United States is that used by California based Nutrition Business Journal (NBJ)²³⁷. NBJ defines a functional food as fortified with added or concentrated ingredients and/or marketed to emphasize 'functionality' to improve health or performance. Unlike Health Canada's definition, NBJ includes 'substantially fortified', 'inherently functional', 'performance' and 'medical' foods within their definition.

These categories include "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.

²³⁷ Anon. 2003. Functional Foods VI. *Nutrition Business Journal*. Vol VIII. No. 2/3. February/March 2003.

2.2 Dietary Supplements

Canada - Canada is the only global jurisdiction that has legislation related to “natural health products (NHP)” also known as dietary supplements in other global areas. These regulations became effective on January 1, 2004²³⁸. The regulations apply to all NHPs including homeopathic preparations, substances used in traditional medicine, a mineral or trace element, a vitamin, an amino acid, an essential fatty acid or other botanical, animal or microorganism-derived substance. These products are generally sold in a medicinal or “dosage” form.

Examples of natural health products include:

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

Until publication of the NHP regulations, the working definition for a *nutraceutical* in Canada has been “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”. Health Canada decided that the product category of nutraceuticals would be encompassed within NHP regulations.

However, like functional foods, although the nutraceutical category is not recognized in law, it is used extensively as a marketing term for plant and animal based bioactives and ingredients that are sold in a medicinal form.

United States - In 1994, the Dietary Supplement Health and Education Act (DSHEA) was passed in the U.S. as an amendment to the Federal Food Drug and Cosmetic Act²³⁹. DSHEA defines dietary supplements as “a product, other than tobacco, intended to supplement the diet that contains at least one or more of the following ingredients: a vitamin, a mineral, a herb or other botanical, an amino acid, or a dietary substance [used] to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, or extract or combination of any of the previously mentioned ingredients.”

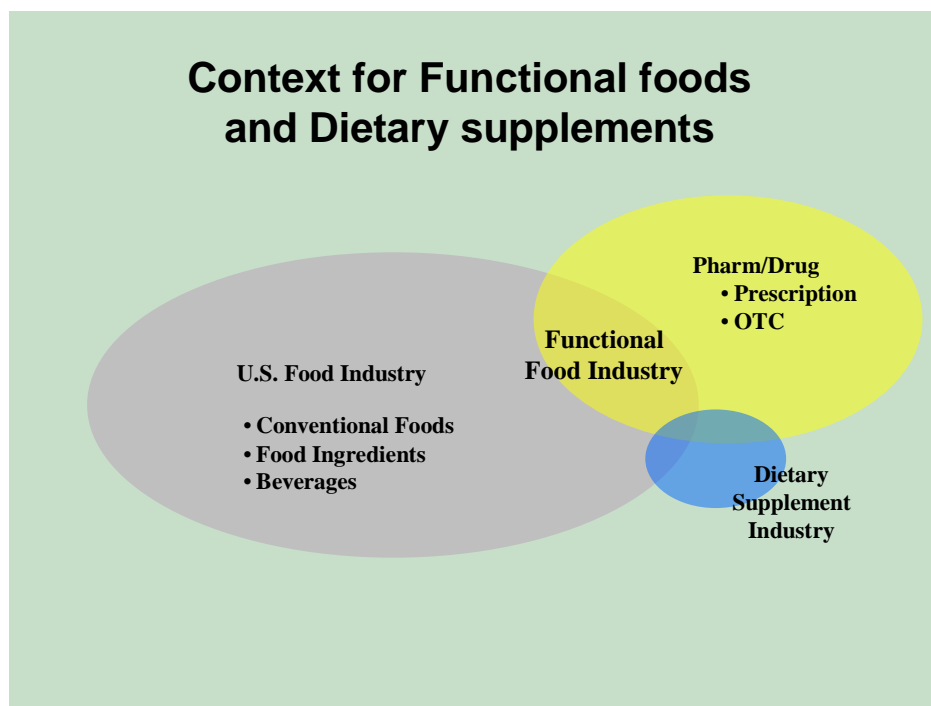
Dietary supplements are delivered in the form of a capsule, powder, softgel, or gelcap and are not to be represented as a conventional food or as a sole item of a meal or a diet. These products are meant to supplement the diet by increasing the total dietary intake of a substance.

²³⁸ Government of Canada. Natural Health Products Regulations. Canada Gazette Part 2. June 2003. <http://canadagazette.gc.ca/partII/2003/20030618/html/sor196-e.html>.

²³⁹ United States Food and Drug Administration, Dietary Supplements, February 11 2004, Internet: <http://www.cfsan.fda.gov/~dms/supplmnt.html>

DSHEA allows dietary supplement labeling to bear statements known as structure/function claims (S/F claims). Such claims “describe the role of a nutrient or dietary ingredient that is intended to affect the structure or function in humans” or “characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function”. Under DSHEA, a dietary supplement cannot make a drug claim, whereby the supplement is “intended to be used to diagnose, cure, mitigate, treat or prevent disease.” In addition, the labels of such products must carry a disclaimer that states, “This product has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, prevent or cure any disease.”

Globally and by their nature in the diet, functional foods and dietary supplements (NHP) lie between the health care continuum of foods and drugs as indicated in the following diagram²⁴⁰.



Though the definitions may vary amongst regions, the evolution of the development of foods for health has followed a similar pathway in most countries.

²⁴⁰ Anon. 2003. Functional Foods VI. *Nutrition Business Journal*. Vol VIII. No. 2/3. February/March 2003.

3.0 MARKET FOR HEALTH PRODUCTS

The market for FF and NHP (dietary supplements in the United States) is described in this section.

3.1 Canada

The Canadian marketplace for functional foods and NHP is difficult to quantify, due to a lack of data availability. Most market research groups simply estimate the Canadian FFNHP market to be 10% of the United States' market and reduce this number somewhat for a perceived lower use of dietary supplements in Canada relative to the United States. Estimates of demand for these products are also complicated by variations in the definition of the industry.

Statistics Canada estimates the total revenue in Canada from FFNHP at \$2.9 billion in 2004, of which \$823 million came from firms producing functional foods, \$1.6 billion from firms producing NHP and \$442 million from firms producing both²⁴¹.

For 2003, data from the Nutrition Business Journal (NBJ) indicates that the Canadian nutrition industry including supplements, personal care products, and natural/organic and functional foods was valued at US \$ 4.8B, a steady increase over the last four years²⁴². This estimate is higher than Stats Canada due to the inclusion of personal care and natural/organic foods. While functional food sales in the U.S. represent approximately 4.0% of total food sales, Canada's portion of total food sales is only 2.2%.

According to NBJ, the Canadian market is experiencing a respectable 7.8% overall annual growth rate surpassing the 2-3% growth rate of the traditional food industry.

Global Nutrition Industry			
Growth in Consumer Sales in 2003 (\$mil)			
By Region	2002	2003	2003 Growth
USA	58,520	63,690	8.8%
Europe	53,570	56,730	5.9%
Japan	28,820	31,520	9.4%
Canada	4,480	4,830	7.8%
China	6,040	6,940	14.9%
Rest of Asia	6,860	7,640	11.4%
LatAm	3,350	3,670	9.6%
Aust/NZ	2,990	3,210	7.4%
EE/Russia	1,360	1,610	18.4%
MidEast	800	880	10.0%
Africa	790	860	8.9%
Total Global Market	168,150	182,220	8.4%

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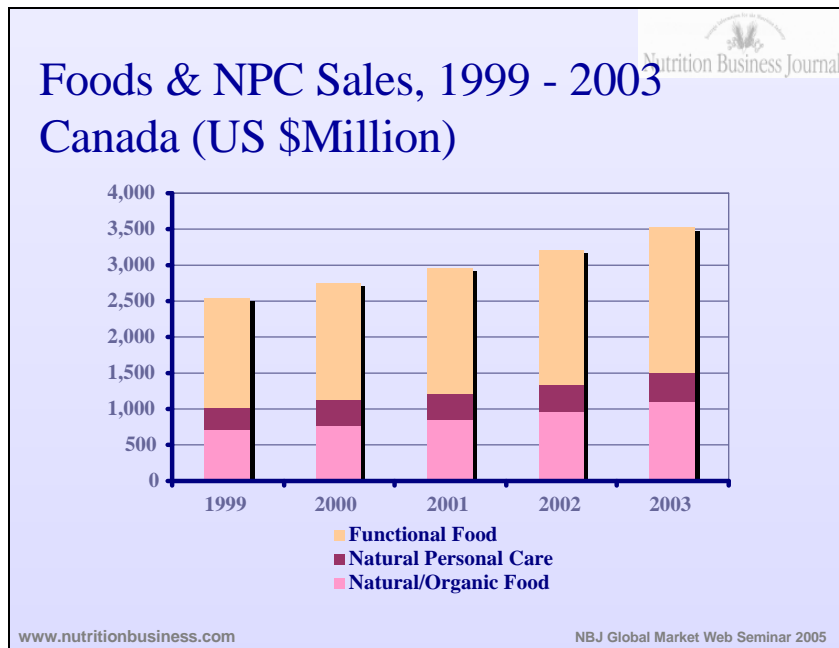
²⁴¹ Palinic, R. 2007. *Results From the Functional Foods and Nutraceuticals Survey - 2005*.

Statistics Canada. <http://www.statcan.ca/english/freepub/88F0006XIE/88F0006XIE2007003.pdf>

²⁴² Ferrier, G. 2005. Nutrition Business Journal. NBJ Industry Overview. Webcast. April, 2005. www.nutritionbusiness.com.

3.1.1 Functional Foods

Evidence suggests that Canadians are increasingly turning to food and other products that are perceived to be healthy. The following chart from NBJ illustrates a 40% growth in sales over a five-year period from 1999 – 2003 for functional foods, natural personal care (e.g. cosmeceuticals), and natural and organic food. The functional food industry was estimated to represent US \$2B by 2004²⁴³.



Similar to other global regions, functional foods do represent a good opportunity to attract the traditional Canadian food industry as margins are higher and the sector is growing quickly.²⁴⁴

3.1.2 Natural Health Products

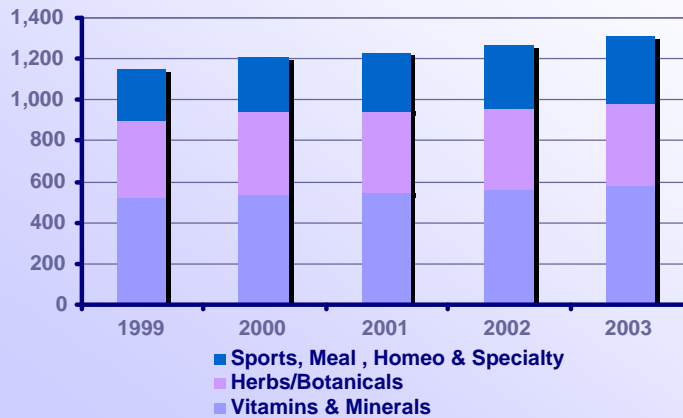
NBJ has reported Canadian sales figures for sport, meal, homeopathic and specialty supplements, vitamins and minerals, herbs and botanicals to be \$1.3 B U.S. in 2003²⁴⁵, a 10% increase over 2002 figures.

²⁴³ Leverus Inc. 2005. *Canada's Natural Health Products Sector in 2005: State of the Industry Report*. Prepared for Canadian Health Food Association, Canadian homeopathic Pharmaceutical Association and Canadian Natural Products Association by Leverus Inc in co-operation with Inter/Sect Alliance Inc.

²⁴⁴ Inter/Sect Alliance Inc., "Business and Market Impact of the Food and Drugs Act and Regulations on Functional foods in Canada", prepared for Agriculture and Agri-Food Canada, July 2001.

²⁴⁵ Ferrier, G. 2005. Nutrition Business Journal. NBJ Industry Overview. Webcast. April, 2005. www.nutritionbusiness.com.

Supplement Sales, 1999 - 2003 Canada (US \$Million)



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In the fall of 2006 the Canadian Health Food Association, the Canadian National Product Association and the Canadian Homeopathic Pharmaceutical Association undertook a study to more clearly determine the size of the NHP industry. It found that the sector is one of the fastest growing product categories in Canada²⁴⁶.

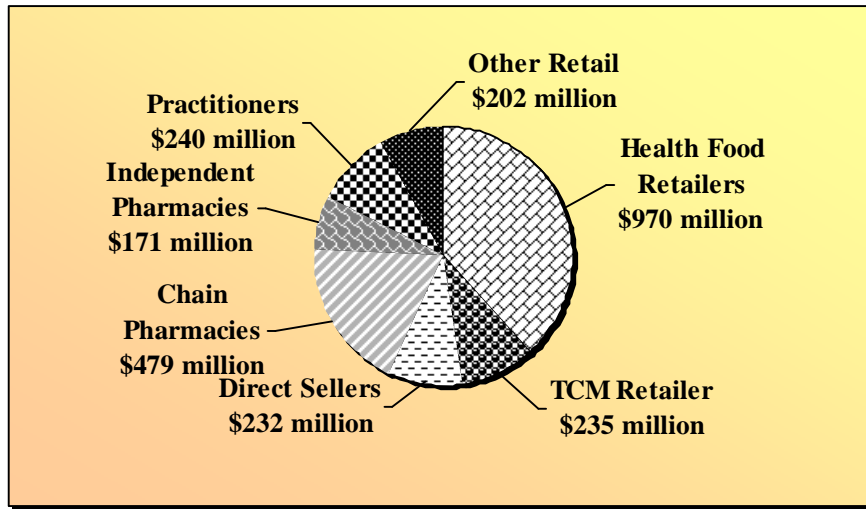
The sector represents over \$2.5 billion in retail sales in Canada and employs over 25,000 Canadians. Over 42,000 products are available on the Canadian market.

According to this study, the NHP market has doubled in size in the last five years and is conservatively estimated to grow to over \$2.75 billion or more by 2010. Over 90% of its participants envision growth in the next 3 year period. The Canadian retail environment includes over 10,000 establishments, 3,000 health food and Chinese medicine retail establishments, 800 natural health product suppliers (manufacturers and importers) which are relatively evenly distributed across Ontario Quebec and British Columbia with less than 10% of the total in the Prairies and Atlantic Canada. The participants range in size from sales of less than \$200,000 to over \$50 million in revenue annually.

Nearly 75% of NHP sold by health food retailers are purchased from Canadian based manufacturers with the remainder from importers or distributors. Canada remains a net importer of NHP however the trade deficit has narrowed in recent years to about \$50 million in 2004. The value of exports reached nearly \$200 million in 2004 and is increasing by 2% annually. The value of NHP imports is equivalent to approximately 10% of retail sales in Canada.

²⁴⁶ Canada's Natural health products Sector, 2005; State of the Industry Report: Volume 1 Sector Overview, Prepared for the Canadian Health Food Association, Canadian Homeopathic Pharmaceutical Association and the Canadian Natural Products Association by Leverus Inc, September 2005.

Value of the Canadian NHP Retail Sector⁴⁷



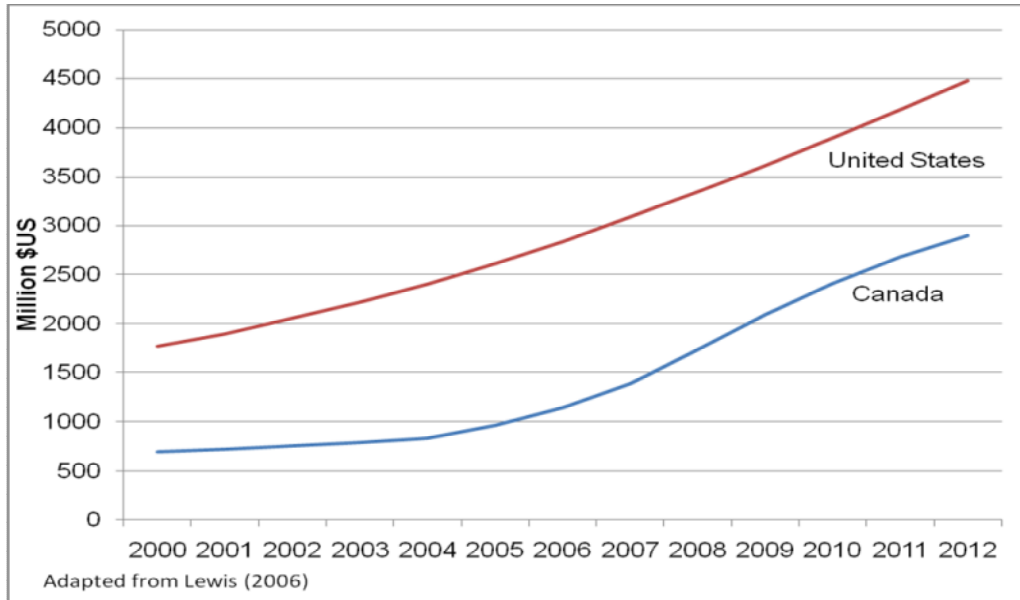
3.1.3 Future Domestic Demand

Canada does not currently possess a significant portion of the international market. The Canadian functional food market significantly lags behind markets in the UK, Germany and the US. In 2005, Canadians spent US\$36.70 per capita on fortified/functional packaged foods and beverages whereas this figure was US\$68.60 in the US, US\$82.80 in the UK and US\$138.60 per capita in Japan⁴⁸.

However, domestic demand is expected to increase. Research conducted by Leverus Inc revealed that a 0.5% increase in the share of total spending translates to a \$500 million (20%) increase in the size of the NHP sector at the retail level⁴⁷. Similarly, despite the Canadian market lagging behind other national functional food markets, the government interest in improving the regulatory framework will assist in developing the industry to supply the increasing demand for functional foods. Lewis (2006) estimates that by 2012 the Canadian functional food market value will be 2.9 billion as noted below²⁴⁷.

²⁴⁷ Lewis, H. 2006. *Global Market Review of Functional Foods- Forecasts to 2012*. Just Food. from: <http://www.just-food.com/store/product.aspx?id=44028&lk=pop>.

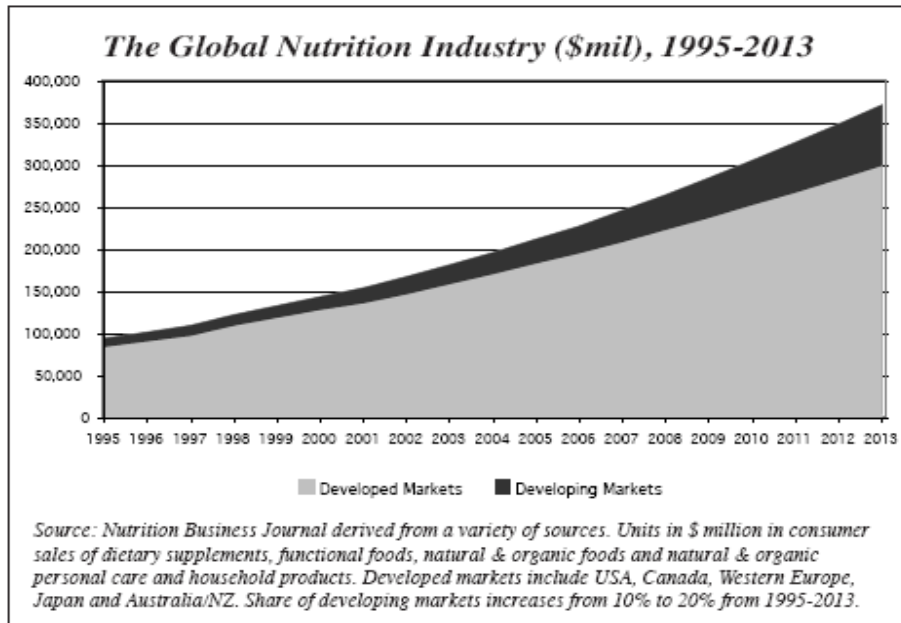
Figure 1: Functional Food Market Value for Canada and the United States, 2000-2012



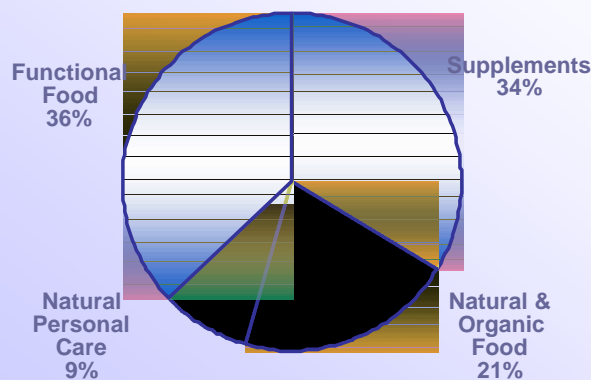
3.2 The Global Market

According to Nutrition Business Journal (NBJ), in 2006 world consumption of NHP (supplements), natural and organic foods, natural personal care and FF was approximately \$ 228 billion U.S.²⁴⁸. This market is dominated by the FF sector at \$85 billion U.S.

²⁴⁸ Nutrition Business Journal. May/June 2007. The Global Nutrition Market. www.nutritionbusiness.com.



Global Nutrition Industry \$228 Billion in Consumer Sales in 2006



The global nutrition industry has grown around 7-9% a year since 1995, or more than twice the rate of the traditional food sector, and forecasts are for continued growth in the 6-8% range to 2013. Functional foods are at various stages of development in different regions. Japan's market based primarily on its regulatory apparatus is well established, for instance, while other developed markets are debating definitions, labeling and dosage standards⁴⁹.

What distinguishes NBJ from other statistical resources is their all encompassing definition of the 'nutrition' industry which comprises not only supplements and foods but also 'personal care products' – a category that includes household cleaners and other in-home natural products. NBJ also uses a broad definition of functional foods to include all foods with a valid health claim, with added ingredients for a health benefit, or marketed or perceived to have a significant health or performance benefit. NBJ data reveals that all areas in the global nutrition arena have experienced growth rates in 2006⁴⁹. As noted below, the “healthier for you” foods area which includes natural/organic and FF dominates. However, the specialty supplement (NHP) category that includes specialty fatty acids, pre-and pro-biotics and fibre continues to grow at an impressive rate.

By Product Category	2005	2006	2006 growth
Vitamins & Minerals	27,020	28,100	4%
Herbs/Botanicals	19,000	19,700	4%
SHM&S Supplements**	19,280	20,470	6%
Total Supplements	65,300	68,270	5%
Natural & Organic Food	49,000	53,780	10%
N&O Personal Care/HH*	18,790	21,270	13%
Functional Food	79,400	85,010	7%
Total Nutrition Sales	212,480	228,320	7%
By Region	2005	2006	2006 growth
USA	77,210	84,950	10%
Europe	60,550	64,240	6%
Japan	36,690	36,620	0%
Canada	5,620	6,150	9%
China	9,030	9,710	8%
Rest of Asia	9,370	10,680	14%
LatAm	5,120	5,790	13%
Aust/NZ	3,700	4,030	9%
EE/Russia	3,080	3,730	21%
MidEast	1,060	1,210	14%
Africa	1,040	1,210	16%
Total Global Market	212,480	228,320	7%

*Source: Nutrition Business Journal derived from a variety of sources. Units in \$ million in consumer sales. *Natural & Organic Personal Care and Household Products **Sports, Homeopathic, Meal & Specialty Supplements. Secondary sources for global data include Euromonitor, United States Commercial Service, IADSA member associations, Mintel, Organic Monitor and many others.*

The primary markets for NHPs and FF are the United States, Europe, Japan and Asia. Canada accounts for 3% of the global market. These regions are, for the most part, characterized by greater levels of economic development and more sophisticated economies. In the case of Asia, historical consumption patterns play a role.

Emerging markets include Eastern Europe and Latin America with 17% and 13% growth, respectively, in 2006. China has been the largest growing market for supplements since

2000 and now generates 10% of global sales. Other developing regions like the Middle East and Asia—where the wealthy are aging and the middle class is expanding—also are posting double-digit growth in supplements. Overall, supplement sales in developing markets will grow from 10% of the global market in 1995 to 20% by 2013⁴⁹.

The United States, Japan and European markets represent over 90% of global sales and are considered by industry experts as the key markets for Canadian food and health products.

The following chart reveals the differences in product breakdown amongst regions in 2003. FF dominate in the US, Europe and Japan. Historical usage patterns of supplements (herbs and botanicals) are apparent in Asian countries.

Table 1: Global Nutrition Industry Sales (\$M): 2003²⁴⁹

	US	Europe	Japan	Canada	China	Rest of Asia	LatAm	Aust/NZ	EE/Russia	MidEst & Africa	GLOBAL
Vitamins & Minerals	8,410	5,900	4,220	580	1,900	1,360	800	600	500	440	24,710
Herbs/Botanicals	4,200	6,220	2,900	400	2,400	1,760	310	360	290	220	19,060
Sport/Meal/Home./Splty.	7,210	2,970	2,960	330	600	1,040	360	340	450	160	16,420
Total Supplements	19,820	15,090	10,080	1,310	4,900	4,160	1,470	1,300	1,250	820	60,200
Natural & Organic Food	16,240	16,290	2,610	1,100	340	930	1,250	780	370	230	40,140
Natural Personal Care	4,920	4,640	2,420	400	900	1,190	430	290	80	100	15,370
Functional Food	22,730	20,710	16,420	2,010	790	1,360	530	840	550	590	66,530
Total Nutrition Industry	63,710	56,730	31,520	4,830	6,940	7,640	3,670	3,210	2,250	1,740	182,240

Projections for the global nutrition market to 2008 indicate steady growth in the areas of functional and natural/organic foods.

²⁴⁹ Anon. NBJ's Raw Material and Ingredient Supply Report. June 2006. Penton Media. San Diego, CA.

Global Nutrition Market Growth 2004-2008 (Annual Average)

Product Category	04-08 growth
Vitamins & Minerals	2-3%
Herbs/Botanicals	1-3%
<u>Sport/Meal/Homeop/Specialty</u>	<u>6-8%</u>
Total Supplements	4-5%
Natural/Organic Food	8-11%
Natural Personal Care	6-10%
<u>Functional Food</u>	<u>6-10%</u>
Total Nutrition Sales	6-9%

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3.3 The Global Functional Food Market

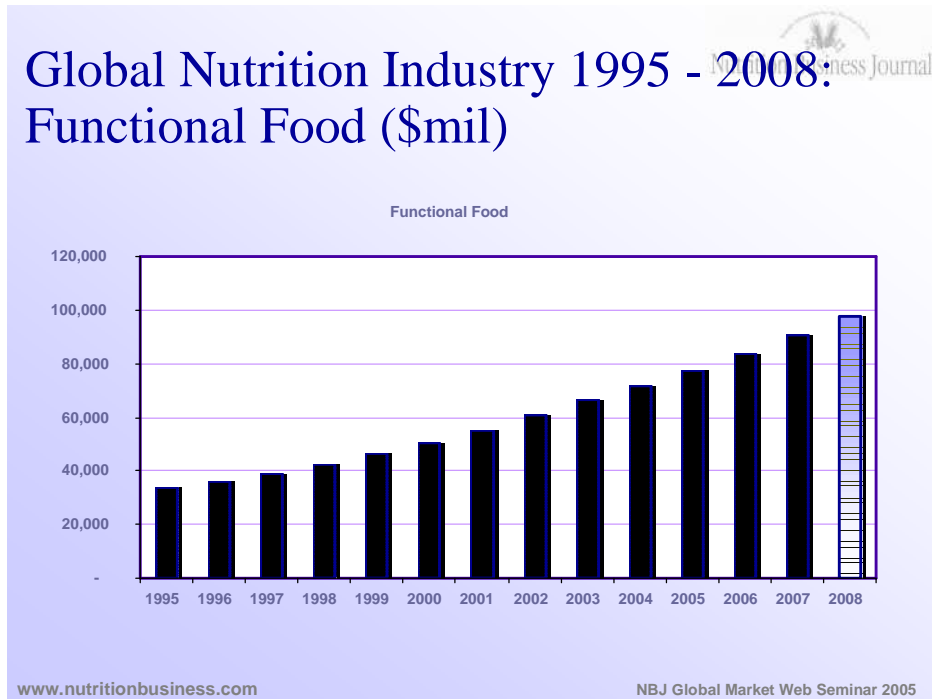
NBJ has valued the 2006 global functional food (FF) market at over \$85 billion dollars up from \$79 billion in 2005⁴⁹. Natural and organic foods are experiencing impressive growth increasing 44% from \$ 24 billion in 2005 to a market value of \$54 billion in 2006⁴⁹.

Segment	USA	Global	% in USA
Supplements	22,460	68,270	33%
Natural & Organic Food	23,600	53,780	44%
N&O Personal Care/HH*	7,490	21,270	35%
Functional Food	31,400	85,010	37%
Total Nutrition Industry	84,950	228,330	37%

*Source: Nutrition Business Journal derived from a variety of sources. Units in \$ million in consumer sales. *Natural & Organic Personal Care and Household Products*

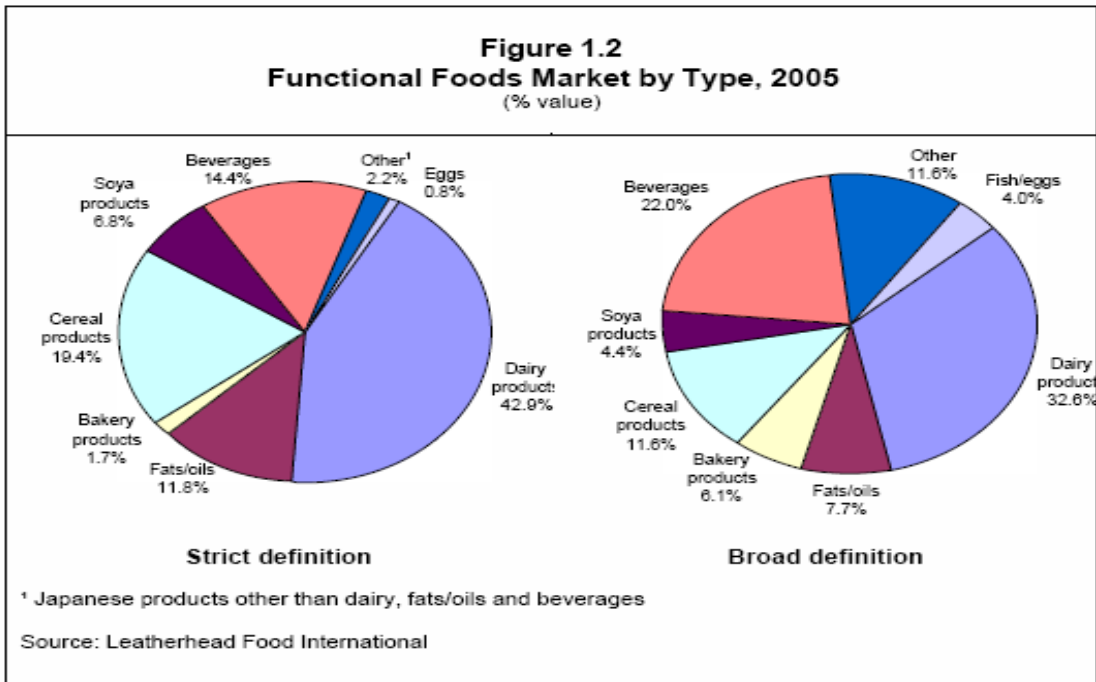
The United States, Europe and Japan are the major markets for FF, capturing approximately 30% each, similar to the overall market capture for total sales in all nutrition categories. The United States is the most dynamic market for FF, with a growth rate of more than triple that of conventional foods at ~9% to 12% per annum.

It is anticipated that, based upon past data, the industry will witness steady and continuous growth to 2008 when projections of sales for FF globally will approach \$95 billion dollars.



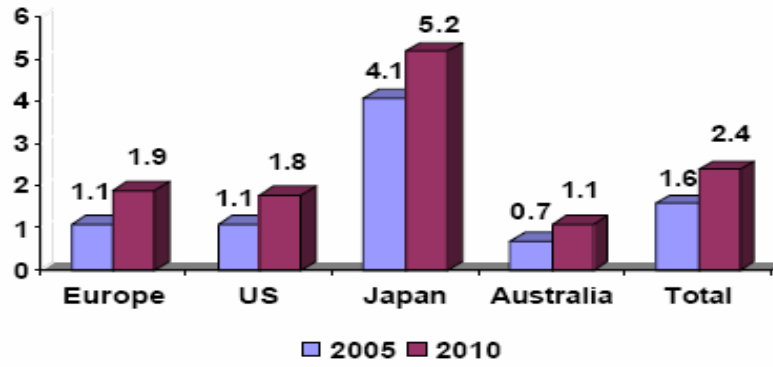
Leatherhead Food International has released 2005 global statistics for the global functional food market²⁵⁰. The company identifies two categories of FF, a “strict definition”, limited to food and drinks that make specific health claims on the packaging or in advertising, and a “broader definition” that includes a wide range of healthy products not necessarily making claims, but often perceived as functional. Their data shows that FF are dominated globally by the dairy sector – with every product line from margarines to milk to ice cream being enriched with bioactive ingredients. Using their broader definition (which is more in line with other statistical organizations) this is followed by beverages, cereals, fats/oils and bakery products as shown below.

²⁵⁰ Leatherhead Food International. June 2006. The International Market for Functional Foods. 3rd edition. ISBN 1 904007-82-1. Surrey UK



Globally, functional foods have penetrated the food and drink markets to various degrees as noted in the following figure⁵¹. Despite all the excitement related to functional foods, a relatively small part of the food and drinks market as a whole has been penetrated by these new products. Japan has the longest experience with functional foods but these products only represent less than 5% of the total food and drink industry. It is anticipated however, that these penetration rates will increase over the next decade and the area will continue to outperform the food and drinks market as a whole.

Figure 1.6
Penetration of Functional Foods in Total Food and Drinks Market
(Broad Definition), 2005-2010
(% Value)



Source: Leatherhead Food International

3.4 The Global Dietary Supplement Market

The global supplement industry reached sales of \$68 billion in 2006 on growth of 5%, according to NBJ⁴⁹. The U.S. market contributed one-third or \$22 billion to the total, followed by Europe at 23% and \$16 billion. Japan was the third largest regional market with declining sales of \$11 billion in 2006.

China (\$6.7 billion) together with the rest of Asia—the largest target of growth for direct marketing companies—accounted for another \$5 billion and supplement growth of 12% in 2006 as strong double-digit growth in vitamins & minerals outpaced more modest gains in herbal & botanical supplements.

<i>Global Supplement Market (\$mil)</i>				
	2005	2006	Growth in 2006	Share in 2006
USA	21,320	22,460	5%	33%
Western Europe	12,940	13,520	4%	20%
Eastern Europe	1,630	1,910	17%	3%
Japan	11,640	11,180	-4%	16%
Canada	1,750	1,820	4%	3%
China	6,300	6,660	6%	10%
Rest of Asia	4,860	5,440	12%	8%
Latin America	2,400	2,700	13%	4%
Australia/NZ	1,440	1,530	6%	2%
Middle East	500	560	12%	1%
Africa	460	490	6%	1%
Global Sales (\$mil)	65,240	68,280	5%	100%

Source: Nutrition Business Journal derived from a variety of sources. Consumer sales in \$mil. Supplements include all vitamins, minerals, herbal & botanical, specialty supplements and homeopathic remedies, even those sold as medicines, plus all sports nutrition and meal replacement products.

Regarding global spending, the Japanese spent \$130 per person per year on nutritional supplement products compared with \$77 per person per year in the US, \$46 for Europeans and an estimated \$3 or so for other Asian countries²⁵¹.

²⁵¹ Paul Yamaguchi & Associates, Inc . Nutritional Supplement Japan Market Report 2005. www.functionalfoods-japan.com.

4.0 MACRO ISSUES IMPACTING THE FOOD and HEALTH SECTOR

Several macro trends are driving the global growth of the functional food and NHP industries and the interest in the area by the research community, governments and consumers. Global macro trends include the increasing prevalence of chronic disease and rising obesity rates, the increasing cost of health care, changes in public policy and the role that science will play in the development of functional foods. An assessment of these trends is important in the determination of opportunities for research, innovation and development of the hemp industry in Canada.

4.1 Disease is the Market Driver of the 21st Century

In the area of health and nutritional products, an identification of the market opportunities for new products must focus on key diseases and their impact over the short and longer term – disease issues are of utmost importance to consumers and hence to the industry that develops consumer ready products.

The upward spiral in the prevalence of diseases such as cardiovascular disease, diabetes and cancer, as well as the emerging awareness of the epidemic of obesity are, and will continue to be, major consumer motivators of the future. Companies around the globe are recognizing and acting on this trend to ensure that they are at the forefront of new product development and consumer interest. PepsiCo, Coca Cola, Kellogg, Bayer Consumer Health, Novartis, DSM, Cargill, Nestle and Kraft are some examples of companies that are reorganizing themselves around disease opportunities (wellness).

When determining market opportunities as related to disease, it is important to assess the total population currently afflicted with, and projected to be affected by, each condition. Opportunities for innovation and product development are in diseases that have large, affected populations and where the disease state can be mitigated through the use of bioactives found in hemp. The majority of emerging and existing diseases that are of prime importance to consumers and governments have several possible nutritional solutions that present opportunities for the industry. These are summarized in this section.

4.2 Disease Drivers

The World Health Organization's 2003 report²⁵² on diet, nutrition and the prevention of chronic disease noted that, "the burden of chronic disease is rapidly increasing worldwide. In 2001, chronic diseases contributed approximately 60% of all deaths worldwide and 46% of the total burden of disease. Almost half of these deaths are from cardiovascular diseases, obesity and diabetes." These three chronic health problems, now classified as the 'metabolic syndrome', are widely considered the plague of developed nations. Increasingly, however, cardiovascular diseases (CVD), obesity and diabetes are also becoming more prevalent in developing countries. The WHO estimates that chronic disease will account for 70% of all deaths worldwide by 2020.

²⁵² WHO Technical Report Series #916, "Diet, Nutrition and the Prevention of Chronic Diseases" 2003.

4.2.1 Obesity

According to the WHO²⁵³, obesity has reached epidemic proportions globally, with more than 1 billion adults overweight and at least 300 million obese. Obesity is defined as a body mass index (BMI) of 30 or greater. BMI is calculated from a person's weight and height and provides a reasonable indicator of body fatness and weight categories that may lead to health problems.

This rapidly growing problem shows no sign of slowing.

Country	20–29	30–39	40–49	50–59	60–69	>70	Total
US	10,008	11,548	13,510	12,288	8,652	7,428	63,4351
Japan	2,981	2,981	2,904	2,828	2,828	8,767	23,2892
France	431	841	1,101	1,095	701	1,301	5,4713
Germany	775	1,893	2,797	2,536	3,277	2,622	13,9004
Italy	297	493	730	967	673	1,175	4,3365
Spain	386	591	933	1,711	539	1,670	5,8306
UK	1,225	1,878	2,122	1,992	1,639	1,627	10,4837
Total	16,102	20,226	24,098	23,418	18,310	24,590	126,744

Note: Obesity defined as BMI > 30

Source: National Health and Examination Survey 1999–2000 (NHANES), Anuurad et al., 2003, Obépi 2003 study, Federal Health Monitoring System, National Institute of Statistics' (ISTAT) Health for All database, Spanish Society for the Study of Obesity's SEEDO 2000 study, Department of Health's Health Survey for England, 2002
Business Insights Ltd

United States

In the United States, an estimated 75% of deaths are related in some way to obesity in people age 70 or younger²⁵⁴. Over the past two decades obesity rates have doubled in adults, and the percentage of children and adolescents who are above their normal weight has doubled and tripled during the same period.

The U.S. Centers for Disease Control and Prevention (CDC)²⁵⁵ indicated that approximately 129.6 million Americans, or 64% of the population, are overweight or obese. The latest data from the National Center for Health Statistics of the CDC show that 30 percent of U.S. adults 20 years of age and older—over 60 million people—are

²⁵³ World Health Organization. February 2003. Global Strategy on Diet, Physical Activity and Health. <http://www.who.int/dietphysicalactivity/publications/facts/obesity/en/>

²⁵⁴ US Centre for Disease Control and Prevention and the National Institutes of Health. April 2005. As reported in Flegal K, Graubard B, Williamson D, Gail M. Excess Deaths Associated with Underweight, Overweight, and Obesity. *JAMA* 2005;293(15):1861-1867.

²⁵⁵ Statistics. 2004. Center for Disease Control and Prevention. <http://www.cdc.gov/nchs/fastats/>.

obese. This increase is not limited to adults. The percentage of young people who are overweight has more than tripled since 1980. Among children and teens aged 6–19 years, 16 percent (over 9 million young people) are considered overweight.

Overweight among children and teenagers contributes to the development of Type 2 diabetes and risk factors for heart disease. Sixty-one percent of overweight 5 to 10 year olds already have risk factors for heart disease, and 26% have two or more risk factors⁴. Several decades may lapse for the effects of this epidemic to appear as health problems in adults. Although one of the national health objectives in the U.S. for the year 2010 is to reduce the prevalence of obesity among adults to less than 15%, current data indicate that the situation is worsening rather than improving. The CDC estimated that 400,000 American deaths (that is 1 out of every 700) were related to eating badly and physical inactivity in 2000.

A recent review of the obesity epidemic in the U.S. reported that in minorities and those of low-socioeconomic-status groups, a disproportionately high level of obesity and overweight is common at all ages²⁵⁶. Annual increases in the prevalence of both obesity and overweight ranged from 0.3 to 0.9 percentage points across all ages, gender, nationality and socioeconomic status. This report supports the observations of previous literature which suggests that obesity has increased at an alarming rate in the United States over the past three decades. Finally, by 2015, it is estimated that 75% of adults will be overweight or obese, and 41% will be obese.

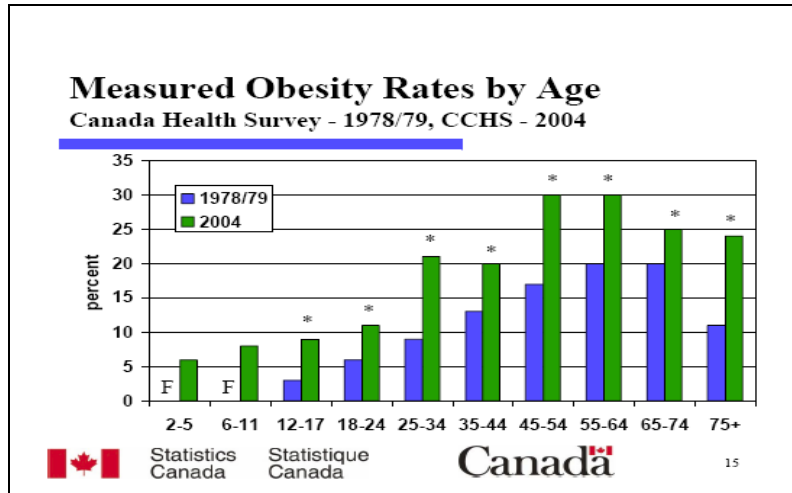
Canada

Canadian obesity rates have increased over the past 25 years, with nearly one-quarter of all Canadian adults now considered seriously overweight, according to Statistics Canada²⁵⁷. In 2004, about 23 per cent of Canadian adults were considered obese, up from 14 per cent in 1978-79. As the chart²⁵⁸ below indicates, the rate of obesity in Canada has increased dramatically since the late 1970's in all age groups.

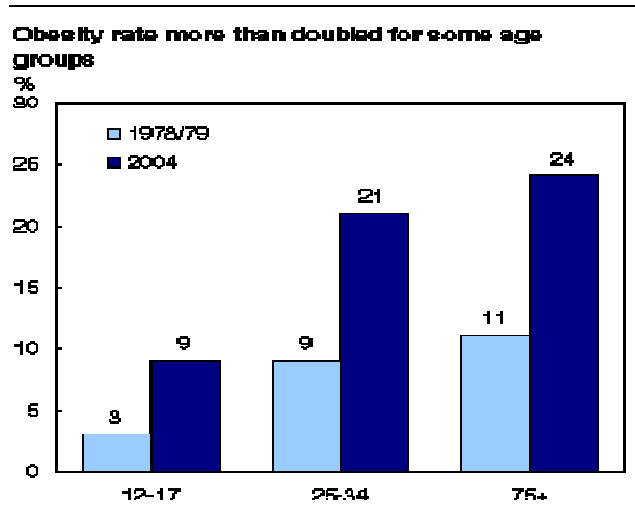
²⁵⁶ Youfa Wang and May A. Beydoun. 2007. The Obesity Epidemic in the United States—Gender, Age, Socioeconomic, Racial/Ethnic, and Geographic Characteristics: A Systematic Review and Meta-Regression Analysis. *Epidemiologic Reviews Advance Access* published May 17.

²⁵⁷ Statistics Canada. July 2005. Canadian Community Health Survey: Obesity among children and adults 2004. <http://www.statcan.ca/english/research/82-620-MIE/82-620-MIE2005001.htm>.

²⁵⁸ Gravel, R., "Canadian Community Health Survey – Cycle 2.2(2004) – Nutrition", Statistics Canada.

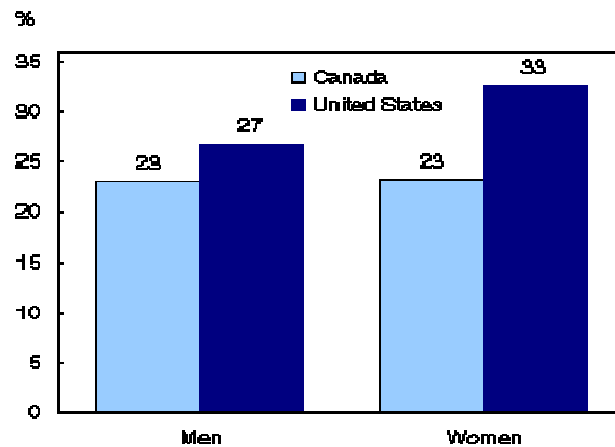


The most striking increase in obesity rates among adults was seen in the 25 to 34 and 75 and older age brackets, where the obesity rates doubled to 21 per cent and 24 per cent respectively as indicated in the following graph.



Most of the differences between Canada and the US in obesity rates are among women - about 23 per cent of Canadian women are obese, compared with 33 per cent of American women.

Canadian adult obesity rates lower than the United States



In Canada, with few exceptions obesity rates did not vary by province, although men in Newfoundland and Labrador and Manitoba were significantly above the national average in 2004. Women in Newfoundland and Labrador, Nova Scotia and Saskatchewan were also above the national average.

Though North Americans have a reputation of being of the most obese in the world, many European countries closely follow. In some countries such as UK, Germany and Spain, rates of obesity are nearly equal to those in the US. Few European countries have obesity rates below 10%, and prevalence rates, particularly among women have risen to more than 20% in countries such as the UK and Germany. In France, the prevalence of obesity has grown from 8.2% in 1997 to 11.6% in 2003²⁵⁹.

The Childhood Obesity Pandemic

Childhood obesity is the pandemic of all pandemics. It will likely be the number one health crisis that society will face in our lifetime. As obesity continues to take a firm hold on society, governments, researchers and the food and pharmaceutical industries are under growing pressure to tackle the issue.

According to the National Health and Nutrition Examination Survey (NHANES) 1999²⁶⁰, the number of overweight children in the United States rose nearly 20 percent in the past decade. One in every four children is now classified as either overweight or at risk for overweight. In the US, only 4% of children were considered overweight in 1982 – a number that had increased to 16% overweight in 1994. In 2001, 25% of all white children and 33% African American and Hispanic children were considered overweight.

In Canada's younger population, obesity rates have more than doubled over the last quarter century. Similarly, 8 per cent of children aged two to 17 fell into the same category. Twenty-five years earlier, just 3 per cent of Canada's children were classified

²⁵⁹ Sadler, J. 2005. Future Health Trends in Foods and Drinks. Business Insight. U.K.

²⁶⁰ Statistics. 2004. Center for Disease Control and Prevention. <http://www.cdc.gov/nchs/fastats/>.

as obese. Among young people, the biggest increases in obesity rates occurred among adolescents aged 12 to 17, where the rate tripled from 3 per cent to 9 per cent. Obesity rates were similar among boys and girls, although trends differed by age groups. The Government of Canada has announced a number of initiatives and specific funding incentives to address several financial, health and societal issues outlined by the Standing Committee of Health in its 2007 report *Healthy Weights for Healthy Kids*²⁶¹.

Recent studies on human life expectancy have projected that because of the obesity pandemic, today's generation of children will be the first group to die younger than their parents.

Impact of Obesity on Disease – the Metabolic Syndrome

Metabolic syndrome is a generic term for a cluster of risk factors that includes hyperinsulinemia, hypertriglyceridemia, obesity and hypertension. The condition has also been called the deadly quartet, syndrome X and insulin resistance syndrome. Obese individuals who accumulate fat mainly in the abdominal area are more likely to exhibit symptoms of metabolic syndrome than those who do not.

4.2.2 Cardiovascular Disease and Heart Health

Cardiovascular disease (CVD) is a blanket term used for a variety of indications including chronic heart failure (CHF), atrial fibrillation (AF), angina and peripheral arterial disease (PAD). Cardiovascular diseases are defined as diseases and injuries of the cardiovascular system: the heart, the blood vessels of the heart, and the system of blood vessels (veins and arteries) throughout the body and within the brain. Stroke is the result of a blood flow problem in the brain. It is considered a form of cardiovascular disease.

The Development of CVD²⁶²

At the core of CVD is the buildup of plaque in arteries, the thick-walled vessels that carry oxygenated blood. Accounting for much of the thickness is a layer of smooth muscle that helps to propel the blood along. The interior vessel wall is lined with endothelial cells, a sort of inside skin. According to the most popular theory, the "response to injury hypothesis," plaque begins with damage to the endothelial layer.

The injured artery lining undergoes a complex series of changes that can narrow the passageways and reduce the flow of blood. Defensive cells attach to the injured walls, secreting growth factors, which attract wound-healing proteins. The smooth muscle layer then expands into the artery and this highly inflammatory process invites the attachment of cholesterol. This is because the injured wall has more cholesterol receptors. The growing mass becomes vulnerable to rupture and the formation of a deadly clot, which if lodged in a narrowed artery that feeds the heart, can halt blood flow and starve a portion of the heart muscle resulting in a heart attack.

²⁶¹ Healthy Weights for Healthy Kids. March 2007. Report to the Parliament of Canada by the Standing Committee on Health.

²⁶² American Heart Association. 2005. www.heart.org

Prevalence of cardiovascular disease

CVD accounts for the death of more Canadians than any other disease. In 2002 (the latest year for which Statistics Canada has data), cardiovascular disease accounted for 78,942²⁶³ Canadian deaths. 35% of all male deaths in Canada in 2002 were due to heart diseases, diseases of the blood vessels and stroke. For women, the toll was even higher – 37% of all female deaths in 2002 were due to cardiovascular disease. 54% of all cardiovascular deaths are due to coronary artery disease; 21% to stroke; 16% to other forms of heart disease such as problems with the electrical system of the heart, viral heart infections, and heart muscle disease, and the remaining 9% to vascular problems such as high blood pressure and hardening of the arteries.

The total cost of heart disease and stroke to the Canadian economy was approximately \$18.5 billion – more than any other disease²⁶⁴.

The US has the highest prevalence of cardiovascular diseases among global nations²⁶⁵. One in 3 adult men and women has some form of CVD²⁶⁶ which has been the primary killer in the U.S. every year but 1918. Nearly 2500 Americans die of CVD each day, an average of 1 death every 35 seconds. CVD claims more lives each year than the next 4 leading causes of death combined, which are cancer, chronic lower respiratory diseases, accidents, and diabetes mellitus. Of the over 71 million American adults with 1 or more types of CVD, close to 28 million are estimated to be age 65 or older.

Coronary heart disease (CHD), the main type of CVD and the number one cause of death in the U.S., is a major cause of disability among men and women in the prime of life. The American Heart Association has identified that 13 million Americans (6.9 percent of the population) suffer from CHD, with men experiencing their first heart attack at the average age of 65.8 years and women at 70.4 years. CHD caused 1 of every 5 deaths in the United States in 2003 and is the *single* largest killer of American males and females. About every 26 seconds an American will suffer a coronary event, and about every minute someone will die from one. About 40% of the people who experience a coronary attack in a given year will die from it.

Risk Factors for Cardiovascular Disease

The risk factors for CVD are complex. What causes the original injury is uncertain, but risk factors such as smoking, elevated blood pressure and high blood cholesterol are the usual suspects. Risk factors are perceived as individual contributors, but frequently risk factors are clustered.

The American Heart Association (AHA) has indicated that the three key risk factors for heart disease are (in order) elevated cholesterol levels, high blood pressure and diabetes. High levels of risk associated with obesity and low-grade inflammation (as

²⁶³ Statistics Canada, Causes of Death 2002. Released 2004.

²⁶⁴ Health Canada. Economic Burden of Illness in Canada, 1998.

²⁶⁵ Heart Association Statistics Committee and Stroke Statistics Subcommittee Heart Disease and Stroke Statistics--2006 Update. A Report From the American Members of the Statistics Committee and Stroke Statistics Subcommittee. 2006. Circulation. February.

<http://circ.ahajournals.org>

²⁶⁶ NHANES 1999–02. Center for Disease Control. American Heart Association. www.aha.org.

measured by the inflammatory marker C-reactive protein) have recently gained widespread medical acceptance as recognized risk factors for CVD.

4.2.3 Diabetes

Diabetes is a term that is used to describe symptoms involved with various degrees and forms of insulin resistance. There are two types of diabetes -Type 1 and Type II. Type 1 diabetes occurs most often in children or young adults and accounts for 5–10% of the diagnosed diabetes patient population. Type 1 is thought to be the result of an autoimmune attack on the body's own pancreatic cells, resulting in failure of the pancreas to produce an adequate amount of insulin to aid glucose absorption. Type 2 diabetes, previously called non-insulin-dependent diabetes mellitus (NIDDM) or adult-onset diabetes, accounts for 90–95% of diagnosed diabetes cases worldwide and typically develops in middle-aged adults. Unlike type 1 patients, pancreatic beta-cells in type 2 patients are able to produce insulin. However, there is an inability of tissue to respond to the effects of the insulin, which ultimately results in high levels of blood glucose.

Prevalence of Diabetes

There are currently more than 246 million people with diabetes worldwide and at least 50% of all people with diabetes are unaware of their condition. By 2025, it is estimated that this number will rise to over 380 million. Diabetes is the fourth main cause of death in most developed countries and is the leading cause of blindness and visual impairment in adults²⁶⁷. From 1935 to 1996, the prevalence of diagnosed type 2 diabetes climbed nearly 765%²⁶⁸.

United States

The number of Americans with diabetes had risen to 20.8 million in 2005 or 7% of the U.S. population²⁶⁹, 1.5 million new cases from 2004. Individuals with metabolic syndrome (obesity, CVD and/or diabetes symptoms) are estimated to number over 50 million²⁷⁰. The prevalence of adult obesity increased 57% in the brief period between 1991 and 1999, and currently over 60% of US adults are overweight²⁷¹. These increases cannot be explained by the aging of the population alone, as similar increases are also being seen in US children²⁷².

²⁶⁷ International Diabetes Federation. 2007 Facts and Figures. <http://www.idf.org/>.

²⁶⁸ Centers for Disease Control and Prevention. 1997. Division of Health Interview Statistics. Census of the population and population estimates.

²⁶⁹ American Diabetes Association. 2005 statistics: Total Prevalence of Diabetes & Pre-diabetes. <http://www.diabetes.org/diabetes-statistics/prevalence.jsp>

²⁷⁰ Ford, E.S., Giles, H.W., and Dietz, W.H. 2002. Prevalence of the metabolic syndrome among US adults: findings from the Third National Health and Nutrition Examination Survey. *JAMA*; 287:356-9.

²⁷¹ Mokdad, A.H., Serdula, M.K., Deitz, W.H., et al. 1999. The spread of the obesity epidemic in the United States, 1991-1998. *JAMA*; 282:1519-22.

²⁷² American Diabetes Association. Consensus Statement. 2000. Type 2 diabetes in children and adolescents. *Diabetes Care*. 23:381-9.

An estimated 54 million Americans have 'pre-diabetes', or impaired glucose tolerance, in which blood sugar levels are higher than normal and lead to high risk of developing type 2 diabetes.

The prevalence of diabetes in younger generations is also increasing. In 2005, about one in every 400 to 600 children and adolescents had type1 diabetes.

Obesity is a major risk factor for type 2 diabetes. The incidence of diabetes is 2.9 times higher in overweight than in non-overweight subjects between the years of 20 and 75²². Studies have shown that the relative risk of diabetes increases by approximately 25% for each additional unit of BMI over 22.

The US has the highest prevalence of diabetes, as indicated in the chart below. Disease rates are increasing in Germany, Italy and the UK. In Europe, Spain has the lowest prevalence of diabetes and is expected to remain the lowest to 2011²⁷³.

Table 1.2: Future prevalence of type 2 diabetes, 2003-2011						
Prevalence (m)	2003	2005	2007	2009	2011	CAGR (%)
US	16.2	17.3	18.6	20.0	21.5	3.6
Japan	6.6	7.0	7.4	7.9	8.4	3.0
France	2.4	2.5	2.7	2.8	3.0	3.0
Germany	3.5	3.7	4.0	4.3	4.6	3.6
Italy	4.0	4.3	4.6	5.0	5.4	3.6
Spain	2.0	2.1	2.2	2.4	2.5	3.0
UK	2.1	2.2	2.4	2.6	2.7	3.6
Total	36.7	39.2	41.9	44.9	48.1	3.4
Source: Business Insights, WHO; Gale, 2002; Janka, 2002						Business Insights Ltd

Canada

Currently in Canada, over 2 million Canadians have diabetes, up from 722,491 in 1995²⁷⁴. Approximately 80% of people with diabetes will die as a result of heart disease or stroke. Diabetes is a contributing factor in the deaths of approximately 41,500 Canadians each year. Canadian adults with diabetes are twice as likely to die prematurely, compared to persons without diabetes. For example, a Canadian with diabetes is four times as likely to die at age 35 than a 35-year-old without diabetes. Life expectancy for people with type 1 diabetes may be shortened by as much as 15 years. Life expectancy for people with type 2 diabetes may be shortened by 5 to 10 years.

²⁷³ Sadler, J. 2005. Future Health Trends in Foods and Drinks. Business Insight. U.K.

²⁷⁴ Canadian Diabetes Association. 2005 statistics. The prevalence and costs of diabetes. http://www.diabetes.ca/Section_About/prevalence.asp

4.2.4 Inflammatory Disorders

Inflammation is part of the normal host response to infection and injury²⁷⁵. However, excessive or inappropriate inflammation contributes to a range of acute and chronic human diseases and is characterized by the production of inflammatory cytokines, AA derived eicosanoids (prostaglandins, thromboxanes, leukotrienes, and other oxidized derivatives), other inflammatory agents (eg, reactive oxygen species), and adhesion molecules. When inflammation occurs in an uncontrolled or inappropriate manner, excessive damage to host tissues and disease can ensue. High concentrations of TNF-alpha, IL-1beta, and IL-6 are particularly destructive and are implicated in some of the pathologic responses that occur in chronic inflammatory diseases such as rheumatoid arthritis and inflammatory bowel disease.

Prevalence of Inflammatory Disorders

The most common form of inflammatory is rheumatoid arthritis (RA) which affects more adults than cancer, heart disease, respiratory conditions and spinal cord trauma. Arthritis is a term used to describe more than 100 different conditions that affect joints, as well as other parts of the body. Arthritis is one of the most prevalent chronic health problems and the leading cause of disability in North America.

As the leading cause of disability in Canada today, more than 600,000 Canadians with RA are unable to work. More than four million Canadians are affected by RA. As the baby boomer population ages, one million more Canadians per decade will be diagnosed with arthritis, at least until 2031. Of the more than 40,000 hip and knee replacements done in Canada in 2000/01, over 80% had arthritis related diagnosis.

According to the 2000 Canadian Community Health Survey (CCHS)²⁷⁶, arthritis and other rheumatic conditions affected nearly 4 million Canadians aged 15 years and older – approximately 1 in 6 people. Two-thirds of those with arthritis were women, and nearly 3 of every 5 people with arthritis were younger than 65 years of age. By the year 2026, it is estimated that over 6 million Canadians 15 years of age and older will have arthritis.

In 2002, 66 million Americans reported arthritis or chronic joint symptoms and 23 million (11 percent) had chronic joint symptoms or possible arthritis²⁷⁷. As the population ages, the number of U.S. adults with doctor-diagnosed arthritis is projected to increase from 42.7 million in 2002 to 64.9 million in 2030.

4.3 Aging Demographics

United States

The boom in births during an 18-year period post World War II (1946-1964) created a generation of 78 million “baby boomers” in the United States that now represent the

²⁷⁵ Calder, PC. 2006. n-3 Polyunsaturated fatty acids, inflammation, and inflammatory Diseases. *Amer. J. Clin. Nutr.* 83(S):1505-19.

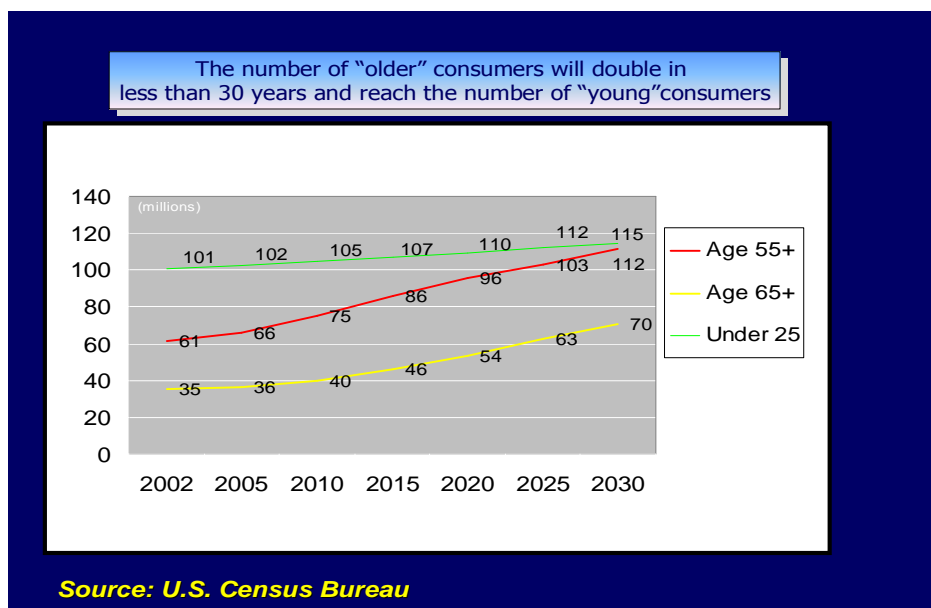
²⁷⁶ The Burden of Arthritis in Canada: Mortality, Life Expectancy and Health-Adjusted Life Expectancy (HALE), Economic Burden. 2000. CCHS.

²⁷⁷ CDC. Prevalence of disabilities and associated health conditions among adults – United States, 1999. *MMWR* 2001; 50: 120 – 5

largest consumer group. This group, in many circumstances has a generally high disposable income. In the United States, baby boomers represent an aggregate annual income of 4.1 trillion dollars and constitute a significant market opportunity for the food and beverage industry. Boomers are currently 42 to 60 years old and by the year 2020 one-quarter of them will be over 60 years old²⁷⁸.

The needs and wants of this large group of consumers represents a significant global market of at least 1.4 billion people and more than 2 billion consumers, if one includes the children in their households. The vast majority of the world's baby boomer generation lives in Asia. In fact, there are more baby boomers in Asia than in all of Europe, North America and South America combined.

During the 20th century, the number of Americans age 65 years and above increased 1100%. By the year 2035, it is estimated that 70 million people will be in this age bracket²⁷⁹. By 2010, the number of people over 50 years old will increase by 48%; in contrast, the group aged 13-24 years will increase by only 16%. As presented in the following graphic, the number of individuals over the age of 55 will be more than that of those 25 years and younger.



Data from Europe show similar trends as in the U.S²⁸⁰.

²⁷⁸ Chaudhari, R. June 2006. Fortifying Foods for the Baby Boomer Market - Technical Paper. FloriTech Ingredients.

²⁷⁹ U.S. Census Bureau. 2005. Population Estimates. <http://factfinder.census.gov/>

²⁸⁰ Sadler, J. 2005. Future Health Trends in Foods and Drink. Business Insight Ltd.

Millions	Men			Women		
	2003	2008	2003-2008 CAGR	2002	2007	2002-2007 CAGR
France	9.1	9.9	1.6%	11	11.8	1.7%
Germany	13.5	14.6	1.5%	16	17.1	0.8%
Italy	9.7	10.2	1.1%	12	12.3	0.8%
Netherlands	2.4	2.7	2.0%	3	3	1.6%
Spain	6.2	6.5	1.2%	7	7.8	1.1%
Sweden	1.5	1.6	1.0%	2	1.8	0.8%
UK	9.2	9.8	1.2%	11	11.3	0.8%
Other Europe	10.2	11.3	2.0%	12	13	1.8%
Europe overall	61.9	66.6	1.5%	74	78	1.0%
US	37.6	43.0	2.7%	41	43.4	1.0%
Overall	99.5	109.6	2.0%	115	121.4	1.0%

Source: Business Insights Business Insights Ltd

Canada

As with other Western countries, Canada faces the difficult and ongoing policy challenge of ensuring the future financial sustainability or integrity of its health care system as it deals with an aging of its demographic.

In a recent Conference Board of Canada report, "The Future Cost of Health Care in Canada, 2000 to 2020: *Balancing Affordability and Sustainability*", the significance of the aging of the population was highlighted²⁸¹. The report provided the following observations:

- Public health expenditures are projected to rise from 31 per cent in 2000 to 42 per cent by 2020 as a share of total provincial and territorial government revenues.
- The proportion of Canadians over the age of 55 will rise from 22 per cent of the population to 32 per cent by the year 2020 – an increase of 10 percentage points.
- Total per capita expenditures for those currently aged 55 to 64 are expected to double over the next two decades.
- Public health care costs will post an average annual growth of 5.2 per cent over the 2000 to 2020 period. Of this growth, 1.7 percentage points can be attributed to demographics (0.9 per cent due to the ageing population, and 0.8 per cent due to population growth). Private health care costs will increase, on average, by 5.0 per cent over the same period.
- Adjusting for inflation, public per capita spending on health care is projected to increase by 58 per cent, while public per capita spending on all other government

²⁸¹ G.G. Brimacombe, P. Antunes, J. McIntyre. 2005. "The Future Cost of Health Care in Canada, 2000 to 2020: *Balancing Affordability and Sustainability*". The Conference Board of Canada.

- services will increase by 17 per cent over the forecast period.
- In the aggregate, total provincial and territorial public and private health expenditures as a percentage of GDP are projected to increase from 8.7 per cent to 10.2 per cent over the forecast period.

The Conference Board points to at least two critical factors that will contribute to the rise in overall provincial and territorial health care expenditures including the significant rise in the number of seniors; and more than 50 per cent of a person's lifetime health care expenditures occur after the age of 65.

The cost of treating baby boomers in 2000 was \$1,063 per person in real public terms (in 1992 dollars). At the same time, the cost of treating the current 55–74 year-old age cohort—where the baby boomers will be in 13 years—is about \$3,100. Looking ahead to 2020, older age cohort would cost \$4,049 per person. Accounting for the impact of inflation, the cost of treating the baby boomers in 2020 will climb to \$6,718 per person.

The authors of this report stress that it covers only the period to 2020. At that time, those at the tail end of the baby boom, who represent the largest portion of this cohort, will just be reaching their most expensive health care years. Obviously, the strains and competition for resources will not end in 2020. In fact, perhaps the biggest problems will be seen after the current forecast period ends.

According to Statistics Canada and reported by Agriculture and Agri-Food Canada²⁸², by 2016, about 44% of the Canadian population will be 45 years of age or more.

4.4 Rise in Health Care Costs

Currently in North America, more than 75% of those over 65 years old suffer at least 1 chronic disease whereas 50% have at least 2, a situation that imposes a tremendous burden on the health care system²⁸³. An increase in disease incidence leads to overall increases in the cost of health care.

In the US, healthcare costs were \$1.9 trillion in 2004, a 7% increase from 2003, and are projected to reach \$3.1 trillion by 2012 – or 17.7% of GDP²⁸⁴. Spending by private health insurance has increased 10 fold since 1987. Costs increased from \$3.6 billion in 1987 to \$36.5 billion on obesity-linked illnesses in 2002. Total health care spending on obesity in 1987 was 2% compared to 11.6% in 2002⁴². The rise in treated disease prevalence, rather than the rise in spending per treated case, was the most important determinant of spending growth.²⁸⁵

Canada continues to rank among the world's top ten health spenders when compared to other countries in the Organization for Economic Co-operation and Development (OECD). Among 23 countries with similar accounting systems, the U.S. maintained its

²⁸² Agriculture and Agri-Food Canada. 2005. Canadian Consumer Trends. Food Value Chain Bureau. http://www.agr.gc.ca/misb/fb-ba/index_e.php?s1=cons&page=intro.

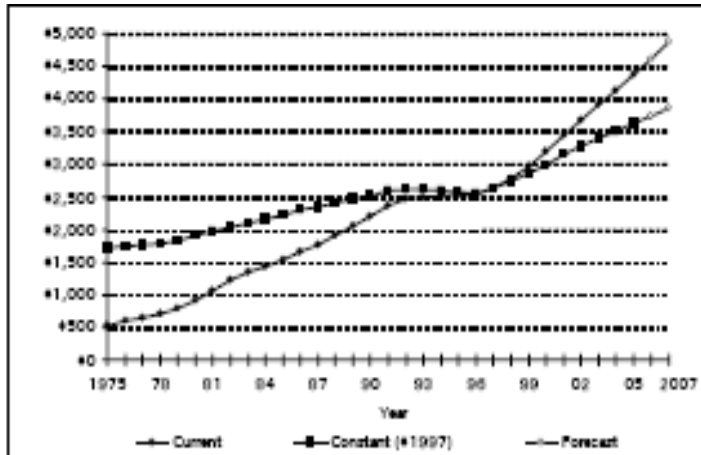
²⁸³ Sadler, J. 2005. Future Health Trends in Foods and Drink. Business Insight Ltd.

²⁸⁴ *Health, United States*. 2007 annual report on trends in health statistics. <http://www.cdc.gov/nchs/fastats/>

²⁸⁵ Thorpe, KE, Florence, CS, et al. June 27, 2005. ***The Rising Prevalence Of Treated Disease: Effects On Private Health Insurance Spending***. Health Tracking Trends.

rank as the highest per capita spender on health care (U.S. \$6,401) in 2005, the latest year for which data are available. Canada ranked eighth in per capita spending (U.S. \$3,326)²⁸⁶.

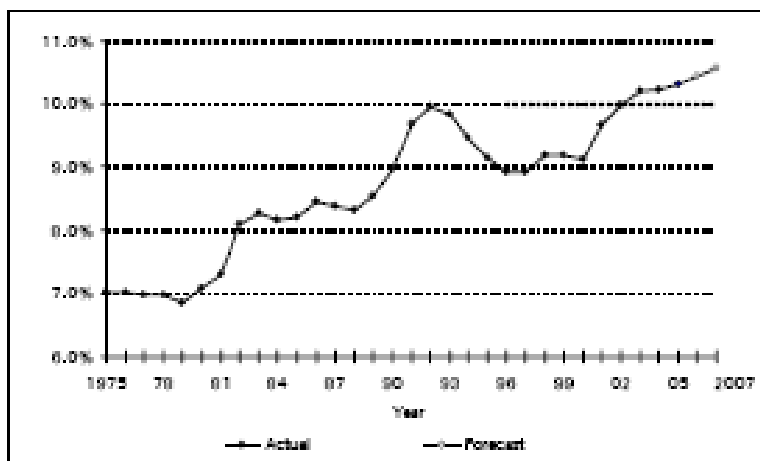
Figure 2: Total Health Care Expenditure per capita, Canada – 1975 – 2007



Source: National Health Expenditure Database, CIHI.

Total health expenditure in Canada was 10.3% of Gross Domestic Product (GDP) in 2005. It is forecast to be 10.6% in 2007, reflecting relatively higher growth in total health expenditure than GDP (Figure).

Figure 3: Total Health Expenditure as a percent of Gross Domestic Product, Canada – 1975 – 2007

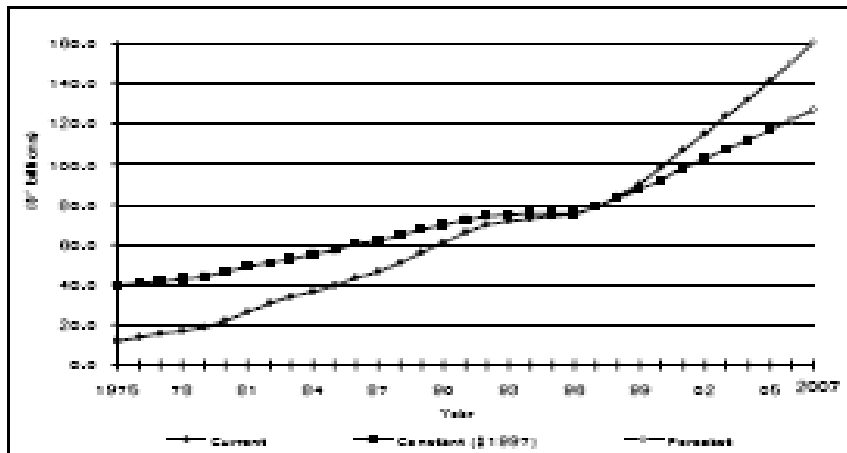


Sources: National Health Expenditure Database, CIHI; GDP, Statistics Canada.

²⁸⁶ Canadian Institute for health Information. 2007. National Health Expenditure Trends – 1975 – 2007.

Total health expenditure in Canada, in current dollars, was estimated at \$141.2 billion in 2005, and is forecast to have reached \$150.3 billion in 2006 and \$160.1 billion in 2007.

Figure 4: Total Health Care Expenditure, Canada – 1975 – 2007



Source: National Health Expenditure Database, CIHL.

After adjusting for inflation, health care spending grew at an average annual rate of 3.8% between 1975 and 1991. From 1991 to 1996 total spending on health care edged up by the rate of 0.8% per year. It increased by 5.0% from 1996 to 2005. Real growth in health care spending in Canada is expected to be 4.0% in 2006 and 4.1% in 2007.

Since 1997, the public sector share of total health expenditure has remained relatively stable at around 70%. It accounted for 70.1% of total expenditure in 2005 and is forecast to account for 70.3% in 2006 and 70.6% in 2007.

With health costs reaching epic proportions, and the staggering rise in the prevalence of diseases that can be prevented by early intervention, it is not surprising that many governments are considering implementing policies to improve the health of their populations – many such strategies involve dietary intervention.

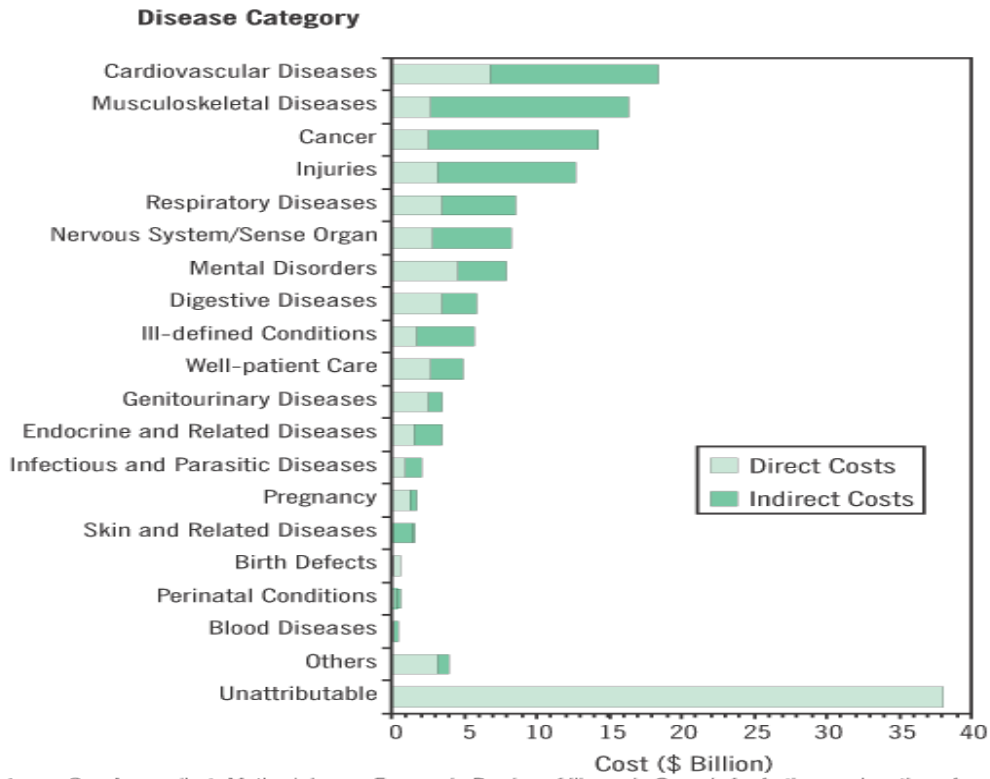
4.5 The Cost of Disease

Chronic disease accounts for a significant portion of health care costs and this is growing. In Canada, cardiovascular diseases, diabetes and cancer combined cost the Canadian economy close to \$60B annually⁴². As a specific example, Canada's health care burden is expected to increase as a result of obesity. The direct cost of obesity to Canada's health care system is estimated to be \$1.8B.²⁸⁷

The breakdown of indirect versus direct expenditure due to various diseases is identified below. Although this data is from 1998, the trends in disease expenditures continue to today.

²⁸⁷ <http://www.medicalnewstoday.com/medicalnews.php?newsid=10170> [sourced: January 26, 2007]

Figure 12.1
Economic Burden of Illness by Disease Category, Canada, 1998



Note: See Appendix 1: Methodology – *Economic Burden of Illness in Canada* for further explanation of assumptions calculations. Based on a total cost of \$159.4 billion .
Source: *Economic Burden of Illness in Canada 1998*, Health Canada

4.5.1 Cardiovascular Disease

The cost of cardiovascular diseases and stroke in the United States for 2006 is estimated at \$403.1 billion²⁸⁸. This figure includes direct cost health expenditures (physicians and other professionals, hospital and nursing home services, the cost of medications, home health care and other medical durables) and indirect cost (loss of productivity resulting from morbidity and mortality indirect costs).

According to Health Canada's 1998 report, *Economic Burden of Illness in Canada*, cardiovascular diseases costs the Canadian economy over \$18 billion a year²⁸⁹. In the U.S., the estimated direct and indirect cost of CVD for 2006 is \$403.1 billion. In 2006, the estimated direct and indirect cost of CHD is \$142.5 billion²⁹⁰.

It is very likely that the financial impact of cardiovascular health issues will become even greater in years to come. As the population ages, the incidence of cardiovascular disease and stroke will continue to increase and the rise in obesity and diabetes will continue to quicken the rate of cardiovascular decline.

4.5.2 Diabetes

In the United States, the total annual economic cost of diabetes in 2002 was estimated to be \$132 billion²⁹¹. Direct medical expenditures totaled \$92 billion and comprised \$23.2 billion for diabetes care, \$24.6 billion for chronic diabetes-related complications, and \$44.1 billion for excess prevalence of general medical conditions. Indirect costs resulting from lost workdays, restricted activity days, mortality, and permanent disability due to diabetes totaled \$40.8 billion.

The per capita annual costs of health care for people with diabetes rose from \$10,071 in 1997 to \$13,243 in 2002, an increase of more than 30%⁵⁰. In contrast, health care costs for people without diabetes amounted to \$2,560 in 2002. One out of every 10 health care dollars spent in the United States is spent on diabetes and its complications.

The financial burden of diabetes and its complications on the Canadian healthcare system is also significant. The personal costs of diabetes may include a reduced quality of life and the increased likelihood of complications such as heart disease, stroke, kidney disease, blindness, amputation and erectile dysfunction. Approximately 80% of people with diabetes will die as a result of heart disease or stroke²⁹².

²⁸⁸ American Heart Association's Heart and Stroke Statistical Update – 2006.
<http://www.americanheart.org/presenter.jhtml?identifier=3038611>

²⁸⁹ Public Health Agency of Canada, *Economic Burden of Illness in Canada*, 1998. Released 2002

²⁹⁰ Heart Association Statistics Committee and Stroke Statistics Subcommittee Heart Disease and Stroke Statistics--2006 Update. A Report From the American Members of the Statistics Committee and Stroke Statistics Subcommittee. 2006. *Circulation*. February.
<http://circ.ahajournals.org>

²⁹¹ American Diabetes Association. 2005 statistics: Direct and indirect costs of Diabetes in the United States. <http://www.diabetes.org/diabetes-statistics/cost-of-diabetes-in-us.jsp>

²⁹² Canadian Diabetes Association. 2005 statistics. The prevalence and costs of diabetes.
http://www.diabetes.ca/Section_About/prevalence.asp

A person with diabetes incurs medical costs that are two to three times higher than that of a person without diabetes and can face direct costs for medication and supplies ranging from \$1,000 to \$15,000 a year. Diabetes and its complications cost the Canadian healthcare system an estimated \$13.2 billion every year. By 2010, it's estimated these costs will rise to \$15.6 billion a year and by 2020, \$19.2 billion a year⁵¹.

The Canadian Diabetes Association argues in their report that all Canadians would benefit from a national plan because there would be fewer long-term diabetes-related complications requiring treatment by the health-care system. These complications include heart and kidney disease, blindness and limb amputation.

4.5.3 Inflammation

In 1998, estimates placed the economic burden of arthritis at \$4.4 billion and \$17 billion annually in health care expenses and lost workdays. In 2004, it was estimated that arthritis cost the U.S. economy \$86.2 billion annually²⁹³.

²⁹³ CDC (2004) Update: Direct and Indirect Costs of Arthritis and Other Rheumatic Conditions -- United States, 1997. MMWR Morb Mortal Wkly Rep, 53: 388-389

5.0 PRODUCT TRENDS

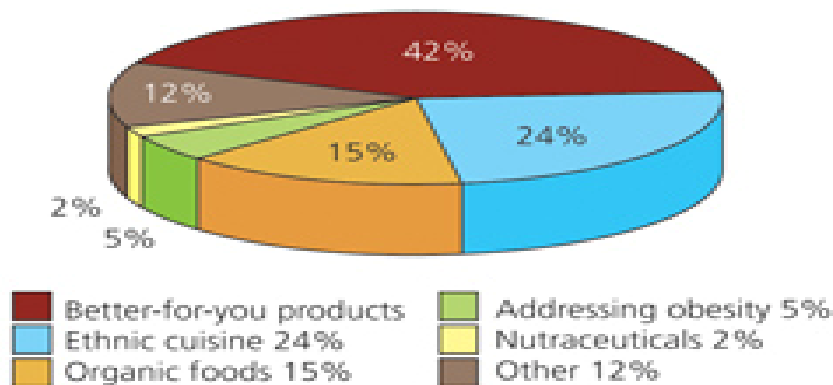
As the cost of health care continues to rise in concert with the prevalence of chronic diseases, consumers and governments are searching for solutions. Food companies are well aware of this trend and are working hard to be ready to respond to consumer needs – leading to some interesting product trends.

5.1 Multinationals Shift Focus to Health and Wellness

Formulating foods for health is one of the leading trends in the food industry. Foods that deliver a well-recognized health benefit to consumers have been a significant market opportunity for many years, as supported by the fact that during the 2000s the market for healthy foods has grown by 10 - 20% yearly²⁹⁴. This growth is in stark contrast to wholesale food prices, which for the 11-month period between January 1 and December 1, 2006, grew at a very slow rate, of less than 2%.

A survey of 100 top global food executives reported that the development of more healthful products, as well as higher quality products, were among their primary new product development focus²⁹⁵. This study by Grant Thornton identified healthful foods as the primary growth market. As indicated in the following chart, nearly two-thirds of survey respondents (64 percent) noted their company's greatest growth in the next year will come via products identified as better-for-you. Respondents also say people are willing to pay more for higher quality food.

Which product areas offer your company the greatest growth potential over the next year?



While the summary report combines those components into “healthier foods,” not all the specific categories scored highly. As the chart shows, organics were identified as key by 15 percent, “addressing obesity” by 5 percent and nutraceuticals (NHP) by 2 percent.

²⁹⁴ Nutrition Business Journal. 2006. Annual Industry Overview 2006.

²⁹⁵ Grant Thornton 2005 Survey of U.S. Food & Beverage Companies. 2005. Food Processing Magazine. www.foodprocessing.com

The most recent 2007 Grant Thornton survey confirms an industry focus on healthier foods²⁹⁶. Again, the “better for you” category was the food group that offered the most potential for revenue growth, reported by 54 percent of firms (up from 42 percent in last year’s survey). Organic foods were cited by 44 percent of firms (up from 15 percent in the previous survey) and high-end/premium foods (a new category on this year’s survey) were reported by 43 percent.

Food companies are aware of the fact that media attention has amplified consumer health awareness, as has the widening availability of health data in the public realm. Across most markets, there has been an increased level of information from health authorities and the media on nutrition and the link between diet and health. This has created a more educated, but often more confused, consumer. Further, ongoing research has led to a number of discoveries of ingredients with health properties, which has been the basis for a huge surge in the functional foods market.

With food markets across the world increasingly competitive, dominated by an ever-smaller number of global companies and subject to discounting from private label, profit margins are falling. This has forced food manufacturers to develop health and wellness products as a means of differentiating their products and boosting flagging margins.

According to Julian Mellentin, the idea of functional foods as some special separate category of foods with added health benefits is becoming redundant as many “everyday foods” – from oats and olive oil to tea, cranberry juice and almonds – are being successfully marketed on their intrinsic health benefits. Mellentin is one of the world’s global specialists in the business of food, nutrition and health. In his recent publication²⁹⁷ “*10 Key Trends in Food, Nutrition and Health for 2008*”, Mellentin presents a convincing argument that health and nutrition have now become firmly established as factors that every company must take into consideration. Delivering a positive contribution to public health has become an everyday strategic necessity for any company that wants to thrive in the future. Increasingly, manufacturers are using the concept of health and wellness as a marketing strategy to alter public perception of their brand’s health benefits.

The world’s largest food and drink companies including Coca-Cola, Pepsi, Kraft, Nestlé, Unilever and Kellogg and fast-food chains like McDonald’s and Kentucky Fried Chicken are all delivering healthier foods and beverages. In response, suppliers of ingredients such as omega-3s, sterols and stanols, protein and fruit extracts as well as fat, sugar and salt alternatives are increasing their supply to this sector.

General Mills²⁹⁸ for example, are actively re-positioning its product portfolio in three areas of priority - weight management, heart health and 'proactive health'. The firm, a \$13.4 billion global packaged food leader, said its strategic advantage in the field of [health and wellness](#) is its portfolio which includes whole grains, probiotics, prebiotics, omega 3, and more vegetables, while at the same time reducing the salt content.

²⁹⁶ Grant Thornton 2007 Survey of U.S. Food & Beverage Companies. 2007. Food Processing Magazine. www.foodprocessing.com

²⁹⁷ Mellentin, J. January 2008 “*10 Key Trends in Food, Nutrition and Health for 2008*”. New Nutrition Business. The Centre for Food & Health Studies. Crown House, London, UK.

²⁹⁸ Belton, M. 2007. General Mills Interview. FoodNavigator-USA.com. August 28.

Kraft has identified the main factors driving its product development as an ageing population, rising obesity rates, nutrient deficiency and consumer demand²⁹⁹. Kraft Foods, one of the world's largest food and beverage companies with annual revenues of more than \$34 billion, have over 500 health and wellness products in the US which are growing two to three times faster than the rest of our products.

Ingredients suppliers have significant challenges when working with food manufacturers incorporating functional ingredients into foods – an important lesson for Canadian hemp. Collaborations between food companies and ingredients suppliers are becoming increasingly critical.

Food manufacturers have very high expectations from ingredients suppliers — regulations, formulation, marketing and product specific challenges such as shelf life studies, third-party advice on product development and science-based communications.

Health is truly is the future of foods and in fact many believe that all foods are fast becoming functional.

5.2 “All Natural”

The terms “all-natural” and “naturally healthy” are popular among marketers to describe a food’s health benefits. To some consumers the word “natural” is synonymous with “healthy”. The term also implies that the health benefit is intrinsic to the product and not the result of added ingredients.

The reformulation of foods so that they can be described as “all natural”, and the marketing of natural health benefits, has accelerated rapidly over the last two years and today these are the most commonly adopted strategies in the business of food and health worldwide.

Of relevance to hemp, the following types of brand communications are used to identify “health” to consumers:

- Free-from wheat/gluten/soy/dairy/lactose
- Free-from artificial additives/preservatives/colors/ trans fats
- Organic
- All-natural
- Contains only natural ingredients
- No unnatural ingredients
- Naturally high in fibre/ antioxidants
- Non GMO

The popularity of the idea of “naturally healthy” means that consumers have options when seeking “health”. As a result, functional foods with added science-based ingredients (such as omega 3 or sterols) do not exist in isolation. No matter how good the science, direct competition exists with any food or supplement that can offer the same health benefits in a way that can be perceived as “all natural”. Most natural foods such as olive oil, pomegranate juice and oats have a benefit that science-based ingredients do not have – a coherent and widely accepted naturally healthy image.

²⁹⁹ Friedmann, L. 2007. Kraft Interview. FoodNavigator-USA.com. August 29.

Research conducted by New Nutrition Business (NNB) has indicated that three messages appeal to consumers³⁰⁰:

1. An absence of anything “bad” that results in a “natural food” or a “free-from” food.
2. Whole foods with an intrinsic health benefit.
3. Natural ingredients that are added to make a food healthier.

Mintel’s Global New Products Database reported that while just 8% of new food and drink products launched in the UK in 2004 claimed to be “additive and preservative-free”, this percentage had risen to 24% of new products launched in 2007. “Low fat” was identified as another very popular message on labels³⁰¹.

Organic foods meet the criteria for foods that “do no harm” and their growth is a key part of the “naturally healthy” trend. NNB found that 80% of people who buy organic products buy them for their own health, not for the health of the planet.

NNB has concluded from over 10 years of industry tracking that many companies have learned the hard way that consumers prefer their health benefits to come, whenever possible, from ingredients that they have heard of and whose function they understand. Using a familiar ingredient and connecting it with a health message that consumers are aware of can make product success much easier.

5.3 Heart Healthy Ingredients

According to a 2005 survey by HealthFocus International, cardiovascular disease is one of consumers’ top three health concerns--not only in the U.S.--but also in regions from India and China to France and the U.K. to Latin America.

In 2007, Mintel International’s Global New Products Database identified close to 560 new products from around the world that referenced cardiovascular and/or heart health. While dietary supplement products frequently use the term “cardiovascular” to describe their health benefits, foods rarely do so, instead preferring the more simple term “heart health.” Food and beverage products targeting cardiovascular and digestive health have shot up in popularity, according to data provided by Mintel. 2008 information from the group’s Global New Products Database reveals a massive 244 percent increase in new introductions in the heart health category - from 43 products in 2006 to 148 in 2007. In 2003, only 22 new products were launched in this category, followed by 19 in 2004 and 54 in 2005.

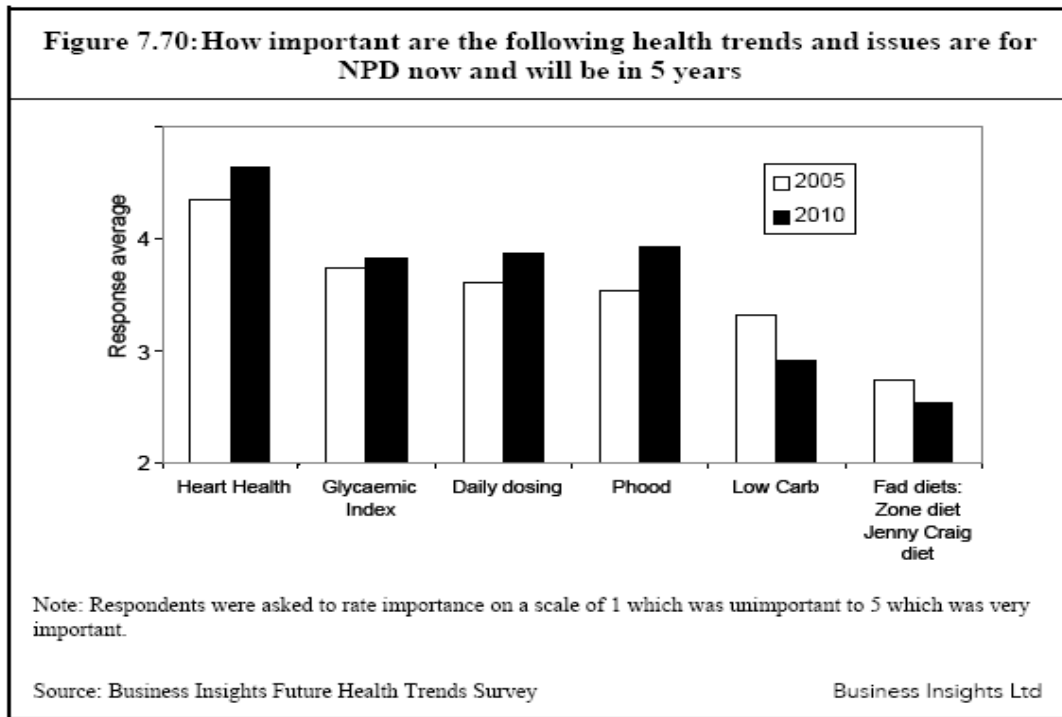
Euromonitor International identified two ingredients which emerged in 2005 and that they predict will dominate heart health food trends in the next ten years of food product development: omega-3 and whole-grains³⁰². Also of note, Euromonitor indicates that there is a significant market for age-specific products, both in foods and supplements, to meet the needs of ageing populations.

³⁰⁰ Mellentin, J. January 2008 “10 Key Trends in Food, Nutrition and Health for 2008”. New Nutrition Business. The Centre for Food & Health Studies. Crown House, London, UK.

³⁰¹ Natural Labelling in the UK. 2007. Mintel’s Global New Products Database.

³⁰² Euromonitor International. January 2006. “The World Market for Health and Wellness Products”. <http://www.euromonitor.com/articles>.

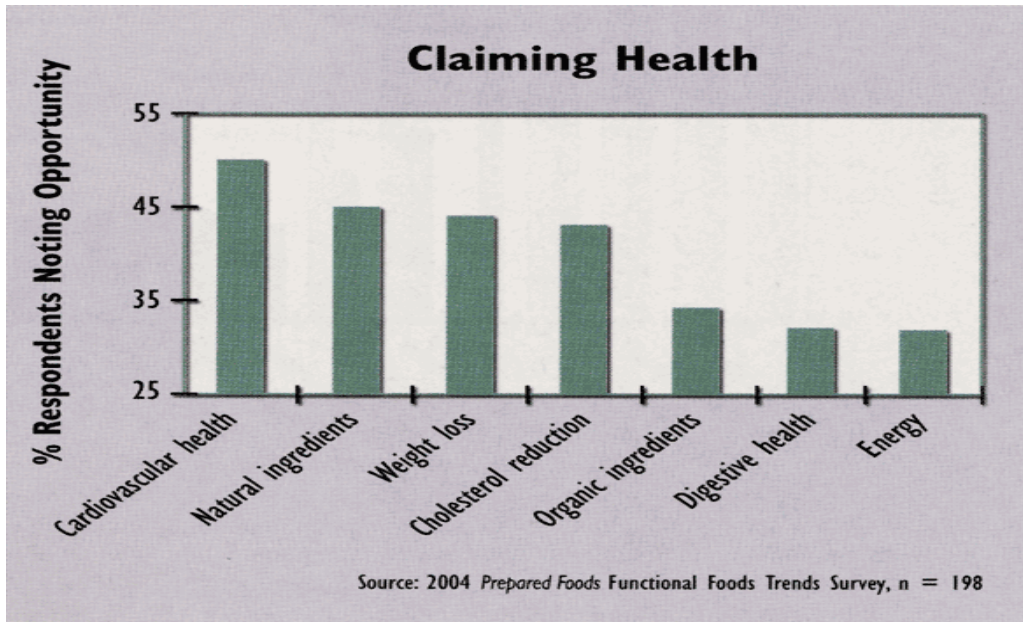
According to industry executives polled for a Business Insights Future Health Trends Survey³⁰³, the heart health diet is currently the most important trend for new product development and is projected to be so for at least the next 5 years.



In the 2006 Functional Foods Trends Survey of over 200 food industry executives conducted by Prepared Foods Magazine³⁰⁴, cardiovascular health followed closely by natural ingredients and weight loss ranked high among key opportunities for new product development as noted below.

³⁰³ Sadler, J. 2005. Future Health Food and Drink Trends. 2005. Business Insights Ltd.

³⁰⁴ 2006 Functional Foods Trends Survey. May 2007. Prepared Foods Magazine. www.preparedfoods.com



According to Business Insights³⁰⁵, the heart health and weight reductions trends are likely to be very important foci for new product development over the next five to seven years due to:

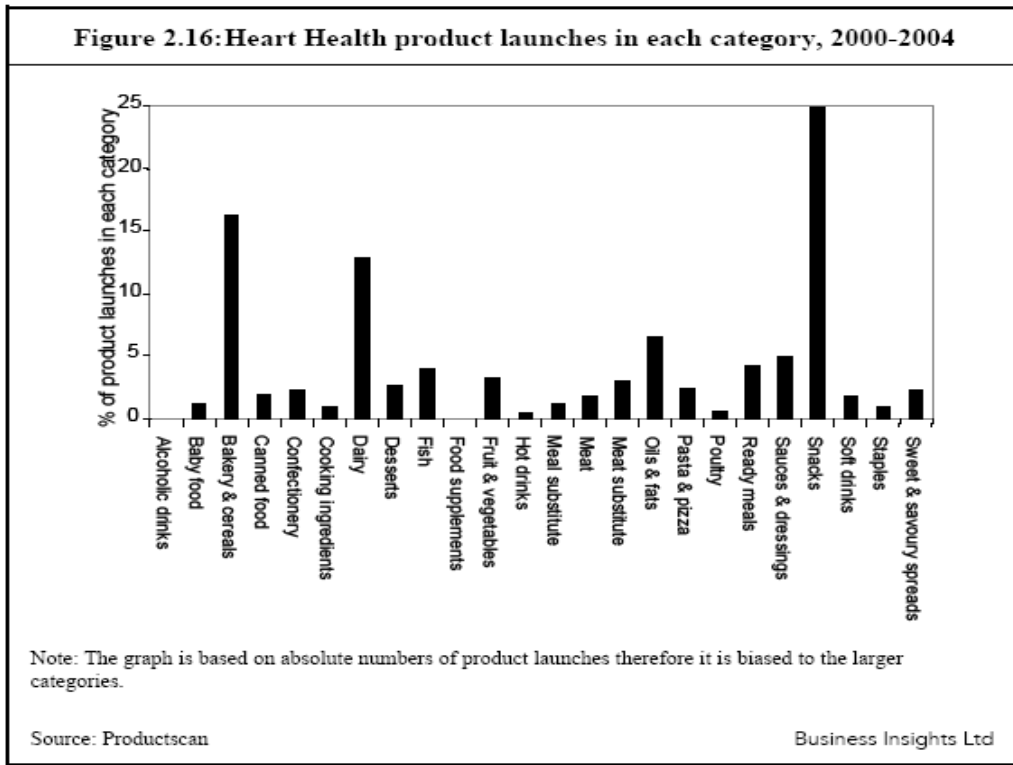
- Obesity, cardiovascular diseases and diabetes are increasing in prevalence and consumers in all countries are becoming more aware
- A wide range of ingredients including essential fatty acids, whole-grains and soluble fibre, are available to add to existing products to make them more healthy
- Government bodies are encouraging initiatives and public campaigns in order to raise awareness of obesity, diabetes and heart health.

Manufacturers are driving the food trends in these three key areas by:

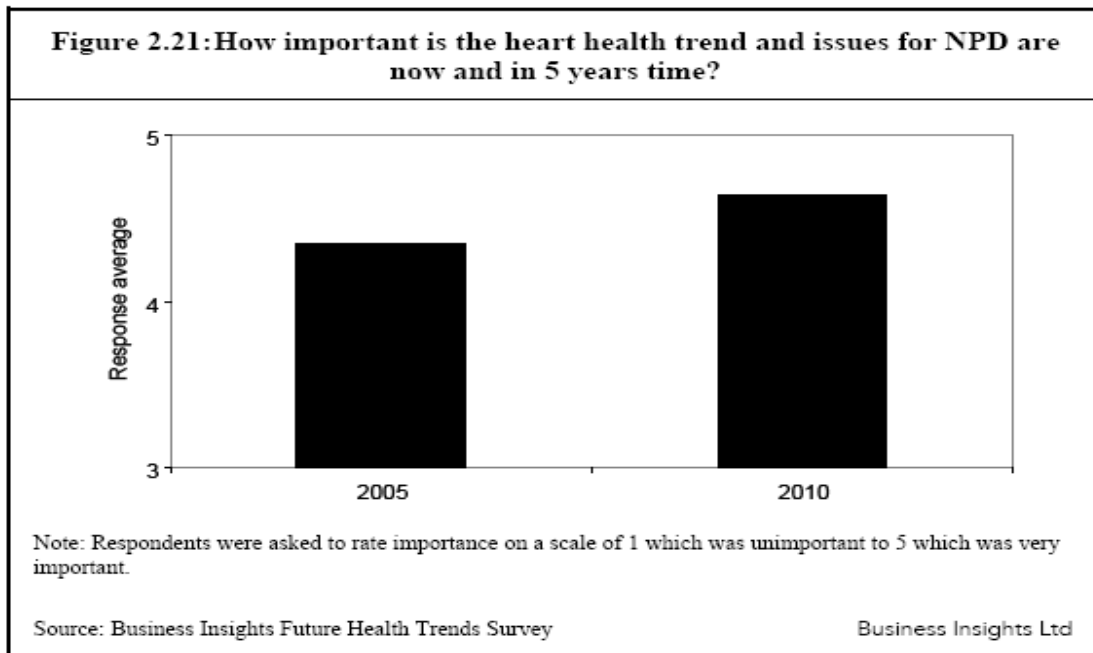
- Reformulating products in order to include ingredients (such as omega 3 and fibres) which actively reduce the risk of heart disease, increase satiety and manage blood glucose
- Specifically branding and marketing products as heart healthy and high in fibre, particularly in the US since the FDA permitted 'qualified health claims' on packaging beginning in early 2004

The lead categories within the heart health, weight management and blood glucose control trend, in terms of new product launches are snacks, bakery and cereals and dairy.

³⁰⁵ Sadler, J. 2005. Future Health Food and Drink Trends. 2005. Business Insights Ltd.



Industry executives have indicated there will be an increase in the importance in the heart health trend in particular related to new product development (NPD) over the next 5 years as noted in the next figure.



5.4 Phytosterols

Phytosterols and stanols are increasingly popular “heart-healthy” ingredients for foods and dietary supplements, especially in the EU and most recently in the U.S. Phytosterols have cholesterol-lowering properties in human subjects by up to 15%. Nutritional studies have reported hypo-cholesterolemic efficacy of phytosterols at levels of 1.5-3.0 g/d administered as a capsule, in a suspension, or as a mixture with margarines or other oils³⁰⁶.

The total U.S. phytosterols market was worth \$104 million in 2005 and is estimated to be 200 million in 2012³⁰⁷. The majority of phytosterols available today are derived from vegetable oil processing such as canola, cottonseed, corn and soybean, are major sources of phytosterols. An alternative commercial source is tall oil, a by-product of paper mills.

During the last ten years, there has been an unprecedented escalation of interest in phytosterols. Most of this interest has focused on the cholesterol-lowering properties of phytosterols and phytostanols, and evidence of this phenomenon includes more than forty patents on phytosterol products. The nutrients can now be found in foods and beverages such as orange juice, granola and nutrition bars, rice milk, yogurt and cheese, milk, sausages, cold cuts, bakery products, spicy sauces, margarines and spreads. It is estimated that over one hundred commercial phytosterol products are currently being marketed in many parts of the world³⁰⁸.

5.5 Interest in Fibre

The importance of dietary fibre in aiding healthy digestion and for overall health has been known for years. Soluble fibre found in many cereals in particular oats, barley and flaxseed lowers blood cholesterol levels and moderates blood glucose levels.

Food companies are increasingly extending brand labels and/or developing new food products containing fibre. The reasons are numerous including the acceptance by the health care community regarding the established health benefits of fibre, label regulations especially in the U.S. that allow positive health statements related to fibre content and steadily increasing consumer awareness of fibre and recognition of its health advantages.

Health Focus International found that 38% of consumers rate ‘high fibre’ as an ‘extremely’ or ‘very important’ statement on a food label, third behind ‘whole grain’ (45%) and ‘fresh’ (68%). The low-carb diet craze was one catalyst for encouraging consumers to look at fibre in new ways, as low carb has very quickly evolved into smart carbs, which equals more fibre and less processed carbs. Consumers now associate fibre with benefits like satiety for weight management, longer-lasting energy, disease prevention and steadier blood sugar.

³⁰⁶ Onge, M and Jones, P. 2003. Phytosterols and human lipid metabolism: efficacy, safety, and novel foods. *Lipids*. 38(4):367-75.

³⁰⁷ Frost & Sullivan. June 2006. Strategic Analysis of the U.S. Phytosterols Market.

<http://www.frost.com/prod>

³⁰⁸ Ibid.

Researcher Frost & Sullivan notes that fibre is an ingredient market worth \$200 million in the US alone in 2004, predicting it will double to \$400 million by 2011, a conservative figure compared to some other market estimates. Euromonitor International puts the global market for foods marketing high-fibre claims including packaged foods, baked goods, bread, biscuits and cereals at about \$80 billion globally, rising to \$95 billion by 2011. In the U.S., ACNielsen³⁰⁹ found sales with fibre label claims rose 15.5% to \$1.6 billion in the year ended August 2005 compared to 11.4% in 2004, 2% in 2003 and 4% in 2002.

5.6 Glycemic Index (GI)

The interest in GI is being driven by:

- *Rising obesity.* Consumers are aware it is an issue, and, especially in the US and the UK, are being empowered to deal with it themselves. In particular, consumers are quite sophisticated about various diets and a significant number are still looking for a more comprehensive solution for weight loss;
- *Rising diabetes.* More and more consumers in the US and Europe are being diagnosed with diabetes. GI is marketed as a diet that can help people with diabetes, because eating low and medium GI foods is a way to help people with diabetes control their blood sugar levels;
- The GI diet can be seen as a sophistication of the Atkins diet. Consumers bought into the Atkins diet in a major way and began to shun carbohydrates as a means to lose weight. However, as the Atkins diet failed to gain the backing of the medical establishment, it is possible that consumers did not see Atkins as a long-term solution to weight management.

There is strong scientific evidence that supporting low GI diets and weight loss as well as diabetic control. This has prompted the Canadian Diabetes Association to advise: "Within the same food category, consume low-Glycemic Index foods in place of high-Glycemic Index foods." The American Diabetes Association reviewed a major study using randomized controlled trials that examined the efficacy of the GI and concluded that: "This technique can provide additional benefit over that observed when total carbohydrate is considered alone." And for the general consumer, the WHO recommends "that in making food choices, the Glycemic Index be used as a useful indicator on the impact of foods on the integrated response of blood glucose."

44% of the North American population is actively trying to lose weight. Almost one in four shoppers in both Canada and the US has decreased their consumption of high-glycemic carbohydrates within the past two years, and one in three have decreased their consumption of carbohydrates, according to the 2005 HealthFocus[®] Trend Report³¹⁰. At the same time, approximately one in ten are increasing their consumption of low-glycemic carbohydrates and "better-for-you" carbohydrates.

In early 2007, the market research firm Packaged Facts reported that sales of low-glycemic foods and beverages reached \$350 million in 2006³¹¹, and predict that sales will keep increasing at a compound annual growth rate of over 45 percent from 2007 to

³⁰⁹ ACNielsen. 2005. Facts on Fibre. www.acneilsen.com.

³¹⁰ HealthFocus. 2005. The 2005 HealthFocus Trend Report: The national study of public attitudes and actions toward shopping and eating. HealthFocus International, Fla.

³¹¹ Packaged Facts. 2007. "Low Glycemic Index Food and Beverages in the U.S."

2011, with sales projected to reach \$1.8 billion in 2011. In a *Wall Street Journal* article³¹², it was reported that the growth in total food and beverage sales in 2005 increased by 3%. Low fat, reduced fat and fat-free foods increased in sales by just over 2%, low carbohydrate food sales declined by over 10%, and low glycemic foods grew 412%!

Most GI products released before 2003 were dietary or nutritional supplements rather than foods and beverages. For the most part, the products were focused specifically on athletes and bodybuilders and sold in natural food stores. As the low-carb diet swept the nation, and as consumers began to understand more about the positives and negatives of carbohydrates, the market seemed more open to the idea of “low glycemic” in foods and beverages.

New product introductions as tracked by Mintel’s Global New Products Database show some interesting changes over time related to low-carb, low-sugar, and low-glycemic³¹³. Introductions of low-carb products (almost exclusively in the U.S.) reached a high very quickly then descended just as fast. Similar product activity was also seen by low-sugar products, which can be partly attributed to the fact that low-sugar claims often appear in conjunction with low-carb claims. Low-glycemic introductions, on the other hand, have shown much smaller, but somewhat steady growth.

As has been witnessed with low fat product awareness among consumers, although GI figures vary widely from product to product and from category to category, there may be some benefit in promoting “a low number is a good number.” Additionally, GI is gaining popularity in diet plans. NutriSystem, for example, has its latest complete diet plan “based on the glycemic index system.”⁷²

The number of low-glycemic-index product introductions, by region, between and 2005 shows the steady growth of GI products⁷².

Region	2003	2004	2005
Asia Pacific	32	51	62
North America	7	73	44
Europe	6	12	64
Middle East & Africa	2	1	6
Latin America	0	0	3

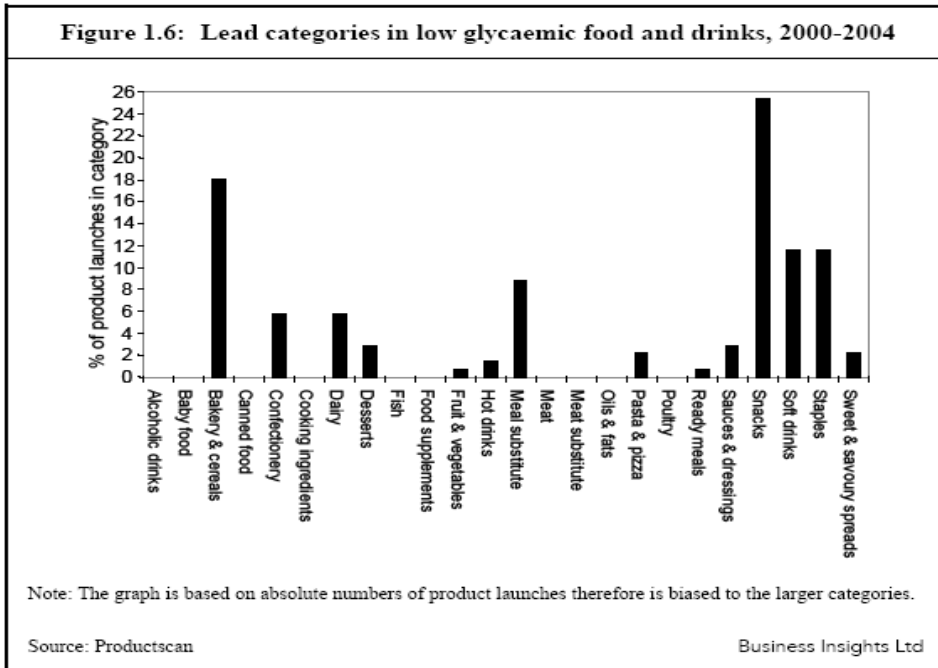
The lead categories include snacks, bakery and cereals and soft drinks³¹⁴.

³¹² Ellison and Ball, 2006. *Wall Street Journal*.

³¹³ Mintel’s Global New Products Database. 2006. Glycemic Index.

³¹⁴ Sadler, J. 2005 Future Health Trends in Food and Drinks. Business Insights Ltd

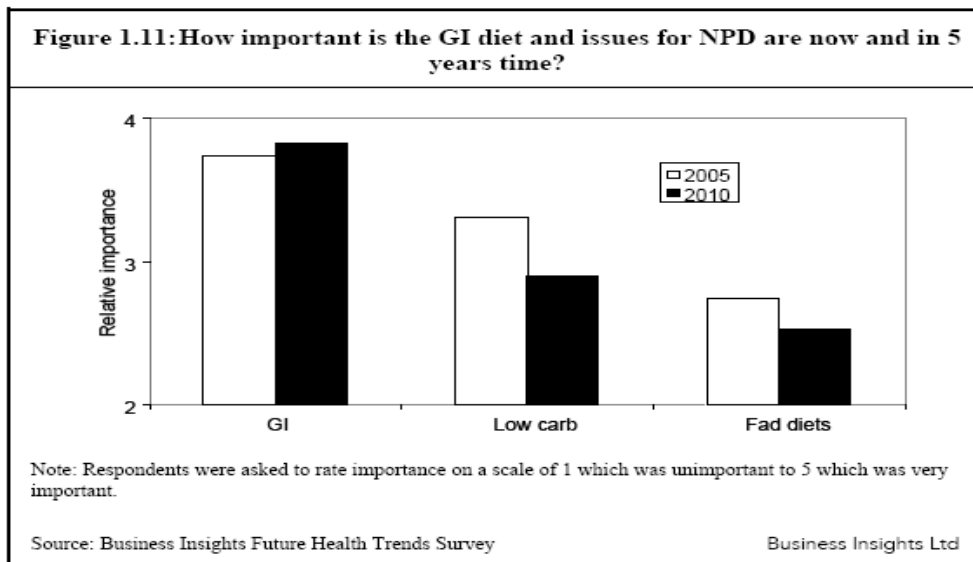
Figure 1.6: Lead categories in low glycaemic food and drinks, 2000-2004



The future of the GI diet

Business Insights⁷³ surveyed industry executives to establish their opinion of the GI trend. When asked how important the GI diet and issues for natural product development are now and will be in 5 years time, they identified a definite increase.

Figure 1.11: How important is the GI diet and issues for NPD are now and in 5 years time?



The demand for low- or reduced-glycemic foods is expected to significantly expand over the next several years, presenting opportunities for ingredients rich in soluble fibre and protein³¹⁵.

Glycemic Index Regulations

Since early 2000, Australia has allowed low-glycemic index certifications on food packages. The certifications, administered by an independent glycemic index council, are intended to aid diabetics and dieters counting their glycemic loads. There are no plans scheduled to introduce similar measure in the US or Canada.



Canada

In August 2004, apparently due to the number of reduced carbohydrate foods which were appearing on the market, the CFIA released a "reminder" that various carbohydrate claims and statements were not allowable on foods sold in Canada.³¹⁶ The Information letter stated that, in the absence of a defined method for determining the glycemic index of each food, statements like "Low glycemic index", "non-glycemic", and "Glycemic Index = 10" are not acceptable. Similarly, claims such as "rapid absorption", "does not raise blood sugar" and other related claims are not acceptable as these are considered to be drug claims.

United States

However, regulations do not pose a problem for GI foods in the U.S. For food companies, they are allowed to declare other quantitative information outside of the nutrition label provided the additional information is not false or misleading. Following the plethora of low carb foods that entered the market during the "Atkins" phase, the FDA did convene a Working Group on Obesity (OWG) to provide recommendations for analysis and labeling of low carb foods including terminology related to low and high Glycemic

³¹⁵ Business Insights Ltd. 2005. The US Diet Market Outlook To 2008.

³¹⁶ Canadian Food Inspection Agency. August 2004. INFORMATION LETTER: Carbohydrate Claims on Foods Sold in Canada. <http://www.inspection.gc.ca/english/fssa/labeti/inform/choe.shtml>

index³¹⁷. The FDA has received petitions requesting that the agency provide for nutrient content claims related to the carbohydrate content of foods. It is not known when proposed rule making by the FDA related to the carbohydrate content of foods will be announced.

5.7 Gluten Free

The US market for gluten-free foods and beverages is currently estimated at \$696 million US, and is anticipated to grow to \$1.7 billion US by 2010³¹⁸. The same report found that since 2001, the market for gluten-free products has grown at a compound annual rate of 27%, and is anticipated to grow 25% per year until the year 2010.

According to information published by SPINS, the share of total category sales for gluten-free products is increasing incrementally in nearly all key categories, and is outpacing growth of the categories as a whole³¹⁹. SPINS reported that more than 3,150 products with gluten-free label claims are currently on the market in the US. An 86% increase in new product launches in the “gluten-free” category was observed in 2006³²⁰. In 2006, 40% of gluten-free products on the market were sold in health and natural food stores, 20% through specialty food websites and catalogue purchases, and 14% via mainstream supermarkets³²¹.

Following a review of thousands of gluten-free products, SPINS identified the 22 most popular food categories:

Table 2: Categories for Gluten-free Products Currently in the Retail Market³²²

Bread & Baked Goods	Frozen Entrees, Pizza’s, Convenience Foods	Frozen & refrigerated meat alternatives
Beans Grains & Rice	Baking mixes supplies & flours	Baby food
Candy & individual snacks	Cold Cereals	Condiments
Cookies & Snack bars	Chips & Pretzels & Snacks	Crackers & Crispbreads
Energy Bars & Gels	Entrée’s & Mixes	Nuts Seeds Dried Fruits & Trail Mixes
Puddings & Shelf Stable Desserts	Shelf Stable Pastas	Rice Cakes
Shelf Stable Sauces & Salsa’s & Dips	Soup	Seasonings
Sweeteners		

³¹⁷ Report of the Working Group on Obesity. 2004. FDA Center for Food Safety and Applied Nutrition. <http://www.cfsan.fda.gov/~dms/owg-toc.html>

³¹⁸ Packaged Facts. 2006. Gluten Free Foods and Beverages in the U.S. www.marketresearch.com

³¹⁹ SPINS. 2007. Gluten free product sales. www.spins.com

³²⁰ Gluten-free knocks low-carb fad off the shelf. February 2, 2007. www.money.cnn.com

³²¹ Gluten free market set to boom. 2007. www.foodnavigator-usa.com

³²² SPINS Product Library – Gluten-Free Reporting. www.spins.com

Gluten Free Regulations

Regulations will not pose a problem for gluten free foods in the U.S. or Canada for alternative sources of plant based proteins.

United States

On January 1, 2006, the US Food Allergen Labeling and Consumer Protection Act (FALCPA) was established to ensure that the eight most common allergens, including dairy, eggs, fish, peanuts, shellfish, soy, tree nuts and wheat, were declared in the ingredient list on food labels. However, for individuals following a gluten-free diet, the enforcement of this act did not sufficiently address their concerns, as “wheat” not “gluten” is included in the current allergen labeling. As a result, the Food and Drug Administration (FDA) is currently developing a definition for the term “gluten-free”, as there is currently no approved legislature for US food manufacturers or consumers.

In January 2007³²³, the FDA announced a proposal to define the food labeling term “gluten-free” as a food bearing this claim would not contain any of the following:

- An ingredient that is a “prohibited grain”, which refers to any species of wheat (durum, wheat, spelt wheat, or kumut), rye, barley, or their crossbred hybrids
- An ingredient that is derived from a “prohibited grain” and that has not been processed to remove gluten
- An ingredient that is derived from a “prohibited grain” that has been processed to remove gluten, if the use of the ingredient results in the presence of 20 micrograms or more gluten per gram of food
- An ingredient containing 20 micrograms or more gluten per gram of food”

This proposed action is in response to the FALCPA.

It is anticipated that once the FDA establishes these regulations large food marketers on a global level will enter the market.

Canada

In 1994, Health Canada’s Food Directorate established the current policy on the use of food allergen precautionary statements. The only criteria of the precautionary statements is that such statements be **“truthful, clear and non-ambiguous, and that they not be a substitute for Good Manufacturing Practices”**³²⁴.

Health Canada is developing amendments to current labeling requirements for “priority allergens”, including various sources of gluten, in prepackaged foods sold in Canada. Proposed regulatory amendments are planned to be released for public comment in early 2008. Currently, the accepted definition of gluten-free in Canada includes “food

³²³ Food and Drug Administration. January 2007. 21 CFR Part 101 Food Labeling; Gluten-Free Labeling of Foods. <http://www.cfsan.fda.gov/~lrd/fr070123.html>

³²⁴ Health Canada. 2007. The use of food allergen precautionary statements on prepackaged foods. Health Canada. hc-sc.gc.ca/fn-an/label-etiquet/allergen/precaution_label-etiquette_e.html.

does not contain wheat, spelt, kamut, rye, barley, oats or triticale, or any parts thereof³²⁵.

5.8 Emerging Markets for Natural Ingredients

5.8.1 Pet Foods and Products

As noted, the promotion of health and wellness is at the forefront of consumer's minds, and is the driving trend of the functional food and natural health product (FFNHP) industry. The interest of North Americans in health and wellness has become increasingly relevant to companion animals. With the "humanization" of pets, many owners are taking as much care of the health of their pets as they do their own. A recent survey conducted for Purina Pro Plan Selects indicated that 90% of respondents "always try to purchase foods with the most health benefits for themselves and 82% look for foods with the most wholesome ingredients for their pets."³²⁶ Industry analysts have observed that trends in the pet food market not only mirror human food trends; they often do so at an accelerated rate³²⁷.

In 2005, an American Pet Products Manufacturers Association survey reported that 63% of households in the United States owned a pet, which equates to over 69 million homes³²⁸. Consumers spent over \$14 billion on pet food during 2005 in the United States alone. And pet food manufacturers released 175 new dog and cat food products during the first six months of 2006. Euromonitor predicts that the global pet food and pet care products market will increase by 15.1%, from 58.2 billion US in 2005 to 67.0 billion US in 2010³²⁹. Pets are increasingly viewed as a part of the family and this has led to a recent expansion of health and wellness pet foods and products.

According to Productscan, the number of pet products referred to as 'natural' or 'organic' doubled between 2002 and 2003, with the trend continuing into 2004³³⁰. Sales of natural pet food reached \$520 million US in 2005, with forecasted sales of \$1.042 billion US by 2010³³¹. The Organic Trade Association reported that sales of organic pet foods increased more than 40% in 2005, and is anticipated to increase 24% each year from 2006 to 2010. In the "new product introductions" category, 674 were labeled as "natural" in 2006, compared to 535 in 2005. The number of new products labeled as "organic" increased from 62 in 2005 to 243 in 2006³³².

³²⁵ Canadian Celiac Association. 2006. www.celiac.ca

³²⁶ Nutraceuticals World. 2007. New Ipsos poll shows consumers equally concerned about their health and their pets' health. http://www.nutraceuticalsworld.com/news/2007/07/24/new_ipsos_poll_shows_consumers_equally_concerned_about_their_health_and_their_pets%92_health.

³²⁷ Industry Statistics & Trends - American Pet Products Manufacturing Association. www.appma.org.

³²⁸ 2005-2006 National Pet Owner's Survey. American Pet Products Manufacturers Association survey.

³²⁹ Pet Food and Pet Care Products globally. www.euromonitor.com.

³³⁰ Winter, Joysa. 2006. Pet foods get functional. *Functional Foods and Nutraceuticals*. <http://www.fffmag.com/NH/ASP/strArticleID/1038/strSite/FFNSite/articleDisplay.asp>

³³¹ Organic & natural predictions. June 5, 2007. www.petfoodindustry.com.

³³² Organic & natural predictions. June 5, 2007. www.petfoodindustry.com.

Importance of Safety and Quality

Recent quality problems associated with imported ingredients have created opportunities for Canadian pet food ingredient suppliers. Product recalls of tainted foods and animal deaths have forced pet food quality and safety issues into the forefront of consumer's minds. Recalls were initiated in March 2007, when the pet food company, Menu Foods voluntarily pulled products off the market as the result of reported pet deaths and illnesses. The U.S. Food and Drug Administration later identified the problem as being melamine contaminated wheat gluten and rice protein concentrate that originated in China that was ultimately used in over 60 million cans and pouches of wet pet food³³³.

As a result the Canadian Food Inspection Agency (CFIA) issued mandatory testing for melamine and cyanuric acid in all incoming shipments of wheat, rice, soy and corn gluten and protein concentrates imported from China. Additionally, in June 2007, border measures were enhanced and the CFIA implemented a 'robust risk-based import control system' for all vegetable protein concentrates imported from all countries. The new system calls for manufacturers, in countries other than China, to provide a certificate of analysis from an approved laboratory that proved the shipment was free from detectable levels of melamine and cyanuric acid³³⁴.

These problems have placed an increase emphasis on the need for quality guarantees. Consumers are turning to turning not only to "natural" and "organic" pet food choices, but also those with "locally sourced" ingredients. Industry analysts forecast that premium, super-premium, and hyper-premium brands positioned as natural, organic, or human grade, as well as those with ethical claims such as sustainable, fair trade, and no cruelty, are anticipated to witness the strongest level of growth³³⁵ over the next decade.

Protein

High quality protein remains the most important characteristic of pet food for both consumers and pet food manufacturers. The highest quality proteins are animal sources as they are both digestible and highly available.

Plant based sources such as corn are generally lower quality proteins because even though these sources contain digestible protein that is absorbed, but it is not as usable by the body as animal proteins. Plant proteins must be combined with another grain to supply the entire range of essential amino acids (EAAs). In contrast, meat, eggs fish and chicken are 'complete' proteins meaning that they contain all EAAs. Egg has the highest biological value (of 100) and sets the standard for which other proteins are judged. Fish meal has a value of 92; beef, 78 and soybean meal is 67. Meat and bone [meal](#) and wheat are around 50 and corn is 45. Pets will need to eat larger quantities of corn and other grains to obtain the same amount of usable protein that is in an animal source.

The most common forms of protein found in good quality pet foods include real meat, fish, and eggs. Chicken by-product or other meat by-products are not as good but

³³³ Selling Safety. September 18, 2007. www.petfoodindustry.com.

³³⁴ Pet Food and Pet Care Products in Canada. www.euromonitor.com.

³³⁵ Natural, Organic and Eco-Friendly Pet Products in the U.S., 2nd Edition. October 1, 2007. Found at: www.marketresearch.com.

acceptable; meat and bone meal are poorer yet. If grains are listed, they are not as digestible sources of protein and contribute heavily toward the carbohydrate load.

Because cats are carnivores, the majority of their protein is derived from meat, fish, and other high quality animal protein sources (34). Cats are extremely sensitive to deficiencies in amino acids, and therefore receiving a complete and quality protein in their diet is essential. For instance, a deficiency in arginine, which is necessary for the removal of ammonia from the body, may result in a buildup of ammonia in the bloodstream (34). Similarly, deficiencies in taurine can result in a multitude of metabolic and clinical problems including feline central retinal degeneration and blindness, deafness, cardiomyopathy and heart failure, inadequate immune response, poor neonatal growth, reproductive failure, and congenital defects (34). Because taurine is either absent or present in only small amounts in plants, it is critical that cats receive their protein from animal sources. Dogs on the other hand are omnivores – that is they can obtain their protein from either plant or animal sources as long as it is complete³³⁶.

Fibre

Dietary fibre is not considered an “essential nutrient” in the diets of dogs and cats; however, it is present in almost every commercial pet food. The most common sources of fibre in pet foods include rice hulls, corn and corn by products, soybean hulls, beet pulp, bran, peanut hulls, pectin, and cellulose³³⁷. Both soluble and insoluble fibres are used in pet food products mostly for their effects on stool. The rate that fibre ferments will determine the water holding capacity and overall bulk of the stool. Soluble fibres such as mucilage found in hemp ferment slowly and are most effective in bulking the stool. A mix of both soluble and insoluble fibres is considered the most desirable, unless a specific condition is being treated.

Products aimed at overweight cats and dogs (an ever increasing category) contain soluble fibres which can assist in improving satiation and reducing caloric intake, important in weight reduction and weight management diets³³⁸. Dietary fibre is also found in soft and hard foods geared towards reducing hairballs in cats.

Diabetes mellitus is a chronic disease that is increasingly impacting companion animals. Diets high in soluble fibres slow down absorption of sugar from the intestines and can assist in insulin control. In dogs, a diet high in insoluble fibre has also been shown to help regulate glycemic control, as well as assist in weight management³³⁹. Diabetic cats show an improved glycemic response to a high fiber diet; however, many cats with type-2 diabetes appear to benefit from a diet high in protein and low in carbohydrate³⁴⁰.

Dietary fibre is being studied in cats and dogs in related to gastrointestinal health. In particular, the binding and gelling properties of soluble fibre may potentially be beneficial

³³⁶ Your pet's Nutritional Needs: A Science Based Guide for Pet Owners. 2006. National Research Council of the National Academies. www.nap.edu

³³⁷ Fiber in Dog Foods. 2005. www.peteducation.com.

³³⁸ Butterwick, RF, Hawthorne, AJ. 1998. Advances in dietary management of obesity in dogs and cats. J Nutr; 128(12 Suppl); 2771S-2775S.

³³⁹ Fleeman, LM, Rand, JS. 2001. Management of canine diabetes. Vet Clin North Am Small Anim Pract; 31(5): 855-80.

³⁴⁰ Kirk, CA. 2006. Feline diabetes mellitus: low carbohydrates versus high fiber? Vet Clin North Am Small Anim Pract; 36(6): 1297-1306.

in the treatment of small bowel diarrhea³⁴¹. For diseases of the large bowel, diets high in both soluble and insoluble fibres may have utility³⁴².

Specialty Ingredients

Specialized and supplemented products are gaining prevalence. The premium and super-premium pet food and pet treat sector have experienced the most growth, with many pet foods and treats introduced with functional benefits.

Consumers are looking for pet food products containing health promoting compounds. For example, 80% of pet owners believe omega-3 fatty acids are important in the food they and their pets consume, 90% would like to include antioxidants in their pet's diets, and 74% believe Vitamin A is imperative to the health of their pet's eyes³⁴³. It is also important to note that pets do not consume the variety of foods that humans do, and thus owners "...are relying on what's in the bag twice a day – so the entire recipe needs to be functional".³⁴⁴

A wide range of bioactive compounds and specialized ingredients are added to pet food to increase functionality and to target specific health issues. Between 1998 and 2005 in the US, the most prevalent areas of pet health in which products were developed include:

- Weight loss
- Urinary health
- Dental care
- Digestive health
- Coat and skin care
- Decreased fecal volume
- Decreased fecal odor
- Slowing aging
- Easing joint pain
- Hairball control

Pet food manufactures recognize that pet owners tend to assume that dietary ingredients which are good for their health are also good for their pets and therefore produce products containing popular human health promoting ingredients. Examples following this theme are: antioxidants to reduce free radical damage and age related

³⁴¹ Guildford, WG. 1994. Nutritional management of gastrointestinal tract diseases of dogs and cats. *J Nutr*; 124(12 Suppl); 2663S-2669S.

³⁴² Leib, MS. 2000. Treatment of chronic idiopathic large-bowel diarrhea in dogs with a highly digestible diet and soluble fiber: a retrospective review of 37 cases. *J Vet Intern Med*; 14(1): 27-32.

³⁴³ Nutraceuticals World. 2007. New Ipsos poll shows consumers equally concerned about their health and their pets' health. http://www.nutraceuticalsworld.com/news/2007/07/24/new_ipsos_poll_shows_consumers_equally_concerned_about_their_health_and_their_pets%92_health

³⁴⁴ Winter, Joysa. 2006. Pet foods get functional. *Functional Foods and Nutraceuticals*. <http://www.ffnmag.com/NH/ASP/strArticleID/1038/strSite/FFNSite/articleDisplay.asp>

conditions, pre- and pro-biotics to promote gut health, and omega-3 fatty acids to improve skin and coat health³⁴⁵.

Flaxseed, as a source of omega-3 fatty acids, has become a popular pet food ingredient due to the notion that “flaxseed has the same reported health benefits in companion animals that it does in humans.”³⁴⁶ Pulses have also seen an increase in use because they are believed to reduce the risk of obesity and prevent heart disease in humans, pets like the taste. Peas also offer excellent nutritional benefits, with both the protein and carbohydrate component being highly digestible in dogs³⁴⁷. Pet products focused on the maintenance of joint health and mobility contain ingredients often used in human supplements such as glucosamine, chondroitin sulfate, MSM, green-lipped mussel, and yucca.³⁴⁸

Pet Food Regulations

Canada

In Canada, three federal government departments are involved with overseeing various aspects of pet food marketing. The Canadian Food Inspection Agency (CFIA) regulates the movement of inedible meat products and administers legislation requiring the certification of certain imported pet foods containing animal products. Health Canada administers legislation prohibiting unsubstantiated health claims in the advertising and labelling of pet food. The Competition Bureau of Industry Canada administers legislation requiring that prepackaged pet food destined for retail consumption be labelled with a bilingual common name, metric net quantity declaration and dealer name and address. The legislation also prohibits false and misleading representations and deceptive marketing practices. There are no specific regulations for pet foods.

Volunteer guidelines for pet food labelling and advertising guide for dog and cat foods were adopted by the industry in September 2001. The [Guide for the Labelling and Advertising of Pet Foods](#)³⁴⁹ was updated in August 2005. Although not law, it addresses labelling, ingredient statements, guaranteed analysis and nutrient profiles. Products that are considered to be “drugs” as defined by the *Food and Drugs Act* are not covered by this guide.

The Pet Food Association of Canada (PFAC) is a trade association representing the manufacturers of pet foods sold in Canada; and manufacturers of Canadian-made pet food sold in Canada and for export. Members of the PFAC manufacture under *The*

³⁴⁵ Phillips Brown, L. 2001. Pet nutraceuticals. *Nutraceuticals World*.

<http://www.nutraceuticalsworld.com/articles/2001/01/pet-nutraceuticals.php>

³⁴⁶ Rees, C.A., Bauer, J.E., Burkholder, W.J., Kennis, R.A., Dunbar, B.L., and Bigley, K.E. Effects of dietary flaxseed and sunflower seed supplementation on skin and hair coat clinical scores in normal dogs. *Vet. Dermatol.* 12:111–117 (2001).

³⁴⁷ Phillips Brown, L. 2001. Pet nutraceuticals. *Nutraceuticals World*.

<http://www.nutraceuticalsworld.com/articles/2001/01/pet-nutraceuticals.php>

³⁴⁸ Phillips Brown, L. 2001. Pet nutraceuticals. *Nutraceuticals World*. and Flicking, E. A. and G. C. Fahey Jr. 2002. Pet food and feed applications of inulin, oligofructose, and other oligosaccharides. *British Journal of Nutrition* 87(2):S297-S300.

³⁴⁹ Competition Bureau. 2007. 2005 Guide for the Labelling and Advertising of Pet Foods. <http://www.competitionbureau.gc.ca/internet/index.cfm>

*Manufacturing Guidelines for the Canadian Pet Food Industry*³⁵⁰. PFAC nutrition guidelines mirror the United States “American Association of Feed Control Officials” (AAFCO) described in the next section.

Natural Health Products used in Pet Products

Stemming from product quality concerns, an increasing number of pet owners are turning to natural health products (NHPs) and natural sourced health foods for their pets. Historically veterinary NHPs (vNHPs) have been subject to division 8 of the “Food and Drugs Regulations” which has classified a majority of products as “new drugs”. Currently, NHPs that have received a Natural Product Number (NPN - marketing authorization for products sold to humans) cannot be marketed for use in veterinary products, they must receive a Drug Identification Number (DIN).

Health Canada’s Veterinary Drugs Directorate (VDD) is currently developing a strategy that will take into consideration the unique aspects of vNHPs³⁵¹. There may be increased opportunities for hemp bioactives should the proposals for vNHP be accepted by health Canada. These proposals reflect the current NHP Regulations for human products so it is likely that the vNHP will also become law.

It has been proposed that non-homeopathic vNHP include substances that are 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 animals; or
- restoring or correcting organic functions in animals; or
- modifying organic functions in animals, such as modifying those functions in a manner that maintains or promotes health.

Safety and quality assurance is required for products entering the natural pet health market. Should product health claims be of interest, efficacy testing in animals would be required.

Hemp could be used as a source of plant based fibre under proposals for vNHP’s definition of a plant based extract, that is “a substance prepared by treating a plant or a plant material, ... with solvents to remove any constituents”. An isolate is defined as “a purified constituent of a defined molecular structure obtained from a plant or a plant material, an alga, a bacterium, a fungus or a non-human animal material”.

³⁵⁰ Pet Food Association of Canada. www.pfac.com

³⁵¹ Health Canada’s Veterinary Drugs Directorate . August 2007. Consultation on Natural Health Products. http://www.hc-sc.gc.ca/dhp-mps/consultation/vet/consultations/vnhp_intro_psnv_e.html.

Examples of proposed vNHP substances are included in the following table.

	Substance	Examples
1.1	Vitamins	Niacin, ascorbic acid
1.2	Minerals	Calcium, molybdenum
1.3	Enzymes	Amylase, protease
1.4	Plants and botanical material	Senna, flax seed
1.5	Amino acids	Phenylalanine, methionine
1.6	Non-human animal material	Elk antler velvet, green lipped mussel
1.7	Algae	Blue-green alga, <i>Laminaria digitata</i>
1.8	Fungi	Yeast, <i>Lentinula edodes</i> (Shiitake mushroom)
1.9	Extracts and isolates of plants, alga, fungi, fatty acids and non-human animal material	Chlorophyll, alginic acid, glucosamine, fructo-oligosaccharide, lycopene, resveratrol
1.10	Fatty acids	Marine lipid triglyceride, conjugated linolenic acid, omega 3-6-9
1.11	Synthetic duplicates of the above (1.1-1.10)	d,l-alpha-tocopherol
1.12	Probiotics	<i>Lactobacillus acidophilus</i>
1.13	Veterinary homeopathic medicines	<i>Arnica Montana 2X</i>

United States

In the U.S., pet foods are subject to federal and state regulations. At the federal level, animal feeds are regulated under the Federal Food, Drug, and Cosmetic Act. The Act itself requires that pet food, like human foods, be pure and wholesome, contain no harmful or deleterious substances, and be truthfully labeled³⁵². It is the responsibility of the FDA is to ensure both human and animal foods are safe and properly labeled.

The Center for Veterinary Medicine (FDA/CVM) regulates the distribution of food additives and drugs for pets and is responsible for the regulation of animal drugs, medicated feeds, food additives, and feed ingredients, including pet food. There is no requirement for pre-market approval of pet foods. There are specific regulations for pet food ingredients, labeling and advertising including:

- Canned foods must be processed in accordance with low acid canned food regulations (Title 21, Code of Federal Regulations, Part 113 [21CFR 113].
- Approved colour additives (21 CFR 73,74,81).
- Approved additives (21CFR 582).
- Labelling of pet foods (21 CFR 501).

At the State level, the Association of American Feed Control Officials (AAFCO) plays a pivotal role in the regulation of animal feed and feed ingredients (including pet food). The AAFCO is an organization, not a government agency, which develops laws and regulations, uniform feed ingredient definitions, and appropriate labeling requirements to

³⁵² U.S. Federal Food, Drug, and Cosmetic Act. Code of Federal Regulations, Title 21, Food and Drugs, Part 500. www.fda.gov/cvm/petfoodflier.html

ensure the safe use of animal feed. AAFCO is composed of officials from all states and Federal government that are responsible for enforcing laws and regulations that pertain to the “production, labeling, distribution, and/or sale of animal feeds”³⁵³. The organization together with the CVM reviews new food ingredient petitions for inclusion in pet foods for listing in the accepted Official Publication of AAFCO. Each State can either adopt the regulations established by the AAFCO, or can set up regulations similar to them.

Nutrition health claim regulations do not apply to pet foods (even though many pet foods are marketed in the same way as human foods). CVM policies however, do permit meaningful health information on pet foods such as use of urinary tract health claim on cat food diets or AAFCO guidelines for light, lean, less or reduced calories, lean, and less and reduced fat.

The CVM requires safety and efficacy data prior to marketing of new pet food ingredients. Pet food products with labels bearing drug claims are subject to regulation by CVM as drugs as well as foods. Existing claims not allowed by CVM include: hypoallergenic, omega-3 fatty acids and inflammatory skin disease.

³⁵³ Association of American Feed Control Officials. 2007. www.aafco.org/

5.8.2 Natural Personal Care

The health industry is being increasingly driven by aging demographics in industrialized nations. With the global population having more than tripled since the 1950s, more people than ever before are reaching the age of 50. Demand for anti-aging solutions is therefore increasing. The signs of physical aging often prompt mid-life consumers to change their lifestyle in order to improve the way they feel and their chances of longevity. Older consumers are open to adding dietary supplements to their health regimes to retard the mental and physical effects of aging, as well as “trading up” in terms of luxury topical skin care products that fight (or cover up) signs of aging³⁵⁴.

Younger consumers too are increasingly conscious of ways to ensure health and wellness and are seeking ways to delay aging and maintain soft and vibrant skin.

The natural, organic and cosmeceutical segments of the personal care market have experienced significant growth in recent years, and are expected to continue to expand in the foreseeable future as Natural Products Companies (NPC) and large consumer marketers increase their investments into this segment of the Health and Beauty Care (HBC) market. Retail sales of natural and organic personal care products, which represented over 10% of the HBC market in 2005, exceeded \$5.5 billion in 2005 growing at 14.6% (\$12 billion globally). In comparison, the overall U.S. cosmetics and toiletries market grew by a 3.5% in 2005³⁵⁵.

While it is still not possible to reverse the effects of ageing, its mechanisms have been identified by scientific studies, together with various active biological compounds that interact with such mechanisms.

The skin is the largest organ of the body. The functions of the skin include protection of the body against injury, heat and light radiation, regulation of body temperature, elimination of waste products, and secretion of hormones and enzymes. The skin also acts as an external sensory organ and plays an immunological role. The surface of the skin is made up of mostly of dead cells. Underneath the surface, there are three thin distinct layers, including the epidermis, the dermis and hypodermis.

The epidermis is responsible for the look and the health of the skin. It protects the skin from moisture loss and the penetration of chemical products and bacteria. It is also the initial barrier to oxidant assault. The epidermis holds a large amount of water. The skin's capacity to retain water decreases with age, making it more vulnerable to dehydration and wrinkles.

Transepidermal Water Loss (TEWL) describes the amount of water that escapes from the epidermal layer of the skin via diffusion and evaporation processes. TEWL is associated with aging of the skin as well as dryness and scaling of the skin, [fine lines and wrinkles](#) and mild [irritant contact dermatitis](#). TEWL can be minimized by emollients which can soften skin and moisturizers which add moisture. Essential fatty acids are very important to reduce TEWL.

³⁵⁴ Fear of Aging, 2003. Datamonitor, New York, NY

³⁵⁵ Natural Personal Care Overview. August 2006. Nutrition Business Journal.

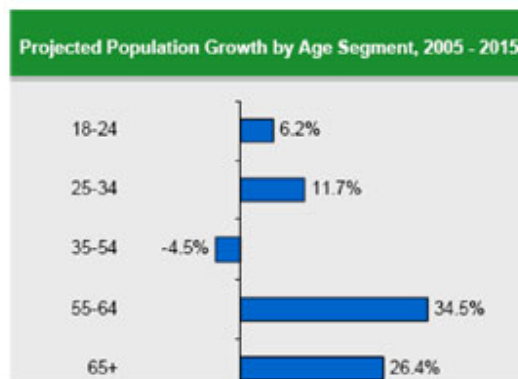
6.0 CONSUMER AWARENESS

Consumers are becoming increasingly aware of the relationship between diet and health, and are the driving force behind the development of new health food and supplement products. Generally, most North American surveys report that the majority of consumers (over three-quarters) feel that eating healthfully is a better way to manage illness than medication³⁵⁶. Consumers are increasingly changing their eating habits due to health or nutrition concerns.

61 Demographic Trends

Aging adults in the U.S. are a key target group for Canadian FFNHP industries. In 2008, over one-third of the U.S. population, or 98 million adults, will be age 50 or older and 107 million by 2015³⁵⁷. The demographic aged 55 to 64 is projected to grow another 35 per cent by 2015 and seniors 65 and over by 26 per cent (Figure).

Figure 1



Reference: US Census Bureau 2005.

Seniors aged 65 to 74, followed by those 75 years and older, and older Boomers 55 to 64, are the most likely to use NHPs, condition-specific and multi-formula products, and to take supplements more than once a day³⁵⁸. This survey reported that seniors 65 years and older are twice as likely as any other age group to take fish oil, vitamin E and calcium supplements and are heavy users of vitamin C, B12, B-complex, antioxidants and herbal products. Antioxidants, vitamin E, C, calcium and fish oil top the list of supplements used by older Boomers aged 55 to 64.

Despite increasing health issues, older adults remain nearly three times more focused on prevention than treatment³⁵⁹. Three-quarters of Boomers and 71 per cent of those 60

³⁵⁶ Princeton Survey Research Associates. 2004. Consumer Attitudes: Food and Health. www.psrai.com/news.jsp.

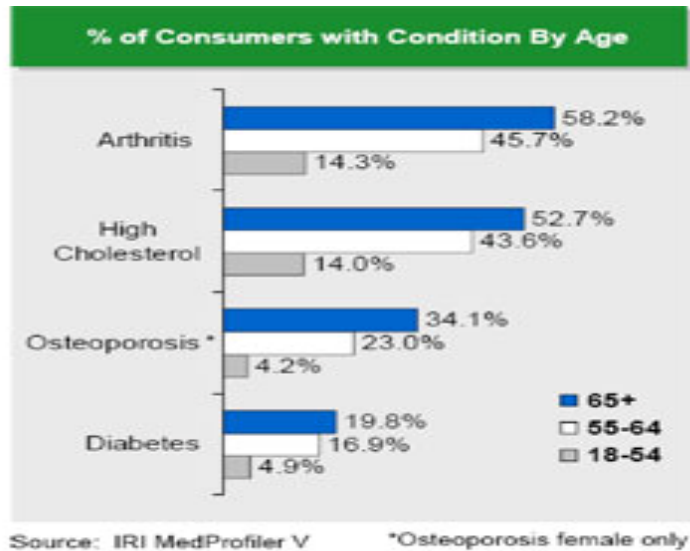
³⁵⁷ Census. 2005. Current Population Reports. U.S. Census Bureau, Washington, D.C. www.census.gov.

³⁵⁸ SMRB, 2006. Fall 2006 Experian Simmons National Consumer Studies. Simmons Market Research Bureau, New York. NY. www.smr.com

³⁵⁹ GfK Roper, 2007. Health and Well-Being. GfK Roper Reports Monthly. www.gfkamerica.com.

years and older say prevention is a regular part of their lifestyle. SMRB reports 40 per cent of those 55 years and older frequently use FF and NHP for preventive measures and believe that these products for their long-term benefits⁶⁷.

As 31 million Americans turn 65 over the next 10 years, the demand for condition-specific products is anticipated to increase. IRI's MedProfiler reports that six in 10 aged 65 years and older suffer from arthritis, half from high cholesterol, one-third from osteoporosis and one in five from diabetes³⁶⁰.



Reference number 6 IRI

Eye and gastrointestinal (GI) problems have increased the most over the past two years among self-reported conditions afflicting those 50 years and older; heart disease and cancer top the list of conditions about which they're very/extremely concerned, according to Health Focus³⁶¹.

³⁶⁰ IRI, 2006. 55+ Consumers: the New Must Win Market Webinar. Aug. 17, 2006.

³⁶¹ HealthFocus, 2007. U.S. 2007 Trend Report. HealthFocus, International. St. Petersburg, FL. www.healthfocus.com

HealthFocus International, 2007.

Top 10 Conditions Very/Extremely Concerned About			
	Age 65	65+	Age 50-64
1. Heart disease		63%	Heart disease
2. Cancer		61%	Cancer
3. Arthritis		60%	Arthritis
4. Eye health		55%	Eye health
5. High blood pressure		52%	High cholesterol
6. High cholesterol		51%	High blood pressur
7. Alzheimer's		48%	Lack mental sharpness
8. Diabetes		45%	Stress
9. Lack mental sharpness		43%	Tiredness/lack energy
10. Tiredness/Osteo (each)		41%	Alzheimer's

HealthFocus International, 2007.

Half of seniors and 43 percent of older Boomers have high cholesterol, two-thirds of women and 75 per cent of men aged 65 to 74 have high blood pressure³⁶². As boomers age 45 years and older confront a greater risk of heart attack and stroke, ingredients that increase circulation and prevent dangerous clots, which also increase blood flow to the brain, will be of increasing interest to this group.

Adults 65 years and older account for 40 per cent of the diabetic population³⁶³, and people 50 years and older are very/extremely concerned about diabetes rose 9 per cent in the past two years³⁶⁴. Regarding vitamin and mineral consumption, calcium, vitamin D and vitamin B-12 deficiencies are of particular concern in this demographic³⁶⁵.

Boomers are increasingly interested in keeping active with nearly nine in 10 (88 per cent) aged 55 years and older focused on exercise. ACNielsen found that 60 per cent of global consumers see 60s as the new "middle age." Only 17 per cent of older Boomers (55 to 64) and 22 per cent of those 65 to 74 are in fair/poor health or to have chronic conditions affecting their mobility and adults 50 years and older are the fastest growing exercise segment³⁶⁶. Health Focus reports that they exercise at almost the same rate as those 18 to 24 years of age⁷⁰. With 40 per cent of older Boomers and 34 per cent of those 65 years and older self reporting a lack of energy/tiredness, vitality products are increasing in popularity.

However, Boomers are nearly twice as likely as the rest of the population to be overweight and to be currently trying to lose weight³⁶⁷. Nearly two-thirds of boomers (65 per cent) versus half (54 per cent) of non-boomers are trying to lose weight. Mature adults (60 years and older) are the population group most likely to say their diet is healthy enough, having already made dietary changes for health. Those 40 to 58 years

³⁶² NIDDK, 2005. Digestive Disease Statistics. Natl. Inst. Of Diabetes and Digestive and Kidney Diseases. Bethesda, MD. www.niddk.nih.gov

³⁶³ IRI, 2005. Chronic Disease. Times & Trends. June. Information Resources Inc. www.infores.com

³⁶⁴ HHS/CDC, 2007. Health, United States, 2006. CDC National Center for Health Statistics. www.cdc.gov/nchs/jus06.htm

³⁶⁵ USDA Human Nutrition Research Center on Aging Report, Tufts University, August 2006.

³⁶⁶ AC Nielsen, 2007. Health, Beauty & Personal Grooming. March. www.ACNielsen.com

³⁶⁷ Harris Interactive, 2007. Healthy Living among Boomers. Harris Interactive. May 31, 2007 Webinar.

were the least satisfied with their eating habits, weight, and health and are the most likely to be making healthy changes in their diets³⁶⁸. Whole grains top the list of healthy ingredients older consumers are trying to include in their diet followed by dietary fiber, protein, calcium and antioxidants, e.g. vitamin C and E.

Willingness to consume functional foods and beverages for the maintenance of health, or the prevention of treatment of disease is widespread not only among seniors and the boomer generation but also younger sectors. The National Marketing Institute (NMI)³⁶⁹ has found that two thirds of Americans surveyed consume functional or fortified products, and that this consumption spreads fairly evenly across all age groups. The Generation X sector aged 30 to 42 of the US population number close to 53 million. The Millennials aged 29 and under represent 113.4 million people. According to NMI, these groups represent very lucrative targets for FFNHP in the future.

6.2 Consumer Focus on Health and Wellness

Consumers are a critical driving force behind the development of healthier foods and FFNHP. As they strive to maintain good health into old age, they are attempting to take greater control over their health care needs. With the rising incidence of obesity and the significant increases in the rates of chronic disease, consumers are becoming increasingly aware of the link between diet and medical disorders. Given the serious statistics related to the increasing death rates and of course, the costs of disease, to Western societies, it is no surprise that consumers are seeking alternatives to conventional medicine which has been dominated for decades by an attitude of “treat” rather than “prevent” illness.

6.2.1 Canadian Consumers

Recent studies on Canadian consumers have illustrated significant interest in health and wellness products. Findings have shown:

- “Canadians are willing to try new things ...and want safe and effective products but they also want access to as many options as possible”. Canadians are very responsive to new research, media coverage and advertisements of dietary supplements – the opportunity is to provide consumers with proven science³⁷⁰.
- “Canadians are very health conscious ... say nutrition is important because they want to stay healthy, active and young”. Canadians are demanding more innovative products that are convenient, provide consistent high quality, taste and value, are healthful, and provide clear and substantiated labeling and other information”.

³⁶⁸ FMI, 2006. Shopping for Health. Food Marketing Institute. www.fmi.org

³⁶⁹ French, S. 2007. Consumer trends in health. National Marketing Institute (NMI). Presentation at the Supply Side East Meeting. Las Vegas. November 2007.

³⁷⁰ International Business Strategies, “Natural health products in Canada”, June 2004.

Functional Foods

The Canadian Council of Food and Nutrition released its sixth version of the Tracking Nutrition Trends (TNT) consumer research study in October 2006³⁷¹. This survey has assessed what Canadians know, think and do about nutrition since it was first launched in 1989. A telephone survey of 2014 Canadians nationwide was employed in data collection.

The results show that taste, nutrition, cost and convenience continue to be key drivers of food choices. Taste and nutrition were rated as very or somewhat important by 96% of respondents. When asked 'what makes a food healthy?' the most frequently cited factor, identified by 30%, is that it 'contains good nutrients'. 'Maintaining good health' was found to be the most influential factor motivating food choices: 93% of respondents thought it was at least somewhat influential, followed by 'to get energy or stamina' (76%), 'weight management/body image' (70%), and 'following a special or prescribed diet'(39%).

Although most of those surveyed rated their eating habits and health as at least good and their nutrition knowledge as high, there appear to be gaps in understanding. Only 20% claimed to have ever heard about functional foods before the survey. Some of the other key findings in this report include:

- 62% said that they had changed their eating habits in the previous 12 months.
- 77% said they used food labels, the most popular source of nutrition information, at least once.
- 32% responded that a nutrition or health claim had attracted their attention.
- Only 23% said they had personally received nutrition information from a dietitian.

Canadians are also looking for health information from credible sources and are increasingly seeking out physicians and nurses for assistance. However, these groups appear to be less informed on this topic than others such as pharmacists, dietitians, etc. In a recent study conducted by Environics, 66% of the physicians and nurses surveyed believe foods and supplements provide benefits for our health beyond basic nutrition, but there is still concern over the efficacy of the products. This group expressed a desire for more information regarding these products.³⁷²

Decima Research recently conducted telephone interviews with a representative sample of 2,012 Canadians (aged 18 years and older)³⁷³. The focus on the survey was foods and beverages. Some of the key findings were:

- 75% of Canadians choose food and beverages for reasons other than taste and preference at least some of the time; 57% of Canadians choose foods for desirable nutritional qualities contained in the food such as fibre, antioxidants, and fatty acids.
 - 39% of Canadians choose foods for health concerns such as diabetes, cardiovascular disease, and high blood pressure.

³⁷¹ Canadian Council of Food and Nutrition. October 2006. "Tracking Nutrition Trends VI report". www.ccfm.ca/events.

³⁷² Environics Research Group Ltd., "Health Professional Survey of FFNs (Phase II)", Prepared for Agriculture and Agri-Food Canada, June 2005.

³⁷³ Decima Research Inc. 2004. *Demand for Food Products Supporting Health and Wellness*. Research conducted for AAFC. http://www.agr.gc.ca/misb/fb-ba/nutra/deman/pdf/decima_e.pdf.

- Canadians recognize the health benefits of some foods, but health is not the main reason they choose one food over another:
 - 75% of Canadians choose food based on what the whole family will eat.
 - Although choosing based on what the whole family will eat is the biggest contributing factor when choosing food Canadians will also eat a wider variety of foods for health reasons (68%), will choose food to maintain a 'heart healthy' diet (63%), and generally select foods for health reasons (62%). These responses were given by survey participants who were read a list of reasons for choosing foods and asked to indicate how often they decide to purchase/eat food on that basis. Percentages are based on the number of respondents that answered "always" and "usually".
 - Foods eaten specifically for health benefits are vegetables (53%), fruit (40%) and fish (17%).

Canadians exhibit a high level of awareness of functional foods and the diseases they are related to:

- 60% were able to name at least one functional food on an unaided basis.
- 24% were able to match at least one food with a health condition associated with it.
- On an aided basis, 68% of respondents were able to name a food associated with a certain condition.

Natural Health Products

In 2005, Ipsos Reid conducted a national random telephone survey of 2004 adults, aged 18 and over. The purpose of the survey was to measure "the awareness levels, attitudes towards, knowledge about, and behaviours of Canadians as they pertain to NHP."³⁷⁴

Some of the important overall findings are as follows:

- More Canadians are unfamiliar (45%) than familiar (36%) with NHP.
- Among those who have used a NHP, 38% report that they do so, on a daily basis.
- The most commonly used NHPs are vitamins (57%), Echinacea (15%), herbal remedies and algal and fungal products (11%), glucosamine (8%), homeopathic medicine (5%), natural organic products (5%) and supplements (5%).
- Users of NHPs use NHPs because they believe that NHPs are better than conventional drugs (18%), personal health concerns (18%) or to help promote personal health (14%).
- Users of NHPs in Canada tend to be residents of British Columbia and Alberta, are women with a higher level of education and household income, and are between the ages of 18 and 54.
- Primary reasons for not using NHP include: no need (20%), lack of information on NHPs (17%), the attitude "I am healthy" (13%), a lack of belief in the efficacy of natural health products (11%) and the sense that the products are too expensive (5%).

Canadians are aware that food and nutrition has a positive impact on overall and long-term health, and there is a general awareness of Canadians regarding functional foods

³⁷⁴ Ipsos Reid. 2005. *Baseline Natural Health Products Survey Among Consumers*. Prepared for Health Canada.

and the different diseases they are associated with. As well, Canadian consumers are interested in learning more about the health benefits of functional foods. However, educating health professionals and consumers on the benefits of the functional food and NHP industry remains a key challenge.

6.2.2 Consumers in the United States

With more public information about the health benefits of foods or food components than ever before, consumers' interest in health issues is at an all-time high and has become a leading factor in their food-purchasing decisions. As early as 1998, an International Food Information Council survey of 1000 consumers in the U.S., 95% expressed the belief that certain foods provided benefits that could reduce disease risk or improve health³⁷⁵.

Princeton Survey Research Associates recently reported that 76% of consumers feel that eating healthfully is a better way to manage illness than medication. The top five factors motivating food purchase decisions, according to the results of this survey, are ensuring overall good health, reducing fat intake, following a physician's advice, and to control weight and cholesterol intake³⁷⁶. In 2002, the annual "Shopping for Health" study, a joint survey between the Food Marketing Institute and Prevention Magazine, noted that 68% of shoppers are more likely to treat themselves before seeing a physician, up from 31% in 1998³⁷⁷.

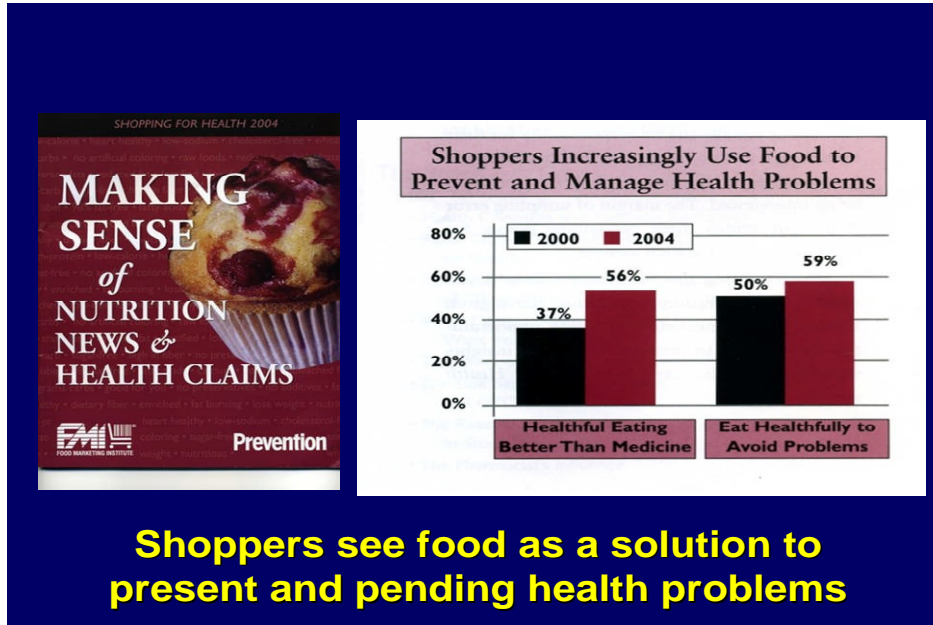


In a subsequent report published by the same group in 2004⁶⁹, results showed that shoppers continue to see food as a solution to present and pending health problems.

³⁷⁵ International Food Information Council (IFIC), "Consumer reactions to Functional foods" 1999. <http://www.ific.org/research/obesitytrends.cfm>

³⁷⁶ Princeton Survey Research Associates. 2004. Consumers attitudes: Food and Health. <http://www.psrai.com/news.jsp>

³⁷⁷ Shopping for Health. Self Care perspectives. 2002. Food Marketing Institute. <http://www.fmi.org/>



Prevention remains the main focus of the majority of healthy products today, with nearly 100 million adults in the United States soon to be age 50 or older, and many at the age where they are likely to experience a serious health condition for the first time. Approximately 65% of consumers in the United States used food to prevent obesity, 61% high cholesterol, 60% heart disease, 53% cancer, 50% hypertension, 42% osteoporosis, 33% vision problems and 30% arthritis.

While consumers are becoming more concerned about the health consequences of their diet, the majority of people still believe that taste is the most important factor in determining what they eat. The days are gone when people expect something that is good for them to be unpleasant. The global consumer is increasingly seeking brands that they recognize to offer foods with functional benefits.

Although obesity and related health conditions are causing concern on a global scale, this is only part of the reason why global sales of 'healthier for you' foods are growing at a rapid pace. Dietary changes have been the primary means that consumers are using in an effort to prevent disease and obesity in the first place. The 2007 International Food Information Council's Food & Health Survey revealed that 75% of Americans polled were concerned with their weight, as opposed to 66% in 2006. In addition, 70% of those surveyed felt that dietary changes could help significantly with losing extra pounds. Eighty percent said they agreed that certain foods and beverages could improve "heart health," and 76% maintained that what one consumes can contribute to overall health and wellness³⁷⁸.

A global survey by AC Nielsen found that U.S. consumers are less likely than the average global consumer to purchase functional food products such as yogurts with acidophilus cultures/probiotics, fermented drinks containing good bacteria and soy

³⁷⁸ International Food Information Council (IFIC) Foundation, 2006. Food & Health Survey: Consumer Attitudes toward Food, Nutrition & Health, Washington, DC. <http://ific.org>

milk³⁷⁹. However, U.S. consumers were more inclined to purchase functional foods such as whole grain, high fibre products (50 percent versus 40 percent global average), cholesterol reducing oils and margarines (36 percent versus 31 percent global average) and bread with added supplements/vitamins (24 percent versus 17 percent global average).

Among US consumers who do not buy functional foods, the most frequently cited claims were uncertainty about the products' health claims, cost and taste.

The following Table shows the percent of American consumers who regularly buy functional foods versus the global average.

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

As summarized in the next Table, total annual spending was greatest for the occasional consumer group (US\$10,154 million total spending per year), followed by the regular consumer group (US\$9,686 million total spending per year) and the heavy consumer group (US\$4,871 million total spending per year).

³⁷⁹ AC Nielsen. 2005. *Organic and Functional Foods: Room to Grow in the US*. Consumer Insight - Trendwatch. http://us.acnielsen.com/pubs/documents/2005_ci_q4_trendwatch.pdf.

Table 3: Summary of United States Consumer Functional Food Use, 2005³⁸⁰

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

In order to find out why US consumers purchase functional foods, a survey by Mintel³⁸¹ asked 566 adults who had bought a functional food in the past three months and had internet access to respond to the following statement, "Please tell us whether you buy functional foods for any of the following reasons." The results shown below indicate that the primary reason to purchase functional foods was to make up for less than healthy eating habits (48 percent agreed with this purchasing reason).

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

Mintel³⁸² also asked 1,315 adults who had not purchased a functional food in the past three months and had internet access to respond to the following statement, "Please tell us whether you have not bought functional foods or drinks in the past three months for any of the following reasons." The primary reason for not purchasing functional foods was because the respondents felt functional foods were over priced (43% of respondents).

³⁸⁰ NBJ. 2007. *NBJ's Healthy Foods Report 2007*. Nutrition Business Journal.

³⁸¹ Mintel. 2006. *Functional Foods Market Intelligence*. Mintel International Group Ltd.

³⁸² Mintel. 2006. *Functional Food and Beverages*. Mintel International Group Ltd.

Reason for not purchasing functional foods	Percent who did not purchase functional foods for the given reason
I think they are overpriced	43
I don't believe the claims they make	35
I take vitamin and mineral supplement(s) instead	32
I already maintain a healthy diet and lifestyle	30
I don't know enough about them	29
They cost more than regular versions	28
Regular food or drinks already give me what I need	17
My prescription medication already gives me what I need	11
They could be bad for me	8
Other	7

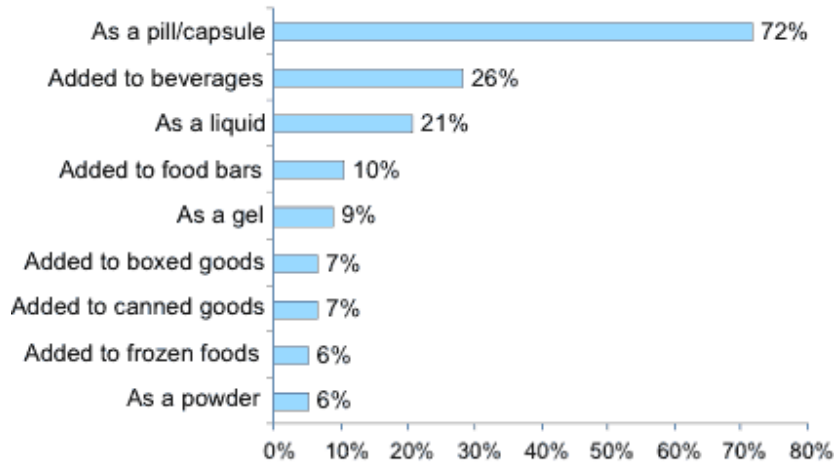
Dietary Supplements

Supplements may not be as popular with US consumers as in the early 2000's, but the importance of vitamins and minerals, and specialty supplements which include essential fatty acids, fiber and probiotics, to consumers' health and wellness lifestyles should not be overlooked nor their role diminished. A consumer study conducted by the Hartman Group³⁸³ indicates that consumers continue to purchase and use nutritional supplements, but with less intensity and exploratory nature than in 2000. The study found new interest in key supplements such as green tea, probiotics and omega 3 fatty acids.

When consumers are experiencing chronic or acute health problems (allergies, diabetes, high blood pressure, stroke, osteoporosis, etc.), they shift from more general watching behaviors and high level dietary overhauls (with the requisite focus on avoiding "bad things") to more proactive and targeted health behaviors. Many consumers with chronic health conditions turn to alternative medicine. The chart below illustrates consumers' preferred delivery of functional ingredients when asked which format they preferred vitamins, minerals and nutrients delivered in. Overwhelmingly, respondents chose pills (72%) compared to the next most popular format beverages (26%).

³⁸³ The Hartman Group. February 2006. "Don't count supplements out". http://www.hartman-group.com/products/HB/2006_02_15.html

PREFERRED DELIVERY OF FUNCTIONAL INGREDIENTS, 2005



Consumers view dietary supplements as a key component in good health and increasingly avoid pharmaceutical approaches to wellness. The most successful dietary supplement products are those that focus on offering not only treatment but prevention.

7.0 REGULATORY REVIEW

Of significant relevance to the marketing of foods for health is the fact that the ability to link a food or food component to health must be based on sound scientific evidence, with the desired standard being replicated, randomized, placebo-controlled, intervention trials in human subjects³⁸⁴. Once a sound scientific basis has been established for a food or ingredient, the process for obtaining a health claim for the product can be initiated.

There are three basic types of health claims: structure/function (e.g. calcium helps to build strong bones), risk reduction (e.g. calcium helps reduce the risk and progression of osteoporosis), and therapeutic (e.g. product X is indicated for the treatment of osteoporosis).

It appears that the key success factor for manufacturers of FF is to remember that first and foremost, they are promoting a food. As such, health claims should be seen as a competitive addition to healthy foods, but should not become a replacement for the standard features of foods – namely taste, ease of preparation, and quality. Foods are related to health and drugs to illness; this distinction will be important in the future for any company that wishes to penetrate this market.

In an effort to make the disease-diet link clear to consumers, there has been a global movement by the food industry towards using health claim statements on food packages. However, the introduction of diet-related health claims has been slow in most countries due to the regulatory constraints. The main issue impacting both regulatory and market perception of functional foods is their hybrid nature – acting as both “treatment or risk reduction” and food. In the mind of regulators and consumers, highly technical scientific claims are associated with pharmaceuticals, not foods. Regulations world-wide are starting to adapt to include functional foods. Japan and the United States are at the forefront of the regulatory progression, while Canada, the European Union and Australia/New Zealand are moving more slowly with the concept.

Although each jurisdiction has its own definition of a health claim, generally, health claims are a statement or representation (through graphics, brand name, trade name) on a food that states, suggests, or implies that a relationship exists between a food or a component of that food and health or disease risk-reduction. Generally, health claims do not refer to dietary information alone that quantitatively or qualitatively makes reference to the level of a nutrient in a food –e.g., “zero fat” or “high in fibre”. Such claims are referred to as nutrient content claims or nutritional claims.

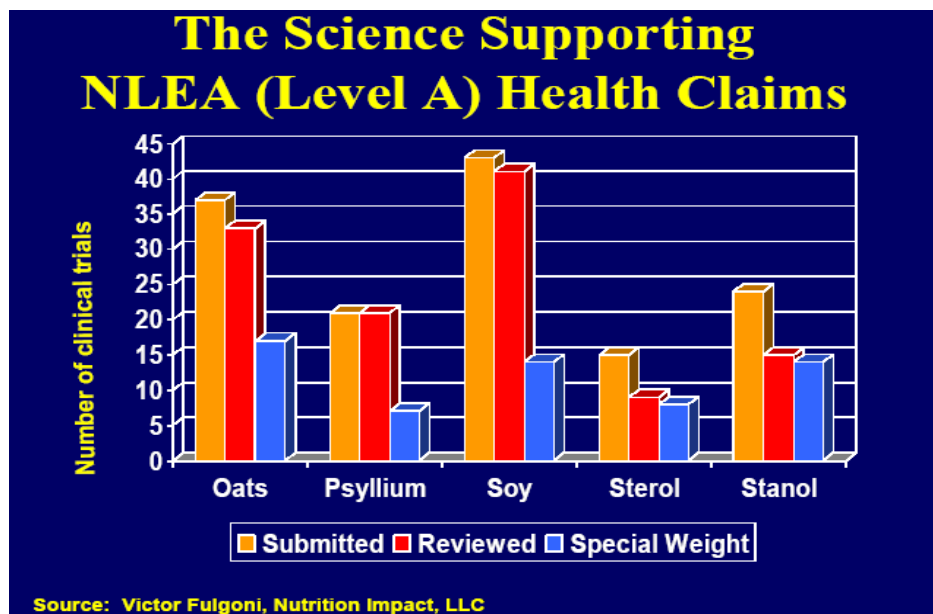
7.1 Efficacy

The surest way to grow the market for FFNHP is to prove they work. Efficacy is, after all, their unique selling proposition, the characteristic that sets them apart from other consumer products and makes them an industry or "category." Manufacturers of such products are increasingly sponsoring clinical reviews of their branded products and ingredients to evaluate and prove their efficacy. Scientific and clinical research, validating the effectiveness and safety of these products, and increasing media coverage of such information, are crucial for market success.

³⁸⁴ Hasler CM (2002). Functional Foods: Benefits, Concerns and Challenges – A Position Paper from the American Council on Science and Health. *J. Nutr.* 132(12):3772-3781.

The importance of randomized, double blind clinical trials focused upon Western populations for health claim substantiation is growing. The US Food and Drug Administration (FDA) under the regulatory environment known as “Nutrition Labeling and Education Act” (which was the original piece of legislation passed in the US for claim allowance and will be described in detail in the next section), will review only very well-controlled studies for consideration of claims. For example, Quaker Oats submitted 37 clinical trials to support the first food related health claim, oats and risk reduction for coronary heart disease – yet only 16 were considered of relevance for the claim. Protein International (now Solea) submitted 42 clinical publications of which only 13 were considered by the US FDA and used as the basis for the decision to allow a health claim related to the consumption of soy protein and the reduced risk of coronary heart disease.

Of note, on December 20, 2007 the FDA announced its intent to reevaluate the scientific evidence for the soy protein and risk of coronary heart disease health claim noting that a reevaluation of the scientific basis for these claims is required because of new scientific evidence that has emerged. According to the FDA, “the new scientific evidence may have the effect of weakening the substance-disease relationship for these authorized health claims”³⁸⁵. The importance of strong science for health claim approval can not be understated.



7.2 Safety

Bioactive ingredients, although intended to produce a physiological effect to reduce chronic disease risk or otherwise optimize health, may also produce adverse effects under certain circumstances due to the fact that they encompass elements of drugs,

³⁸⁵ Food and Drug Administration. Docket No. 2007N-04641. Reevaluation; Opportunity for Public Comment. <http://www.cfsan.fda.gov/~dms/qhc-sum.html>

nutrients and food additives³⁸⁶. Thus, assurance of safety for such ingredients is critical, particularly because the general population consumes them in an unsupervised manner (e.g., without medical oversight). When evaluating functional ingredients, clinical substantiation of safety is critical and in particular, whether current or historical human exposure is associated with an adverse health outcome.

In the U.S., bioactive ingredients can be marketed as dietary supplements, food additives, or as generally recognized as safe (GRAS). The regulatory requirements to determine safety are different for each of these categories⁹⁰. In 1997, the Food and Drug Administration (FDA) proposed replacing the current GRAS affirmation process with a notification procedure whereby any person may notify FDA of a determination that a particular use of a substance is GRAS. Under the proposed notification procedure, the FDA evaluates whether the submitted notice provides a sufficient basis for a GRAS determination and whether information in the notice or otherwise available to FDA raises issues that lead the agency to question whether use of the substance is GRAS. Notification is not mandatory if the sponsor chooses to inform the FDA of its GRAS determination. The FDA does not make its own determination of the GRAS status of an ingredient. The cost to conduct a GRAS affirmation depends on the level of science that exists, and can range from \$50K U.S. to over \$150K U.S.

Unlike the U.S. GRAS system, new foods and food ingredients are assessed under “novel” food regulations in Canada³⁸⁷. Novel foods are defined in the Novel Foods Regulation as products that have never been used as a food; foods that result from a process that has not previously been used for food; or, foods that have been modified by genetic manipulation. This last category of foods has been described as genetically modified foods.

Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), pre-market approval is not required for dietary supplements, which include “vitamins, minerals, herbs or other botanicals, amino acids, or other ‘dietary substance[s] for use by man to supplement the diet...including concentrate, metabolites, constituents, extracts, or any combination...”. Such ingredients must not present “a significant or unreasonable risk of illness or injury” a standard, which has been criticized by some experts as reducing the criteria of safety compared with food additives or GRAS ingredients³⁸⁸.

There are several issues critical to the evaluation of the safety of a bioactive ingredient⁹⁰. First, due to the fact that these ingredients are physiologically active, mechanisms of action for pharmacologic activity are essential to determine consequences of exposure at varying doses. Second, bioactive ingredients can be single compounds, complex mixtures or products derived from novel sources/processes—each of which presents unique safety issues, which must be assessed on a case-by-case basis. Third, potential exposure from a bioactive ingredient must be compared to its determined safe level of intake. Finally, potential adverse drug-food interactions must be assessed.

³⁸⁶ Kruger CL, and Mann SW., “Safety evaluation of functional ingredients” *Food Chem. Toxicol.* 2003, 41:793-805.

³⁸⁷ Health Canada. “Regulation of Novel Foods” <http://www.hc-sc.gc.ca/food-aliment/mh-dm/ofb-bba/nfi-ani/>.

³⁸⁸ Burdock GA., “Dietary supplements and lessons to be learned from GRAS” *Regulatory Toxicol. Pharm.* 2000, 31:68-76.

For bioactive ingredients, the primary evidence of safety must be derived from human clinical intervention trials; epidemiological studies (cohort studies, case-control studies, cross-sectional studies, ecologic and case-series studies. The following list of criteria is generally accepted by experts evaluating literature to determine not only efficacy, but the potential for adverse health effects from consumption of a functional/nutraceutical ingredient⁹⁰:

- Strength of the association (magnitude of relative risk);
- Consistency of the association (repeatability);
- Specificity of the association (between exposure and effect);
- Temporality (sequence);
- Coherence (does association make sense);
- Dose-response;
- Biological plausibility (effect consistent with mechanism(s) of action);
- Experimental support; and
- Analogy (has a similar agent been found to cause the disease in a similar way).

Although a functional food or NHP ingredient is intended produce optimize consumer health; because there is potential for lifetime exposure and consumption is unsupervised, the assurance of safety is critical. The assurance of safety and efficacy must be derived from well-controlled randomized, double blind human clinical intervention trials. Safety must encompass an understanding of the physiologic activity of the bioactive component, not only as it relates to a potential health benefit, but any potential toxicological effect that may result.

7.3 Canada

The following sections describe the regulatory frameworks for ‘functional’ foods, NHPs and novel ingredients in Canada.

7.3.1 ‘Functional’ Foods

Federal responsibility for the regulations dealing with foods sold in Canada, including novel foods, is shared by Health Canada and the Canadian Food Inspection Agency (CFIA). Health Canada is responsible for establishing standards and policies governing the safety and nutritional quality of foods and developing labelling policies related to health and nutrition. The CFIA develops standards related to the packaging, labelling and advertising of foods, and handles all inspection and enforcement duties. The CFIA also has responsibility for the regulation of seeds, veterinary biologics, fertilizers and livestock feeds. More specifically, CFIA is responsible for the regulations and guidelines dealing with cultivating plants with novel traits and dealing with livestock feeds and for conducting the respective safety assessments, whereas Health Canada is responsible for the regulations and guidelines pertaining to novel foods and for conducting safety assessments of novel foods.

The Canadian Food and Drugs Act and Regulations was passed into law in 1953. 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."

Through its definitions of "food" and "drug", this legislation currently restricts health-related claims for foods and food ingredients. Since 1953, these products have been considered as either foods or drugs depending on the type and concentration of the "active ingredient" and whether claims are made. 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.

Further limiting the development of health claims in Canada are statements in Section 3³⁸⁹ of the Act and Regulations which prohibit the sale or advertisement to the general public of any food, drug, cosmetic or device which indicates a treatment, cure or preventive role for diseases or disorders referred to in Schedule A which include heart disease, diabetes, cancer, hypertension, obesity and arthritis. These are the most common causes of morbidity and mortality in Canada and are diseases for which functional foods have the potential to be the most beneficial. Physiological effects that relate to these conditions, such as lowering of serum cholesterol or glucose, are also considered under the umbrella of Schedule A and are precluded from appearing on labelling and in advertising. In order for health claims to appear in Canada, changes would have to be made to allow claims about Schedule A diseases or physiological effects related to these diseases.

Canada has three categories of health claims and two categories of claims not considered health claims. Health claims include structure/function claims, risk-reduction claims and therapeutic claims – all are claims related to the definition of a drug by claiming uses related to the prevention or management of a disease or abnormal physical state, including their symptoms (applies to risk-reduction claims and therapeutic claims) or the modification of organic functions beyond what is considered normal and required for the maintenance of good health (applies to structure/function claims)³⁹⁰. Because such claims bring food under the definition of a drug, regulatory amendments are required to approve the use of these claims.

Nutrient content claims and biological role claims are not considered health claims since they do not bring food under the definition of a drug. As such, no regulatory amendments are required for their use. Nutrient content claims describe or imply levels of a nutrient in a food while biological role claims describe the function of nutrients or energy in the body for normal growth and development or health maintenance.

Canada's definition of biological role claims (generally recognized nutritional function of energy or nutrients in maintaining good health and normal growth and development) is comparable to the U.S. definition of structure/function claims (intended to affect normal

³⁸⁹ Smith BL, Marcotte M, Harrison G (1996). *A Comparative Analysis of the Regulatory Framework Affecting Functional Food Development and Commercialization in Canada, Japan, the European Union and the United States of America*. Inter/Sect Alliance for Agriculture and Agri-Food Canada. http://www.agr.gc.ca/misb/fb-ba/nutra/index_e.php?s1=nutrareg&page=intro

³⁹⁰ Government of Canada (2002). B.01.603 of Food and Drugs Act: Regulations Amending the Food and Drugs Regulations (Nutrition Labelling, Nutrient Content Claims and Health claim). Canada Gazette <http://canadagazette.gc.ca/partII/2003/20030101/html/sor11-e.html> .

structures or functions in humans or describe general well-being) and therefore the two countries' definitions of structure/function claims are not comparable.

Regulatory Activity to 2007

In November 1998, Health Canada released a policy recommendation to address health claims for foods³⁹¹. The policy paper states that "structure/function and risk reduction claims for foods should be permitted while all other products claiming to cure, treat, mitigate or prevent illness should continue to be regulated as drugs". A number of consultations and proposals followed this recommendation but little progress has been made.

Despite the barriers surrounding the use of health claims, six generic claims have been authorised for use in Canada. Generic claims apply to a food or a group of foods that have compositional characteristic(s) that contribute to a dietary pattern associated with reducing the risk of a disease or health condition. Once the claim is authorized, any food that meets the specified conditions for composition and labelling may carry the claim without further assessment.

Generic claims were approved through the implementation of a regulatory amendment which provides an exception to the Section 3/Schedule A combination³⁹². The allowed statements, labelling and advertising conditions, as well as nutritional requirements for allowable food were laid out in the 2003 amendment to the *Regulations*⁹⁰.

The six allowed generic health claims were approved following a scientific review by Health Canada. The review, initiated in 1998, looked at the first ten NLEA-authorized health claims from the United States and allowed:

1. Sodium/potassium and hypertension
2. Calcium/vitamin D and osteoporosis
3. Saturated/*trans* fat and coronary heart disease (CHD)
4. Fruits/vegetables and cancer
5. Sugar alcohols and dental caries

In 2006, upon further review Health Canada announced pending approval of two additional claims:

- 1. Vegetables, fruit and whole grain products and risk of CHD**
- 2. Folate and reduction in neural tube defects**

Health Canada is currently reviewing the following claims:

1. Soluble fibre from certain foods (oats, psyllium, and barley) **and risk of CHD**
2. Soy protein **and risk of CHD**
3. Plant Sterol/stanol esters **and risk of CHD**

³⁹¹ Health Canada (1998). *Final Policy Paper on Nutraceuticals/Functional Foods and Health Claims on Foods*. http://www.hc-sc.gc.ca/food-aliment/ns-sc/ne-en/health_claims-allegations_sante/e_nutra-funct_foods.html.

³⁹² Government of Canada (2002). *B.01.603 of Food and Drugs Act: Regulations Amending the Food and Drugs Regulations (Nutrition Labelling, Nutrient Content Claims and Health claim)*. Canada Gazette <http://canadagazette.gc.ca/partII/2003/20030101/html/sor11-e.html>.

Each of these health claims requires an individual amendment to the *Regulations*. Health claims based on authoritative statements from organizations (e.g. ‘the Canadian Medical Association recommends.....’) and qualified health claims used in the US were not considered for use in Canada at this time.

To provide industry guidance for the approval of additional claims, Health Canada developed an interim guidance document for preparing health claim submissions. This document, published in 2000, would apply to both generic and product-specific claims³⁹³. Product specific claims were proposed for specific foods having a direct, measurable metabolic effect beyond normal growth, development or health maintenance, reducing disease risk or aiding in the dietary management of a disease or condition. Of significance, unlike generic health claims, in the case of product-specific health claims, the authorization of each claim would not entail a claim-specific regulation and claims for “Schedule A diseases” would not be permitted³⁹⁴.

From a regulatory perspective, generic claims would be permissible through amendments to the list of authorised claims initially published in 2003^{395,396}. Of significance, no product-specific claims are currently allowed and industry appears reluctant to test the submission process.

For the **evaluation of claim validity**, the guidance document recommends a similar systematic approach be used to capture and evaluate the totality of evidence, favourable and unfavourable, on a food/health relationship, regardless of the subject of the claim – *i.e.*, a modified or unmodified food. The totality of evidence should demonstrate causality, be of acceptable quality (research conduct and research design), be relevant and generalizable to the target population, and should substantiate the health claim with a “high level of certainty” (*i.e.*, reasonable assurance that the claim is unlikely to be reversed by new and evolving science). The only difference in the evaluation of claim validity for generic *versus* product-specific health claims is in the requirement for human intervention studies on the specific food as intended for sale for product-specific claims. This is not a requirement for generic health claims which can rely on a combination of human intervention studies, observational studies, and systemic reviews to support their validity.

For the **evaluation of safety**, the breadth of required information is dependant on the degree of food modification. For unmodified foods, assessment of safety is more

³⁹³ Health Canada (2000). *Interim Guidance Document. Preparing a Submission for Foods with Health Claims incorporating: Standards of Evidence for Evaluating Foods with Health Claims*. http://www.hc-sc.gc.ca/food-aliment/ns-sc/ne-en/health_claims-allegations_sante/pdf/e_guidance_doc_interim.pdf.

³⁹⁴ Health Canada. Consultation Document: Standards of Evidence for Evaluating Foods with Health Claims: A Proposed Framework. June 2000. Internet: http://www.hc-sc.gc.ca/food-aliment/english/subjects/health_claims/standards_of_evidence.

³⁹⁵ Government of Canada (2002). *B.01.603 of Food and Drugs Act: Regulations Amending the Food and Drugs Regulations (Nutrition Labelling, Nutrient Content Claims and Health claim)*. <http://canadagazette.gc.ca/partII/2003/20030101/html/sor11-e.html>

³⁹⁶ Health Canada (2000). *Interim Guidance Document. Preparing a Submission for Foods with Health Claims incorporating: Standards of Evidence for Evaluating Foods with Health Claims*. http://www.hc-sc.gc.ca/food-aliment/ns-sc/ne-en/health_claims-allegations_sante/pdf/e_guidance_doc_interim.pdf.

simplified and requires an evaluation of current and expected (with approval of claim) intakes of the food calculated for the target group and groups at risk.

For modified foods containing a bioactive, a safety assessment would additionally include a discussion on the history of use of the bioactive; intakes (current and expected; for target group and groups at risk) of the bioactive from inclusion in a food applicable to the claim, with a comparison to current dietary recommendations; intakes (current and expected; for the target group and groups at risk) of the bioactive from all sources in the diet, with a comparison to current dietary recommendations; impact of consuming the bioactive on usual dietary patterns (*i.e.*, the potential replacement of existing foods with the food containing the bioactive that is the subject of the claim); data on adverse effects from relevant human studies; an upper safe limit of intake of the bioactive; interactions of the bioactive with other components in the food (nutrients, dietary components), diet and drugs; potential adverse effects of the bioactive on meeting essential nutrient requirements and on the gastrointestinal tract; and population subgroups at risk of adverse effects from excessive intake of the bioactive.

For the **evaluation of quality**, the breadth of required information is also dependant on the degree of food modification. For an assessment of quality of unmodified foods, analytical testing of product composition are required to ensure expected levels of a nutrient/food component, critical to the claimed effect, are present in the food. For modified foods, additional details are required, including description of the method used to process/produce the bioactive and the food containing the bioactive; compliance with good manufacturing practices (identification of critical control points from raw materials to finished food, including packaging and labelling); evidence of good laboratory and clinical practices; stability data (on bioactive and final product containing the bioactive); for human studies, compliance with established ethical guidelines; characterization of the bioactive; compliance with specifications of the bioactive; and record retention policy and recall procedures.

November 2007 Consultations

In November 2007, Health Canada announced a review of the current framework for the management of health claims for foods. This review is part of the *Blueprint for Renewal*, a major Health Canada initiative aimed at modernizing the oversight for health products and food. In particular, the health claim framework is a component of the *Regulatory Modernization Strategy for Food and Nutrition*³⁹⁷.

An Inter-departmental Policy Team has been established to advise and help guide the development of this discussion document. The objective is an effective framework that will:

- support informed consumer choice by allowing foods with health benefits to be marketed with substantiated claims;
- continue to protect consumers from misleading and unsubstantiated health claims on foods; and
- support conditions for a fair and competitive market environment that will allow for more consumer choice of food products.

³⁹⁷ Health Canada 2005. Regulatory Modernization Strategy for Food and Nutrition. http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/blueprint-plan/index_e.html

The four main themes for consultation and the specific issues of interest in each include:

Theme 1: Efficient and transparent processes

- modernize or improve processes used to approve claims
- develop a more transparent and open approach

Theme 2: Sound evidence for consistent, credible claims

- the nature of the evidence needed to substantiate a health claim and how to interpret it for decision making
- the capacity of petitioners to provide the evidence

Theme 3: Clear policies for today and tomorrow

- functional foods and foods at the food/natural health product interface
- managing a broader range of function claims
- managing diverse front-of-package claims
- eligibility criteria for foods to carry claims

Theme 4: Supporting informed consumer choice

- improving consumer understanding of health claims
- monitoring the impact of health claims on the food supply and on consumer choice

Themes 2 and 3 involve the classification of claims within a new proposed system that separates health claims into a “general” and “specific” category. The “specific” health claims are further categorized into disease risk-reduction claims and function claims. As with the current system, when food relates to the definition of a drug, regulatory amendments would be required to authorize use of the claim on foods. Disease risk-reduction claims and one of the three categories of function claims will bring food under the definition of a drug, requiring regulatory amendments. This process is laborious, and can take upwards of three years to complete the regulatory process³⁹⁸.

³⁹⁸ Health Canada. November 2007. Managing Health Claims for Foods in Canada: Towards a Modernized Framework. http://www.hc-sc.gc.ca/fn-an/consultation/init/manager_health_claims-allegations_sante_2_e.html

Canada's Proposed New System for Categorizing Health Claims ⁹⁵					
	General health claims	Specific health claims			
General Feature	Do not refer to a specific health effect, disease, or health condition	Refer to a specific health effect, disease, or health condition			
Type of claim	General health claim	Disease risk-reduction claim	Function claims		
Specific feature	Promote overall health, healthy eating or provide dietary guidance e.g., "good for you"; "healthy choice"	Link consumption of food/food constituents to a reduced risk of disease in context of total diet ¹	About restoring, correcting or modifying body functions ¹	About maintenance of body functions necessary for maintenance of good health and normal growth and development	About maintenance or support of body functions associated with maintenance of good health or performance
1 Will require regulatory amendments since would be considered drug claims under <i>Food and Drug Regulations</i>					

Key Differences in Canadian and US Regulations

The authorization of diet/disease health claims in Canada requires amendments to the *Food and Drug Regulations*. The reason for this is twofold: 1. health claims in Canada bring a food under the definition of a drug and 2. diseases, disorders, or abnormal physical states listed in Schedule A are prohibited from being advertised or labelled on foods and drugs. Authorization of health claims thus requires exemptions from these conditions which inevitably increases the timeline for Canada's approval of health claims and the time to market health claims. This is unlike the situation in the U.S., wherein health claim authorization does not require regulatory amendments since no exemptions from existing regulations are required.

Structure/function claims in the U.S. are comparable to Canada's biological role claims. These two categories of claims are not considered health claims in their respective countries. The categories of claims are similar in that they cannot mention a disease and generally refer to the maintenance of health or normal growth and development. Whereas biological role claims are a positive list of pre-approved claims, with additional claims requiring approval by Health Canada, structure/function claims for conventional foods in the U.S. do not require pre-approval by the FDA and are not part of a positive list of claims available for use; manufacturers can make structure/function claims so long as they truthful and misleading, the subject of the claim has nutritive value, and the food is in a conventional food form. The scope of allowable claims linking foods to normal health conditions is thus more limited in Canada compared to the U.S.

The positive list of allowable health claims linking food to disease risk-reduction is also narrower in Canada than in the United States. This is a reflection of different values within each country supporting legal processes – e.g., freedom of speech. In addition to authorized health claims (by FDA or a credible, authoritative body) based on a high scientific standard, the U.S. authorizes qualified claims based on weak science. The basis of this is allowing the consumer the right to choose depending upon the available

information. This is unlike Canada's mechanism of approval for health claims which requires health claims to be based on a "high level of certainty".

Canada's current regulatory framework for health claims thus limits the import of products approved for use in the U.S. With a more narrow scope of allowable diet and health or disease relationships on foods, food manufacturers are less able to capitalize on their research and innovation initiatives in Canada, many opting to export their ideas, services and products to the U.S.

Canada's proposed new framework for health claim regulations would not require certain "function claims" to have pre-approval from Health Canada. This would expand the scope of diet and health relationships communicated to consumers, increasing trade and Canada's food industry competitiveness.

Other food related regulations that impact the functional food sector include:

- Nutrient Content Claims
- Biological Role Claims
- Novel Food Regulations

7.3.2 Nutrient Content Claims

In Canada, as part of mandatory nutrition labeling regulations, food manufacturers may claim the nutrient content of specific food labels if the food meets criteria described by the Canadian Food Inspection Agency³⁹⁹. A nutrient content claim is any statement or expression which **describes, directly or indirectly, the level of a nutrient(s)** in a food or group of foods. Positive claims such as "good source" and "high" can be used for nutrients such as protein, potassium, vitamins, and mineral nutrients, dietary fibre and essential fatty acids. The *Food and Drug Regulations* stipulate minimum levels for claims pertaining to protein, vitamins and mineral nutrients.

The terms "good source" and "excellent source" are considered acceptable for protein, vitamins and mineral nutrients. The terms "high" and "very high" are also deemed appropriate. Other terms are evaluated on a case-by-case basis. As an example, the label of a food containing flaxseed or oil can state "Source of n-3" or "Source of Alpha-linolenic acid" if the product contains a minimum of 0.3 g of amount per serving (i.e. one egg = one serving). Although specific claims to omega-3 EFA are not allowed, this label does provide some ability to distinguish a product containing higher levels of ALA from others.

7.3.3 Biological Role Claims

Canadian companies can use "Biological role claims" which permit a statement relating a nutrient to a biological role in a normal healthy state⁴⁰⁰. The claim **may not** refer directly or indirectly to the treatment, mitigation or prevention of any disease, disorder or

³⁹⁹ Canadian Food Inspection Agency: Guide to Food Labelling and Advertising. Section 6: Nutrient Content Claims. <http://www.inspection.gc.ca/english/bureau/labeli/guide/6-tablee.shtml>

⁴⁰⁰ Canadian Food Inspection Agency: Guide to Food Labelling and Advertising. Section 7.5 :Biological Role Claims. <http://www.inspection.gc.ca/english/bureau/labeli/guide/7-0-0e.shtml#7-5-1>

abnormal physical state, or symptoms of same, **nor may it** refer directly or indirectly to correcting, restoring or modifying organic functions. The claim may not refer directly or indirectly to the treatment, prevention or cure of diseases listed in Schedule A.

A claim may be made to the effect that the substance for which the claim is made is generally recognized as an aid in maintaining the functions of the body necessary for the maintenance of good health and normal growth and development. As an example, products containing alpha-linolenic acid can make a reference to essential fatty acids such as "Essential fatty acids are necessary for growth and development." A statement such as "Canola oil (or *this product*) is a "source of ALA, an omega 3 essential fatty acid which is necessary for growth and development" is allowable.

Under current regulations, food package labels may refer to the structure and functions of the human body, such as "Calcium helps build strong bones" or "Canada's Food Guide to Healthy Eating recommends that adults should consume two to four servings of dairy products every day." Section 7.5.2 of the Canadian Food Inspection Agency's *Guide to Food Labelling and Advertising*⁴⁰¹ provides a table of acceptable biological claims for nutrients.

7.3.4 Novel Foods

Health Canada controls the sale of novel foods in Canada through mandatory pre-market notification. Manufacturers or importers are required to submit information to Health Canada regarding the product in question so that a determination can be made with respect to the product's safety prior to sale.

The safety criteria for the assessment of novel foods were developed from internationally established scientific principles and guidelines developed through the work of the Organization for Economic Cooperation and Development (OECD), Food and Agriculture Organisation (FAO), World Health Organisation (WHO) and the Codex Alimentarius Commission.

Safety assessment and approval is required for a novel food ingredient prior to it being eligible for assessment for a health claim in Canada and other global jurisdictions. Novel food (or in the case of new ingredients such as protein, phytosterols and fibres – natural health product assessment and approval) is required for the clinical testing of these components. Any human trials involve safety assessment of ingredients of focus as part of the ethics review and approval for the trial.

Since the enactment of the novel food regulations, Health Canada's Food Directorate has been hesitant to approve novel food ingredients (an example would be phytosterols which applied a number of times to no avail) without a health claim submission. Although Health Canada officials will not state publicly or in writing, novel food ingredients allowance in a food product without a health claim stating the nutritional benefits of the ingredient have been deemed to be 'misleading to the consumer'. Other global jurisdictions have similar safety approval mechanisms in place such as GRAS in the US and Novel Foods in the EU – none require submission of health claim data. These

⁴⁰¹ Canadian Food Inspection Agency (2003). *Guide to Food Labelling and Advertising. Appendix 1: Acceptable Biological Claims for Nutrients.*
<http://www.inspection.gc.ca/english/bureau/labeti/guide/7-0-0e.shtml>

countries have approved numerous ingredients for food enrichment – examples include phytosterols and stanols, soy isoflavones, and ‘novel’ fibres. As such, Canada has fallen behind yet again in global food arena. New individuals have recently been put into place in the Novel Foods Section who has stated that their assessment will deal only with safety issues. If this is the case, this would be of significant benefit to the functional food ingredient industry.

Novel food safety assessments are conducted by the Food Directorate, Health Products and Food Branch of Health Canada. Novel foods can include whole foods, food products, or food ingredients that are derived from plant or microbial sources. The definition of ‘novel food’, and the definitions for ‘genetically modify’ and ‘major change’ are set out in B.28.001 of the *Food and Drug Regulations*⁴⁰²:

7.3.5 Natural Health Products

Canadians want safe and effective products but they also want access to as many options as possible. Satisfying this desire is the goal of the *Natural Health Products (NHP) Regulations*⁴⁰³ that came into effect on January 1, 2004. The new regulations apply to all natural health products, including vitamins and minerals, herbal remedies, homeopathic medicines, traditional medicines, probiotics, amino acids, essential fatty acids and other nutraceuticals. Until publication of the *NHP Regulations*, the working definition for a *nutraceutical* in Canada has been “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”. The product category of nutraceuticals has been encompassed within *NHP Regulations*.

NHP products are allowed to be 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 (i.e. claims that are currently allowed in Canada only for drug products); (ii) resorting or correcting organic functions in humans, or (iii) maintaining or promoting health or otherwise modifying organic functions in humans. In order to allow “drug type” claims within the Foods and Drug Act and regulations, these products will be regulated under a subsection of the Drug Regulations, but will still be referred to as NHPs. Applicants must submit evidence to support a claim they wish to make associated with the product with NHPD allowing therapeutic claims, risk reduction claims and structure-function claims, in addition to non-specific claims. Claims are sub-divided into either traditional or non-traditional use. NHPD has established criteria for the evaluation of the evidence to support the conditions of use of the product, including totality of evidence.

The NHPD has made significant progress regarding the ability for NHP to make health claims currently prohibited under Schedule A. In November, 2005, proposed

⁴⁰² Guidelines for the Safety Assessment of Novel Foods. June 2006. Food Directorate. Health Products and Food Branch, Health Canada.

⁴⁰³ Government of Canada (2003). *Natural Health Products Regulations*. http://www.hc-sc.gc.ca/food-aliment/friia-raaii/food_drugs-aliments_droques/act-loi/pdf/e_natproducts.pdf

amendments to the *Regulations* were announced which would allow NHPs to make schedule A health claims⁴⁰⁴.

According to Health Canada, food is not addressed through the proposed regulatory amendment for two reasons. First, there is already an exemption from section 3 of the *Food and Drugs Act* for food product labels or advertising pertaining to six specific health claims prescribed in the *Food and Drug Regulations*. Second, a new regulatory framework for the use of food labels and advertising will be developed under the Smart Regulations initiative described earlier.

Approval of an NHP includes an issuance of a Natural Product Number (NPN), similar to the Drug Identification Numbers (DIN) used for drug approvals⁴⁰⁵. The Natural Health Products Directorate (NHPD) has developed a Compendium of Monographs as a tool for the timely and efficient evaluation of both safety and efficacy of many medicinal ingredients.⁴⁰⁶ If an ingredient or product has a monograph, manufacturers can make a health claim without having to generate supporting evidence, and be fast-tracked through the claim approval process.

NHPs in Food Form

Since the NHP regulations came into force, the NHPD has received a number of product licence applications for products presented in food-formats and food-mediums (e.g. juices, cakes, drinks, yogurts, butters, etc.). The increasing presence of these products has raised certain concerns regarding potential risk to consumers, confusion amongst the public and the industry, and the true intent and scope of the *Natural Health Products Regulations*.

On October 9, 2007, the NHPD publicly notified stakeholders that NHPs in food formats/matrices that applied to the NHPD for a product license and/or approval of a claim will be reviewed by the Food Directorate while those in therapeutic dosage forms (e.g., pills, tablets, etc) will be reserved for the NHPD⁴⁰⁷. Although food-like products regulated as NHPs are not legally subject to food regulations and standards, Health Canada felt that consumers do not distinguish these products from other foods and thus may consume them *ad libitum*. To ensure the application of safety and efficacy standards consistent with other foods, the Food Directorate will, in addition to existing NHP guidance documents, consider the evidence requirements outlined in the *Interim Guidance Document for Preparing a Submission for Foods with Health Claims*, in their approval of

⁴⁰⁴ Government of Canada. November 19, 2005. Canada Gazette, Part 1 (Vol. 139, No. 47). <http://canadagazette.gc.ca/part1/2005/20051119/html/regle1-e.html>

⁴⁰⁵ Health Canada (2004). *Product Review and Assessment*. http://www.hc-sc.gc.ca/hpfb-dgpsa/nhpd-dpsn/regs_product_review_e.html

⁴⁰⁶ Health Canada (2004). *Compendium of Monographs*. http://www.hc-sc.gc.ca/hpfb-dgpsa/nhpd-dpsn/monograph_compendium_list_e.html

⁴⁰⁷ Health Canada, Drugs and Health Products. 2007. http://www.hc-sc.gc.ca/dhpm/ps/prodnatur/index_e.html

health claims on food-like NHPs. Health Canada is considering a regulatory amendment that would result in food-like NHPs being regulated under food regulations⁴⁰⁸.

⁴⁰⁸ Health Canada. November 2007. Managing Health Claims for Foods in Canada: Towards a Modernized Framework. http://www.hc-sc.gc.ca/fn-an/consultation/init/man-gest_health_claims-allegations_sante_2_e.html

7.4 United States Regulatory Review

In the United States, changes in food labeling regulation have been spurred by the efforts of the food industry and public interest groups to increase consumer health awareness. The United States has a wide variety of fortification policies and health claims labeling to assist consumers in making informed dietary choices.

Since 1996, the United States has made major advances in their development of regulations for functional foods and dietary supplements. Although they still have no legal definition of a functional food, there are several methods by which the U.S. Food & Drug Administration exercises its oversight in determining whether health claims may be used on a food label:

1. the 1990 Nutrition Labeling and Education Act (NLEA),
2. the 1997 Food and Drug Administration Modernization Act (FDAMA) and
3. the 2003 FDA Consumer Health Information for Better Nutrition Initiative.

The development of these pieces of legislation has helped bring the total number of U.S. health claims in use to twenty-eight.

Nutrition Labeling and Education Act (NLEA)

In 1996, NLEA-approved health claims were just being introduced, with only a few being approved. Currently, 12 NLEA-approved health claims are in place:

1. Calcium and osteoporosis
2. Sodium and hypertension
3. Dietary fat and cancer
4. Dietary saturated fat and cholesterol and risk of coronary heart disease
5. Fibre-containing grain products, fruits, and vegetables and cancer
6. Fruits, vegetables, and grain products that contain fibre, particularly soluble fibre, and risk of coronary heart disease
7. Fruits and vegetables and cancer
8. Folate (0.4mg/day) and neural tube defects
9. Dietary sugar alcohol and dental caries
10. Soluble fibre from certain foods and risk of coronary heart disease
11. Soy protein and risk of coronary heart disease
12. Plant sterol/stanol esters and risk of coronary heart disease

On December 20, 2007 the FDA announced its intent to reevaluate the scientific evidence for the soy protein and risk of coronary heart disease health claim noting that a reevaluation of the scientific basis for these claims is required because of new scientific evidence that has emerged. According to the FDA, “the new scientific evidence may have the effect of weakening the substance-disease relationship for these authorized health claims”⁴⁰⁹.

⁴⁰⁹ Food and Drug Administration. Docket No. 2007N-04641. Reevaluation; Opportunity for Public Comment

Food and Drug Administration Modernization Act (FDAMA)

The Food and Drug Administration Modernization Act of 1997 (FDAMA) allows for health claims to be made if such claims are based on current, published, authoritative statements from a recognized scientific body of the U.S. Government, as well as from the National Academy of Sciences. These provisions expedite the process by which the scientific basis for such claims is established. FDA has prepared a guide on how a manufacturer can make use of authoritative statement-based health claims.⁴¹⁰

The authoritative statement health claims currently in use are:

1. Whole grain foods and risk of heart disease and certain cancers
2. Potassium and risk of high blood pressure and stroke.

Qualified Health Claims

Qualified claims are the third type of health claim available for use in the United States. Initially, qualified health claims were restricted to dietary supplements. Dietary supplements are governed by different regulations than “conventional” food and drug products. In the Dietary Supplement Health and Education Act of 1994 (DSHEA), dietary supplements are defined as non-tobacco products intended for diet supplementation. These products are typically in the form of pills, capsules, tablets or liquids consisting of a concentrate, metabolite, constituent, extract of one of or a combination of vitamins, minerals, herbs, other botanicals, amino acids or substances such as enzymes, organ tissues, glandulars and metabolites. Dietary supplements may also be in forms such as bars, as long as they are labeled as dietary supplements and not represented or marketed for consumption as a conventional food or sole item of a meal or diet.

As outlined in DSHEA, dietary supplements are allowed to make a broad range of ‘nutritional support’ statements at the discretion of the manufacturer. The nutritional support statements need not be approved by FDA, although the agency must be notified no later than 30 days after a product bearing the claim is first marketed⁴¹¹. Initially, the statements were limited to well-recognized ‘structure/function’ claims. Dietary supplements are not allowed, without prior FDA review, to bear statements claiming the prevention, treatment, cure, mitigation or diagnosis of a disease.

Qualified health claims are used when more evidence is present for than against a nutrient/disease relationship, yet the evidence does not meet the significant scientific agreement validity standard. The claims must include language clearly stating that there is only limited supporting evidence for the claim and must not mislead consumers.

⁴¹⁰ U.S. Food & Drug Administration (1998). *Guidance for Industry: Notification of a health claim or nutrient content claim based on authoritative statement of a scientific body.* <http://www.cfsan.fda.gov/~dms/hclmguid.html>.

⁴¹¹ U.S. Food & Drug Administration (1995). *Dietary Supplement Health and Education Act of 1994.* <http://www.cfsan.fda.gov/~dms/dietsupp.html>.

Table 4: Standardized Qualifying Language for Qualified Health Claims

Scientific Ranking*	FDA Category	Appropriate Qualifying Language**
Second Level	B	... "although there is scientific evidence supporting the claim, the evidence is not conclusive."
Third Level	C	"Some scientific evidence suggests ... however, FDA has determined that this evidence is limited and not conclusive."
Fourth Level	D	"Very limited and preliminary scientific research suggests... FDA concludes that there is little scientific evidence supporting this claim."
*From Guidance for Industry and FDA: Interim Evidence-based Ranking System for Scientific Data. **The language reflects wording used in qualified health claims as to which the agency has previously exercised enforcement discretion for certain dietary supplements. During this interim period, the precise language as to which the agency considers exercising enforcement discretion may vary depending on the specific circumstances of each case.		

The development of qualified health claims resulted from a 1999 Court of Appeals Decision. *Pearson v. Shalala*, which concentrated on dietary supplements, successfully challenged the rigid standards of evidence applied to NLEA health claims⁴¹². As a result, the FDA was required to allow qualified dietary supplements claims. The use of qualified health claims was extended to food with the regulatory directive 2003 Consumer Health Information for Better Nutrition Initiative⁴¹³.

The new regulations mean that substantial agreement among scientists on whether the food or ingredient provides the health benefit claimed will not be required and food manufacturers will be able to petition the FDA to use health claims that already are approved for dietary supplements. The FDA now will use the standard of the "reasonable consumer" and "weight of evidence" to evaluate claims.

FDA began accepting petitions for qualified health claims on September 1, 2003. Within 45 days of receipt of a qualified health claim petition, FDA determines whether the petition is complete. If so the petition is posted on the FDA website with a request for public comment for 60 days. On or before day 270 after receipt of the filed petition, FDA notifies the petitioner by letter of its determination⁴¹⁴.

⁴¹² U.S. Food & Drug Administration (1999). *FDA's Strategy to Implement the Pearson v. Shalala Court Decision*. <http://www.cfsan.fda.gov/~lrd/fr991201.html>.

⁴¹³ U.S. Food & Drug Administration (2003). *Guidance for Industry and FDA: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements*. <http://www.cfsan.fda.gov/~dms/hclmgui3.html>

⁴¹⁴ U.S. Food & Drug Administration (2002). *Guidance for Industry: Qualified Health Claims in the labelling of conventional foods and dietary supplements*. <http://www.cfsan.fda.gov/~dms/hclmgui2.html>.

The following QHC have been approved (some with significant qualifying language and many with quite a negative tone) as of the latest update, November 2005:⁴¹⁵

1. [Qualified Claims About Cancer Risk:](#)
 - Tomatoes and/or Tomato Sauce & Prostate, Ovarian, Gastric, and Pancreatic Cancers
 - Calcium and Colon/Rectal Cancer & Calcium and Recurrent Colon/Rectal Polyps
 - Green Tea & Cancer
 - Selenium & Cancer
 - Antioxidant Vitamins & Cancer

2. [Qualified Claims About Cardiovascular Disease Risk](#)
 - Nuts & Heart Disease
 - Walnuts & Heart Disease
 - Omega-3 Fatty Acids & Coronary Heart Disease
 - B Vitamins & Vascular Disease
 - Monounsaturated Fatty Acids From Olive Oil and Coronary Heart Disease
 - Unsaturated Fatty Acids from Canola Oil & Coronary Heart Disease
 - Corn Oil & Heart Disease

3. [Qualified Claims About Cognitive Function](#)
 - Phosphatidylserine & Cognitive Dysfunction and Dementia

4. [Qualified Claims About Diabetes](#)
 - Chromium Picolinate & Diabetes

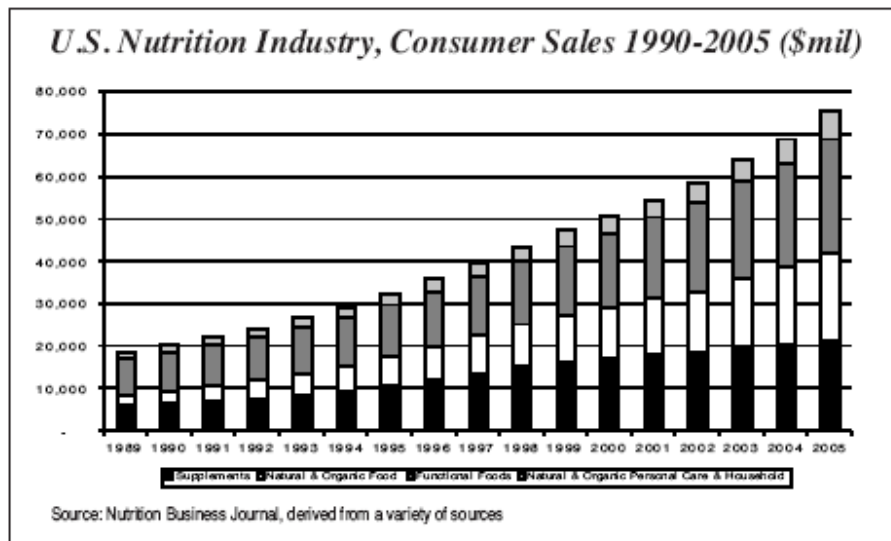
5. [Qualified Claims About Hypertension](#)
 - Calcium & Hypertension, Pregnancy-Induced Hypertension, and Preeclampsia

6. [Qualified Claims About Neural Tube Birth Defects](#)
 - 0.8 mg Folic Acid & Neural Tube Birth Defects

⁴¹⁵ U.S. Food & Drug Administration. November 2005. CFSAN/Office of Nutritional Products, Labeling, and Dietary Supplements. Qualified Health Claims Subject to Enforcement Discretion. <http://www.cfsan.fda.gov/~dms/qhc-sum.html>

8.0 UNITED STATES MARKET ANALYSIS

The growth of the US nutrition industry since 1980 has been robust as shown in the following graphic. According to NBJ, the U.S. nutrition industry grew 9.3% overall in 2005 for total sales of \$75.37 billion, up from \$68.95 billion the year prior. Growth was led by natural & organic personal care & household products, up 15%, natural & organic food, up 13%, with functional food, at 9% and dietary supplements trailing at 4.5%⁴¹⁶.



2005 U.S. Nutrition Industry Revenues (\$mil in Consumer Sales)

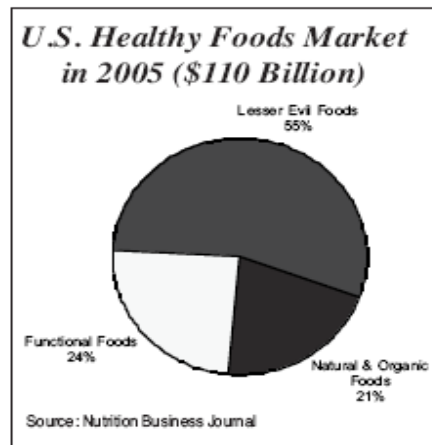
2005	Retail-NHF	Retail-MM	Mail Order	MLM	Practitioner	Internet	Total
Supplements	7,741	6,036	1,287	4,198	1,548	506	21,316
Natural & Organic Foods	11,466	9,307	17	29	6	14	20,840
Functional Foods	2,903	23,337	27	213	32	147	26,660
N&O Personal Care, etc.	3,291	757	222	1,962	233	91	6,556
Total	25,401	39,437	1,554	6,402	1,819	757	75,372

Source: NBJ, Nutrition Business Journal primary research includes NBJ surveys of natural food, supplement and NPC manufacturers, distributors, MLM firms, mail order, internet and raw material companies and numerous interviews with major retailers (WalMart, Costco, etc.), manufacturers, suppliers and industry experts. Secondary sources include Information Resources Inc., SPINS, ACNielsen, Natural Foods Merchandiser, OTC Update, Progressive Grocer, Supermarket Business, US Census Bureau, company data and others. NHF represents natural, health food, supplement and specialty retail outlets. MM represents grocery, drug, mass merchandise, club and convenience stores. Mail Order represents catalogs, direct mail and direct response TV and radio. Practitioners represent conventional and alternative practitioners selling to patients. Note: NBJ classifies soy milk and selected other categories only as functional for the purposes of this all-industry chart to avoid double counting, even though it can also be classified as a natural & organic.

⁴¹⁶ Nutrition Business Journal. June/July 2006. NBJ's Annual Industry Overview 2005.

8.1 Functional, Natural and Organic foods

“Healthier for you food” sales accounted for \$110 billion in 2005 or 20% of total food sales of \$552 billion, not including food service. FF represented \$26.7 billion or 4.8% of total U.S. food sales. Growth in 2005 was 9% in functional foods compared to just under 2% for total food sales¹²⁹.



By major product category, beverages accounted for 57% of U.S. functional foods. Breads & grains were the second largest functional subcategory at 21% with cereals its largest contributor. Snack foods accounted for 10% of U.S. functional food sales in 2005, but the now well-chronicled fall of nutrition bars led to a sales decline in 2004 and 2005.

US Nutrition Industry Growth 2003-2008: Consumer Sales in \$mil

Products	2003	2004	2005	2005 Growth	'06-'08 Growth
Vitamins	6,658	6,892	7,163	3.9%	2-4%
Herbs/Botanicals	4,178	4,320	4,410	2.1%	2-3%
Sports Nutrition	1,963	2,097	2,217	5.7%	4-6%
Minerals	1,765	1,738	1,812	4.3%	2-4%
Meal Supplements	2,522	2,329	2,300	-1.3%	2-5%
Specialty/Other	2,728	3,013	3,414	13.3%	7-9%
Supplements	19,814	20,389	21,315	4.5%	3-5%
Natural & Organic Food	16,240	18,377	20,840	13.4%	9-12%
Functional Foods	22,730	24,460	26,660	9.0%	6-8%
Natural Personal Care	5,096	5,722	6,556	14.6%	9-12%
Nutrition Industry	63,879	68,948	75,371	9.3%	6-8%

Source: Nutrition Business Journal, nutritionbusiness.com, derived from a variety of sources. Forecast is annual average. Copyright 2006 NBJ and Penton Media Inc. May not be reproduced without permission.

NBJ’s data indicates that the natural/organic and functional foods categories continue to grow faster than supplements in the US. Highest growth categories in supplements in 2005 were specialty supplements (led by fish and plant oil sales growth) and sports nutrition supplements. Projected sales to 2008 show strong growth in natural/organic and functional foods categories while supplement sales will increase at a lesser rate.

Organic products led growth in the nutrition industry for the fifth year in a row, and despite shortages in several categories showed no signs of slowing in 2005. NBJ's research concluded that organic foods grew 16% to \$13.8 billion in U.S. consumer sales in 2005 and represented 61% of the \$22.8-billion natural & organic foods market and 2.5% of the \$557-billion U.S. foods market (excluding food service), up from a penetration rate of 0.8% in 1997. With the addition of \$740 million in 2005 organic sales in non-food segments like personal care, household goods and fiber products, the total U.S. organic industry was \$14.6 billion in 2005, and overall growth was 17%.

Natural & specialty retailers represented 47% of organic sales, with the mass market at 45% and 19% growth compared to 15% for natural retail. Direct sales, farmer's markets, delivery, mail order, etc. accounted for the remainder of sales.

Propelling these growth statistics is growing consumer usage. NBJ surveys show that two-thirds to three-quarters of U.S. households now buy some organic items compared to less than half four to five years ago. Last November Whole Foods Market's organic survey found the number of Americans who've tried organic foods has jumped to 65% in 2005 compared to 54% in 2003 and 2004, and a quarter of 1,000 respondents said they're consuming organics more than they did a year ago. Wal-Mart plans to double its number of organic SKUs, because studies show a majority of U.S. consumers buy at least some organic food.

NBJ predicts continuing double-digit growth for organic products through the rest of the decade, with overall organic food growth projected at 10-14% per year through at least 2010¹²⁹.

According to Leatherhead Food International (2006), the size of the US market for functional foods is between US\$5.3 billion (2005) and US\$9.75 billion, depending on the breadth of the definition used⁴¹⁷. Estimates for even less conservative definitions go as high as US\$20 billion US, or four percent of the total foods market.

A key characteristic of the U.S. functional food market is a large focus on disease and disease prevention. Products aimed at lowering blood cholesterol levels, cancer risk, and weight loss characterize the market. Breads and grains, especially enriched breakfast cereals, followed by functional beverages (teas and energy drinks) are the primary functional food products in the U.S. market. Snack foods, especially nutrition bars, are one of the fastest growing functional categories, experiencing a 17% rate of growth in 2004. Snack foods and functional beverages dominate the functional food market as noted in the chart and graphic below.

The following table shows the US sales of functional foods by type of functional food for 2005.

⁴¹⁷ Leatherhead Food International. 2006. *The International Market for Functional Foods: Moving into the Mainstream?*

Table 5: US Functional Food Market Size (2005 \$'s) by Type of Functional Food

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

Cereal, beverages and soya products make up 85 percent of the US functional foods market due to FDA approved claims that can be applied to these products (for example, claims such as “whole grain” or “oat” for cereal products). The cereal products, by the strict definition (products making claims) of functional foods, have a 50 percent share of the functional foods market in the United States. Within the cereal market, breakfast cereals are the largest product area and the only area that falls under the strict definition of functional foods. Heart health has been a growing area of interest with breakfast cereal products containing FDA approved claims related to oatmeal, cholesterol reduction/heart health, psyllium, wholegrains, soya proteins and omega-3 acids. Breakfast cereals with heart health related claims are valued at US\$600 million a year.

Unlike Europe, where functional food markets are well developed in dairy products, the US has a relatively small dairy product functional food market, especially with respect to products such as functional yogurts and health drinks. The US functional foods market also distinguishes itself from these markets in Australia, Japan and Europe by its greater focus on dietary supplements¹³⁰.

Functional food firms fall into three groups: mainstream food and drink companies (Kellogg, PepsiCo, Danone), pharmaceutical companies (Johnson & Johnson) and one-product specialists^{129, 130}. In the United States, acquisition in the functional food area has been increasing with the growth of the functional food market.

Some of the major suppliers of functional food products in the United States include:

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

According to Mintel (2006), the US market for functional foods is mainly domestic due to the non-uniformity of health food claim regulations from country to country. However,

some companies based overseas – Group Danone, Nestle, Red Bull, Cadbury Schweppes, and Unilever Bestfoods – are well positioned in the US market⁴¹⁸.

The primary firm structure of the US functional food market is multinational corporations. Some of these corporations market individual brands within specific segments of the functional food market but many also offer multiple brands across segments. The top functional food and beverage sales by manufacturer include PepsiCo, Kellogg Co., Coca-Cola Co., and General Mills representing 16.3 percent, 14.3 percent, 10.8 percent and 10.6 percent of the share of 2005 sales, respectively¹³¹.

Table 6: Top Manufacturer Food, Drug and Mass Merchandiser Sales of Functional Foods and Beverages in the US, 2005

Manufacturer	Sales (million US\$)	Share (percent)
PepsiCo	2,397	16.3
Kellogg Co.	2,100	14.3
Coca-Cola Co.	1,591	10.8
General Mills	1,558	10.6
Kraft Foods, Inc.	847	5.8
Group Danone	643	4.4
Nestle USA, Inc.	545	3.7
Ocean Spray	427	2.9
Welch Foods, Inc.	330	2.2
Dean Foods	292	2.0
Ferolito Vultaggio & Sons	241	1.6
Red Bull North America, Inc.	226	1.5
Sunny Delight Beverages Co.	217	1.5
H.J. Heinz Co. (The Hain Celestial Group)	186	1.3
Cadbury Schweppes	166	1.1
Egglan's Best	156	1.1
Unilever Bestfoods	139	0.9
Old Orchard Brands	121	0.8
Campbell Soup Co.	118	0.8
Hansen Natural, Inc.	91	0.6
Private label	1,024	7.0
Other	1,289	8.8
Total	14,703	100

Notes: 1) Data may not equal totals due to rounding; 2) Excludes sales through Wal-Mart

⁴¹⁸ Mintel. 2006. *Functional Foods Market Intelligence*. Mintel International Group Ltd.

Table 7: Functional Food Brands by Type of Functional Food and Company¹³⁰

Functional Food Area	Functional Food Product	Company	Brands
Dairy Products	Probiotic yogurt/kefir	Dannon (Stonyfield Farms)	DanActive (marketed as Actimel outside the US) ; Activia; YoBaby; All Natural Fruit Blends; YoSelf
		CoolBrands Internationals	Breyers Light! Probiotics Plus Yogurt
		Lifeway Foods	Lifeway Organic ProBugs Milk Drinks
	Cholesterol-lowering yogurt	General Mills	Yoplait Healthy Heart
		Dannon	Light'n Fit with Fiber
	Active health drinks	Dannon	Actimel
Fortified milk	Deans; Borden (Dairy Farmers; Mayfield Farms; Kemps; Suiza)	None are major, market shares distributed among these.	
Bakery Products	Wholegrain (heart healthy) and fortified breads	Sara Lee	Heart Healthy Plus; Soft & Smooth
	Breads with omega 3 fatty acids	Wegmans Food Markets	
		The Baker	
		Arnold Foods	Arnold Smart & Healthy
	High fibre cookies	RD Foods	Right Direction Cookies
		Quaker	Quaker Breakfast Cookies
Nabisco		Wholegrain Chips Ahoy!, Wheat Thins and Fig Newtons	
Cereal Products	Heart health cereals	Quaker	Take Heart Instant Oatmeal
		General Mills	Cheerios; All Big G brands
		Kraft's Post	Grape Nuts; Raisin Bran; Shredded Wheat; Toasties; Bran Flakes
		Kellogg	Smart Start brands; Heart to Heart (under Kashi, Kellogg subsidiary)
	Calcium fortified cereal bars	Quaker	Chewy
		Kellogg	Cereal and Milk Bars
	High fibre cereal bars	Kellogg	All Bran
Heart Healthy cereal bars	Nature Valley	Healthy Heart	
Soya Products	Soya milk	Barilla	Barilla Plus
		Kraft	Supermac & Cheese Pasta and Sauce
		Odwalla	Odwalla soymilk
Beverages	Fruit juices and juice blends	Tropicana (PepsiCo)	Pure Premium Orange Juice with Calcium and Extra Fiber; Pure Premium Essentials (Immunity Defense, Healthy Heart, Healthy Kids, Light & Healthy)
		Minute Maid (Coca-Cola)	Heartwise; Minute Maid Extra
		Ocean Spray	Cranberry Juice Cocktails
		POM Wonderful	POM Wonderful
	Enhanced waters	Gatorade (PepsiCo)	Propel Fitness Water
		Energy Brands	Glaceau Vitaminwater

Functional Food Area	Functional Food Product	Company	Brands
		PepsiCo	Aquafina flavoured water; SoBe Life Water
		Coca-Cola	Dasani
Meat, Fish and Eggs	Canned fish with omega-3	Star Kist	
		Chicken Of the Sea	
	Fish oil supplements	Bumble Bee and Leiner Health	
	Omega-3 DHA enriched eggs	Gold Circle Farms	
		Eggland's Best	

8.2 Dietary Supplements

Sales of supplements grew fairly steadily on the strength of vitamins and minerals until the 1990s. At this point, the market saw the introduction of herbal, botanical and other alternative supplements—stimulated and supported further by the passage of DSHEA in 1994. A high-growth period of five or six years continued until around 1998. Negative growth in many categories occurred and by 2004, supplements were growing at rates of less than 3%⁴¹⁹.

Specialty supplements have been the only product category to exceed the growth of the entire supplement in each year from 1990 through 2013e. Essential fatty acids (EFAs) found in fish and plant oils have driven recent growth - in 2004, the category grew 20-30%. Probiotics, homeopathics and enzymes were also among significant subcategories in double digits in growth⁴¹⁹.

Table 8: U.S. Specialty Supplement Consumer Sales & Growth 1997-2005

US Specialty Supplements	1997	1998	1999	2000	2001	2002	2003	2004	2005	05 Growth
Glucosamine Chondroitin	160	280	476	619	674	683	761	762	810	6.3%
Homeopathics	260	295	313	338	358	405	460	532	619	16.4%
Fish/Animal Oils	50	60	70	82	100	133	183	262	359	36.9%
CoQ10	110	140	151	169	196	212	258	283	339	19.9%
Probiotics	100	115	124	134	148	160	174	204	243	19.2%
Plant Oils	40	50	60	75	90	106	140	177	197	11.2%
Digestive Enzymes	55	61	69	80	100	105	130	147	166	12.9%
MSM	10	34	55	90	108	111	115	111	107	-3.4%
SAMe	-	8	56	70	76	77	92	93	96	3.5%
Bee Products	50	55	59	62	66	67	74	81	91	11.2%
Melatonin	90	80	75	69	62	62	62	67	73	9.6%
5 HTP	30	35	39	40	41	44	53	59	68	15.3%
DHEA	55	50	49	48	48	47	47	48	50	3.4%

⁴¹⁹ Ferrier, G. 2005. Nutrition Business Journal. NBJ Industry Overview. Webcast. April, 2005. www.nutritionbusiness.com.

Gelatin	31	34	40	45	55	55	58	52	48	-7.7%
Others	141	156	150	130	100	106	122	134	148	9.7%
Total	1,182	1,453	1,785	2,052	2,222	2,373	2,728	3,013	3,414	13.3%

Dietary supplements in 2005 were worth \$21.3 billion, a 4.5% gain on 2004. Sales were led by specialty supplements, which rose 13.3% in 2005, followed by sports nutrition at 5.7%, minerals at 4.3% and vitamins 3.9%, with herbs and botanicals at 2.1%¹²⁹.

Supplement growth rates are provided in the next chart. It is projected that strong growth will continue in specialty supplements and that this area will represent an increasing share of total supplement sales and possibly capture the interest of the larger pharmaceutical companies as an area of growth potential.

Table 9: NBJ Supplement Sales Growth Rate Forecasts by Product Category, 2006-2013¹³²

Supplement Category	2006	2007	2008	2009	2010	2011	2012	2013
Vitamins	3.6%	3.8%	3.8%	3.7%	3.7%	3.6%	3.6%	3.5%
Herbs/Botanicals	2.4%	2.6%	2.7%	2.8%	2.7%	2.6%	2.6%	2.5%
Sports Nutrition	4.6%	4.9%	4.9%	4.7%	4.4%	4.2%	4.0%	3.7%
Minerals	2.0%	3.0%	4.0%	5.0%	5.1%	5.2%	5.3%	5.4%
Meal Supplements	2.0%	2.2%	2.4%	2.6%	2.8%	3.0%	3.2%	3.4%
<i>Specialty/Other</i>	8.0%	7.7%	7.4%	7.1%	6.8%	6.5%	6.2%	5.9%
Supplements Total	3.9%	4.1%	4.2%	4.2%	4.1%	4.1%	4.0%	4.0%

Success factors for Health Products in the United States

US market development in functional foods has been driven by FDA approval of health claims associated with food ingredients. The majority of these approvals have been in the area of heart health. Development in the area of heart healthy cereal products began with FDA approval of the claim that products with oatmeal could lower cholesterol and development in this area continued to grow with FDA approval of claims related to psyllium, soya protein and whole grains.

However, not all FDA approvals of claims have promoted market development. For example, although the industry reacted to the 2000 FDA approval of health claims related to plant sterol/stanol esters by focusing on developing and marketing cholesterol-lowering margarine products, this market is now stagnant. This is due mostly to consumer distrust of what is perceived as “medical foods” and poor marketplace positioning.

Key Trends

- Food in the US is an \$800 B industry which is equally split between food service and retail and is experiencing a slow growth of 1- 3%. Functional foods represent a new value-added opportunity.

- Large companies are generally conservative in nature and are slow to adopt new innovations – this is often left to smaller companies to develop the innovative new ingredients and technologies that will be of interest to the larger players.
- Positive regulations in the US and new dietary guidelines are driving positive impacts on the development of functional foods and driving innovation and sales in key categories, as well as new product launches.
- Greater consumer awareness.
- GRAS (Generally Recognized as safe status) are key/mandatory for adoption of new ingredients by large food companies. Often the burden to provide GRAS affirmation is left to the ingredient supplier – GRAS can cost \$60K US to upwards of \$250K US depending upon the complexity of the application and data review.
- Products - Large focus on disease and prevention.
- Category & Ingredient Focus
 - Lowering blood cholesterol & glucose levels
 - Reducing cancer risk
 - Weight loss
 - Fortification
 - Functional beverages (teas and energy)
 - Snack Foods
- Product development centered around fortifying existing foods, rather than introducing new types of products.

Appendix C – Literature Review of Hemp for Industrial Applications



**The
AGRICOLA
Group**

National Industrial Hemp Strategy

Appendix C: Literature Review of Hemp for Industrial Applications

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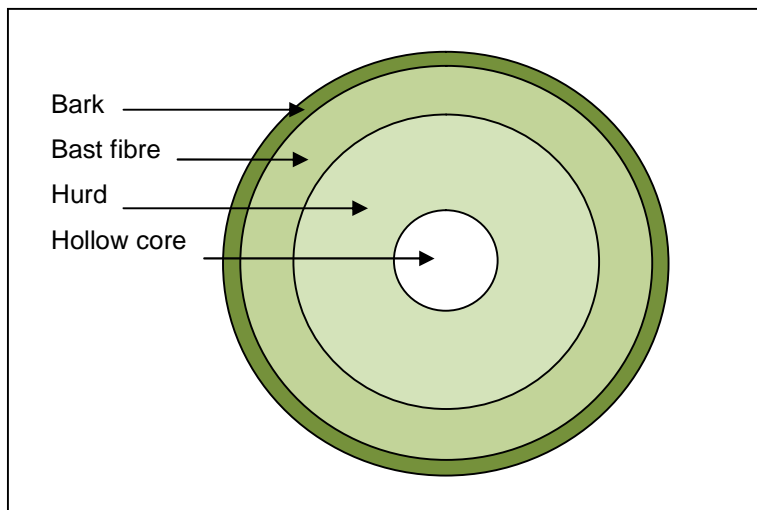
February 26, 2008

Overview of industrial hemp products

The hemp plant has been used to make useful products for thousands of years. Hemp cord was used 12,000 years ago,⁴²⁰ and hemp fabrics were used in ancient Mesopotamia and Southeast Asia during the Stone Age.⁴²¹ The Vikings produced rope, sailcloth, caulking, fishing line and nets from hemp, and for many centuries, woven hemp fibre was the primary fabric from which clothing was made in Southeast Asia, Europe and North America.⁴²² Today, hemp can be used to produce over 25,000 different products.⁴²³

There are three main parts of the hemp used to produce products: long fibres called primary fibres or bast fibres, inner fibres called hurd, and oil from the seed.⁴²⁴ The bast fibres are found along the outside of the hemp stalk just under the bark, while the hurd forms the woody core of the hemp stalk. The figure below illustrates where these fibres can be found in a cross-section of the hemp stalk.⁴²⁵

Figure 1: Cross-section of hemp stalk



Hemp bast fibres are among the strongest and most durable of natural fibres, with high tensile strength, wet strength, and other characteristics favourable for various industrial products.⁴²⁶ It has been estimated that hemp produces three to four times as much useable fibre per acre per year as forests, and the bast fibre contains a low amount of

⁴²⁰ Pottery shards 12,000 years old were discovered in Taiwan with hempen cord marks covering the surface, along with stone tools used to pound hemp (Nelson, pg. 1).

⁴²¹ Montana Hemp Council

⁴²² Nelson, pg. 6

⁴²³ Ontario Hemp Alliance

⁴²⁴ These are also sometimes referred to as shives, although this term more commonly applied to the inner core of flax straw.

⁴²⁵ This figure is a schematization only, and does not reflect the proportions or complete biology of the hemp stalk.

⁴²⁶ Karus and Leson (1996)

lignin (the natural polymer that binds plant cells together),⁴²⁷ which allows it to be bleached without the use of chlorine.⁴²⁸ Hemp bast fibre is used in the production of a wide range of products where its strength and durability are advantageous, including cordage (rope, twine, etc.), specialty papers, fabrics for clothing and other applications, and industrial textiles such as geotextiles and carpeting. The strength of hemp fibre also makes it ideal for use in a range of composites for applications such as moulded car parts and fibreboard for construction.

Hemp hurd is composed of cellulose-rich, short fibres, and make up approximately 75% of the hemp stalk. They are spongy and absorbent, ideal characteristics in applications such as animal bedding and industrial absorbents. They may also be used to produce low-quality paper. More recently, hemp hurd has been used to produce a concrete-like substance for use in building applications, as well as for insulation and to produce fibreboard.

The **whole hemp stalk** can also be used to produce various **biofuels** such as bio-oil (or pyrolytic liquid), cellulosic ethanol, syngas (synthetic gas) and methane. Alternatively, the bast fibre can first be removed for use in high-value fibre applications, and the remaining hurd can then be processed into biofuel.⁴²⁹ The processes by which hemp is converted to biofuels may also produce valuable chemicals and other materials as bi-products.

Hemp oil is extremely nutritious, and is used in foods and natural health products for humans and animals, as well as in personal care products.⁴³⁰ Hemp oil is also suitable for use in industrial products such as paints, varnishes, inks and industrial lubricants, and can be used to produce biodiesel.

In addition, growing hemp has significant soil remediation or **phytoremediation** advantages; this may therefore be considered another application of hemp. Figure 2 outlines the range of products that can be produced from industrial hemp (with the exception of soil remediation) and illustrates which part of the hemp plant they are derived from.

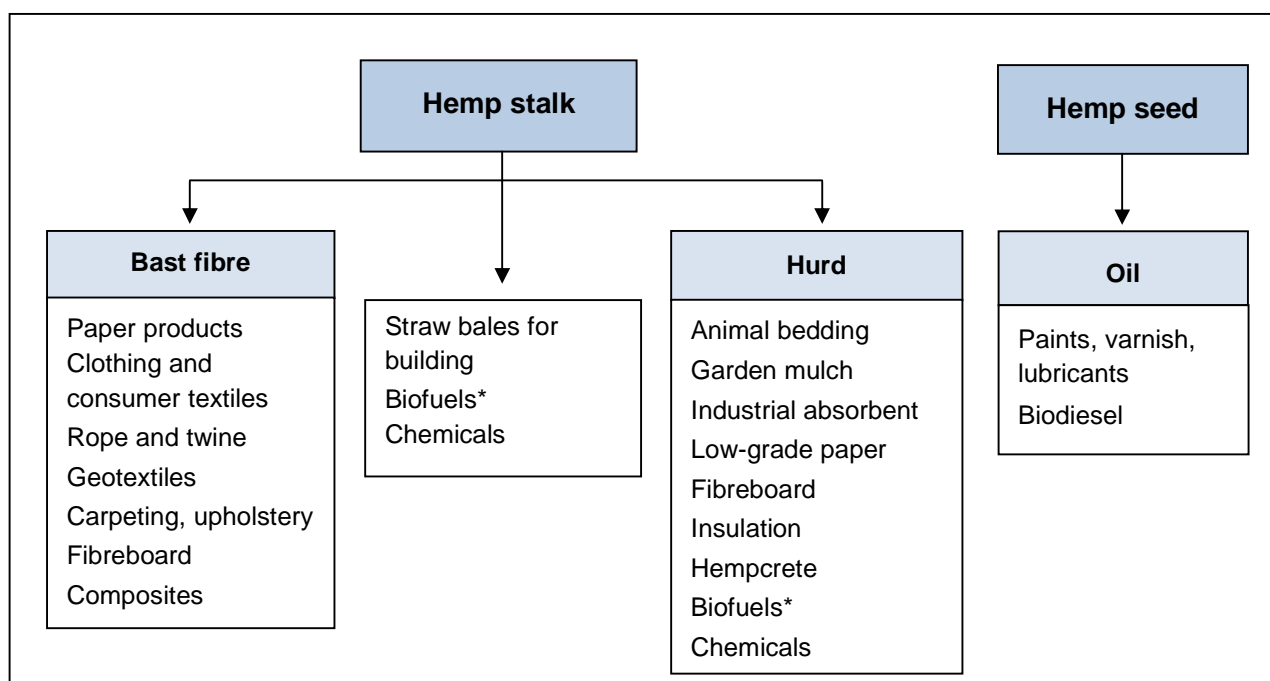
⁴²⁷ Low lignin content is also beneficial for ethanol production.

⁴²⁸ Roulac, 1997

⁴²⁹ Whether the fibre is removed before biofuel production should be determined by econometric modeling of the various product opportunities (see discussion on page 16).

⁴³⁰ These properties are discussed in Appendix B, and these products will therefore not be covered in this section.

Figure 2: Sources of Industrial Hemp Products



* The hemp stalk, or the hurd portion of the stalk, can be processed into all biofuels except biodiesel.

Hemp in Canada

Industrial hemp is an emerging industry in Canada,⁴³¹ and as such the infrastructure required for processing hemp into a range of valuable products does not currently exist.⁴³² Because of the currently limited supply of domestically-grown hemp and its associated high price, it is not economically feasible to produce many products from it at the present time.

However, it should be emphasized that this is only the *current* economic reality of hemp in Canada. The number of hectares licensed for hemp farming in Canada has grown substantially in the decade since commercial cultivation was authorized,⁴³³ from 2,400 in 1998 to 20,554 in 2006.⁴³⁴ Production costs can be lowered by exploiting hemp as a dual-purpose crop, with viable end markets for both the grain and fibre.⁴³⁵ The continued growth of industrial hemp production in Canada and the establishment of growing markets for hemp products may have a significant impact on the economic viability of many hemp products in the future.

⁴³¹ The commercial cultivation of hemp has been legal in Canada since 1998, under licenses and permits issued by Health Canada. (Agriculture and Agri-Food Canada^a)

⁴³² Manitoba Agriculture, Food and Rural Initiatives

⁴³³ In 2007, the acreage dropped substantially. See discussion on page 19.

⁴³⁴ Agriculture and Agri-Food Canada^b

⁴³⁵ *Ibid.*

The establishment of a robust hemp products industry in Canada will require (at least) four conditions:⁴³⁶

- 1) an adequate supply of feedstock (hemp seed, fibre and hurd);
- 2) a low enough price for that feedstock;
- 3) adequate characteristics for end use; and
- 4) available proven technologies for processing the raw material into products.

The EU spent the equivalent of about 50 million dollars to develop new flax and hemp harvesting and fibre processing technologies between 1982 and 2002 (far more than North America),⁴³⁷ and various European nations and private firms have also contributed significantly to the development of hemp technologies. Accordingly, Europe is far more advanced in the production of many hemp products than other parts of the world, and much of the information regarding potential hemp products is derived from information from the EU.

Structure of this Appendix

For the sake of organizational clarity this Appendix is structured according to the end use of industrial hemp products rather than according to the part of the hemp plant they are derived from. Those products that generally require less processing are discussed first, followed by those that require more processing to produce:

- Animal bedding
- Garden mulch
- Oil and waste absorbent
- Paper products
- Clothing and other consumer textile products
- Industrial textiles
- Building materials
- Paints, varnishes, inks and industrial lubricants
- Biofuels
- Biocomposites and bioplastics

Animal bedding

Because of their absorbent properties, hemp s make remarkably good animal bedding;⁴³⁸ this application in fact is the largest current market for hemp hurd in the EU.⁴³⁹ Hemp bedding is most often used for horses, particularly for race horses. The hurd is sometimes molded into small pellets for bedding applications, which do not produce dust (and therefore do not trigger human or equine allergies as straw does), are easily composted, and can absorb up to five times their weight in moisture (typically 50%

⁴³⁶ From Bolton, 1995. Although the author is specifically referring to the establishment of an industry based on hemp fibre, the same requirements apply to hemp seed.

⁴³⁷ Karus et al. (2000)

⁴³⁸ The most minute hurd particles can also be molded into pellets and commercialized as cat litter.

⁴³⁹ Karus et al. (2000)

higher than wood shavings), reducing labour and material usage. Although the European market for hemp animal bedding is large, it is marked by consistent overcapacity, and the market is widely regarded to have reached its maximum size.⁴⁴⁰ In North America, some companies do currently offer hemp-based animal bedding,⁴⁴¹ but there is currently an insufficient supply of hemp hurd available to meet demand. Therefore, there may be the potential for development of this market as domestic production of hemp increases.

Garden mulch

In addition to animal bedding, hemp hurd can also be used as a garden mulch to retain moisture and protect plants.⁴⁴²

Oil and waste absorbent

The high absorbency of hemp hurd has also led to its occasional use as an industrial absorbent for oil and waste spill cleanup. This potential application has generated some interest in Alberta, for use in land reclamation in the oil and gas industry. Because hemp hurd is currently a costly product, however, it is unlikely that this market will develop on a large scale in the near term.

Paper products

The oldest surviving paper was made from hemp fibre over 2,000 years ago in China.⁴⁴³ Hemp and flax were once the chief paper-making materials, but the introduction of the chemical wood pulping process in the early 19th century considerably lowered demand for hemp. Today, at least 95% of paper is made from wood pulp.

Hemp fibre is used today in the production of specialty papers such as cigarette papers, paper for bank notes and security documents such as stock certificates, fine art stock and bible paper, where the lightness of hemp fibre allows for many thin pages. Hemp can also be used to produce specialty writing paper and printing paper, tea bags, technical filters, and hygiene products.

Hemp hurd has rarely been used for papermaking, since the fibres are generally considered too short for high grade paper applications.⁴⁴⁴ However, hurd could potentially be used to make lower-grade papers where shorter fibres are acceptable, such as newspaper, tissue and packaging materials.

Specialty papers form a highly stable, high-priced niche market in Europe, where hemp has an 87% market share of the "specialty pulp" sector.⁴⁴⁵ Specialty papers are expected to remain the core market for hemp in Europe in the foreseeable future.

⁴⁴⁰ *Ibid.*

⁴⁴¹ For example, Ontario company Stemergy (formerly Hempline) and Manitoba company Emerson Hemp Distribution Company process hemp and sell hemp-based animal bedding

⁴⁴² Saskatchewan Hemp Association

⁴⁴³ Fleming and Clarke (1998)

⁴⁴⁴ The higher lignin content in hemp hurd, relative to hemp bast fibre, also makes it more difficult to separate the fibres and presents an additional obstacle to hurd-based paper production.

⁴⁴⁵ Karus et al. (2000)

Paper produced from hemp fibre has several advantages over wood-based paper. As a non-wood fibre source, the use of hemp fibres for papermaking can reduce the harvesting of primary forests and the concomitant threat to biodiversity. It has been estimated that hemp produces three to four times as much useable fibre per acre per year as forests. The low lignin levels in hemp fibre also accommodate environmentally benign bleaching, without the use of chlorine compounds, harmful glues and bleaching agents that are utilized in the wood pulping process.⁴⁴⁶

Further, hemp bast fibre is superior to wood fibre in strength and durability, and due to its low acidity, hemp paper does not turn yellow and disintegrate like wood-based paper does.⁴⁴⁷ Hemp paper can be recycled an average of seven times, while wood-pulp paper can only be recycled an average of three times. This has led the wood-based pulp and paper industry to consider the use of hemp to strengthen and extend the number of times that wood pulp can be recycled.

Despite the many benefits of hemp-based paper, various analyses have concluded that the use of hemp for conventional paper pulp is not currently profitable.⁴⁴⁸ Hemp paper is high-priced for several reasons. Since the supply of hemp is extremely limited compared to the supply of wood fibre, hemp paper operations cannot achieve the same economies of scale as larger wood-based paper companies. Hemp processing may require specialized, non-wood-based facilities and machinery, further increasing the cost of producing hemp paper. High-quality hemp papers are made only from bast fibres, which require separation from the hurd, which also increases costs. Hemp is harvested annually, and therefore needs to be stored throughout the year. Hemp stalks are very bulky, requiring significant handling and storage, and causing higher transportation costs than for wood chips. Hemp also must compete against less expensive sources of fibre, such as waste straw from cereals and other crops,⁴⁴⁹ and scrub trees. And, finally, the wood-based pulp and paper industry receives direct and indirect government subsidies, making it more difficult for other fibres to compete with wood as a feedstock for paper applications.

Clothing and other consumer textile products

Textiles are one of the oldest applications for hemp fibres. The best canvas sailcloth was made from hemp; in fact, the word 'canvas' is derived from *Cannabis*.⁴⁵⁰ Until the 1920s, 80% of clothing was made from hemp textiles. The demand for hemp decreased with the advent of the steam and petroleum engines, which obviated the need for hemp sails, and with the development of the cotton engine⁴⁵¹ in the 1800s, which significantly reduced labour costs in the cotton industry.

⁴⁴⁶ Mercury and other toxins are released during the wood pulping process and can contaminate water supplies (Roulac, 1997).

⁴⁴⁷ According to the US Library of Congress, hemp paper as old as 400 years is still in good condition.

⁴⁴⁸ Fertig (1996)

⁴⁴⁹ Although generally not as desirable as hemp, these fibres can produce bulk pulp far more cheaply than can be made from hemp.

⁴⁵⁰ Online Etymology Dictionary

⁴⁵¹ The cotton engine (or "cotton gin") quickly and easily separated cotton fibres from the seedpods and seeds, a job done by slave workers prior to its introduction.

Although the demand for hemp was greatly decreased as a result of these technological advances, some textile production from hemp continued, and in the 1980s, researchers developed an enzymatic process enabling hemp to be spun into fine textiles for apparel. Hemp bast fibre can be woven or knitted into fabrics for clothing and other consumer products such as hats, scarves, change purses, pencil cases, and bags. Production of hemp textiles and apparel is primarily done in China, Hungary, Romania, Russia, the Ukraine, and the EU.⁴⁵² Hemp fabrics have a similar appearance to cotton or linen, but with more variation in the yarn.

Hemp textiles have a number of properties that are advantageous in clothing and other applications. Textiles made from hemp are lightweight, and since hemp has about three times the tensile strength of cotton, they are also very strong and durable. Hemp fibre is breathable and has insulative qualities that allow the wearer to stay cool in summer and warm in the winter. Hemp fibre is also less prone to fading than other fabrics such as cotton, is UV-resistant and water-resistant, and has anti-microbial and mold-resistant properties, making it excellent for outdoor wear.⁴⁵³

Although hemp fabrics do soften with use and repeated laundering, one of the drawbacks of hemp textiles is their relative abrasiveness compared to cotton and other fabrics. As well, the methods currently used to process hemp fibre for textile production have not so far been able to produce fabrics as white as cotton. In addition, because industrial hemp fibres differ from more commonly used fibres such as cotton, the use of specialty machines is necessary for the production of textiles. Specialty machinery entails higher production costs as compared to cotton or other textiles, which translates into higher prices for the consumer. Hemp fibres are currently often blended with materials such as linen, cotton or silk to produce whiter, softer fabrics at a lower cost than those made exclusively of hemp.

The National Research Council Canada is currently collaborating with a Canadian company to patent an innovative enzyme process that transforms industrial hemp into a soft, white fabric called Crailar that can be used for clothing applications.

Industrial textiles

Hemp fibre is suitable for the production of a range of industrial textiles such as rope or twine, geotextiles, carpeting and coarser fabrics for use as upholstery, sacks, and tarpaulins.

Cordage

Like textile production and papermaking, rope and twine production is one of the traditional uses of hemp, and has a long history; in addition to hemp sails, tar-covered hemp ropes were commonly used on ships for centuries, until the introduction of manila and steel wire ropes.⁴⁵⁴ In support of the war effort, both the Canadian and American

⁴⁵² Small and Marcus (2002)

⁴⁵³ *Ibid.*

⁴⁵⁴ zu Mondfeld (2005), pg. 270.

governments subsidized hemp farmers during World War Two to supply fibre for use in rope and other applications.⁴⁵⁵

As in textile applications, hemp fibre's strength, durability and resistance to decay make it ideal for manufacturing cordage. Although production of hemp rope and twine continue, the market is small, representing only about 2% of the total market for hemp fibre in the EU in 1999, for example.

Geotextiles

Geotextiles are permeable fabrics used to filter, reinforce, protect, or drain soil for landscaping and other applications. Geotextiles include biodegradable matting designed to prevent soil erosion (especially to stabilize new plantings by preventing soil slippage as root systems develop), and ground covers designed to reduce weeds in planting beds.

Although the majority of geotextiles are currently produced using synthetic fibres or glass fibres, the demand for products from natural fibres is increasing. Hemp fibres can be arranged in a fibre matrix that can be secured to eroding slopes as erosion control blanketing and matting, as well as into fibre logs that help in the prevention of shoreline erosion. Unlike synthetic fibres, natural fibres such as hemp biodegrade over time. This may be unacceptable for some applications where long-term stability is required.

However, in other applications this property affords a significant advantage. For example, the current use of plastic netting to reinforce grass sod is problematic, since the plastic remains for many years and may interfere with lawn care. A substitute product made from biodegradable natural fibres would not present this problem. Biobased geotextiles are used for short term applications (6 months to 10 year) where biodegradability is a positive attribute, such as mulching and erosion control. Natural geotextiles decompose gradually after they have supported the establishment of deep-rooted plants as for example in the case of slope protection projects.

Although production of hemp erosion control mats is ongoing in Europe and in Canada, the economic viability of using industrial hemp for geotextile applications is yet to be determined. Hemp may not be as effective for geotextile applications as other fibres (such as coco fibre, which has a higher lignin content), nor is it currently as cost-effective as other fibres such as coco and flax fibre.⁴⁵⁶ This application for hemp is not likely to grow beyond a small niche market. However, TTS in Edmonton AB and The Pildysh Group in Calgary AB are in the process of developing hemp fibre mats for geotextile applications such as temporary road construction and erosion control.⁴⁵⁷

Carpeting and upholstery fabrics

In addition to textiles used in clothing, coarser woven cloth (canvas) can be produced from hemp and used in applications such as upholstery, tarpaulins, and carpeting. A blend of industrial hemp and wool fibres can produce a carpet that retains the durability of wool carpet, but produces a softer carpet than pure wool. There is minimal

⁴⁵⁵ Nelson, pg. 8

⁴⁵⁶ Karus et al. (2000)

⁴⁵⁷ Personal correspondence with Tamrat Tekle, Projects Department, TTS, February 19, 2008.

effort in North America to produce such woven products, although one Canadian company, Stemergy (formerly Hempline), is concerned with production of fibre for upholstery and carpeting, and there are companies in North America that produce hemp carpeting.⁴⁵⁸

Building Materials

Both the fibre and hurd from hemp can be used to produce building materials for use in construction. Building materials that can be made from hemp include: straw bales, fibreboard, roofing tiles, flooring, caulking, cement, paneling, plaster, insulation, and bricks.

Hemp fibre and other biofibre materials are expected to have a significant impact on home and commercial construction in the future. Hemp may in fact represent the best alternative to wood in construction products such as plywood, particleboard and other composite building materials, with the potential to revolutionize the building materials industry.⁴⁵⁹

As with many other hemp products, the current limited supply and high price of hemp present significant obstacles to commercial-scale production of hemp building materials in North America, this use of hemp has thus far only reached the level of a cottage industry. The Canadian market for hemp building products is currently at the developmental stage, but some Canadian provinces have invested in research to study the manufacturing and use of panel boards made from industrial hemp, for example.⁴⁶⁰

Four of the main uses of hemp for construction are discussed below: straw bale and cob building, fibreboard, insulation, and hempcrete. In addition to these applications, hemp fibre can be added to traditional construction materials such as concrete to increase tensile strength while reducing shrinkage and cracking.

Straw bale and cob building

In straw bale construction, walls are created by stacking bales of dry straw like bricks, then plastering the interior and exterior of the bales to form finished, sealed walls. This building technique produces walls that are strong⁴⁶¹ and have twice the thermal insulation value of wood stud walls,⁴⁶² good seismic stability,⁴⁶³ and fire resistance properties. Further, straw bale buildings are both environmentally sound and cost-effective.

Because of its exceptional strength and insulative properties, and because it is a renewable resource that can be farmed sustainably, hemp straw (well-dried hemp stalks) is well-suited to straw bale building applications. One drawback of using hemp in straw bale buildings is that, precisely because of the strength of the fibre, hemp bales may be

⁴⁵⁸ Thompson, Berger and Allen

⁴⁵⁹ Osburn and Osburn (1994), p. 9.

⁴⁶⁰ Alberta Agriculture and Food

⁴⁶¹ Tests at Queen's University have shown the straw-bale walls to be equally as strong as ordinary wood stud construction.

⁴⁶² Queen's University

⁴⁶³ Steen (1994)

more difficult to cut and handle than other types of straw; in addition, the current limited or sporadic supply of hemp straw in North America is a barrier to its use in straw bale building on a larger scale.

Hemp straw can also be used in cob building, another alternative building method.⁴⁶⁴ Cob is a mixture of clay, sand, straw, water, and earth that is moist enough to mold but dry enough to allow walls to be built without frames or forms. Cob buildings are typically monolithic, or built in one continuous structure rather than by stacking bricks or other blocks, which gives them greater strength. Although cob buildings are not suitable for use in extremely cold climates, a modified cob building technique can be applied which uses more straw in the cob mixture, therefore increasing the insulating quality of the structure. Hemp straw may be particularly desirable in these applications because of its high thermal insulation properties.

Fibreboard

There is increasing interest in the development of hemp building products as a substitute for the wooden boards and panels used in mainstream building. Fibreboard (also referred to as pressboard or composite board⁴⁶⁵) of various densities can be manufactured by combining the fibre with a binder and applying heat and pressure.⁴⁶⁶ Although hemp bast fibres may be desirable in composite wood products because of their length and strength, hemp hurd may in fact produce a superior product.⁴⁶⁷

The use of hemp as a replacement for wood fibre in these applications appears to be very promising.⁴⁶⁸ Hemp fibreboard is lighter, twice as strong, and three times as elastic as wood fibreboard, allowing nails to be driven into the board easily.⁴⁶⁹ Further, hemp fibreboard has sound proofing and pressure isolative characteristics absent from wood fibreboard, and is resistant to pests, moisture, and fungus.⁴⁷⁰ The use of hemp to produce fibreboard would contribute to forest conservation, and it may even be possible to manufacture hemp fibreboard using existing production equipment for wood-based fibreboard.⁴⁷¹

Wheat straw is currently the most common non-wood fibre used to produce fibreboard,⁴⁷² but fibreboard made from straw alone is inferior to wood fibreboard. However, when

⁴⁶⁴ Green Home Building

⁴⁶⁵ Although fibreboard is composed of fibres in a matrix or binder and therefore is often referred to as a composite, composites are usually composed of 70%-30% reinforcing fibre in 30%-70% matrix, whereas fibreboard is usually composed of approximately 90% fibre and 10% binder. (Small and Marcus, 2002) For more on composites from hemp, please see pages 22-26.

⁴⁶⁶ Medium-density fibreboard (MDF), which is denser than particleboard but lighter than high-density fibreboard, has been the target of much of the research in this area.

⁴⁶⁷ Small and Marcus (2002)

⁴⁶⁸ According to the lab director Tom Maloney, "the use of hemp fibre in multi-density fibreboard and other composites look very promising". (Roulac, June 1995)

⁴⁶⁹ Washington State University Wood Composite Laboratory

⁴⁷⁰ Osburn and Osburn (1994), p. 9

⁴⁷¹ Roulac (1997)

⁴⁷² Fortenbery, and Bennett (2004), pg. 99

blended with hemp it exceeds all standards for comparable composites and wood products, providing another potential application for hemp fibre in building.⁴⁷³

One of the obstacles to the establishment of a “green” fibreboard market is the binders used in their production. Traditional petroleum binders are effective but harmful to the environment, and ecologically-friendly binders that have been developed from natural sources have not yet been optimized for use. However, it is possible that hemp hurd could be used to make glues for composite construction products; if developed further, this technology may provide an opportunity for the production of non-toxic composite boards made entirely from hemp.⁴⁷⁴

Molded hemp fibreboard products are commercially viable in Europe, but in North America the use of non-wood fibres in fibreboard products is relatively undeveloped at the present time.

Insulation

Hemp hurd has largely been overlooked as a potential structural material due to its short fibre length and its low density. In hemp processing, it is considered a waste product with limited value mainly as an absorptive material, although the hurd comprises up to 75% of the hemp stalk. However, hemp hurd has considerable potential for use as insulation in the construction of buildings.

Hemp hurd may be processed into insulation rolls or mats and applied in the same way as fibreglass insulation. Alternatively, hemp hurd can be used in loose form and blown into spaces such as rafter voids. The high thermal insulation value of hemp hurd makes it ideal for use as insulation. Additionally, hemp hurd has the ability to absorb and release moisture, and resist the growth of mold, dust and other pollutants. Hemp insulation presents an alternative to fibreglass, which has caused concerns about health dangers such as potential airborne glass particles that may cause respiratory problems.⁴⁷⁵

There are a number of companies currently producing hemp-based insulation in the EU - thermal insulation products are the third most important sector of the hemp industry of the EU.⁴⁷⁶ This market is growing rapidly due to the high cost of heating fuels, ecological concerns about conservation of non-renewable resources, and political-strategic concerns about dependence on current sources of oil.⁴⁷⁷ These factors are also driving the transition to a bioeconomy in North America, where a significant market for natural-fibre based insulation products could potentially be developed, given sufficient and reliable supply.

⁴⁷³ Osburn and Osburn (1994), p. 9

⁴⁷⁴ *Ibid.*

⁴⁷⁵ Hemp Resources Ltd.

⁴⁷⁶ Small and Marcus (2002)

⁴⁷⁷ *Ibid.*

Hempcrete

Hemp hurd possess another unique and notable property: it can be mixed with lime and water and applied like cement in a wide number of construction applications.⁴⁷⁸ Because hemp hurd is rich in silica, it reacts to the lime and undergoes a mineralization process, producing a stone-like material that resembles cork and which is sometimes referred to as 'hempcrete'.⁴⁷⁹

Hempcrete can be used in many ways in construction: it can be poured into a frame to form foundations and walls, formed into bricks, used to produce light drywall-like panels or it can be used directly as a plaster.⁴⁸⁰ Hempcrete is approximately seven times stronger than concrete, has excellent thermal and sound-insulating properties, is half the weight and three times as elastic as concrete.⁴⁸¹ This means that buildings constructed with hempcrete are resistant to stress-induced cracking and breaking, and resilient in earthquakes and other natural disasters. Hempcrete, like other hemp products, is also resistant to moulds, rodents and insects, and is fire retardant and weather resistant. Since hemp hurd is currently considered a bi-product of the hemp fibre separation process, they represent a relatively inexpensive feedstock that could potentially be very competitive in the building products industry. Further, given that approximately 7% of global CO² emissions are generated as a result of concrete production, the increased use of hempcrete could have significant environmental benefits.

TTS is currently in the process of developing fibre-cement composites from hemp hurd for use in siding and sound insulation applications.⁴⁸² This work is presently at the pre-commercialization stage.

Paints, varnishes, inks and industrial lubricants

Hemp oil has a long tradition of use in products such as lamp oil, paints, varnishes, sealants, lubricants for machinery, and printing inks. Until the 1930s, most paints and varnishes were made with hemp oil. Hemp oil is classified as a semi-drying oil,⁴⁸³ and can be used in a range of oil-based industrial products including paint, varnish, detergent, solvent, and lubricating oil. Paints made from hemp oils have been found to penetrate wood better than other paints and provide high resistance to water. Hemp oils can also be used in non-toxic printing inks in offset printing, for example.⁴⁸⁴ Most plant-based inks are currently made of soybean oil, but soy ink requires more processing and takes longer to dry than hemp oil based inks.

However, such industrial end uses may not presently be economically feasible. Because of the relatively limited production of hemp in North America, and the resulting necessity

⁴⁷⁸ Materials such as gypsum, sand, or reinforcing fibres may also be added.

⁴⁷⁹ Hempcrete takes one to two weeks to cure, and its strength increases progressively as it cures.

(Eires, Rute and Jalali, 2005)

⁴⁸⁰ An experimental tile made of hemp has also been produced. (Oldham and Oldham, 1995)

⁴⁸² Personal correspondence with Tamrat Tekle, Projects Department, TTS, February 19, 2008.

⁴⁸³ A semi-drying oil (determined by the degree of saturation of the fatty acids) is an oil which partially hardens on exposure to air, in contrast with a drying oil, which hardens completely.

⁴⁸⁴ Hemp Resources Ltd.

of importing hemp seed or oil, hemp oil remains very high-priced compared to similar oils such as flax oil. Therefore, it may be difficult for hemp to compete with other products until a larger domestic supply of hemp is available. If larger production volumes and lower prices are achieved, hemp oil may find industrial uses similar to those of linseed (flax), soybean, and sunflower oils, which are presently used in paints, inks, solvents, binders, and in polymer plastics.

Biofuels

Overview

Biofuel is fuel derived from **biomass**, where biomass is defined as any material, excluding fossil fuels, which is or was a living organism that can be used as a fuel directly or after a conversion process.⁴⁸⁵

When used on a sustainable basis, biofuel offers several benefits:

- potential greenhouse gas reductions;
- potential reduction of urban smog pollutants and air toxics;
- energy and energy infrastructure security; and
- local economic development, particularly in rural areas.

Biomass can be used in relatively unmodified form as a simple biofuel, particularly as a solid fuel. Already, biomass-driven combined heat and power, co-firing, and combustion plants provide reliable, efficient, and clean power and heat. Production and use of biofuels are growing at a very rapid pace. Sugar cane-based ethanol is already a competitive biofuel in tropical regions. In the medium term, ethanol and high-quality synthetic fuels from woody biomass are expected to be competitive at crude oil prices above US\$45 per barrel.⁴⁸⁶

Additional biofuels include: vegetable oils used directly as diesel, biodiesel, starch-based and cellulosic ethanol, butanol (also referred to as biobutanol or biogasoline) methane gas, synthetic gas, hydrogen and other carrier compounds. **Energy crops** used for biofuel production include hemp, flax, wheat, corn (or maize), canola (or rapeseed), soybean, sugarcane, sunflower, and purpose-grown short-rotation woody species.⁴⁸⁷

Recent criticisms of biofuels

Several reports published in late January 2008 by the environmental audit committee of the U.K. government, the Royal Society⁴⁸⁸ and the European Commission all suggest that **first-generation biofuels** (i.e. all current biofuels – ethanol, biodiesel, etc.) do not actually reduce greenhouse gases.⁴⁸⁹ Several articles published in the prestigious

⁴⁸⁵ ASTM Standard (2002)

⁴⁸⁶ International Energy Agency Bioenergy, *Potential Contribution of Bioenergy to the World's Future Energy Demand*, 2007.

⁴⁸⁷ Fast-growing species grown specifically for the production of energy, including switchgrass, poplar and willow.

⁴⁸⁸ United Kingdom House of Commons Environmental Audit Committee (January 21, 2008)

⁴⁸⁹ Chairman of the U.K. committee, Mr. Tim Yeo, added that, "Advanced second generation biofuels may have an important role in the future, but these technologies are some years away.

journal *Science* in early February 2008 echo this concern. Converting cropland to biofuel actually increases greenhouse emissions because of emissions generated through land use change. When the use of land is changed, carbon storage and sequestration from the crops previously grown on the land is sacrificed.

For example, "instead of producing a 20% savings [corn-based ethanol] nearly doubles greenhouse emission over 30 years and increases greenhouse gases over 167 years. Biofuels from switchgrass, if grown on US corn lands, increase emissions by 50%".⁴⁹⁰ This problem also exists for converted forests, grasslands, peatlands or savannas. In general, converting such lands in Brazil, Southeast Asia and the US has created a "biofuel carbon debt" by releasing 17 to 420 times more CO₂ than the annual greenhouse gas reductions these biofuels provide by displacing fossil fuels".⁴⁹¹

Current view of hemp as a feedstock for biofuels

In the raft of recent reports on biofuels, hemp is conspicuous in its absence.⁴⁹² The prevailing view is that the currently limited supply of hemp, coupled with the high price for hemp oil for natural and other health product applications and the high prices for hemp fibre for paper and composites, eliminate hemp for serious consideration as a biofuel crop.

The current value of a 45-gallon barrel of hemp oil for the health food market is CAN\$1,000, making it prohibitively expensive for a biofuel feedstock.⁴⁹³ Currently, conventionally grown hemp seed brings in about 45 Canadian cents a pound, while certified organic seed garners 85 Canadian cents a pound, or nearly CAN\$40 a bushel.⁴⁹⁴ Production is also currently limited. In 2005 in Canada, 9.7 kilohectare (kha) of hemp was planted. Although this acreage doubled to 20.2 kha in 2006, that amount is still extremely small compared with other Canadian crops. (For example, in 2006, 805 kha of flax, 1,214 kha of soybeans, 5,283 kha of canola and 8,316 kha of wheat were planted in Canada.⁴⁹⁵) In 2006, oversupply (due to low prices for other crops) coupled with an excellent hemp crop with above average yields, led to a high inventory.⁴⁹⁶ As a result, a lower hemp acreage of 4.7 kha was planted in 2007.⁴⁹⁷

When former U.K. environment secretary Ian Pearson was asked in 2007 about the potential for hemp as a biofuel crop, he responded, "it is not currently competitive compared to other sources of biomass. [...] As a result, there is little interest in this country at present in growing it for biofuel production".⁴⁹⁸ The influential magazine *Biodiesel* published an article in February 2007 on hemp for biofuel that observes, "there

The government should support their development by creating a stable investment climate out to 2020." (Aldred, January 21, 2008).

⁴⁹⁰ Searchinger, Timothy et al. (February 7, 2008), pg. 1

⁴⁹¹ Fargione, Joseph, et al. (February 7, 2008), pg. 1

⁴⁹² Sica, pg. 6

⁴⁹³ Jessen (February 2007)

⁴⁹⁴ *Ibid.*

⁴⁹⁵ AAFC^c

⁴⁹⁶ Personal correspondence with Keith Watson, Diversification Specialist, Agri-Food and Adaptation, Manitoba Agriculture, Food and Rural Initiatives

⁴⁹⁷ Health Canada

⁴⁹⁸ Sica, pg. 6

are too many factors working against the use of hemp as a biodiesel feedstock”.⁴⁹⁹ These factors are cited as the high price currently paid for hemp for traditional markets, limited supply, and the relatively low oil productivity of hemp.⁵⁰⁰

However, limited supply and the current price of hemp are both a direct consequence of the fact that there are only niche markets currently available for hemp (in natural health product uses, and some paper and composite applications). It is clearly circular to rule out emerging markets for hemp based on the fact that current supply is inadequate for those markets. Emerging markets always involve an evolving interplay between supply and demand. This is a challenge common to all bioeconomic development, however, not an insurmountable barrier. Rapid growth in bioproducts sectors requires simultaneously optimizing entire value chains, from feedstock producers right through to end markets to ensure that no unaddressed links hold back the emerging sectors.

Advantages of hemp as a crop for biofuels

Hemp has a long and famous history of use as a source of biofuel. Henry Ford designed his automobiles to run on ethanol, including the 1908 Model T. Ford expected that ethanol, made from renewable biological materials, would be a major automobile fuel. Ford built a plant to produce ethanol from hemp in the Midwest and formed a partnership with Standard Oil to sell it in their distributing stations. During the 1920s, ethanol derived from hemp comprised 25% of Standard Oil’s sales in the Midwestern United States.⁵⁰¹

Hemp has several advantages compared with other energy crops used for biofuel production:

1. Can be grown on marginal land

Because it can be grown on extremely marginal land, hemp offers a significant advantage over other purpose-grown energy crops, particularly in the context of recent findings about the emissions caused by land use changes. Indeed, in one of the seminal recent articles in *Science*, the authors note that, “feedstocks produced on lands that generate little carbon today might also keep land use change emissions low, but the ability to produce biofuel feedstocks abundantly on unproductive lands remains questionable.”⁵⁰² Since hemp can be grown on land that has not been cleared, it is an excellent candidate for a biofuel with low carbon emissions.

2. Resistant to pests and disease

The fact that hemp is susceptible to few serious pests and diseases⁵⁰³ reduces the energy (in the form of labour) and chemicals (pesticides) required to grow hemp,

⁴⁹⁹ Jessen (February 2007)

⁵⁰⁰ “Hemp seed does have a relatively high oil content of about 33 percent, compared with canola at about 40 percent. However, it has a low seed per-acre yield. Typically, an acre of hemp yields about 700 pounds of seed, although some farmers have enjoyed production numbers as high as 1,200 pounds an acre in good years...Canola growers, on the other hand, can reap a crop of anywhere from 1,500 to 2,600 pounds an acre.” (Jessen, February 2007)

⁵⁰¹ Yokayo Biofuels

⁵⁰² Searchinger, Timothy et al. (February 7, 2008), pg. 3

⁵⁰³ Sparks, 404

improving its environmental profile against other energy crops. (Currently in Canada, however, no herbicides are fully registered for use in pedigreed hemp seed cultivation.)

3. Grows faster than other energy crops

Hemp grows quickly and can reach heights of just over 3 meters to 3.7 meters in 75 to 90 days.⁵⁰⁴ It thus grows faster than any of the other energy crops used for biofuel production.⁵⁰⁵

4. High energy yield

Hemp produces more energy per acre per year than corn, sugar, flax, or any other crop currently grown for ethanol or biodiesel.⁵⁰⁶ Biomass energy expert Lynn Osburn estimates that 1 ½ to 3 ½ million acres of hemp would replace all of Canada's fossil fuel demands.⁵⁰⁷

Uses of hemp for biofuel production

There are many conversion pathways by which hemp can be processed into biofuels, as summarized in Table 1 on the following page.

⁵⁰⁴ Hempline

⁵⁰⁵ Sica, pg. 9

⁵⁰⁶ Wikipedia

⁵⁰⁷ Ecological Agriculture Projects

Table 15: Summary of conversion pathways for biofuels from industrial hemp

Source	Primary Process	Secondary Process	End Product		
Seed Oil	Oil extraction	n/a	Use of hemp oil as plant oil fuel		
		Transesterification ⁵⁰⁸	Biodiesel		
Stalk	Direct combustion	n/a	Heat or combined heat and power (CHP) generation		
	Direct fermentation	n/a	Hydrogen or other products		
	Hydrolysis	Fermentation	Ethanol or other fermentation products such as butanol		
			Gasification	Combustion of syngas	Heat or CHP
			Purification of syngas	Hydrogen	
	Catalytic reforming of syngas	Fischer Tropsch (FT) fuels ⁵⁰⁹			
			Pyrolysis	Combustion of bio-oil	Heat or CHP
			n/a ⁵¹⁰	Use of bio-oil as diesel fuel	
	Gasification of bio-oil and combustion of resulting syngas	Heat or CHP			
			Gasification of bio-oil and catalytic reforming of resulting syngas	Methanol or FT fuels	
			Anaerobic digestion	Combustion of biogas	Heat or CHP
	Purification of biogas	Methane			
			Catalytic reforming of biogas	Methanol or FT fuel	

The following sections will consider the biofuel production possibilities for hemp in more detail.

Direct combustion of hemp stalk⁵¹¹

The stalk of the hemp plant can be pelletized and combusted directly in pellet-burning wood stoves to produce heat, or to co-generate heat and electricity, in so-called **combined heat and power (CHP)**.⁵¹² This is likely the most important near term energy application for hemp. Hemp stalk has a relatively high energy content, low moisture content, low ash content and low content of undesirable contaminants, and is known to burn well in a combustion system. The energy content is likely to be more than 7,000

⁵⁰⁸ With methanol and a catalyst.

⁵⁰⁹ The Fischer-Tropsch process is a catalyzed chemical reaction in which carbon monoxide and hydrogen are converted into liquid hydrocarbons.

⁵¹⁰ The extraction of valuable chemicals from the bio-oil (pyrolytic liquid) improves its quality as a fuel. The phenolic fraction of this bio-oil may contain valuable nutraceutical compounds. In the case of flax straw, for example, recent analysis by the Canadian Forest Service of the pyrolytic liquid from pyrolyzed flax straw found high levels of molecules and compounds beneficial to human health (Goodfellow Agricola Consultants Inc., 2007).

⁵¹¹ This discussion was written by Dr. Robert Parsons, Manitoba Science, Technology, Energy and Mines.

⁵¹² Davis, (2007), pg. 23

BTU per pound.⁵¹³ The value of hemp for combustion applications is determined by energy content and (referenced to coal and natural gas) is in the range of \$50 to \$150 per tonne. This is a relatively low value, for example as compared to bast fibre for paper or fabric or hurd for absorbent. However, the quality characteristics required are much less stringent – depending essentially on energy content – and volume requirements are very large. Combustion potentially represents a low value but high volume use applicable for off-spec and residual hemp or non-usable waste components such as nut shells for which other uses may not readily exist.

Plant oil fuel

Hemp oil has a long history of being used for fuel. In the 1920s, Henry Ford found that 30% hemp seed oil could be used as high-grade diesel fuel, and as a machine lubricant and an engine oil.⁵¹⁴ Recent studies have indicated that, for example, up to 25% of blend of hemp oil without heating and up to 50% blend with preheating can be blended with diesel fuel without any engine modification.⁵¹⁵

A recent study by nova-Institut (Germany) observed that there are several developments required before hemp oil could be used as a **plant oil fuel**. Relatively high residue, coupled with relatively high reactivity with oxygen causes hemp oil to produce resinous deposits within fuel injection systems and other parts of engines. This can lead to increased maintenance cost and problems with motor operation. Additives could be developed to mitigate these problems, although nova-Institut notes that this would lead to “additional costs...and there is hardly any experience on hand for this”.⁵¹⁶

nova-Institut notes that hemp oil is currently too expensive to be used for fuel, and that higher seed yields per hectare and increased oil content will both be needed to make hemp oil viable as a plant oil fuel. Further, they suggest that motors must be developed and modified for the use of hemp oil, which will not be possible in the near future. This leads them to conclude that, “the use of hemp oil as a pure plant oil fuel will be restricted to niches and special cases”.⁵¹⁷

The most promising near-term option may be blending hemp oil with canola oil, which has been rigorously tested for use as a plant oil fuel. The resulting blended oil complies with the technical standard for pure plant fuel oil fuels, can be used in pure plant oil compatible motors, and has improved low-temperature behavior and better ‘flowability’ than pure canola oil.

Biodiesel

In addition to being used directly as a plant oil fuel, hemp oil can be modified through **transesterification**. This chemical reaction involves migrating ester chains from a triglyceride (fat) molecule and reconnecting the ester chains with an alcohol molecule,

⁵¹³ US DOE cites the energy content of dry biomass to be approximately 8,600 BTU / lb.

⁵¹⁴ Yokayo Biofuels

⁵¹⁵ Hebbal (October 2006), pg. 2188

⁵¹⁶ nova-Institut GmbH and Technologie- und Förderzentrum (August 2007)

⁵¹⁷ *Ibid.*

thus creating a methyl ester molecule, which is commonly called **biodiesel**.⁵¹⁸ Typically the alcohol has been methanol but others can be used, particularly ethanol.

Biodiesel has only 8% less energy content per gallon than No. 2 Diesel.⁵¹⁹ Hemp biodiesel is green in colour, which could be used as part of a marketing strategy. Biodiesel can be made from hemp oil in a chemical reaction involving oil, an alcohol (usually methanol) and a catalyst (usually sodium hydroxide). The reaction produces biodiesel and a small amount of glycerol or glycerin. The cost of these inputs adds up to approximately US\$0.66 / gallon of hemp biodiesel, not including the cost of producing the hemp oil itself (or the costs associated with sales, transportation, maintenance, depreciation, insurance and labour).⁵²⁰

In Canada, the Canadian Biodiesel Initiative has concluded that feedstocks must be found that do not compete with food production, or else “lipid feedstock supply is likely to cause production and market constraints for the emerging industry, should demand for biodiesel by more than a few percent (>2%) of Canada’s total transportation diesel use”.⁵²¹ Because hemp oil would not compete with food production once supply outstripped the relatively limited (and relatively inelastic) demand for hemp oil for health products, it would be an excellent crop for biodiesel production. (Biodiesel also represents a potential outlet for low quality oils, such as if heat stressed or aged.)

Cellulosic ethanol

Hemp stalks can be processed into cellulosic ethanol through the **hydrolysis** of cellulose, a biological process used to break down chemical compounds by reaction with water. In cellulolysis, hemp biomass must first be physically or chemically pretreated in order to isolate the cellulose from the lignin and make it accessible for hydrolysis. The long chains of sugar molecules that make up the cellulose molecules are then broken down through chemical or enzymatic hydrolysis to free the sugar, followed by fermentation to convert the sugars into alcohol (cellulosic ethanol).

High cellulose content and low lignin levels in biomass facilitate the production of cellulosic ethanol. Hemp bast fibre has a much higher cellulose content and is lower in lignin than many other biomass sources, and hemp hurd has comparable levels of cellulose and lignin to other biofuel feedstocks such as switchgrass. Further reductions in lignin can be achieved by cultivation and harvest techniques, germplasm development and custom enzyme development, optimizing processing output and efficiency.⁵²² Hemp, whether whole stalk or hurd, offers potential as a feedstock for cellulosic ethanol production, however, little direct work has been undertaken for hemp.⁵²³

⁵¹⁸ BFuel Canada Corp.

⁵¹⁹ Knothe (2005), p. 20

⁵²⁰ Ian S. Watson (biodiesel expert) at Lawrence Livermore National Laboratory, cited in Fuel and Fiber.

⁵²¹ Biocap Canada, p.3

⁵²² Even incremental advances in system efficiencies related to these production improvements create a significant financial incentive for investors. (Fuel and Fiber Company)

⁵²³ Dr. Robert Parsons, Manitoba Science, Technology, Energy and Mines.

The chemical compositions of industrial hemp are compared to other sources of biomass in the table⁵²⁴ below:

Table 16: Cellulose and lignin content of biomass

Biomass	Cellulose	Lignin
Hemp bast fibre	64.8 %	4.3 %
Hemp hurd	34.5 %	20.8 %
Soft Pine	44%	27.8%
Wheat Straw	34%	18%
Corn Stover ⁵²⁵	28%	11%
Switchgrass ⁵²⁶	32.5%	17.8%

Gasification

Hemp stalks can also be converted into synthesis gas (or **syngas**) through **gasification**, a process in which carbon-rich materials such as biomass are heated at high temperatures with a controlled amount of oxygen. The syngas mixture consists primarily of hydrogen and carbon monoxide but can also include other gases such as methane. Syngas can be either combusted directly as a fuel, or further processed into ethanol through fermentation, or into **Fischer Tropsch fuels** through catalytic conversion.

Pyrolysis

Pyrolysis is a process in which organic matter is heated at high temperatures in the absence of oxygen, yielding pyrolytic liquid (commonly referred to as **bio-oil**), syngas, and char. The char can be used as a fertilizer, and all of the products of pyrolysis can also be used directly as fuel for the production of heat and electricity.

Before combusting or further processing occurs, a range of chemicals can be extracted from the bio-oil for further processing into a spectrum of products such as binders, polymers, concrete additives, etc. For example, the bio-oil from pyrolyzed flax straw has been found to contain high levels of molecules and compounds beneficial to human health.⁵²⁷ A complete chemical assay of the pyrolytic liquid utilizing a NIRS (Near Infrared Reflectance Spectroscopy) analysis coupled with a careful market analysis can reveal numerous product opportunities. (The extraction of valuable chemicals from the pyrolytic liquid actually improves its performance as a fuel.⁵²⁸)

Anaerobic digestion

Anaerobic digestion (AD) is a natural biological process involving the microbiological conversion of organic matter into methane in the absence of oxygen, through a process

⁵²⁴ Table adapted from Fuel and Fiber Company, *Hemp Biomass for Energy*.

⁵²⁵ The leaves and stalks of corn or other crops that are left in a field after harvest.

⁵²⁶ A common North American grass that can be grown as an energy crop for cellulosic ethanol production.

⁵²⁷ Goodfellow Agricola Consultants Inc, (2007), pg. 4

⁵²⁸ Ensyn Corporation

called 'methanogenesis'. Methanogenesis occurs throughout nature when high concentrations of wet organic matter are found in the absence of dissolved oxygen, and has been harnessed by humans since at least 1859, although the bacterial mechanisms involved were only identified in the 1930s. A properly run anaerobic digester will efficiently convert feedstocks into two streams, a nutrient-rich and stabilized slurry that can be used as fertilizer, and a biogas that is roughly 65% methane. This biogas can be captured and combusted to create heat and electricity, and a reasonably sized anaerobic digester can be a significant small-scale contributor of electricity to the grid.

Anaerobic digestion can be used on agricultural residuals such as corn silage, and could also be applied to hemp hurd and bast fibres. AD technology may be attractive in some cases when co-located with a hemp fibre processing facility or in remote locations to provide local power generation.⁵²⁹

Alternatively, the methane gas produced through AD can be further processed into **methanol** (also known as methyl alcohol or wood alcohol). Methanol can be used as a fuel, a solvent, or an antifreeze. It is also the alcohol commonly used in the transesterification reaction to produce biodiesel.

Biocomposites and Bioplastics

Plastics and composites

Plastics are polymers, or long chains of atoms bonded together. (The definition of plastic is not standardized at the present time.⁵³⁰) In the 1850s, the earliest forms of plastic were based on cellulose, a natural polymer that is the primary component of plant cell walls. Myriad kinds of plastic based on synthetic polymers derived from petroleum were developed after WWI and during the 1950s: nylon, polyethylene (PE), polypropylene (PP), Teflon (PTFE), and others.

The majority of plastic products are made from pure plastic, such as toys and soda bottles. When additional strength is needed, however, many types of plastics can be reinforced with reinforcing fibres. The resulting **reinforced plastics** consist of fibre⁵³¹ in a plastic (polymer) matrix. These products are not pure plastics, they are **composites** – two or more dissimilar materials combined to make a stronger and more durable material.⁵³² There are many natural composites, including wood, which are made up of cellulose fibre and lignin; the fibre provides strength and the lignin binds the fibre into a three-dimensional structure. Artificial composites have existed since 5500 B.C., when Egyptians used mud and straw bricks for construction.⁵³³ Reinforced plastics are an important class of modern composites, and are referred to in the composite manufacturing industry as **fibre-reinforced polymer (FRP)** composite materials.⁵³⁴

The **polymer matrix** in FRPs supports the **reinforcing fibres**, which in turn impart their particular mechanical and physical properties to the composite. Fibres used include

⁵²⁹ Fuel and Fiber Company

⁵³⁰ The Society of the Plastic Industry

⁵³¹ The reinforcing substance can also be ground minerals.

⁵³² Composites have two distinct macroscopic phases as well. American Composites Manufacturers Association

⁵³³ Roth (2006), pg. 193

⁵³⁴ Also referred to as fibre-reinforced thermoplastics (FRTs) (Markarian, 2007, p. 36).

glass, carbon and aramid,⁵³⁵ and polymer resins include polyester, vinyl ester, epoxy, phenolic, polyurethane, polyimide, polyamide, PE, PP, PEEK and others. Globally, glass fibres are the most widely used fibre type in FRPs. In North America, glass fibres have more than 90% of the market share in reinforcing fibres.⁵³⁶

The first major uses of FRPs were in the early 1940s in aerospace and naval applications (although they had first been produced in 1908), and in commercial applications made from glass-reinforced plastic, commonly referred to as fibreglass. Other FRP composites have high strength-to-weight ratios and are highly resistant to corrosion, making them ideal for many military applications.⁵³⁷ Since the 1940s a myriad of applications have made composites an inextricable part of the modern landscape.

The largest market of modern composites has changed over time with automotive and transportation applications surpassing marine in the 1970s.⁵³⁸ The growth market for fibre-reinforced polypropylene (PP) in automotive and appliance applications is the main driver for modern composites.⁵³⁹

Bioplastics and biocomposites

Bioplastics are a form of plastics derived from renewable biological materials (or **biomass**) rather than from petroleum. Henry Ford experimented with **soy plastics** throughout the 1920s, ultimately manufacturing a car from soy plastic reinforced with hemp fibre called the 'soy car', which he unveiled publicly in 1941. The rise of petroleum based plastics completely sidelined bioplastics in mainstream production, until increasing societal concerns about the vast quantities of non-biodegradable plastic accumulating in landfills and in the global ecosystem (particularly oceans) in the last few decades triggered renewed interest in bioplastics.

Feedstocks for bioplastics include soy bean oil, corn starch, sugar cane, and microbiota. There are five kinds of bioplastics,⁵⁴⁰ and they are used primarily for applications in packaging, as well as for catering, gardening, medical and sanitary products.⁵⁴¹ The market for bioplastics is currently 10-15% of the global plastics market and is growing at more than 8-10% per year with projections that it will increase its market share to 25-20% by 2020.⁵⁴² This amounts to over \$1 billion (US dollars) in 2007 and is projected to be over \$10 billion by 2020.

⁵³⁵ Aramid fibres (aromatic polyamides) are a class of heat-resistant and strong synthetic fibres used in aerospace and military applications and as a substitute for asbestos.

⁵³⁶ Markarian, 2007

⁵³⁷ Composites also have high-impact strength (Kevlar), allow for design flexibility and part consolidation, exhibit dimensional stability and low thermal conductivity, and are nonconductive, nonmagnetic, transparent to radar and extremely durable.

⁵³⁸ ACMA site, "History of Composites"

⁵³⁹ Markarian (2007) p. 36.

⁵⁴⁰ Thermoplastic starch (which make up 80% of the bioplastics market), polylactide acid plastics (PLA), polyhydroxyalkanoic acid (PHA) plastics, the most common of which is polyhydroxybutyrate (PHB), cellulose acetate and polyamide 11 (PA 11).

⁵⁴¹ European Bioplastics

⁵⁴² Helmut Kaiser Consultancy

As discussed, most plastics by themselves are not suitable for load-bearing applications, due to their lack of strength, stiffness, and dimensional stability.⁵⁴³ When additional strength is needed, bioplastics can be reinforced with fibres, just as is the case for petroleum-based plastics. If natural fibres (such as hemp, jute, ramie and sisal) are used to reinforce bioplastics (such as derivatives of cellulose, starch and lactic acid⁵⁴⁴) the resulting product is a **biocomposite**, or a green composite. Biocomposites are fully biodegradable, making them attractive for environmental reasons.

Since the 1990s, natural fibres have been used as reinforcing fibres in composite applications that utilize petroleum-based plastics, and can thus be referred to as '**hybrid biocomposites**'.⁵⁴⁵ The majority of these hybrid biocomposites have been used for compression molded interior automotive applications. Natural fibres are lighter, cheaper and stiffer than glass fibres. These performance benefits have been the primary driver of their inclusion in the automotive industry, with 'green image' being only a secondary driver.⁵⁴⁶ The use of hybrid biocomposites in injection molding is beginning to be commercialized, which would allow natural fibres to be used as reinforcing fibres in many more products.

Hemp-based bioplastics

Hemp is not currently used for pure bioplastic production. Because hemp hurd has an extremely high cellulose content (up to 85%), it could theoretically be used to produce one of the five kinds of bioplastics – cellulose acetate – which has been traditionally produced from wood flour since the 1920s (cellulose acetate fibre is rayon).

While hemp oil could also theoretically be used as a feedstock for bacteria to produce PHA plastics, these plastics are already overly expensive, which is forcing manufacturers to try to switch to activated sludge for use as a feedstock in order to cut costs. (The future of PHA production is growing plastic polymers through biosynthesis within plants.) Hemp oil is too valuable to compete with sludge as a feedstock on cost alone, and offers no unique benefit to PHA production.

Dr. Michel Huneault of the Industrial Materials Institute of the National Research Council has conducted extensive research on bioplastics and is unaware of any ongoing research into hemp oil bioplastics.⁵⁴⁷ Dr. Mohini Sain at the Centre for Biocomposites and Biomaterials Processing at the University of Toronto confirmed that hemp oil is not suitable for PHA production.⁵⁴⁸

⁵⁴³ Mohanty et. al (2005), pg. 5

⁵⁴⁴ Also called 'biodegradable resins' when used as a matrix in a biocomposite. (Goda and Cao 2007, pg. 1073)

⁵⁴⁵ Mohanty et. al (2005), pg. 5

⁵⁴⁶ Markarian (Feb. 2007), pg. 38

⁵⁴⁷ Information obtained through personal correspondence with Dr. Michel Huneault, Industrial Materials Institute of the National Research Council

⁵⁴⁸ Information obtained through personal correspondence with Dr. Mohini Sain, Professor, Centre for Biocomposites and Biomaterials Processing, Faculty of Forestry, University of Toronto.

Hemp fibre reinforced biocomposites

Automotive composites

Presently, the single largest use for hemp fibre produced in North America is for automotive composite products.⁵⁴⁹ Hemp fibre is typically blended with petroleum-based plastics⁵⁵⁰ and compression molded into interior trim applications: door panels, window pillars, package trays, and trunk liners. The advantages of hemp-reinforced hybrid biocomposites for automotive use are the same as those of other natural fibres: light-weight (can weigh up to 30% less than glass fibre counterparts),⁵⁵¹ high tensile strength, low cost (compared to fibreglass), and the ability of the resulting product to be recycled.

Producing composites using hemp also eliminates the respiratory problems caused by working with fibreglass. Further, like other natural fibres, hemp is less abrasive than fibreglass, reducing the wear on machinery. (Among natural fibres, hemp has the advantage of consistent and regular supply because hemp grows well on marginal land and with minimum care.) A low-hanging fruit might be hybrid fibre applications with different percentages of glass and hemp fibre.

In order to produce biocomposites using hemp, a biopolymer resin would be required to replace the petroleum-based resins. Research is underway (at Ford among others) into PLA bioplastic resins to make truly green biocomposites for use in automotive construction. A technical obstacle to such applications is in reformulating the bioplastic resins to adhere better to the hemp fibre. This is not surprising, however, given that resins have traditionally been developed for compatibility with glass fibres, not natural fibres.

TTS currently utilizes hemp fibre mats as a fibreglass replacement in reinforced resin matrices for use in ground transportation applications such as truck canopies.⁵⁵² This production line is currently at the pre-production stage.

Injection molded plastic

Companies like GreenGran (Netherlands) and AFT Plasturgie (France) are beginning to commercialize injection molding applications for plastics reinforced with natural fibres. This will allow for many more applications using hemp fibre. Problems such as excessive friability, which causes feeding difficulties, high moisture content, which requires venting and which can slow production, are being overcome through the development of specialized compounding techniques.⁵⁵³

Composites for building materials and other applications

As discussed above, hemp has also shown significant promise for use in composite building materials such as fibreboard (see pages 14-15). As well as developing fibre-cement composites from hemp hurd for use in sound insulation and siding applications,

⁵⁴⁹ Hempline

⁵⁵⁰ This makes the resulting products "hybrid biocomposites".

⁵⁵¹ Due to the hollow tubular structure of natural fibres, which reduces their bulk density (Goda, and Cao, 2007, p. 1073).

⁵⁵² Personal correspondence with Tamrat Tekle, Projects Department, TTS, February 19, 2008.

⁵⁵³ Markarian (Feb. 2007), pg. 37.

TTS is currently in the process of developing lightweight hemp⁵⁵⁴ alternatives to particleboard or MDF for use in furniture applications.⁵⁵⁵

Phytoremediation

In addition to the broad range of products that can be manufactured using industrial hemp, the very process of cultivating hemp benefits the soil it is grown in. As noted above, the water requirements of industrial hemp are negligible, so it can be grown with minimal irrigation and in arid regions, and since it matures from seed in only 120 days, it does not require a long growing season. Industrial hemp establishes a twelve-inch taproot in thirty days, which prevents topsoil erosion. The hemp plant also concentrates nutrients in its roots and leaves; after harvest, these parts of the plant can be re-incorporated into the soil, preserving soil nutrients.

Industrial hemp has also shown potential for **soil remediation**, (also called **phytoremediation** or **bioremediation**) in which plants are used to decontaminate polluted soils, water or air. Hemp has successfully been used to remove heavy metals such as copper, lead, zinc and cadmium from contaminated soils, eliminating the threat of their introduction into the food chain through livestock, for example.⁵⁵⁶

⁵⁵⁴ Using hemp fibre and/or hurd

⁵⁵⁵ Personal correspondence with Tamrat Tekle, Projects Department, TTS, February 19, 2008.

⁵⁵⁶ Blackburn (2005), pg. 55

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**Appendix D – Literature Review of the Agronomics of
Industrial Hemp: Seeding and Harvesting**

Strategy Development for the Canadian
Industrial Hemp Industry:
Literature Review:
Agronomics: Industrial Hemp
Seeding and Harvesting

Prepared for the National Industrial Hemp
Strategy

Composites Innovation Centre
Project Sponsor: ARDI III B-27

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Introduction

The Canadian Hemp Trade Alliance (CHTA), Composites Innovation Centre (CIC), Agri-Food Research and Development Initiative (ARDI), Manitoba Agriculture, Food & Rural Initiatives (MAFRI) and the participating industry members are proud to present this historical and agronomic hemp review. The purpose of this review is to provide up-to-date information on hemp production and management to industry stakeholders. Access to peer reviewed research publications in Canada is lacking. This document will serve as a base for solid peer reviewed documents and brief review of seeding and harvesting applications for future Canadian researchers.

Hemp is a viable dual-purpose crop in rotation and requires little input beyond that of crop nutrition. For 6,000 years hemp has been cultivated for its primer seed and fibre characteristics. Since 1997, cultivation, processing and marketing of industrial hemp in Canada has excelled. Developing best management and agronomic practices are key to positioning Canada as a global leader for hemp cultivation and processing. Agronomic, breeding and equipment modification research along with food and fibre quality and marketing opportunities have been supported by industry stakeholders and by federal and provincial bodies. This support has contributed to the overall success of hemp production in Canada thus far.

This paper contains information obtained from research publications, reference texts and industry related experts. We have made every effort to reference all works in a respectful manner and have requested permission to borrow included text, tables, figures and appendixes material. In such case that we have unintentionally overlooked any copyright formatting, arrangements will be made to credit due source.

1. Plant Description

1.1 Taxonomy

Industrial hemp has been the longstanding generic name for fibre and grain cultivars of *Cannabis*. Hemp is an adaptive successful dual-purpose herbaceous annual domesticated for its bast and hurd fibres, for its pressed seed and leaf essential oils and for its epidermal resins (Small and Marcus 2002, Booth 2003, Callaway 2004).

The classical Greek word for hemp, κάνναβις; *kannabis*, was derived from the Sanskrit epithet *canna* (Abel 1943), the word *kan* historically was used in reference to hemp, cane or reed (<http://www.cannabisculture.com>) while the third syllable *bis*, more than likely came from the Hebrew word *bosm* or the Aramic word *busma*, meaning 'aromatic'. Thus *Cannabis*, means 'fragrant cane' (Booth 2003) and the Latin rooted word *sativa* means 'sown or cultivated' (www.answers.com, 10/5/2006).

The distinct aroma is produced from volatile mono- and sesqui-terpens rather than by terpenophenolic cannabinoids (Kaniewski and Konczewicz 2005). The essential oil of *Cannabis* mono- and sesqui-terpens posses bacteria inhibiting effects (bacteriostatic), particularly to Gram-positive bacteria (*Staphylococcus* and *Streptococcus*), compable to that of thyme essential oil (Kaniewski and Konczewicz 2005). It was observed in a Cranfield University, UK trial that the approved cultivar Fedora emitted a much stronger odour than that of the cultivar Chameleon (Riddlestone et al. 2006).

In 1586, Jacques Daléchamps or D'Aléchamps (1513-1588), a French doctor, botanist and naturalist used the botanical name *Cannabis mas* (male form) and *Cannabis femina* (female form) in reference to the *Cannabis* plant, in his most important work *Historia generalis plantarum* (1586, translated 1615). The Swiss botanist, Casper Bauhin (1560-1624), used the name *Cannabis sativa* (*C. sativa*) in his 1596 publication of *Pinax theatri botanica* and in the 1738 publication *Hortus Cliffortianus*. In 1753, Carolus Linnaeus', a Swedish botanist, initiated the modern botanical nomenclature and taxonomic descriptors. At which time he formally keyed the *Cannabis* plant as *Cannabis sativa* (Schulthes 1970, Booth 2003).

The *Cannabis* plant has been debated over whether or not it exist monotypically, having one species with different varieties or polytypically, having distinct species (Booth 2003). In 1783, Jean-Baptiste Lamarck supported the polytypic view, noting that hemp grown in Europe and India was distinctively different from each other; the latter recognized by its narrow leaf and relatively elongated loose inflorescence (Clarke 1999). Therefore, Lamarck named the Indian hemp plant as *Cannabis indica* (Lam) after its 'center of origin' while retaining Linnaeus classification *Cannabis sativa* for the European hemp plant (Booth 2003). In 1924, the Russian botanist D.E. Vanischewsky, studied feral wild *Cannabis* in Volga River system of western Siberia and central Asia (Booth 2003). Vanischewsky supported the polytypic argument, claiming that in addition to *Cannabis sativa* and *Cannabis indica* there was a third distinct wild species: *Cannabis ruderalis* (Vavilov 1926, and <http://www.druglibrary.org/schaffer/hemp>). In 1926, Nikolai I. Vavilov, a Russian botanist and geneticist, stated that the morphological differences between hemp that appeared as a field weed (crop) and completely wild plants were hard to draw in that "the forms can hardly be distinguished from each other as far as characteristics of the seeds were concerned." This statement holds true today.

In 1976, Small and Conquist concluded that *Cannabis sativa* was monotypic with two subspecies. These subspecies were classified by the percentage of cannabinoids, mainly delta⁹-tetrahydrocannabinol (Δ^9 -THC or THC), present in the dry weight of the upper part of the female inflorescence. THC is the intoxicating psychoactive substance found in the Cannabis plant family at varying levels. The presence of the psychoactive component in the hemp plant does not have an adverse affect on fibre quality (Mechtler et al 1999).

Small and Conquist keyed the two subspecies: *C. sativa* subspecies *sativa*, less than 0.3% THC (3000 parts per million) and *C. sativa* subspecies *indica* (Lam), more than 0.3% THC. Within the subspecies *sativa* are variety *sativa* and *spontanea*, and within the subspecies *indica*, are variety *indica* and *kafiristanica* (De Meijer 1994). Hilling and Mahlberg (2004) examined the cannabinoid variations in 157 *Cannabis* accessions, in which their research findings concurred that the cannabinoid variation in *Cannabis* supported a two-species theory, thus chemotaxonomically authenticating the *C. indica* biotype. The *C. sativa* subspecies with a THC percentage designation of 0.3% or less are today classified as industrial hemp. This designation is today agreed upon by the majority of the 30 countries that recognize *Cannabis sativa* L. for industrial cultivation.

The genus *Cannabis* belongs to the Order Rosales, Family Cannabaceae (Small and Marcus 2002). It was formally classified as belonging to the Urticaceae (Nettle) Family (Dewey 1901) and at one time was classified as part of the Moraceae (Mulberry) Family (Dempsey 1975, Frank 2005). Even though, a consensus has been reached pertaining to the taxonomic classification, the origin is truly unknown (McPartland et al. 2000), due mainly to the Cannabis plants' ability to acclimatize to its environment, no matter the origin of its seed.

Cannabis is an Old World plant (Schultes 1970, Callaway 2004) that has been grown for the production of fibre (Rabelais 1546: In Van der Werf 1994a, Friesen 2006), cannabinoids (Beaudelaire 1860: In Van der Werf 1994a, Hilling and Mahlberg 2004) or seed (Deferne and Pate 1996, Callaway 2004). In which it is impossible to say with certainty which of these viable products were recognized and used first (Clarke 1999).

1.2 Center of Origin

The origin of cannabis is decidedly unknown, because of its documented wide dispersion across Eurasia early in history (Clarke 1999). A. de Candolle (1806-1893) suggested in Origin of Cultivated Plants (1885) that cannabis may have originated east of the Caucasus between the Black and Caspian Seas, bordering Russia, Turkey and Iran. In 1926, Vavilov suggested that the cultivation of Cannabis arose concurrently and separately in different locations and that it likely originated in Central Asia: having a cultivated area from the Equator to the Polar Circle. After an extensive cultural and literature review Clarke (1999) supported Vavilov's origin theory, stating that by far Central Asia is the most credible location of origin of Cannabis. Clarke (1999) further concluded that East Asia, South Asia, and Europe served as the primary centers of domestication and secondary gene pools.

2. Historical review

2.1 Major uses/event pre 1900's

Cannabis hemp is one of the oldest dual purpose plants, dating at least 6,000 years: used for cordage, cloth and oil (Schultes 1970, Holmes 1982). The similarity of its name in various languages is a strong indication that it has taken the course indicated above; thus, in the Sanscrit it is called *goni*, *cana*, or *shanapu*; Persic, *canna*; Arabic, *kannah* or *kinnub*; Greek, *kannabis*; Latin, *cannabis*; Italian, *canapa*; French, *chanvre* or *chanbre*; Danish, *kamp* or *kennep*; Lettish and Lithuanian, *kannapes*; Slavonic, *konopi*; Erse (Gaelic), *canaib*; Scaninavian, *hamp*; Swedish, *hampa*; German, *hauf*; Anglo-Saxon, *haenep*; Dutch, *hennep*; Spanish, *canamo*; Portuguese, *canhamo*; Russian, *konopli*; Chinese, *ta-ma*, *si-ma* and *tse-ma*; and English, *hemp* (Dewey1913, <http://www.botanical.com>, 2/13/2007).

Coarse hempen cloth has been found in some Europe's oldest human inhabited sites (Schultes 1970) and extant remains of hempen cloth have been dated at being 6 millennia old (Small and Marcus 2002). Archaeological specimens have been found in Egypt (3,000-4,000 years of age); in Ankara, Turkey 3,000 years of age during the 8th Century B.C., the Scythians, a nation of nomadic pastoralist horse-riders, grew hemp in the Volga region and in 150 B.C. the Roman satirist Lucilius wrote of hemp (Booth 2003). Approximately 4,800 years ago Emperor Shen-Nung, considered to be the first hemp (*ma*) agronomist, taught his people how to cultivate domesticated hemp for fibre (Schultes 1970). In 1896, Hermann Busse, unearthed an ancient German tomb, near modern day Brandenburg, where he identified Cannabis seeds and other plant fragments that had lain buried in an urn for almost 2500 years (Abel 1943).

The Philosophical Transactions of the Royal Society in England, Scotland and Ireland (1665-1678), included hemp in its Enquiries Concerning Agriculture for arable land, as a kind of 'ufual' (useful) grain or seed. Cannabis has played an important role in times of peace and war. In 1533, King Henry VII placed a royal diktat commanding farmers to allocate a part of their land to cultivating cannabis (Grinspoon 1977, Roffman 1982). It has been documented that in 1606 the British began cultivating hemp in its Canadian colonies. In which the French Botanist, Louis Hebert planted the first hemp crop in North America in Port Royal, Acadia (present-day Nova Scotia) and by the late 1700's, under the French Regime, hemp was grown along the St. Lawrence (French: *Saint-Laurent*) River in Québec while cultivation began for Virginia in 1611 (Grinspoon 1977, Roffman 1982, www.globalhemp.com and www.hemphesis.com, 2/12/2007, Fair 2004).

It is said that in 1801, hemp seed was distributed for free to Canadian farmers on behalf of the King of England. Dewey (1913) stated that in the year of 1632 The Pilgrims of New England introduced *Cannabis* to the northern United States. In Massachusetts (1637-38) (Roffman 1982) and Connecticut (1639), families were mandated to plant at least one teaspoon of hemp seed for colonial trading and manufacturing (Herer 1990). Colonies in the New World even passed laws deeming hemp as payables for taxes and in Virginia between 1763 and 1767 persons could be jailed for not cultivating hemp during times of shortage (Herer 1990). Hemp cultivation began in Kentucky in 1775 and in Missouri in 1835 (Dempsey 1975).

In 1850, the United States Census counted 8,327 hemp "plantations" for fibre cultivation; this production success heavily relied on the abundance of slave labour (Roffman 1982, Holmes 1982). The founding fathers of the United States favoured hemp, penning the first drafts of the Declaration of Independence (1776) on Dutch hemp paper (the final being on parchment (animal skin)) (Booth 2003). George Washington ordered his Mt. Vernon caretaker to "Make the most of the hemp seed. Sow it everywhere" (Rosenthal and Kubby 1996). Hemp has been used in papermaking since its invention, which spread across the world and was used in the Americas first paper mills.

Production excelled throughout North America during the 1840s and into the late 1890s, primarily supplying cordage and sail cloth to the U.S. Navy. By the late 1900's hemp cultivation had almost disappeared in North America except for in Kentucky. Mainly due to The Civil War which ultimately resulted in the loss of slave labour and southern markets, increased foreign agri-fibre competition, the lack of on farm mechanized fibre production and the political air all laid hand to hemp's demise as a viable agricultural crop (Holmes 1982).

2.2 Hemp Today

Since the late 1800's early 1900's, cultivation of hemp declined throughout the western world. This was in part due to the increased innovation in synthetic chemicals replacing agri-based fibres and a political uprising to classify all of the Cannabis plant family, even industrial hemp, as an illegal drug.

In 1938, the Opium and Narcotics Control Act, made cultivation of any form of *Cannabis sativa* L. illegal in Canada (MAFRI 2006). Despite this ban, hemp agronomic research continued to be conducted by the Division of Economic Fibre Production, Dominion of Canada, and Department of Agriculture until 1944. Throughout the 1920's, 30's and 40's, hemp germplasm was sourced from Russia, France and the United States and was examined for its agronomic adaptability in Eastern and Western Canada.

In 1997, after 50 years of prohibition, the Canadian Controlled Drug and Substances Act was passed, which provided the legislative authority and infrastructure to allow and facilitate the commercial production of hemp in Canada. On March 12th, 1998, under the Industrial Hemp Regulations section, authorized by Health Canada's (HC) Office of Controlled Substances (OCS), Canada re-legalized industrial *Cannabis sativa* L. for the purpose of agricultural production. This established the crucial regulatory framework for industrial hemp fibre, grain and certified seed production (MAFRI 2006).

HC and the OCS regulations require licensing, which authorizes all facets of plant breeding, cultivation, possessing, processing, distribution, and importing and exporting (all licensing application can be located at http://www.hc-sc.gc.ca/dhp-mps/substancontrol/hemp-chanvre/index_e.html). In addition, strict guidelines set the legal percentage of THC at a limit of 0.3% or 3000 parts per million of THC present when 50% of the seeds in the head are resistant to compression. The THC level is monitored during the cropping season and throughout the processing of the hemp seed. Because it is known that the percentage of THC in live plant material is influenced by environmental conditions, mainly stress, for example: weather, pest pressure, temperature and nutrients. In response to THC content concerns with in the hemp food industry, leaders created a Test Pledge, which requires that pledging companies commit to the following THC limits: hemp oil: 5.0 parts per million and hemp nut: 1.5 parts per million.

Since 1997, the amount of acres licensed and seeded has varied (Table 1.1). For license and permit holder information link to (http://www.hc-sc.gc.ca/dhp-mps/substancontrol/hemp-chanvre/about-apropos/licen/index_e.html).

The industrial hemp industry has not only prospered in Canada but also throughout Eurasia, the European Union and the United Kingdom. Unlike in the United

States, where currently twenty-eight states have initiated state controlled hemp legislations only fifteen of those have passed; only seven of the fifteen states have passed legislation facilitating research and production (VoteHemp.com 17/10/07). The proposed state legislation follows in suite with international recognized standards. Even though these states have initiated hemp legislation supporting hemp as value added crop, it is still a federal offence to possess viable Cannabis seed, under the Marijuana Tax Act, 1937, thus making industrial hemp illegal to cultivate. Historically, The Drug Enforcement Agency (DEA) has actively enforced and discouraged hemp, including product development and agronomic research (de Meijer 1995).

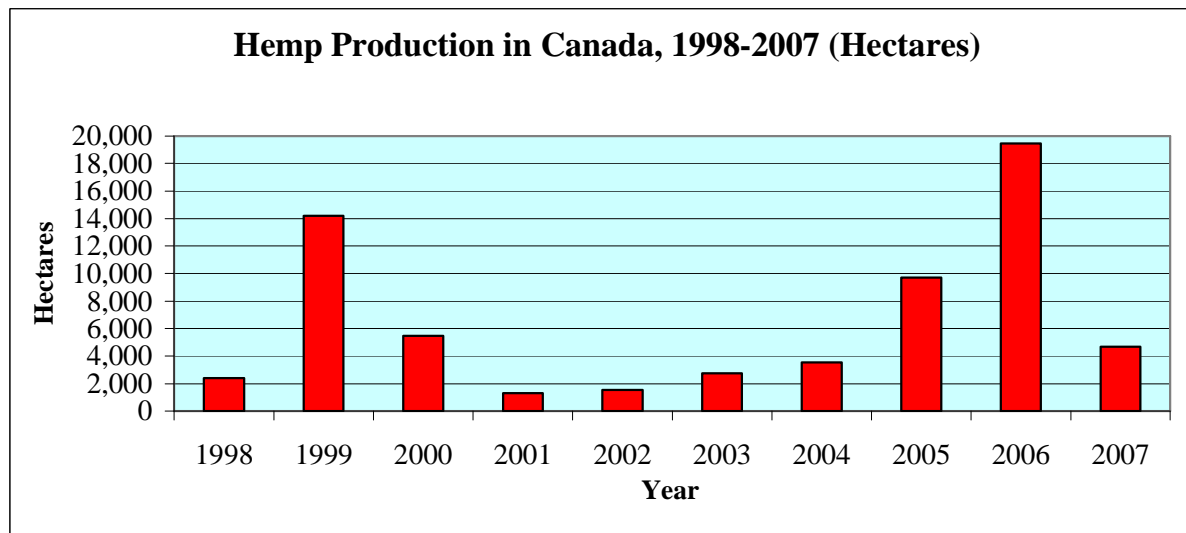


Table 1.1 Canadian national average licensed hemp hectares by year (1998-2007)

(Source: Health Canada)

To date, the market demand for value added hemp products and raw materials are on a rise. This increased demand has been a direct result of the 'green building movement' (Ivanyi 2005) and because of the increased demand for enriched balanced foods produced via sustainable agricultural systems. It is known through out the industry that if hemp is to be a productive sustainable marketable agricultural crop that modernized technology must not only be innovated but must practical in its delivery.

Seed/grain production and processing technology were transferable and adaptable (per comm. S. Crew 2005) which allowed hemp seed processors and the products produced to become the driving industry source of the thus far Canadian economic success. Products produced from hemp grain ranges from food, body care, fibre and bio-energy feedstock's which are derived from the oil, milled seed cake and stalk.

2.2.1 Food

Hemp seed can be eaten whole; it can be pressed for its oil and cake. Products made from hemp include non-dairy milk and cheese, protein powder, flour, bread, omega and essential fatty acids rich oil, alternative pet food, toasted snacks, and nut (Roulac 1997). Some varieties of hemp seed oil have been determined to have over 80% polyunsaturated fatty acids (PUFAs) ('good fats') (Callaway et al. 2005, 2004) which is not only important as a food but has been used as a wood preservative and printer ink (Sacilik et al. 2003). Highly digestible hemp foods have become a safe and healthy alternative to other less desired plant food products. Dietary research conducted in 2005-2006 will be published in early 2008.

2.2.2 Fibre

The quality characteristics of hemp fibre have been studied abroad but little research has been conducted in Canada. Renewable hemp fibres can be incorporated in to a wide range of commercial products such as composites, pressed boards, insulation, fibre-glass replacement, injection moulding, good-quality paper, non-woven's, plastics, hemp concrete, cordage and industrial and fine textiles. Sankari (2000) stated that even though quality parameters for non-woven hemp fibre products have not been determined, the attributes of the secondary (tow) fibres may be advantageous as a non-woven fibre

2.2.3 Energy

There is an international trend towards renewable energy sources. One of those sources is cellulose sequestered from the straw and stalk material from agricultural feedstock crops, such as hemp (Levine 2007). Since hemp bast fibres are a good source of cellulose which consist of a relatively high holocellulose (total cellulose) and low lignin, it is a desirable feedstock alternative for bio-fuels (Kovas et al. 1992). Even though hemp stalks possess attributes that make hemp a strong bio-fuel feedstock candidate, some claim that it may not be as economical as other readily available feedstock sources like switchgrass (*Panicum virgatum*) and corn (*Zea mays*) (Roulac 1997). It is known that hemp oil can be made into bio-diesel as hemp seed contains 30-35% oil (per comm. S. Crew 2006). However, to date, hemp oil seed varieties currently available do not have any advantage over rapeseed (*Brassica napus*). An overall hemp oil content exceeding 40% would be necessary for hemp to compete with other seed oil sources (Carus 2007).

2.2.4 Body Care

The market is no stranger to hemp oil body care products. These products range from designer cosmetics, body moistures, body and lip balms and soaps. Studies have determined that when specific fatty acids applied externally they can alleviate skin ailments such as dry skin (Leson et al. 1999). Callaway et al. (2005) determined upon a 20-week clinical trial comparing ingested hemp seed oil and olive oil that the hemp oil treatment significantly improved the plasma fatty acid profile and that qualities of both skin dryness and itchiness decreased. The subjects whom were randomly and blindly assigned the hemp oil treatment stated that after taking the treatment their typical application of dermal medicine was reduced.

2.2.5 Phytoremediation

It has been suggested that Cannabis has the capability to take up and amass heavy metals in its roots and shoots. Bona et al. (2007) investigated this theory in Italy, in which they concluded that fibre hemp is an excellent candidate for phytoremediation in soils contaminated with heavy metals, such as copper. Additional research should be conducted to evaluate this claim further in different contaminated environments.

3. Anatomy

3.1 Root system

The cannabis root tip consist of the root cap, meristematic, elongation and maturation zones which emerge from the germinated achene (seed) typically 3 to 7 days after spring planting (Clarke 1981). Secondary roots form laterally from the downward growth of the primary taproot system (Figure 3.1.1). Root growth is controlled by naturally occurring plant hormones i.e. *auxins*, *cytokinins* and *gibberellins*. Depths of the primary and secondary root growth are dependent upon the soils physical and chemical characteristics, the cultural agronomic practices employed and the vegetative period. A well-developed taproot can penetrate depths of 2.0-2.5 meters in well-cultivated soils that have a permeable subsoil while secondary roots may latterly extend 60-80 centimeters (Dempsey 1975, Bosca 1998). The root mass of fibre hemp contributes 8-15% of the plants entire mass which supplies the above ground biomass nutrients (Bosca 1998, Scheifele et al. 1996). The Cannabis root system has been extolled for preventing soil erosion while increasing water infiltration and soil aeration.



Figure 3.1.1 Hemp tap and secondary roots A. S-Hermann, 2006

3.2 Stalk

The hemp stalk can reach heights of 1 to 5 m (Hunt 1912; Bailey 1924; Hayward 1948; Stearn 1970; Dempsey 1975; Nykter 2006) and stem diameters of 2-3 cm (Bosca 1998) in 90 to 120 days, depending upon cultivar and environmental conditions.

The exterior the Cannabis stalk is covered with a thin protective pubescent (non-glandular trichomes) epidermis layer that allows for stomatic regulated ventilation and evaporation. The next layer inward contains a cortex of non-fibrous chlorophyll (which gives the stalk its green color), then a layer of primary and secondary phloem and parenchyma fibre cells (bast and tow fibres), then a cambium growth layer and lastly the inner most portion, the primary xylem (woody hurd and pith). The anatomy of the Cannabis stem is depicted in Figure 4.1.1.

The stalk of the hemp plant consists of two main components, bast and hurd. Together, they comprise approximately 59-67% of the above ground biomass (Scheifele et al. 1996). The first of these two components is the stem tissues outside the vascular cambium, commonly referred to as bark or bast. Bast fibres are comprised mainly of non-starch polysaccharides (Weightman and Kindred 2005). This component contains heterogenous primary bast fibres which arise from the prodesmogen and contains secondary bast fibres approximately 2 mm in length which arise from the cambium (Kundu 1942; Hoffmann 1957: cited in Van der werf et al. 1994a, 1995; Ranalli 1999). The second stem tissue component is located on the inside of the stem's vascular cambium, commonly referred to as the hurd, core or shive (shiv) Hurd is libriform in nature (Esau 1965; Ranalli 1999) and measures 0.2-0.6 mm in length (Bosia 1976: cited in van der Werf et al. 1994a; Vignon et al. 1995). Bast fibres are considered to be a "soft" fibre while the hurd, is considered to be a "woody" or hard fibre.

The primary and secondary fibres within the stalk overlap in bundles containing ten to 40 cells per bundle running from the roots to tops (McPartland et al. 2000) and are generally referred to as the bast fibres. These bundles are embedded in a ring of phloem, parenchyma and sclerenchyma cells that are located amid the epidermis and cambium (McPartland et al. 2000). These bundles contain chemical constitutes such as cellulose, hemicelluloses and lignin.

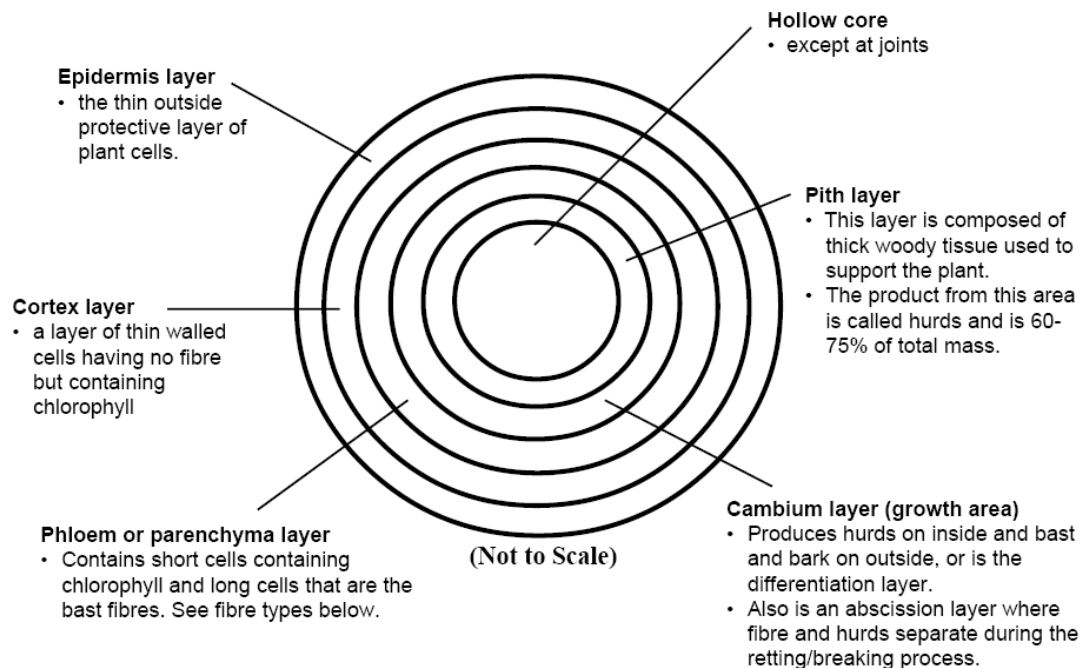


Figure 4.1.1 Cross section of a hemp stem (Oliver and Joynt 1999 p.3)
(permission granted by British Columbia Ministry of Agriculture and Food to reprint)

Cellulose is the principal structural component in green plants (Thomsen et al. 2005). Cellulose is a major quality component in agri-fibres and can be converted into mass produced products such as cellophane. Lignin, which is indigestible by mammalian and animal enzymes, fills the spaces between the cells and is key for strength. When the double bonded lignin structure is broken down by bacterial growth during a rotting or retting process or with chemical or enzymatic preparations the fibre color changes from a dark to bright hue (Thomsen et al. 2005). The primary and secondary phloem layers amalgamate with the lignified primary xylem layer.

The primary xylem, otherwise referred to as hurd, is woody and thins to a pith which surrounds the hollow stalk (McPartland et al. 2000). The stalk consists of approximately 0.8%-2.5% pectin which is considered to be the main binder of the primary cell wall, middle lamella and the cellulosic and non-cellulosic network (Wang et al. 2003). Pectins help to prevent the collapse of the structural and chemical constituent network (Taiz and Zeiger 2002; Corriea and Roy 2005). Bast and hurd fibres contain both cellulosic and non-cellulosic properties (lignin) that differ in proportion. Thomsen et al. (2005) stated that while both bast and hurd fibres are cellulosic, a greater percentage of cellulose is located in the bast fibres while the hurd consist of a greater percentage of hemicellulose and lignin and less cellulose. Hemicellulose is made up of a group of tightly bonded heterogeneous polysaccharides located within the cell wall (Taiz and Zeiger 2002) which connects the cellulose and lignin. Glucose and xylose are the primary monosaccharides constitutes in hemp's hemicellulose, which are similar to that of Canadian grown aspen tree fibre and are readily extracted with alkali solutions (Corriea and Roy 2005).

Hemp bast fibres range from 0.5-10 cm in length with average lengths ranging from 1.5-5.5 cm with average thicknesses of 18-25 μ (micron) (Vignon et al. 1995; Bocsa and Karus 1998). The hurd fibre lengths typically do not exceed 0.5 mm (Bocsa and Karus 1998). Increasing fibre lengths have been associated with increasing the strength paper (Bocsa and Karus 1998).

Bast fibre tensile strength ranges from 593.72 to 1073.72 k N/g, depending upon the fibre separation method, i.e. untreated or NaOH alkalized treated (Mwaikambo and Ansell 2006). Preliminary results from Manitoba grown hemp indicate that fibre from mature stalks produced stronger but stiffer and less elastic fibre from stalks cut early in the flowering stage (Moes and Empson 2000). Kamat et al. (2002) concluded that hand paper sheets produced from unbleached pulp of hemp stalks harvested at 60- and 90-days after sowing produced insignificant differences in tensile strength (59 and 56 kN/g, respectively). Research conducted by Müssig and Martens (2003) further concluded that plant age in hemp did not significantly affect fibre strength.

In 1997 and 1999, UK researchers from collected matured hemp stems that were processed into composites. They determined that even though composite strength was not affected by delayed harvest, composite stiffness was reduced at an approximate rate of 10% per delayed harvest week. In addition, the authors (Murphy-Bokern and Bruce 2005) concluded that harvest date did not affect the stiffness of the hand-extracted fibre.

Meijer et al. (1995) stated that hemp fibres could be used as a wood substitute in pulp and paper production. Correia et al. (1998) determined that the physical properties of hemp bast fibre cells were similar to that of softwood tree species; that are currently used in Canadian pulp and paper production.

European fibre hemp stems have been determined to consist of high-cellulose low-lignin bark (bast-long fibre) and low-cellulose high-lignin core (hurd-short fibre) (Van der werf et al. 1994b). Since the greatest percentage of cellulose is located in the bark (bast), Van der werf et al. (1994b) stated that stem value primarily depends on the proportion of bast in the stem. Today, hurd value is on a rise due to its superior qualities (i.e. absorbance, reduced dust, thermal and antibacterial properties) for animal bedding, building materials and bio-composites.

3.3 Leaf Characteristics

All plants in the Cannabaceae plant family are dicots (Hayward 1938) (Image 3.3.1), that share common leaf characteristics, that differ slightly amongst varieties. During the pre-floral vegetative stage the usual leaf phyllotaxy is decussate, in which the leaves along the stem appear to be opposite, having two leaves per node and during the floral generative stage leaves are usually alternate, in which one leaf appears at each node along the stalk, resulting in a staggered affect (Clarke 1981, Schumann et al. 1999) (Image 2.3.2). Schaffer (1926) determined that the phyllotaxy transformation was caused by a change in the photoperiodicity (Schaffner 1926). Heslop-Harrison (1956) greenhouse experiments determined that the phyllotaxy of hemp plants under a short-day photoperiod treatment (16 hour dark) transitioned at the eighth or ninth node while plants what remained in a long-day treatment (21-22 hours light) no phyllotaxy transition occurred before the 18th node. Lisson et al. (2000d) noted that there was slower rate of node production as well as a reduced leaf area per node as plant density increased. Female plants produce thicker vegetative leaves than that of male plants (Tibeau 1936).

Image 3.3.3 shows the compound palmate leaf type of the hemp plant. The serrated palmate pubescent leaflets are attached to the node by a petiole (2 to 8 cm in length (Homes 1982)) and have a net pinnate venation. The number of leaflets increase with the age of the plant and vary in number from 5 to 11 (Bocsa and Karus 1998, Hayward 1938, Clarke 1981) and comprise approximately 20.0% of the total above ground biomass (Scheifele et al. 1996).

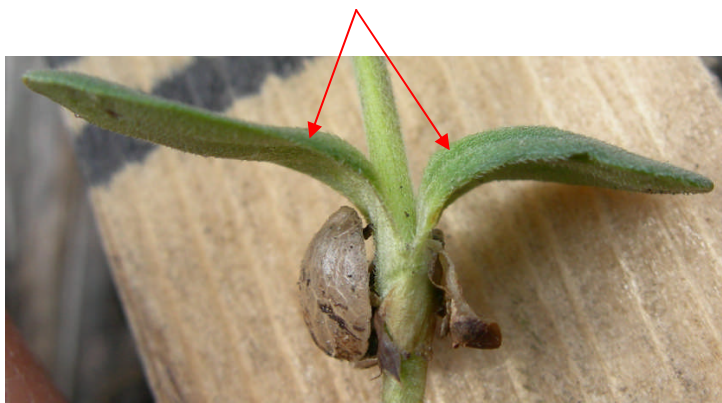


Image 3.3.1. Dicotyledonous June 9, 2006. A. S-Hermann.

Decussante

Alternate



Image 3.3.2. Leaf phyllotaxy change from decussante to alternate July 18th, 2006. A. S-Hermann.



Image 3.3.3 The compound palmate leaf type of the hemp plant July 18th, 2006. A. S-Hermann.

3.4 Flower Structure

In angiosperms (flowering plants) the reproductive structures are located in the flowers. Cannabis flowers are conspicuous and imperfect, possessing separate male (staminate) or female (pistillate carpellate) reproductive structures and within the Cannabis family, reproductive structures can be found in both dioecy and monoecy states. In which the reproductive structures are indistinguishable during the undifferentiated primordial formation.

Dioecy is the production of pistillate and staminate flowers on different plants: true dioecy promotes cross pollination (Poehlman and Sleper 1995) (Image 3.4.1). True unisexual gynoeceous (female) pistillated structures produce axil paired flowers that posses paired stipule subtending bracts which rest aside a glandular trichome covered pistillate calyx (floral sheath) and posses an indeterminate raceme type inflorescence . Enclosed within the calyx is the placenta, ovule and the ovary with two extended fused

style and stigma. True dioecious male plants tend to be taller than pure female plants and die off after dehiscence (pollen release).



Image 3.4.1 Dioecious plants. (Friesen 2006)

Unlike the pistillated flowers, the androecious (male) staminate floral buds have indeterminate panicle paired sac development. Within the simple non-glandular trichome calyxes (approx. 5 millimeters long (Bosca and Karus 1998), that vary in shades of yellowish green, enclose five filament attached suspended stamens which contain anthers (pollen sacs) that hold the microsporangia (pollen grains). According to Small (1972) the size of Cannabis pollen grains vary from 25 to 30 microns (μ) (Clarke 1981, Small and Cronquist 1976). Pollination can occur by both means of anemophily (wind) (Small 1973 & 1976, Schumann et al. 1999) and entomophily (insect) pollination (Image 3.4.2).



Image 3.4.2 Honey Bee collecting pollen. (A. S- Hermann 2007)

It is known that feral Cannabis populations will emerge, if allowed to escape from controlled agricultural practice. These populations have become well established, due in part to long-distance genetic interchange and inter-crossing (Small 1972, Small and

Cronquist 1976). Bosca and Karus (1998) concluded that pollen can travel as far as 12 kilometers and reach altitude of 20-30 meters. 18th century, low THC feral hemp populations in the Upper Canada region of southern Ontario have been genetically re-captured and are being re-introduced as pre-extinction fibre cultivars. de Meijer (1995) concluded that there is a “considerable mutual genetic relatedness among modern European and West Asian cultivars.” Hilling (2005) strongly suggested that germplasm from feral, local and wild Cannabis landraces should be collected and maintained before foreign or hybrid strains are introduced to a region, thus preventing loss of adapted parental germplasm.

Monoecious plants are characterized by the staminate and pistillate reproductive structures being located on the same plant stalk (Image 3.4.3). The above flowering structural description holds true for monoecy hemp plants as well except that structures are present on one plant. Within the Canadian hemp breeding industry the standard guide for determining the degree of monoecy is the IHSDC Modified Sengbusch Scale for Monoecious Hemp of Intersex Inflorescence types (Type1-5) (Appendix 1). This scale rates the degree of monoecy by the percentage of male and female flowers present on one stalk. It has been noted that hemp will ‘revert’ to its natural dioecious state if not properly maintained and even though monoecious varieties of cannabis can be found, it is not the natural state (van der Werf 1994) that must be maintained by strict rouging breeding procedures (Schumann et al. 1999). Breeding programs assess and maintain the degree of monoecy and dioecy, chemical phenotypes and plant characters upon the varieties classification.



Image 3.4.3. Monoecious plant: staminate and pistillate (A. S- Hermann 2007)

3.4.1. THC (delta⁹-tetrahydrocannabinol) Regulations

The dominant cannabinoid phenotype of interest in hemp is THC. THC is concentrated in the trichomes, calyxes and bracts of the flowering parts (Kim and Mahlberg 1997). In Canada, the level or percentage of THC is determined in ordinance with Health Canada's Industrial Hemp Technical Manual (http://www.hc-sc.gc.ca/dhp-mps/pubs/precurs/hemp-indus-chanvre/tech-man/index_e.html). The regulatory methods for sampling THC vary slightly between countries for example: Canada requires a random sample of 60 plant tops no matter the size of area planted, in the EU, regulation number (VO (EG) 1177/2000), requires a random sample size of 50 plant tops (Mechtler

et al. 1999) and regulations in the UK require THC analysis to be conducted on at least 20% of the total area of hemp production for each cultivar which must be comprised of at least 20% of the registered producer fields (Weightman and Kindred 2005). Since 1988, the allowable THC content for industrial hemp cultivated in the Ukraine has been 0.1% of dry weight plant material (Holoborod'ko 17/03/2005), even lower than that of Canada's 0.3% limit. Mechtler et al. (1999) determined that the presence of the psychoactive component, THC, did not have an adverse effect on fibre.

3.5 Seed Structure

The cannabis seed is not a true seed at all, it is actually an achene (nut) fruit. For the purpose of this report the achene fruit of Cannabis will be referred to as a seed (Image 3.5.1). The hemp seed is prized for its nutritional balance of omega-6 to omega-3 fatty acids, its relatively high contents of gamma-linolenic acid (GLA, 18:3 omega -6) and stericonic acid (18:4 omega-3) which have been determined to be 4 and 2 percent, respectively, in the Finland bred Canadian grown cultivar, Finola (Fin-314) (Leson et al. 1999).

Hemp is day length sensitive, in that the seed maturity occurs as day length shortens. Harvested hemp grain must be dried to at least 9% for storage and is by weight 25 - 35% oil, 20-30% carbohydrates, 10-15 % insoluble fibre and the seed cake (after cold pressing) contains approximately 24-40% protein and is rich in minerals (Saciilik et al. 2003). Wang et al. (2008) compared hemp protein isolates (HPI) to soy protein isolates (SPI) in which the results determined that HPI was a good source of readily digestible human consumption suitable protein than that of SPI. The hemp seed has a mottled pericarp (fruit husk), is orbicular (egg or oval) shaped and ranges in size from 2 to 6 mm long and 2 to 4 mm in diameter (van der Werf 1994, Bosca and Karus 1998). The thousand kernel weight (TKW) varies from 2 to 70 grams, depending on cultivar.

Canadian Researchers' in 1934-1936 examined total and line fibre yield, from 'large and small' sized hemp planting seed. The total fibre yield was greater from 'large seed' plots (6,267 lb/ac) than that of the 'small seed' (5,920 lb/ac) and the 'small seed' plots yielded more line fibre per acre (583 lb/ac) than that of the 'large seed' plots (557 lb/ac). They concluded that the difference in the 'large and small seed' plots total fibre and line yield, was more than likely due to a thicker stand of plants in the 'small seed' plots (Hutchinson 1938).

The seed contains two cotyledons, a rootlet and a thin undeveloped starch containing endosperm (Bosca and Karus 1998). It is pertinent that the handling (i.e. seeding, harvesting, cleaning, storage, and processing) of the seed/grain be done with great care; cracking of the seed hull will result in rancidity and increased peroxide levels, which will cause delivery refusal. A decimal code for the development stages of hemp was determined by Mediavilla et al. (1998) which formulated standard definitions and codes for the growth stages of *Cannabis sativa* L. plants. (Appendix 2).

The goal of certified seed production is to breed and maintain cultivars that are uniform and that possess predetermined quality characters i.e. oil, nut, protein, nutritional and fatty acid profiles.



Image 3.5.1 Hemp seeds A.S-Hermann 2006

4. Agronomic Practices

Agronomy is the study of field-crop production, soil management and encompasses areas of cropping systems, methods and physiology. Agronomic practices employed differ by region, crops type, equipment availability and cultural knowledge.

Optimum agronomic practices are important for all crops. The development of best management practices (BMP) are therefore important. Developing an understanding of how the crop acts and reacts in different spatial and temporal environments, cropping systems and under different cultural regimes is key to the success of wide spread sustainable cultivation. By creating BMP's we are able to advise producers on how to efficiently cultivate and harvest industrial hemp.

Because of the lack of hemp agronomy research, Canadian agronomic BMP's for hemp have been based on producer and processor experience and innovation, which have stemmed from trial and error. Even though the Canadian hemp seed industry has become a world leader in hemp seed production, Canada still lacks national BMP standards. Gaining a positive understanding of sound agronomic practices is the goal of farming system and agronomic research projects world wide which in return increases overall production efficiency.

4.1 Crop Rotation

Crop rotation can improve or maintain soil fertility (Tilman 1998), reduce erosion (Carroll et al. 1997), reduce the build-up of pests and diseases (Abawi and Widmer 2000), reduce reliance on agricultural chemicals (Belay et al. 2004) and increase net profits (Zacharias and Grube 1984). Cropping hemp in rotation with other broadleaf crops, for instance; sunflower (*Helianthus annuus*), canola (*Brassica spp.*), buckwheat (*Fagopyrum spp.*) and peas (*Pisum sativum*) should be avoided due to disease pressure, mainly *Sclerotinia sclerotiorum*. Buckwheat in rotation with hemp can cause problems because the seeds of the buckwheat plant are similar in size to that of the hemp seed making the buckwheat seeds difficult to separate out during cleaning. Ideal preceding crops for hemp include recently broken pastures, fields sown to perennial grasses and crops like

alfalfa, clover and other legumes (Friesen 2006). Even though, alfalfa is known to be affected by *Sclerotinia* it has yet to pose an economic impact on the hemp production in Canada (per comm. K. Friesen). According to Friesen (2006) green manure crops (alfalfa breaking or annual legume) are particularly good rotation crops in organic hemp production. Rotating hemp with spice crops should be avoided due to contamination of flavour during the hemp seed processing (Friesen 2006). Crops that produce allelopathic compounds, such as fall rye (*Secale spp.* L.) have been observed to completely prevent germination of the hemp seeds thus resulting in complete crop loss (per comm. K. Friesen 2007). Boyd and Kahar (1998) state upon interviewing hemp researchers Gordon Scheifele and Peter Dragla at University of Guelph, Ontario that even though hemp can be grown in monoculture for two to three years it is not recommended. It was however suggested that hemp could be included in crop rotation with corn, soybeans or cereal crops.

Barron et al. (2003) conducted a feasibility study into the integration of hemp in to organic farming systems in the UK, France and Denmark based on interviews with producers, advisors and researchers. They concluded that hemp is a viable crop for rotation especially in organic systems, because it relies on minimal inputs, is competitive with weeds and can improve soil conditions. Thus, integrating hemp would contribute to the local economy by creating diversity in the food and fibre industry sectors. No formal research has been conducted to determine the best management practices for hemp in crop rotation regimes in Canada.

4.2 Canadian Industrial Hemp Varieties

Adapted cultivars are important to any crop production system. When the Canadian hemp breeding industry restarted in 1997, cultivars used by farmers were mostly imported from Ukraine cultivars: Zolo 11, USO 14, USO 31 and Finola (Fin 314) from Finland. These relatively well-adapted cultivars provided the basic germplasm for the Canadian hemp breeding programs. Canadian bred cultivars now include Alyssa, Anka, Carmen, Crag, Deloris, Esta 1 and Petera (per comm. K. Watson 2007). Cultivars Alyssa, Carmen, Deloris and Petera are maintained by the Parkland Industrial Hemp Growers breeding program. Anka and Esta1 are maintained by Ontario breeders while Crag, USO 14 and 31, Finola and Zolo 11 are maintained by a Saskatchewan breeding project. Health Canada requires that all industrial hemp cultivars grown in Canada be approved for commercial cultivation and must have pedigreed seed status. List of Health Canada's approved hemp cultivars for 2007 are provided in Table 5.2.1. The Sengbusch Scale for monoecious intersex inflorescence types (Appendix A) provides a standard visual scale for maintaining monoecious hemp cultivars such as USO 14 and 31.

Upon examining 14 European hemp fibre cultivars, Sankari (2000) found that a cultivar significantly differed in bast fibre yield (ranging from 1220 to 1511 kg dry matter ha⁻¹). Sankari (2000) suggested that it might be possible to identify cultivars with more stable fibre qualities that are less susceptible to experimental management or weather conditions.

Table 4.2. Health Canada list of approved cultivars, country where maintained and THC testing exemption standing for the 2007 cropping season. (Adapted from Health Canada's 2007 list of approved cultivars, PCDF 2004, 2005)

Cultivar	Country of Cultivar Maintenance	Thousand Kernel Weight (g)/1000 seeds	Industrial Hemp Regulation subsection 16(1) cultivars exempt from THC testing indicated by **
<i>Alyssa</i>	Canada	18	** in Manitoba only
<i>Anka</i>	Canada	18	** in Ontario only
<i>Carmagnola</i>	Italy		
<i>Carmen</i>	Canada	22	
<i>Crag</i>	Canada	16	**
<i>C S</i>	Italy		
<i>Deni</i>	Canada		
<i>ESTA-1</i>	Canada		
<i>Fasamo</i>	Germany	13	
<i>Fedrina 74</i>	France		
<i>Felina 34</i>	France	16	
<i>Ferimon</i>	France		
<i>Fibranova</i>	Italy		
<i>Fibriko</i>	Hungary		
<i>Fibrimon 24</i>	France		
<i>Fibrimon 56</i>	France		
<i>Finola</i>	Canada (Finland)	12	
<i>Kompolti</i>	Hungary		
<i>Kompolti Hibrid TC</i>	Hungary		
<i>Kompolti Sargaszaru</i>	Hungary		
<i>Lovrin 110</i>	Romania		
<i>UC-RGM</i>	Canada	11	
<i>Uniko B</i>	Hungary		
<i>USO 14</i>	Canada (Ukraine)	14	**
<i>USO 31</i>	Canada (Ukraine)	16	**
<i>Zolotonosha 11</i>	Canada (Ukraine)	16	** in Manitoba only
<i>Zolotonosha 15</i>	Canada (Ukraine)		

4.3 Seeding

4.3.1 Seedbed

Seed bed preparation and seed placement facilitates uniform germination, quick emergence and canopy closure (Benech-Arnold and Sánchez 2004). Hemp grows best when planted in to well drained, clean, moist but warm (6-10 °C) uniform medium textured soils, that are weed and chemical residue free (Friesen 2006). Cultivation of hemp in wet, heavy clay soils should be avoided (Baxter and Scheifele 2000). Since hemp is not tolerant to wet soil conditions, especially during germination and emergence, cultivation in such environments will result in stunted chlorotic plants and/or total crop loss. Hutchinson (1923) reported a total hemp trial loss due to heavy clay soils in the Ottawa region of Canada. The suggested pH limit for hemp growth is above 6.0, where neutral to slightly alkaline soils (pH 7.0 - 7.5) are preferred (Bosca and Karus 1998; Baxter and Scheifele 2000). The effects of pH on hemp plant characters have not been examined to date.

Van der Werf et al. (1995a) concluded that the germination of hemp seed requires a base temperature of 1-2°C. However, hemp seeds and seedlings have been reported as being frost tolerant (Scheifele et al. 1996; Friesen 2006). In the Netherlands, van der Werf et al. (1995a) noted a linear increase in leaf appearance and stem elongation at temperatures between 10°C and 28°C.

4.3.2 Depth

For maximum yield, hemp seeds develop best when planted shallow at a depth of 2 – 3 cm (Scheifele et al. 1996). However, producers have had great results with broadcasting the seed followed by an incorporating light tillage pass with heavy harrows (per. comm. K. Friesen 2008). The light tillage pass ensures good seed to soil contact.

4.3.3 Row spacing

The Institute of Bast Crops, in the Ukraine, suggest a wide row spacing of 45-60 cm for dual purpose production and 7.5-15 cm for fibre only hemp production (Holoborod'ko 1995). Studies conducted in Denmark determined that total dry matter, stem and fibre yields of hemp were maximized at 24 cm rather than at 48 cm row spacing (Deleuran and Flangmark 2005). On the other hand, Friesen (2006) suggest that for grain and or dual purpose production in Canada, at row spacing greater than 20 cm seeding should be done twice, at half the targeted rate in opposing angles. Baxter and Scheifele (2000) recommended row spacing of 15-18 cm for hemp grown for fibre and/or grain production. Vera et al. (2006) determined row spacing of 18 and 36 centimeters did not significantly affect seed weight, protein and oil content of two Canadian approved hemp cultivars, i.e. Finola and Fasamo.

4.3.4 Sowing date

Early sowing can be advantageous for weed control due to early canopy closure. The likelihood for maximized hemp fibre yield is characteristically reliant upon the interval of time from sowing to flowering, since fibre yield gain occurs shortly after flowering (Lisson et al. 2000c). Sowing late can result in insufficient time for flowering, seed set and retting at the end of the season.

Studies have been conducted to examine the effect of sowing date on grain and fibre yields in the Netherlands and Australia and to a lesser extent in Canada. In a Tasmanian study, Lisson and Mendham (2000a) examined sowing dates in Tasmania between mid-September and mid-November. Their results showed that later sowing dates significantly reduced stem and bark (bast) yield due to a decline of thermal time and calendar days from sowing to flowering. This observation suggests that a long preflowering period is important for hemp quality and early sowing is important for achieving this long preflowering period. Cannabis is photoperiod sensitive which triggers flowering and seed set. Unpublished data collected in Australia, suggested that subtropical hemp varieties should be sowed in October, thus maximizing photoperiod (Jobling and Warner 2000). Photoperiod is the period of time per day that a plant is exposed to daylight.

The optimum sowing date for hemp production in South-Western Ontario was examined by Scheifele et al. (1996). They found that early sowing was important to maximizing seed yield. The limited literature suggests that hemp should be seeded early in the growing season, with a sowing date similar to that of Canadian spring crops (in the Western Prairies May 1-31 and in Ontario 3rd week in April). Similar conclusions have been made for cereals such as oat (Hamill 2002). Preliminary results provided by the Parkland Crop Diversification Foundation (PCDF), concluded that plant height and thus total plant biomass decreased as sowing date was delayed from May 19th to June 14th (Stadnyk et al. 1999 and 2000). However, because the data only represented two site year analysis, further research is required to confirm these preliminary conclusions. Little formal research is available examining the effects of sowing date on seed yield. Preliminary results produced by Stadnyk et al. 1999 saw no positive conclusions when examining the effect of sowing dates ranging from May 19, June 2 and June 14 on seed yield.

4.3.5 Crop Nutrition

Hemp nutrient uptake throughout the Manitoban growing season, partitioning within the plant and nutrient removal rates were examined by Heard et al. (2007). It was determined that although hemp as a crop requires considerable quantities of nutrients the stalk retains most of the assimilated nutrients resulting in a low harvest index. Whereas the total nitrogen uptake was 202 kg ha⁻¹ with 40 kg ha⁻¹ in the grain and total phosphorus uptake was 47 kg P₂O₅ ha⁻¹ with 18 kg P₂O₅ ha⁻¹ in the grain. Further research is required to validate these preliminary results.

Hemp responds well to natural fertility especially to nitrogen and phosphorus which are made naturally available by the soils organic material and uptake can be affected by mycorrhizal activity (Friesen 2006). Fertility requirements for hemp have been successfully met in both organic and conventional cropping systems (Friesen 2006). Organic systems depend mainly upon crop rotation and green manuring crops while conventional systems depend mainly upon synthetic fertilizers. To increase economic returns and decrease input costs, it is prudent that a soil test be taken prior to fertilizing and seeding to determine existing available nutrients. The Institute of Bast Crops, Hlukhiv, Ukraine developed an energy-saving soil preparation method based on the combination of mold-board plowing and post-plowing tillage and a fertilization regime based on soil analysis (Holoborod'ko 1995). Nutrients such as nitrogen and phosphorus are key for plant growth and development. According Iványi (2005) it will be necessary to combine soil and plant analysis to determine nutrient requirements for hemp.

The fertility requirements of hemp have not been comprehensively researched in Canada or elsewhere (Iványi 2005). Preliminary data released by Parkland Crop Diversification Foundation (PCDF) (Stadnyk et al. 1999 and 2000; Kostuik et al. 2001; PCDF 2002 and 2003) concluded that the best economic returns were received from 85 kg N ha⁻¹ (75 lbs/ac) when compared at rates of 63, 85, 113, 141 and 170 kg N ha⁻¹ (50, 75, 100, 125 and 150/lbs actual N/ac, respectively). Vera et al. (2004) concluded that maximum seed yield was obtained at 99-102 kg N ha⁻¹ for seed/grain type hemp cultivars.

In a German study, Höpper and Menge-Hartmann (1995) examined two dual purpose hemp cultivars at two nitrogen rates (60 and 120 kg N ha⁻¹). The overall yield (seed and fibre) was not significantly affected by the highest nitrogen level. In a Finish study, Struik et al. (2000) examined the effect of three nitrogen levels (100, 160 and 220 kg N ha⁻¹) on useable fibre yield and plant mortality. Results showed a steady increase in useable fibre yield with increasing nitrogen fertilizer rates while the number of plants that survived to harvest decreased with increasing nitrogen rate. In an Italian study conducted over a 3 year time period, Amaducci et al. (2002a) examined the same three nitrogen rates as Struik et al. (2000), their results concurred with Struik et al. (2000) findings, concluding that plant mortality increased with increasing nitrogen rates. The authors further stated that the increase in plant mortality was likely due to competitive effects in during the preflowering stage.

Increasing nitrogen fertilizer rates is known to affect stem diameter and plant height in crops such as sunflowers and maize. An Iranian study conducted by Mojiri and Arzani (2003) determined that increasing nitrogen fertilizer from 0, 75, 150 and 225 kg ha⁻¹ increased stem diameter and plant height of sunflowers and in a African study, Sétamou et al. (1995) noted positive effects on diameter and height when nitrogen fertilizer was increased from 0, 60, 90 and 120 kg N ha⁻¹. According to Schäfer, (2005) stem diameter and plant height increased as nitrogen fertilization increased from 0, 60, 120 and 180 kg N ha⁻¹. Forrest and Young, (2006) stated that even though it appeared in their trial "that increased morphological growth occurred (i.e. height, diameter and number of internodes) as a result of increased nitrogen fertilization it did not equate to increased production."

Little previous research has been conducted to examine the affects of phosphorus and sulphur on plant growth and yield. A one year PCDF study conducted in 1999, suggested that hemp seed is tolerant to seed placed and side banded phosphorus at rates of 0, 45, 70, 90 kg P ha⁻¹ and that amending soil sulphur is only beneficial where deficient. Vera et al. (2004) examined the effects of surface-broadcast ammonium nitrate (0, 40, 80 and 120 kg N ha⁻¹) and seed row placed monoammonium phosphate (0 and 20 kg P ha⁻¹) fertilizer on two Canadian registered cultivars (Finola and Fasamo) on growth, seed yield and quality in the Parkland region of Saskatchewan. Overall, the trial concluded that increasing rates of surface-broadcast ammonium nitrate significantly increased plant height, biomass, seed yield and seed protein content while seed row application of monoammonium phosphate typically increased mortality, height, biomass and seed yield. Finola consistently had greater seed yield of 25%, protein content of 7-16% and oil content of 6-12% in comparison to Fasamo in all years (Vera et al. 2004). Vera et al. (2006) determined that on average Finola had a seed protein content of 25.3% and a seed oil content of 35.1 % compared to Fasamo of 23.5% and 32.2 %, respectively. At 40, 80, 120 and 160 kg nitrogen ha⁻¹ seed yield kg⁻¹ of nitrogen were 10.6, 7.7, 6.0 and 4.5 kg ha⁻¹ for Finola, and 9.4, 5.9, 4.5 and 3.7 kg ha⁻¹ for Fasamo,

respectively (Vera et al. 2004). Finola reached maximum seed yield at 102 and at 99 kg N ha⁻¹ while Fasamo did not reach maximum yield at the nitrogen rates tested. Seed protein content increase from approximately 32% to 33% for Finola and decreased from 27% to 25% for Fasamo as nitrogen rates were increased. Seed oil content increased in Finola by 1-3% and decreased in Fasamo by 2-4% as nitrogen rates increased. The addition of seed-applied phosphorus in this study did not affect the hemp seed protein or oil content, but could be an affecting factor if limiting (Vera et al. 2004).

Stadnyk et al. (1999) determined that increasing nitrogen rates from 50 to 100 to 150 lb/ac reduced seed yield in 1999 and increased seed yield in 2000. The author determined that 75 lbs actual nitrogen resulted in the best economic returns overall.

4.3.6 Disease, Insect pest, Parasitic Plants and Weeds

4.3.6.1 Disease

According to McPartland (1996) even though hemp is tolerate to disease and pest pressures, it is not immune and can be affected by over 100 diseases. The major hemp diseases of interest in areas of agricultural cultivation are *Sclerotinia sclerotiorum* (hemp canker) and *Botrytis cinerea* (grey mould).

Sclerotinia is a widely hosted soil-borne fungal pathogen that causes dark water spot like lesions (Figure 4.3.6) and 'cankers' (Figure 4.3.7) on the surface of the stalk and branches of hemp. These lesions are caused by internally located white mycelium, the vegetative part of the fungi. Eventually, the mycelium degrades the internal tissues resulting in pale stalks that contain hard black sclerotia bodies (Figure 4.3.8), which affects the flowering process and reduces yield (McPartland et al. 2000). At harvest the diseased stalks are shredded and the sclerotia bodies are spread over the field. Sclerotia over winters in the soil and infects subsequent susceptible crops. In order to successfully control sclerotinia in the long term, a 4 to 5-year crop rotation is suggested between susceptible crops such as canola, sunflowers, soybeans and peas (SSCA 2007, Bailey et al. 2003). *Sclerotinia* is of particular importance in Manitoba hemp production, since so many other sclerotinia susceptible crops are grown in rotation.

Botrytis, or grey mould, is a fungal disease that attacks crops around the world especially in areas that are prone to wet and high humid environments. In hemp, grey mould attacks the flowering tops and stalks (McPartland et al. 2000). Grey mould has yet to have an economic impact on hemp production in Canada, though the Ontario Hemp Association recently reported incidences of botrytis like symptoms referred to as "head blight" in Southern Ontario (McPartland et al. 2000, pers comm. with Gordon Scheifele 2007).

Other diseases such as root rot, leaf spots, damping off and blights have been known to affect Cannabis production, most of which can be monitored and managed with sustainable practices such as crop rotation, utilizing traps and barriers and by employing beneficial organisms (McPartland et al. 2000).



Figure 4.3.6 *Sclerotinia sclerotiorum* lesions A. S-Hermann, 2004



Figure 4.3.7 *Sclerotinia sclerotiorum* external 'cankers' A. S-Hermann, 2004



Figure 4.3.8 *Sclerotinia sclerotiorum* internal sclerotia bodies and seed head damage. Friesen and A. S-Hermann 2006

4.3.6.2 Insects

Some herbivorous insects have been known to feed on the Cannabis plant leaf material. Hemp research plots in south-east Queensland Australia, were infested with *Nezara viridula* commonly referred to as green vegetable bugs (Jobling and Warner 2000) or southern green stink bug (McPartland et al. 2000) in and around the seed heads with. Stink bugs have not been noted as a problematic insect in Manitoba as of yet. But according to Manitoba Agriculture, Food and Rural Initiatives stink bugs were found in

the summer of 1998, in Manitoban medicinal crop fields and plots of echinacea, valerian, milk thistle and feverfew .

Hemp crops in the Canadian western prairies have been infested with Bertha Army Worms (*Mamestra configurata*) (Figure 4.3.9), Painted Lady Butterflies (*Vanessa cardui*) (Figure 4.3.10) and some species of grasshoppers (Figure 4.3.11). The European corn borer (*Ostrinia nubilalis* (Hübner) has affected hemp crops in southern Ontario and in Manitoba by damaging the stalk (Figure 4.3.12 . In 2007, for the first time, Aster Leafhoppers (*Macrostelus phytolasma*) spread aster yellows, a viral-like phytoplasma, to some the hemp plant stands in Manitoba. The affected plants remained in an undifferentiated vegetative growth stage (Figure 4.3.13). Aster yellows affected plants could result in a total seed crop loss and fibre quality may also be affected. The Canola Council of Canada website states that there is no practical control measure for aster yellows for canola. To date no studies been conducted to determine controls measures for aster yellow in hemp nor have any research been conducted to determine the affects on hemp fibre quality.

Preliminary research conducted by Scheifele et al. (1996) compared the effect of spring cultivation of hemp and soybeans on soybean cyst nematode in Southern Ontario. It was seen that cyst larvae population decreased from 340 in the spring to 60 in the hemp trail and increased to 2680 in the soybean trail. Further research is needed to validate their findings.



Figure 4.3.9 *Mamestra configurata* (Bertha Army Worm) (Friesen and S-Hermann 2006)



Figure 4.3.10 *Vanessa cardui* (Painted Lady Butterflies)
(Friesen and S-Hermann 2006)



Figure 4.3.11 Grasshopper (S-Hermann 2007)

European Corn Borer was identified in a field near Dauphin in 2007. The Corn Borer has been identified in the past as in this year in low numbers.

The Borer is noticeable by a small pin hole in the stalk usually near a node. The worm then develops in the center of the plant and eats it's way up the stem. Damage is usually noticed by plants that will be broken off somewhere up the stem,



European corn borer in Hemp

Figure 4.3.12 European corn borer in hemp

(Source Manitoba Agriculture and Food and rural Initiative 2007- Keith Watson)



Figure 4.3.13 Undifferentiated vegetative growth caused by Aster Yellows (S-Hermann 2007)

4.3.6.3 Parasitic Plants

Hemp broomrape (*Orobanche ramosa* L.) is considered to be the worst Cannabis parasitic plant. Broomrape infects the root system, starves the plant and only appears above the soil level for a short time to flower and set seed. Suggested control measures range from biological methods such as using geese to eat the broomrape, trap crops or fumigations (McPartland et al. 2000).

As with all cultivated crops, increased production will cause a change in the ability for diseases, insects and parasitic plants to adapt to and target the crop.

4.3.6.4 Weeds

Currently in Canada, no herbicides are fully registered for use in pedigreed hemp seed cultivation. One post emergent grass herbicide, quizalofop-o-ethyl (+ oil concentrate (Sur-mix), trademark Assure[®] II, has been granted a minimal usage permit in Ontario for hemp fibre only production. In 2007 an herbicide application research project was initiated in Canada. Hemp Broomrape (*Orobanche ramosa* L.) is considered to be the worst Cannabis parasitic plant. Broomrape infects the hemp root system, starves the plant and only appears above the soil level for a short time to flower and set seed. Suggested control measures range from biological methods such as using geese to eat the broomrape, trap crops or fumigations (McPartland et al. 2000). Other problematic weeds in Canadian hemp production are buckwheat, wild oats and Canadian thistle. Buckwheat seeds are hard to clean out from hemp grain and wild oats can over grow the hemp stand if low hemp emergence or slow development occurs.

Hemp can become a weed of its own and can remain in the soil seed bank. The year after cultivation, 'volunteer hemp' will arise it can be controlled with application of broadleaf herbicide or by tillage. It is the responsibility of the producer to prevent and maintain volunteer hemp free production areas. As with all cultivated crops, increased production will cause a change in the ability for diseases, insects and parasitic plants to adapt to and target the crop. With proper pre-seeding field preparation, a sufficient

seeding rate, sufficient fertilization, good environmental conditions, germination and emergence hemp will tend to suppress most weeds.

5. Plant Population Density and Harvest Timing

Plant population density is known to affect plant height, plant mortality, grain, seed and fibre yield, stem diameter, light interception, canopy closure and plant development (van der Werf 1997 and Weightman and Kindred 2005). The desired plant density is based on the type of end use product for hemp. Riddlestone et al. (2006) recommended a seeding rate of 55 kg ha for production of textile grade fibre; neither the average seed weight nor the number of plants m⁻² was given.

Typically the recommended plant population density decreases as the pedigree (breeding level) of seed increases because the field must be rouged and maintained. For instance, in the Ukraine, it is suggested that for dual purpose elite breeder seed production that the targeted seed density should be 60-90 seeds m⁻², for foundation seed production 120-180 seeds m⁻² and for registered seed production 180-240 seeds m⁻² (Holoborod'ko 1995).

The Bast Institute in the Ukraine suggest a target plant density of at least 450-500 seeds m⁻² for fibre only production. Even though limited Canadian research is available top agronomists, Friesen and Watson, suggest 100 seeds m⁻² for grain only production and 300 seeds m⁻² for fibre only (pers. com. Friesen and Watson 2007).

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5.1 Plant Population Density

5.1.1 Self-thinning

Self-thinning is typically viewed as a limitation to overall plant performance and is known to occur in all cultivated crops (Cade 2000). Density induced thinning can results from inter, intra and con-specific plant competition for resources such as space, nutrients or light. Competition can create a 'size hierarchy' in hemp that causes suppression and death of smaller plants while increasing overall plant size variation (Ranalli 1999, Cade 2000, Amaducci et al. 2002b). Canopy establishment and rate of closure in hemp is in part due to seeding density (van der Werf 1997). A seeding rate which exceeds the maximum number of plants that a set area can sustain will expend valuable nutrients and carbon that would've otherwise be available to healthy plants (Loomis and Connor 1992). Even though hemp is highly plastid and can be extremely productive in varying spatial zones, it is important to understand how final plant counts at harvest are affected by plant density. Thus it is important to determine at what plant density yields are maximized while maximizing the total number of plants alive at harvest and minimizing inputs.

5.1.1.1 Effect of plant density on self-thinning

Plant population density can affect self-thinning counts. According to Ranalli (1999) high plant densities are desirable for hemp fibre production. Preliminary research conducted in Manitoba collected self-thinning data on four Canadian grown dual purpose cultivars, USO 14, USO 31, Alyssa, and Zolo at three targeted plant densities, 100, 200 and 300 plant m⁻² (PCDF 2003). Results showed that the average rate of self-thinning over all four cultivars was 17% with an 83% target-seeding survival rate. See Table 6.1.1.1

The goal in selecting a seeding rate or target plant density is to ensure that the plant population at emergence does not exceed the sustainable maximum density possible (van der Werf 1995a). Optimal plant density of 90-100 plants m⁻² have been suggested by Amaducci et al. (2002a) and 120 -50 m⁻² by van der Werf (1995a).

Table 6.1.1.1 Hemp actual plant stand at emergence verses target plant density (adapted from PCDF 2003).

Cultivar	Target density plant m ⁻²	Actual density at emergence plant m ⁻²
USO 14	100	92
	200	124
	300	295
USO 31	100	78
	200	201
	300	333
Alyssa	100	77
	200	149
	300	300
Zolo	100	80
	200	121
	300	191

5.1.2 Effect of plant density on stem diameter

Several European studies have documented the effects of plant population density on stem diameter of hemp. In most cases stem diameter was conclusively determined to be inversely related to plant population densities ranging from 50 to 350 plants m⁻² (Svennerstedt and Svensson 2006, Schäfer and Honermeier 2006, Höppner et al. 2004, Amaducci et al. 2002a and 2002b, Schumann et al. 1999, Lisson and Mendham 2000a, Scheifele et al.1996). According to Amaducci et al. (2002b) stem diameter of hemp is a function of density, further stating that smaller stem diameter are advantageous for decortication of bast and hurd fibres for textile applications. Höppner et al. (2004) found a significant difference in hemp stem diameter between harvest at initial start of seed maturity for predominant fibre production at 221 plant m⁻² and harvest at seed maturity for predominant seed production 116 plant m⁻² of 4.9 mm and 5.8 mm, respectively.

Hennik (1994) examined the heritability of stem diameter to the parent-offspring relationships. The narrow sense heritability was found to be low at 0.22 concluding that "selection based on stem diameter resulted in a positive correlated response to plant height." Scheifele et al. (1996) found there to be a 95 % correlation between hemp stem diameter and stem length. Sankari (2000) observed in dioecious hemp bio-types that as stem diameter increased bast fibre content decreased. They also found that the bast fibre content in monoecious bio-types was less sensitive to changes in stem diameter than dioecious bio-types.

5.1.3 Effect of plant density on plant height

Plant height in hemp is an important character to examine since height is related to fibre length and thus quality. Research conducted in Italy, Germany and the Netherlands has examined the effects of plant density on plant height in hemp. Previous hemp research conducted in Italy by Amaducci et al. (2002b) determined that the relationship between plant height and plant density were initially positively correlated. The data concluded that initial plant height was greater as plant densities increased from 45 to 90 to 180 plants m^{-2} . There after the relationship between plant height and plant density became inverse in that at final harvest plant height was greater as plant density decreased. Amaducci et al. (2002b) further examined the effects of plant densities of 50, 100, 150, 200 and 250 plants m^{-2} on plant height. They saw a decrease in plant height from approximately 230 to 170 cm with increasing plant densities. Plant density trials conducted by Struik et al. (2000) in England, Italy and The Netherlands determined that plant height decreased from approximately 330 cm to 270 cm as target plant density increased from 30 to 90 to 270 plants m^{-2} . Schumann et al. (1999) examined 40 different hemp accessions it was observed initially that height and plant density were positively correlated at the beginning of plant development growth while at maturity height and density were negatively correlated. In an Australian study Lisson and Mendham (2000a) observed increasing plant densities of 50 to 300 plants m^{-2} in which stalk height decreased from 268 to 244 cm at maturity, respectively.

The current hemp literature shows that even though plant height initially increases with increasing plant density there is a consistent trend for plant height at maturity and plant density to be negatively correlated (Amaducci et al 2002b). Amaducci et al. (2002b) stated that in the first phases of hemp plant development competition for light is demanding causing the plant to physiologically initially grow taller. Ballaré et al. (1997) further explains that the initial increase in plant height is due to red to far-red light induced internodal elongation. The researchers concur that the initial increase in height is more than likely due to inter and intra-plant competition for available spatial, nutrient and light resources.

5.1.4 Effect of plant density on yield

Evidence in the literature suggests that plant density affects fibre yield to some degree. Amaducci et al. (2002b), Cromack (1998), Struik et al. (2000), and Schäfer (2005) determined that European cultivar stem yield was not statistically affected by increasing plant densities. Three European cultivars (Futura 75, Fedora 17 and Felina 34) were examined in southern Sweden in which the two seeding rates (30 and 60 $kg\ ha^{-1}$) resulted in similar biomass and fibre yield (Svennerstedt and Svensson 2006). Results produced by Bennett et al. (2006) at the University of Wales, UK determined that the percentage of total fibre was greater at 300 seeds m^{-2} than at 150 seeds m^{-2} , 47.0 and

51.4% respectively. Bennett et al. (2006) further concluded that the percentage of bast (long) fibre was relatively unchanged from 13.4% at 150 seeds m⁻² and 13.2% at 300 seeds m⁻². Deleuran and Flengmark (2005) concluded in a Denmark study that total stem yield and total dry matter was not influenced by seeding rates of 8, 16, 32, 64 kg ha⁻¹. The authors noted that fibre percentage was greatest at 32 and 64 kg ha⁻¹, 31.8 and 31.6% respectively.

Cromack (1998) determined that in the UK French and Hungarian hemp cultivars (Fedora 19, Felina 34, Uniko B, Futura 77 and Komploti) stem yield (9.57 and 10.38 t dry matter ha⁻¹) was not affected by plant density (200 and 400 seed m⁻² respectively) and that bast fibre content tended to increase on average from 1.3 to 3.5 t dry matter ha⁻¹ with increasing plant density. Agronomy trials conducted in The Netherlands, van der Werf (1995b) concurred that the bark (bast) fibre as a percentage of the total stem fibre yield increased with increasing plant population density. This in turn improves stem quality and increases the overall value of the hemp crop (Van der Werf 1995b). Schäfer (2005) determined that in trials conducted in Germany that the total plant yield (not published, consisting of the epidermis, primary fibres (bast) and xylem (hurd)) decreased from with increasing plant densities of 100 and 300 seeds m⁻². These authors assumed that thinner stem diameters resulting from increased plant densities were due to thinner amounts of the differentiating cell layers.

Preliminary research conducted in the southern regions of Alberta, Canada concluded that hemp fibre cultivars seeded at the lower rates appeared to yield better than those seeded at the higher seeding rates (rates not published). Vera et al. (2006) examined two oil seed cultivars (Finola and Fasamo) in the parkland region of Saskatchewan, Canada. The authors concluded that increasing the seeding rate from 20 to 60 to 80 kg ha⁻¹ with a target plant density at emergence of 150-200, 500 and 750 plants m⁻² (based on average cultivar thousand kernel weight), respectively, increased total crop biomass by 21, 20 and 29% with biomass yields ranging from 2633, 2887 and 3323 kg ha⁻¹, respectively. They further concluded that increasing sowing density increased grain yield in both cultivars by approximately 85-150 kg ha⁻¹, had not affect on seed weight and advantageously decreased the weed pressure. Vera et al. (2006) concluded that increasing plant densities had little affect on hemp seed oil content and no affect on the hemp seed protein content. The change in fibre yield and biomass suggests that plant population density could be an essential crop management tool for specific-production of core and bast fibres (Cook and Scott 1998).

The effects of varying plant densities ranging from 75-350 seed m⁻² of Canadian certified cultivars on seed yield was examined by McGregor (1998), Stadnyk (1999, 2000), Kostuik (2001), PCDF (2002, 2003)(Table 5.1.4.1). Overall, the authors determined that increase plant density had little to no effect on seed yield.

Methods for determining fibre yield vary depending upon researcher. Methods of fibre separation are examined further in the Harvesting section of this document.

Table 5.1.4.1 Effects of plant density on seed yield of four Canadian hemp cultivars. (adapted from McGregor 1998, Stadnyk 1999, 2000, Kostuik 2001, PCDF 2002, 2003).

Cultivar	Treatment (seed m ⁻²)	Year					
		1998	1999	2000	2001	2002	2003
		<u>Seed yield (lbs/ac)</u>					
USO 14	75	602	415				
	100	565	371	620	551	367	526
	125	621	319				
	150			585			
	200					322	503
	300				454	339	468
	350			503			
USO 31	75	438					
	100	564		583	577	306	495
	125	552					
	150			511			
	200					339	394
	300					331	486
	350			459			
Fin 314 (Finola)	75		392				
	100		470	459	205		
	125		365				
	150			376			
Anka	100				530	525	
	200					271	
	300				549	556	
Alyssa	100						696
	200						671
	300						504

5.1.5 Effect of plant density on the bast and hurd chemical constituents

The effect of plant density on the chemical components of hemp has not been thoroughly examined and little detailed information was found in the literature. Previous studies have been sown or hand thinned to varying plant densities and considered the chemical constitute percentage of total cellulose, alpha-cellulose, hemicellulose, holocellulose, lignin and ash present in the bast and hurd fibres of hemp. The percentage of cellulose and lignin are key parameters in determining stem quality, especially for the pulp and paper industry (de Meijer and van der Werf 1994). Table 5.1.5.1 provides a comparison of lignin and alpha-cellulose in various non-wood and wood crops that are typically used in pulp and paper making applications (www.hurterconsult.com 12/30/07).

van der Werf (1994c) compared the effects of plant population densities ranging at harvest between 40 and 100 plants m^{-2} on the chemical constituents of the bast and hurd of the hemp stalk grown of four European certified cultivars (Fibrimon 56, Fédora 19, Kompolti Sárászárú and Kompolti Hybrid TC) grown in The Netherlands. The mean cellulose content present in the hurd varied more so from 31.5% to 37.4% than that of the bast fibre of 53.2% to 74.3%. The lignin and hemicellulose content did not vary with mean percentages of 20.8% and 17.8% in the hurd and 4.3% and 7.7% in the bast fibre, respectively. Thus suggesting that cultivar, environmental conditions and harvest timing have a greater impact on the chemical profile of the hemp stalk than does plant population density.

Kamat et al. (2002) analyzed southern Ontario grown hemp sown at 75 kg ha^{-1} . Information on cultivar, thousand kernel weight, and plant stand at emergence or the number of plants harvested was not given. Based on the recommended seeding rate of 67 kg ha^{-1} for fibre hemp grown in Saskatchewan, Canada plant densities typically range from 300 to 375 plants m^{-2} depending on the cultivar's thousand kernel weight (Mooleki et al. 2006). Data gathered by PCDF (2003) determined that the thousand kernel weight of dual purpose cultivars currently being grown in Canada ranged from 16-18 grams. Therefore based on average thousand kernel weight and the recommended seeding rate it is estimated that Kamat et al. (2002) sown plant density of 75 kg ha^{-1} suggest a target plant stand count at emergence of at least 400 plants m^{-2} . The chemical component percentage results of Kamat et al. (2002) trial of hemp harvested at 60 and 90 days after sowing (technical maturity) is presented in Table 5.1.5.2.

Table 5.1.5.3 provides a summation of a portion of the chemical constituents present in the hemp stalk that was grown for fibre in southern Ontario at an approximated targeted plant density of 200-250 plants m^{-2} at emergence (Correia et al. 2001). Estimated plant density derived from the suggested seeding rate for fibre only production in Ontario (Baxter and Scheifele 2000 and Correia et al. 2001).

Gutiérrez et al. (2006) analyzed hemp fibres grown in Spain for lignin content. Neither plant population density nor cultivar information was given in the report. The trial determined that lignin content accounted for 4.6% of the total bast fibre. The authors stated that the lignin content in the hemp samples were lower than that of other non-wood fibre crops (Gutiérrez et al. 2006). Thus concluding that low lignified hemp fibre would be advantageous in pulp production.

From the available literature the effects of plant density is of less concern than that of harvest timing and environmental conditions on the chemical profile of hemp. This thesis will later present preliminary results examining the effects of plant density on the chemical profile of the partitioned hemp stalk of the cultivar Alyssa.

THE FOLLOWING TABLES HAVE BEEN ADAPTED FROM REFERENCED WORKS

Table 5.1.5.1 Comparison of the percentage of lignin and alpha cellulose in various non-wood and wood crops. (adapted from www.hurterconsult.com 12/30/07)

Fibre Source	Chemical component	
	--Alpha-cellulose--	--Lignin--
Bast fibres		
Hemp bast	55-65	2-4
Hemp hurd	39 – 49	17 - 22
Whole hemp stalk	43 – 51	11 – 14
Kenaf – bast	31 – 39	7.5 - 9.5
Kenaf – core	34	17.5
Oilseed flax tow	34	23
Textile flax tow	50 – 68	10 – 15
Wood fibres		
Coniferous - soft woods	40 – 45	26 – 34
Deciduous – hardwood	38 – 49	23 – 30

Table 5.1.5.2 Chemical components analysis presented as a percentage (%) of extractive free bast fibre of hemp grown at an estimated plant density of 400 plants m⁻² (75 kg ha⁻¹) harvested at 60 to 90 days after sowing (technical maturity) in southern Ontario (adapted from Kamat et al. 2002).

	Holocellulose	α-cellulose*	Lignin
	----% the bast fibre----		
60 days	83	45	11
90 days	84	44	11

*α-cellulose is alpha cellulose

Table 5.1.5.3 Hemp chemical constitutes as a percentage of total mass grown at an approximate plant density of 200-250 plants m⁻²(adapted from Correia et al. 2001)

%	Extractives	Holocellulose	α-cellulose*	Lignin	Ash
Bast	3.02 ± 0.42	84.8 ± 1.78	60.6 ± 2.64	10.0 ± 1.96	2.17 ± 0.07
Core	5.60 ± 0.32	72.3 ± 3.23	33.4 ± 0.76	21.2 ± 1.14	0.90 ± 0.09
Whole stem	3.77 ± 0.38	77.9 ± 2.44	43.0 ± 1.07	15.2 ± 0.58	3.18 ± 0.67

Mean values ± standard deviation n=30

*α-cellulose is alpha cellulose

5.2 Harvest Timing

5.2.1 Effects of harvest date on self-thinning

Upon review of the literature no data was present which examined the effects of harvest timing on hemp plant self-thinning. Mediavilla et al. (2001) observed that the majority of hemp plants self-thinned during the first vegetative growth phase. It has been determined across many crops such as legumes and grasses (Loomis and Connor 1992) that self-thinning is affected more by plant density rather than by harvest timing (Kikuzawa 1999, Lonsdale 1990). Westoby (1976) examined self-thinning in five cultivars of Subterranean clover (*Trifolium subterraneum*) at 32, 51, 73, 100 and 141 days after sowing where plant loss was not significantly affected by delaying harvest. According to Kikuzawa (1999) larger individual plants within a given area will suppress the growth rate of smaller plants as the crop develops. Thus delaying harvest could increase plant loss of individual plants due to competition.

5.2.2 Effect of harvest timing on stem diameter

The effect of harvest timing on stem diameter could be an important crop management tool when growing hemp for hurd and bast fibre-specific applications (Cook and Scott 1998). Little to no literature is available examining the effect of harvest timing on stem diameter in hemp. However, Höppner et al. (2004) found a significant difference in hemp stem diameter between harvest at initial start of seed maturity for predominant fibre production (221 plant m⁻²) and harvest at seed maturity for predominant seed production (116 plant m⁻²) of 4.9 mm and 5.8 mm, respectively. Mambelli and Grandi (1995) determined that basal stem diameter in kenaf (*Hibiscus cannabinus* L.) (an annual fibre crop with potential for pulp and paper) was not significantly affected by delaying harvest timing. Upon the limited data available, stem diameter in hemp seems to be a function of a plant density relationship rather than harvest timing.

5.2.3 Effect of harvest timing on plant height

The effect of harvest timing on plant height in hemp has not been thoroughly examined and little detailed information was found in the literature. Results from a German study suggested that plant height in hemp is influenced mostly by location, length of the vegetative period and plant density but not harvest date (Hendrischke et al. 1998). Bennett et al. (2006) concurred stated that hemp height was affected by plant densities of 150 and 300 seeds m⁻² but not by delaying harvest in the UK. The Parkland Crop Diversification Foundation, Manitoba has noted that maximum hemp stalk height is typically reached during the first week of August in the western Canadian prairies. And that hemp for bast fibre predominate production should be harvested at this time (per comm. Watson 2006).

5.2.4 Effect of harvest timing on fibre yield

Yield and fibre quality can be affected by harvest timing. Amaducci et al. (2000) examined the stem dry matter yield of four annual fibre crops (hemp, kenaf, maize and sorghum) at three successive harvest dates (24 August, 22 September and 17 October) in the Northern Italy (Table 5.2.4.1). They determined that stem dry matter yield did not differ statistically amongst harvest dates. Amaducci et al. (2002b) further concluded that at lower plant densities of 30-40 plants m⁻² hemp stem dry matter yield at final harvest in

the Northern Italy tended to be greatest averaging 16.8 and 17.8 Mg ha⁻¹ (16,800 or 17,800 kg ha⁻¹), respectively. Mediavilla et al. (2001) observed that hemp stem yield and fibre yield peaked at 'technical maturity'. Hemp fibre technical maturity has been determined to occur at the time of flowering of the male plants (Mediavilla et al. 2001). Hoffman (1961) suggested that the increased yield at technical maturity was due to an increased rate of high lignin, production of shorter, thicker cell walled secondary fibres (hurd) which decrease the overall bark quality (cited in: Mediavilla et al. 2001, Bennett et al. 2006). Schäfer (2005) concluded that hemp fibre content decreased by 5% from beginning to the end of flowering and remained unchanged from end of flowering to grain harvest in Germany. Agronomic trials conducted in the UK by Bennett et al. (2006) resulted in similar conclusions; that is fibre yield decreased from 5486 to 3860 kg ha⁻¹ (5.4 to 3.8 t ha⁻¹) as harvest was delayed by 14 days.

Meijer et al. (1995) showed a decline in biomass yield in dual purpose cultivars after flowering in the Netherlands concluding that the reduction in biomass was a direct result of fat and protein synthesis in the seed and canopy senescence. Kamat et al. (2002) examined Canadian hemp harvested at 30, 60 and 90 days after planting. The biomass of air-dried hemp plants approximately increased from 200 to 5000 to 8000 kg ha⁻¹, respectively with delayed harvest. They noted that biomass accumulation between 60 to 90 was substantially less than between 30 and 60 days. van der Werf (1994c) suggested sampling the stalk at 20 to 30% of the total stem height would give a "good approximation" of the percentage of bast to hurd fibre in the stem.

Table 5.2.4.1 Average stem dry matter (t ha⁻¹) of hemp, kenaf, maize and sorghum harvested on 24 August (H I), 22 September (H II) and 17 October (H III) of 1995 in Northern Italy

(adapted from Amaducci et al. 2000)

	H I	H II	H III	Mean
Hemp	13.3	13.1	12.2	12.9
Kenaf	7.9	14.0	14.4	12.1
Maize	8.1	14.8	16.2	13.0
Sorghum	12.3	22.5	21.3	18.7

5.2.5 Effect of harvest timing on the bast and hurd chemical constitues

The effects of harvest date on the chemical constitues of the two main components of the hemp stalk, i.e. bast and hurd have been examined to a greater extent in Europe than in Canada. A literature review conducted by Ranalli (1999) concluded that the chemical composition of bast and hurd fibres change during the growing season.

Amaducci et al. (2000) compared one European hemp cultivar (Futura 77) to three other fibre crops, i.e. kenaf, maize and sorghum, at three harvest time (Table 6.2.4.1). They observed that in the whole stalk the percentage cellulose increased from 56.5 % to 66.8 %, the percentage of lignin decreased from 12.7 % to 7.8 % and the percentage hemicellulose decreased from 17.8 % to 15.8 % as the harvest timing was delayed by 3 weeks. Amaducci et al. (2000) noted that the decrease in the percentage of lignin did not concur with pervious unpublished research findings. They proposed that the reduction in

percentage of lignin as harvest was delayed was more than likely due to crop variability or by the loss of small and dead plants. In addition, Amaducci et al. (2002b) concluded that decreasing plant density from 270 to 180 to 90 to 45 to 30 plants m⁻² and postponing harvest time by approximately seven days resulted in the stem becoming richer in short and lignified secondary hemp bast fibres. In comparison of three European cultivars, Struik et al. (2000) observed that in dry hemp stems the cellulose yield increased until the end of the growing season as lignin advanced. Therefore these observations support those of Amaducci et al. (2000) where lignification increased as the growing season progressed. Previously, van der Werf et al. (1994c) stated that harvest date affected the chemical composition of the bark fibre and to a lesser degree the core. They concluded that hemp stalks harvest at 'technical maturity', after male dehiscence, yielded a superior raw material for paper making. The mean cellulose content in the bark was 64.8% and in core was 34.5%. The mean hemicellulose content was 7.7% in the bark and 4.3% in the core while the lignin content was 17.8% in the bark and 20.8% in the core.

Toonen et al. (2004) determined the percentage of lignin, total lingocellulose (lignin and cellulose combined) and the total lignin, lingocellulose and hemicellulose combined present in the hurd and bast fibre of hemp. Crude fibre analysis, typically employed in forage crops, was used to determine acid detergent fibre (ADF), acid detergent lignin (ADL) and neutral detergent fibre (NDF). The percentage of ADL coincides with lignin content, ADF is considered to be the sum of lingocellulose and NDF coincides with the percentage of total lignin, lingocellulose and hemicellulose (Toonen et al. 2004). They examined three commercial cultivars, i.e. Chamaeleon, Felina 43 and Kompolti hybrid TC at a plant density of 120 plants m⁻² harvest in two intervals, i.e. 40, 54, 68, 83, 96 and 110 days after sowing in The Netherlands. Their results concluded that the percentage of lignin present (based on ADL) did not significantly increase with delayed harvest from 10.12% at 42 days after sowing to 11.41% at 112 days after sowing and that the percentage of cellulose and hemicellulose (based on ADL and ADF: actual amount not provided) content increased with harvest delay.

To date, only one research project has been conducted in Canada examining the effects of plant age on the chemical constituents of whole hemp stems. Kamat et al. (2002) examined hemp stems harvested at 30, 60, 90 and 120 days after sowing in southern Ontario from producer fields. The alpha-cellulose and holocellulose content in the stem fibre tended to increase between 30-60 days and was unchanged between 60-90 days, lignin content decreased from 14 % at 30 days to 13 % at 60 days to 11% at 90 and 120 days. Thus a decrease in the amount of lignin present in hemp stem occurred as harvest timing was delayed. It was apparent that the lignin content of hemp stems was very low in comparison to other raw materials used in pulp and paper industry. Refer to Table 5.1.4.1. One year of data suggested that based on biomass and chemical constituents that hemp produced for the pulp and paper industry should be harvest between 60 and 90 days. The low lignin and high cellulose content in hemp stems, Kamat et al. (2002) concluded that hemp fibres would be a viable raw material option for pulp and paper industries. This would lessen the demand on local forest for the raw less renewable 'tree' material required to supply the paper industry.

6. Harvesting Methods

6.1 Seed and fibre harvest

The success of today's Canadian hemp grain production has been due mainly to innovative farmer's ability to modify conventional grain harvesters to be used in hemp production, processors providing quality products and marketers selling them. Harvesting methods for industrial hemp vary depending whether the cultivar is designated for seed only, fibre only or for dual purpose. Lack of harvesting knowledge i.e. timing, equipment, retting, baling, storage and lastly fibre processing has kept the Canadian hemp fibre industry on hold. Methods for harvesting fibre currently differ between Canada and the EU. In the EU it is common for dual purposed cultivars to be directed combined in which the combine cuts, threshes and cleans seed and binds and/or spreads the remaining stems. In Canada, on the other hand, harvest is typically a two-step process that includes combining harvesting followed by stalk cutting.

Grain harvest in Canada has been successful without the need for dramatic combine modifications. Two modifications have been innovated for John Deere conventional combines and for Case IH axial flow combines for easing harvest for taller varieties (see Appendix 4). It is pertinent that all sickles and guards are either new or sharpened and that the crop is cut a bit on the greener side. Friesen (2006) suggests that short stature hemp cultivars, like Finola, should be straight combined at 75-80% maturity at 14 to 16% seed moisture or swathed at ~85% maturity, windrowed and then combined. Swathing can cause seed yield loss due to shelling, shattering and germination in the windrow.

During grain harvest the straw chopper should be either removed or disabled, the cylinder/rotor speed should be set to low with an open concave. The auger unloading speed should be slowed to reduce shelling all the while watching for fibre wrapping on the feeder chain and other moving machine parts. To further reduce seed cracking and damage after combining, grain should be moved with large diameter augers at low speeds or with belt conveyor systems. Hemp grain moisture content for long-term storage should be below 9%. Hemp grain can be stored in a variety of bin types. Although, smooth sided inverted cone hopper bottom aeration bins tend to work best. To insure proper storage bins should be filled to below maximum bin capacity and the hemp grain should be flattened on top. If using natural air drying systems the hemp grain should be turned 2 days after harvest then turned again in the spring and fall (Friesen 2006).

Harvesting and final processing of hemp total biomass has been problematic because the biomass cannot be fed into conventional grain harvesting combines (Chen and Liu 2003). The decision to straight cut or swath is usually determined by the total plant biomass. After swathing if the weather turns or a prolonged period of rain occurs there is risk of spouting grain in the seed heads and or high degree of mould in the swath, this can result in total crop loss (per comm. K. Watson 2007). Dual purpose cultivars should be direct/straight combined and the remaining fibre stand should be mowed, cut or haybined at opposing angles (preventing fibre loss) immediately after grain harvest then allowed to dry or dew ret. Standard sickle mowers, mower conditioners and hay swathers have been used to cut full-length stalks, though in heavy duty sickle bar cutters work best (Laprise 1998). Forage harvester units with a large rotary blade and a cutter box have been used to cut and chop the stalks into desired lengths (Laprise 1998). To

facilitate field dew retting and easy fibre pickup (baling), hemp stalks should be cut at a swather width of 8 to 10 feet (2.5-3 meters) into a windrow of 3 to 4 feet (0.9- 1.2 meters) wide (Laprise 1998). Turning the hemp windrow using a rotary rake serves the purpose of deleafing the plants and reducing plant volume at baling time (Laprise 1998).

Producers have found that both square and round balers equipped with a heavy duty pick up system can be successfully used to bale hemp and that hard core round balers tend to perform better than soft core balers (Laprise 1998, Friesen 2006). For safe storage, fibre should be baled at ~12% moisture to prevent spoilage (pers. com. Chris Federowich). Hemp bales should be stacked in an orientation that protects the fibre (see Appendix 3). Fibres have a tendency to wrap and bind around rotational machine parts (Chen and Liu 2003). Caution must be taken to guard the under belly of the machine, to inspect equipment during cutting and baling and to prevent fibre wrapping, fire or equipment damage (pers. com. Keith Watson).

Establishment of a standard header height for cutting grain is difficult because of uneven plant height and maturity. This problem was examined by Chen and Liu (2003) in which a double windrower system for harvesting dual purpose hemp in Canada was engineered. Modifications were made to a conventional self-propelled MacDon, Model 972, windrower with a 80 kW tractor and to a hydraulically shifted sickle cutting bar header (7.6 meter) based on the following criteria: (Chen and Liu 2003)

- Unit should perform both seed-head and fibre-stalk windrowing operations (Figure 6.1.1 and Figure 6.1.2)
- Header height should be adjustable for crop height
- Gentle seed-head delivery into windrow
- Easy adaptation to existing windrowers
- Transferable to traditional crops

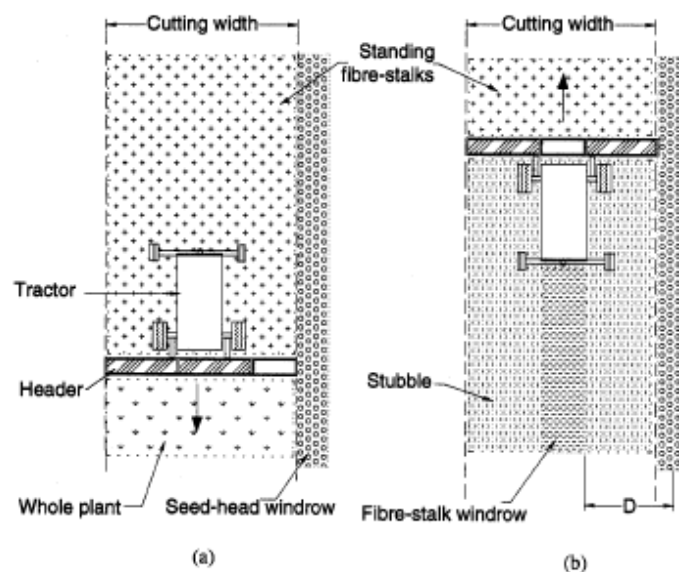


Figure 6.1.1. Diagram showing the two-windrow harvesting concept (Chen and Liu 2003)

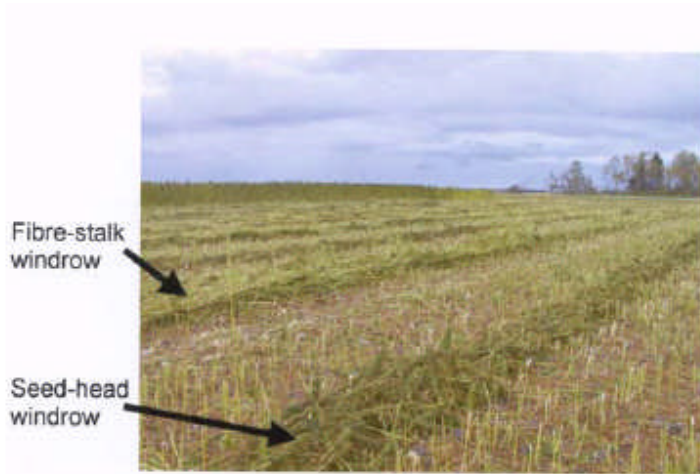


Figure 6.1.2. Field operation results: Seed-head and fibre stalk windrow. Arborg, 2001 (Chen and Liu 2003)

The authors concluded that dual purpose hemp harvesting two-windrow system was practical and that only minor modifications would have to be made to existing conventional header and windrower systems. Chen and Liu (2003), created a new header-lifting mechanism, in which a 0.5 meter header height gain was achieved for a maximum header height of 1.58 meters, increased the delivery opening from 1.0 to 1.63 meters and created an adaptable, transferable and foldable conveyor systems for seed-head delivery onto ground stubble. These Canadian designed modifications have not been revisited nor are they currently being employed in Canada.

As time advances and technologies and innovations are shared, methods of harvesting hemp are becoming easier and are detailed towards the end-use product. Advances in harvesting methods surfacing from Australia, France, Ireland, Asia and the European Union are changing the face of hemp production in Canada.

After the stalk is cut in the field it is either dried and baled or retted and baled. The following section is devoted to different retting methods.

6.2 Retting and Degumming

Retting and/or degumming is the initial process of decomposition of the chemical bonds between the fibre and surrounding tissues, thus allowing the bast and hurd to separate with minimal damage. Historically, the separation of hemp long fibre and core constitutes have been dependent upon a retting process. Today, some production applications do not require 'retting' for further fibre separation and processing. The length of retting, if required, is dependent mainly upon local environmental conditions. Typically water (moisture), micro-organisms (enzymes or bacteria), or chemicals (NaOH) are used to breakdown the pectins which hold the fibrous plant tissues to the non-fibres tissues. 5 basic retting methods are employed to date.

6.2.1 Dew-Ground Retting

Dew-ground retting is a process in which windrowed stalks are allowed to remain in the field where precipitation (rain, dew, irrigation) penetrates and a rotting process begins. 600 mm per month of rainfall during harvest is required for effective dew retting (Franck 2005). Stalks may be turned and allowed to remain in the field up to 5 weeks. Duration of retting is dependent upon end product. This method produces a light brown coarse fibre.

One UK study conducted by Booth (2004), examined the work to peel test on dew-retted and oven dried hemp stems. Peel test measure the strength required to pull apart a bonded surface, in this case the test was used to determine the strength of the bond between the bast and core fibre of dew-retted and oven dried stems. Preliminary results from this study concluded that as moisture content decreased in the oven dried samples, the work to peel significantly increased and that the opposite affect was seen in dew-retted samples. This suggests that peel tests could be 'used to objectively monitor the reduction in work to peel for dew-retted stems and relate this reduction to the progress of retting'. The authors suggest that further research is needed to determine the effects of the relationship of fungal colonization on stem properties (Booth 2004).

6.2.2 Water Retting

Water retting is a process in which stalks are totally submerged and steeped in concrete tanks with circulating water consisting of bacteria liquor. This liquor is typically water stock containing rotting micro-organisms which degrade the pectins and gums which bond the fibres to the stem. Known degumming retting agents such as potash lye, murtiatic acid, rice ash, lime, potassium carbonate, calcium hydroxide and caustic soda have been used (Riddlestaon et al. 2006) Water retting can take up to two weeks, but creates a softer quality of fibre. Retted stalks are then stoked, stopping the retting process and allowed to dry until required for further processing.

One Italian study conducted in 2000 examined the effects of irrigating hemp retting water on the composition of soil bacterial community and on wheat yield. Preliminary results suggested that doses of 0, 80 and 160 m³ha⁻¹ of retting water had no negative effects on telluric micro flora nor on the morpho-biometric and production characteristics of the wheat crop and there was a tendency for yield to improve (Cataldini et al. 2001). Hendrischke et al., (1998) stated that "growing fibre hemp with field retting in water catchments might cause problem concerning nitrate content of water wells."

6.2.3 Warm water retting

Warm water retting is similar to water retting except that the stalks soak in a clean water bath for 24 hours then emptied and fresh water is added. The tank is then heated for two to three days resulting in clean uniform fibres.

6.2.4 Green retting

Green retting also referred to as green ribboning is a process in which fresh green stalks are mechanically separated into the bast and hurd components without retting. Typically the fibre produced from green retting is of less quality than the other methods and is therefore typically used in industrial grade textiles for reinforcement in composites and

fibreboard products. Even though this method has been developing for over 100 years it has yet to become an industry mainstay. Riddlestone et al., (2006) determined that technical and economic issues such as prevention of degrading during processing and storage of green decorticated fibre by removal of water, on-farm handling and storage and degumming, must be addressed for this method to become a mainstay in the industry.

6.2.5 Chemical retting

Chemical retting is a process in which chemicals (such as enzymes or alkalized treatments) break down the bonding pectin's thus producing a high quality fibre in a short amount of time. Chemical retting efficiency is affected by the concentration and pH of the liquor, ratio of the mass of liquor to the mass of fibre, duration of degumming and the tank size for liquor circulation (Franck, 2005).

6.2.6 Milling

One study conducted at the University of Toronto examined non-decorticated hemp and chemically pre-treated black spruce wood chips ground in the SM-440 Szego Mill for evaluation of Kraft pulping for strength and optical properties. It was determined that in comparison, hemp Kraft gave a lighter pulp with longer fibres and increased the tear index.

Conclusion

Even though industrial hemp agronomic research has been conducted abroad, little peer review data is available from Canadian based researchers. The lack of Canadian publications in the areas of industrial hemp agronomics, seed and fibre yield and quality, breeding and equipment modifications has opened a Canadian research door in which many of these areas could be extensively studied under Canadian conditions.

Field agronomic practices are ever changing and vary by location and cultural knowledge. This document has been prepared to provide an agronomic literature review on agronomic practices in Canada and abroad. As new innovations and technologies are coming on line daily every attempt has been made to connect with those innovators in hopes to continue securing viable industrial hemp markets, insuring ethical research and shared knowledge to advance the entire industrial hemp industry and professional stakeholders.

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Addendum A (Appendix 4): IHSDC Modified Sengbusch Scale

(permission requested to reprint)

IHSDC modified Sengbusch Scale for monoecious intersex inflorescence types.
Sourced from the late Peter Dragula M.Sc.

IHSDC Modified Sengbusch Scale
Monoecious Hemp Intersex Inflorescence Types
(Male:Female Percentage)

	<p><i>Type 1</i> <i>Too Male Type</i> 80-90% male flowers 10-20% female flowers</p>
	<p><i>Type 2</i> 60 - 80% male flowers 20 - 40% female flowers</p>
	<p><i>Type 3</i> <i>Ideal Monoecious Type</i> 40 - 60% male flowers 40 - 60% female flowers</p>
	<p><i>Type 4</i> 10 - 40% male flowers 60 - 90% female flowers</p>
	<p><i>Type 5</i> <i>Too Female Type</i> less than 10% male flowers mostly female flowers</p>

Addendum B (Appendix 4): Developmental Stages of Hemp

Decimal code for dioecious plants table adapted from (Mediavilla et al. 1998)

Developmental stages of hemp have been determined by Mediavilla, V., Jonquera, M., Schmid-Slembrouck, I. and Soldati, A. 1998. Decimal code for growth stages of hemp (*Cannabis sativa* L.). J. Int. Hemp Assoc. 5 (2), 67-72

For complete *Cannabis sativa* L. decimal codes for all developmental stages please see (Mediavilla et al. 1998).

Decimal code for dioecious plants table adapted from (Mediavilla et al. 1998)

Developmental stages of hemp have been determined by Mediavilla, V., Jonquera, M., Schmid-Slembrouck, I. and Soldati, A. 1998. Decimal code for growth stages of hemp (*Cannabis sativa* L.). J. Int. Hemp Assoc. 5 (2), 67-72

For complete *Cannabis sativa* L. decimal codes for all developmental stages please see (Mediavilla et al. 1998).

Table A.2 Definitions and codes for the growth stages of *Cannabis sativa* L. (Mediavilla et al. 1998).

Code	Definition	Comments
<u>1. Germination and emergence</u>		
0000	dry seed	
0001	radicale apparent	
0002	emergence of hypocotyl	
0003	unfolded cotyledons	

2. Vegetative stage refers to main stem.

Leaves are considered as unfolded when leaflets are at least one cm long.

1002	1st leaf pair	1 leaflet
1004	2nd leaf pair	3 leaflet
1006	3rd leaf pair	5 leaflet
1008	4th leaf pair	7 leaflet
1010	5th leaf pair	:
	:	:
10xx	11th leaf pair	xx = 2 (n th leaf pair)

3. Flowering and seed formation refers to the main stem including branches

2000	GV point	
2001	Flower primordia	Indistinguishable sexual structures

4. Male plants

2100	Flowers forms	First closed staminate flowers
2101	Flowering begins	First opened staminate flowers
2102	Full flowering	50% opened staminate flowers
2103	Flowering ends	95% of staminate flowers open or withered

5. Female plants

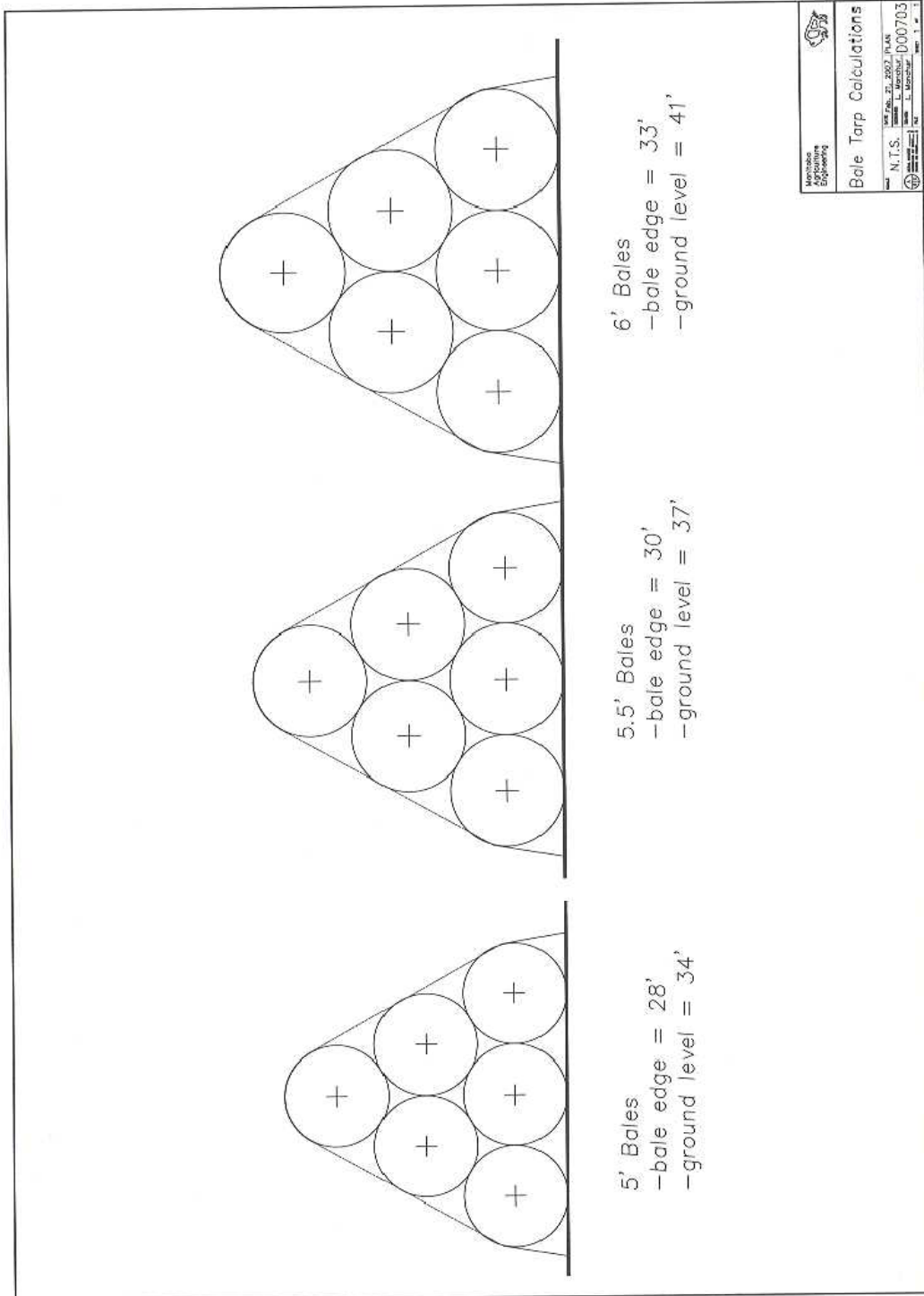
2200	Flowers form	First pistillate flowers: Bract with no styles
2201	Flowering begins	Styles on first female flowers
2202	Full flowering	50% of bracts formed
2203	Seeds start maturing	First seeds hard
2204	Seeds mature	50% of seeds resistant to compression
2205	End of seed maturity	95% of seeds hard or shattered

6. Senescence

3001	Leaves dry	Leaves dry
3002	Stem dry	Leaves dropped
3003	Stem decomposition	Bast fibres are free

Addendum C (Appendix 4): Bale Stacking

(Sourced from MAFRI permission granted to reprint)



Addendum D (Appendix 4): Combine Modifications & Settings

(Reprinted in entirety with permission from Hemp Oil Canada Inc. and Friesen 2006)

1) JD Conventional Combines (i.e. 7720 / 8820 / 9400 & 9600 series)

General Settings

Cylinder speed ~ 400 to 700 RPM

Cylinder setting ½ to 2"

Fan Speed 650 ~ 800 RPM (little less than wheat)

Sieve / Shoe: 3/16 ~ ¼ (similar to wheat)

Some examples of setting used by producers in 2005 for JD combines

Variety	H2O	Model	Modified	Cyl. RPM	Concave	Fan	Sieve
USO 31	25%	8820	No – Note 1	600	½"	650	1/4 inch
Finola	15%	9600	No – Note 2	350	1.5-2	650	
USO 31	20%	7720	No – Note 3	750	½~3/4	800	3/16
Finola	13%	6620	No – Note 4				
Finola	13%	8820	No – Note 5	900	800		

All above were straight cut

Note 1 – producer manufactured a push bar to flatten stubble under header to minimize wrapping under combine on header and drive shafts – crop 10' tall! Got wrapping on every moving part of combine!

Note 2 – chopper disabled / 4 ft crop / minimal wrapping on feeder chain shaft

Note 3 – put plastic pipe over hex shaft to minimize wrapping. Removed chopper

Note 4 – wrapping on upper and lower feeder chain shafts, and return auger shaft above cylinder

Note 5 – wrapping on top of feeder chain shaft

Advice

- Use hook or carpet knife to frequently remove any fibre build-up.
- Try to obtain smooth uniform flow – the fibre will wrap on irregularities
- Clean hopper at end of the day
- Check machine after every hopper
- Unload at half speed

Possible Modifications

- 1) Narrow intake on header 6 inches either side
- 2) Replace feeder chain with baler canvas – see Belt modification for instructions
- 3) Extend hydraulics by about 1 foot to be able to raise header higher
- 4) Shield any exposed bearings
- 5) ABS pipe over front drive shafts
- 6) Tie in cables close to machine (because fibre can catch on anything)
- 7) Mac Don draper header works better than auger type headers
- 8) Drop knives on chopper
- 9) Rubber / Canvas Belt Modification – prevents fibre wrapping on feeder chain shaft

Courtesy of:

SYDOR FARM EQUIPMENT
HWYS 5 & 10
DAUPHIN MB R7N2T9
Canada
204-638-6443
Contact: Tim Cruickshanks

PARTS LIST

144 3/8 nylon loc nuts
17 3/8 metal loc nuts
64 3/8 flange nuts
15 3/8 heavy flat washers 24H1314
64 3/8 x 1 round head bolts
155 3/8 x 1 hex head bolts
15 7/16 jam nuts
2 3/8 x 1 1/4 hex head bolts
4 3/8 x 1 1/2 hex head bolts
8 ski doo sliders
60" x 175" 2ply semi rough belting
557 feeder chain made to fit 9600 combine length
39 spring steel slats [flat bar]

ASSEMBLY INSTRUCTIONS

ASSEMBLE SPRING STEEL SLATS WITH 3/8X1 AND NYLOC NUTS TORQUE 45LBS.
ON THE LAST 2 SLATS ON CHAIN INSTALL WITH 3/8 METAL LOC NUTS IN ALL HOLES. ON THE CENTER CONNECTOR SLAT INSTALL 3 METAL LOC NUTS ON THE CENTER 3 HOLES ONLY. WELD ALL METAL LOC NUTS TO SLATS. THEN WELD LAST 2 SLATS TO FEEDER CHAIN. REMOVE ALL BUT THE OUTSIDE BOLTS THAT HOLD THE METAL LOC NUTS IN PLACE.
ON THE CENTER CONNECTOR SLAT DIE GRIND THE CHAIN MOUNTING HOLES ALONG TO THE OUTSIDE ABOUT 1/4" TO ALLOW FOR SOME ADJUSTMENT ON THE FINAL ASSEMBLY.

FOR THE BELTING SQUARE OFF ENDS FOR A 175"LENGTH. MARK A LINE 2 1/2" FROM EACH END FOR MOUNTING HOLES. USE 3 SLATS TO LOCATE THE MOUNTING HOLES, MARK AND PUNCH OUT HOLES WITH 3/4" BELT PUNCH. THIS WILL RESULT IN THE BELT BEING 170" FROM CENTER OF HOLES TO CENTER OF HOLES TOTAL LENGTH.

FROM CENTER OF MOUNTING HOLES ON ONE END..

MARK A LINE AT

21 1/4"

63 3/4"

106 1/4"

148 3/4"

LINE UP FULL SLIDER/SLATS MARK HOLES AND PUNCH. FOR THE 1/2 SLIDER SLATS [4 FULL LENGTH SLATS CUT IN HALF GIVING 8 SHORT SLIDER/SLATS] MEASURE 14 1/4" FROM FULL SLAT LINE AND MARK HOLES. PUNCH HOLES TO 3/8" FOR MOUNTING SLATS.

THE LONG SLATS SHOULD BE 4 1/8" FROM THE EDGE AND THE SHORT SLATS SHOULD BE 17 1/8" FROM THE EDGE. SEQUENCE OF SLIDER/SLATS SHOULD BE

1 SHORT , 1 LONG, 2 SHORT, 1 LONG, 2 SHORT, 1 LONG, 2 SHORT, 1 LONG, 1 SHORT
3/8 FLANGE BOLTS WILL SLIDE INTO SLAT GROOVE AND INSTALL SLATS ON BELT WITH 3/8 X 1 ROUND HEAD BOLTS AND FLAT WASHERS.

FOR FINAL ASSEMBLY

4 3/8 X 1 1/2" BOLTS

2 3/8 X 1 1/4" BOLTS

9 3/8 X 1" BOLTS

15 7/16" JAM NUTS

15 3/8" HEAVEY FLAT WASHERS

THE JAM NUTS ARE USED AS SPACERS ON THE BOLTS FOR THE BELT CONNECTION.

TIM CRUICKSHANKS

IH Axial Flow Combines (ie 1400 to 2100 series)

General Settings

Rotor speed ~ 350 - 400 when 17 – 25% moisture (speed up as it gets drier)

Rotor Setting ~ 3 – 5 (close to corn setting – fairly open)

Fan Speed 700

Shoe: top 1/2 bottom 1/8

Concaves like canola, open as it gets drier

Some examples of setting used by producers in 2005

Variety	H2O	Model	Modified	Rotor RPM	Concave	Fan	Sieve
Crag	21%	1688	Yes -Note 1	500	4	800	1/2 inch
Finola	12-18%	1680	No - Note 2	425	4-5	800	3/8~1/2 & 1/8 inch
Finola	17%	2188	No – Note 3	400	5	700	1/8
Finola	11~18%	1480	None	450	3-4	700	1/2

All above were straight cut

Note 1 – 1688 modified with rotor kit from Joe F – field on irrigation in AB – yield 30 bu /acre, crop 6.5 ft tall. MacDon draper header.

Consistent wrapping on rock trap beater, and some near front bearing on rotor

Note 2 – IH 1010 header 3 ft organic crop dryland yield low

Note 3 – Fibre wrapping on rock trap – will try to narrow opening next year

Advice

Use hook or carpet knife to frequently remove any fibre build up.

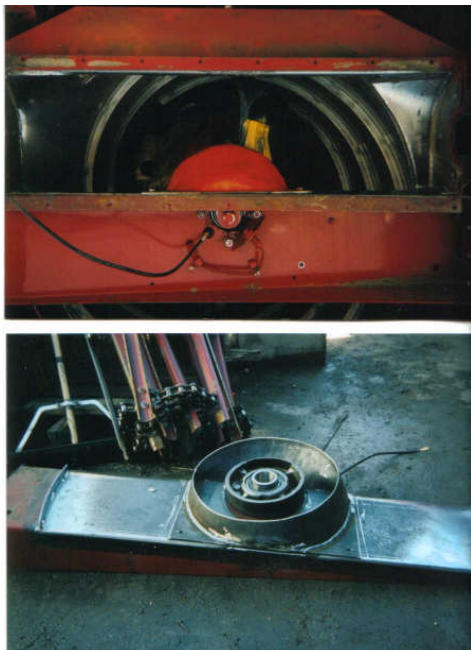
Try to obtain smooth uniform flow – the fibre will wrap on irregularities.

Clean hopper at end of the day.

Unload at half speed.

Possible Modifications

- 1) New knife and new guards
- 2) Narrow intake on header 6 - 8 inches either side
- 3) Put matching sprockets on feeder and beater – ie corn sprockets (Ask Dauphin CIH dealer Miller Farm Equipment as per below.)
 - a. Strip beater bar, grind off bolts and any imperfections.
 - b. Or, Reverse beater bars – so “L” faces inward.
- 4) Extend hydraulics by about 1 foot to be able to raise header higher for taller varieties
- 5) Shield any exposed bearings
- 6) Puckboard underneath combine to reduce fibre catching
- 7) Tie in cables close to machine (because fibre can catch on anything)
- 1) Drop knives out of chopper, or drop chopper.



For IH Axial Flow combines there is a kit (designed by long time hemp grower Joe Fedorowich) which greatly increases harvesting efficiency for hemp crops. This kit fits over the front on the rotor, replaces the elephant ears, bearing, and adds a paddle, smoothing out feeding, reducing pounding and fibre wrapping and also reduces overall maintenance costs. The kit costs approximately \$2750+, with parts exchange, and possibly some other upgrades may be required. Contact Warren Cowling at 1-204-638-5558 at Miller Farm Equipment in Dauphin MB for more details.

Some examples of setting used by producers in 2005 for other combines

<u>Variety</u>	<u>H2O</u>	<u>Model</u>	<u>Modifications</u>	<u>Cyl. RPM</u>	<u>Concave</u>	<u>Fan</u>	<u>Sieve</u>
USO 31	25%	860MF	Some -Note 1	800	½ open	low	front ½ open, back 0 clearance
Finola	12%	CR 960 NH	No -Note 2	800	1.1/4"		
Finola	9~12%	NH TR95	No-Note 3	720	9-10	580	Chaffer 3/8-1/2 Sieve 1/8-1/4
Finola	14%	TX-66 & CX-880	Yes-Note 4	650	3/4"	480	Shoe 1/4"

NOTE 1: retimed feeder house paddles / fibre wrapping on feeder house & cylinder / no chopper / height 8 ft

NOTE 2: some wrapping on rear beater / checking each hr / as grain dried from 12.5% to 11.5% slowed from

3\mph to 1 mph! Advise starting at 16% - sharp cutting bar. No modifications

NOTE 3: Finola SWATHED. Best window 10.5 to 12.5% - up to 18% OK. Minor wrapping on Redekop Straw Chaff, and also on feeder chain shafts when moisture below 10%.

NOTE 4: Installed canvas belt modification on feeder chain for TX-66

All above were straight cut except NH TR 95/Note 3 which was swathed Finola