Potential Benefits of Functional Foods and Nutraceuticals to Reduce the Risk and Costs of Diseases in Canada

Disclaimer
Information contained in this report consists of opinions expressed by the author; consequently, the views expressed herein are those of the originators and do not necessarily represent the opinions of the department or the government of Canada. The Government of Canada and its employees, servants or agents make no representations or warranties as to the accuracy or completeness of the information contained in this report. Parties who rely on the information do so at their own risk.

(B.J. Holub, February/2002)
Revised version: May 28/02
Potential Benefits of Functional Foods and Nutraceuticals to Reduce the Risk and Costs of Diseases in Canada

I  Executive Summary (p. 3-22)

II  Introduction and Background (p. 23-26)

III  Prevalence and Costs of Diet-Related Risk Factors and Diseases in Canada (p. 27-30)
   i)  Prevalence of Disease Burden, Risk Factors, and Diet-Related Diseases in Canada
   ii) Costs of Diet-Related Risk Factors and Diseases in Canada

IV  Evidence for Dietary Factors and Nutraceuticals/Functional Foods in Risk Factor Modification, Prevention, and Management of Disease (p. 31-36)

V  Rationale for the Potential for Functional Foods containing Natural Nutraceutical Components to Significantly Reduce the Prevalence of Chronic Diseases, Predisposing Risk Factors, and Associated Conditions in Canada as well as Lowering Corresponding Health Care Costs (p. 37-42)

VI  Attitudes of Public and Health Professionals to Functional Foods and Nutraceuticals (p. 43-45)

VII  Estimates of Reductions in Health Care Costs from Introduction of Functional Foods containing Natural Nutraceuticals in Canada (p. 46-50)

VIII  Policies and Health Claims for Functional Foods and Nutraceuticals in other Global Jurisdictions (p. 51-52)

IX  Global Commercial Activity in Functional Foods and Nutraceuticals (p. 53-54)

X  Research Issues regarding Functional Foods and Nutraceuticals – Past, Present and Future Needs (p. 55-56)

XI  Summary of Characteristics of a Successful Functional Food (p. 57)

XII  Methodology (p. 58)

XIII  Concluding Statements and Recommendations (p. 59-60)

XIV  Appendix (References plus other Supplementary Information)
Potential Benefits of Functional Foods and Nutraceuticals to Reduce the Risk and Costs of Diseases in Canada

Executive Summary

i Introduction
ii Definitions
iii Lifestyle-related disorders
iv Health expenditures in Canada
v Disease and disorders related to diet
vi Rational for functional foods
vii The ‘preventive’ health-care model using functional foods
viii Savings in health-care costs
ix A Canadian strategy
x Shift of agri-food sectors from commodity to value-added perspective
xi Functional foods and status in other countries
xii Health claims for functional foods
xiii Shift in public policy
xiv Research funding
xv Educational programs
xvi Concluding statements and recommendations
xvii Related references
i Introduction

Functional foods and nutraceuticals offer the opportunities for the agri-food sectors in Canada to become the ‘pharmacy for disease prevention’ as the pharmaceutical industry represents the pharmacy for disease management.

The purpose of this project is to:

- delineate potential and actual reduction of disease, and improvement in markers of health that can be attributed to functional foods and nutraceuticals;
- determine the magnitude of savings in health care costs possible from increased consumption of specific functional foods and nutraceuticals;
- evaluate the proportion and amount of the health care costs associated with diet related disease;
- estimate possible and likely reduction in diseases, and costs associated with those diseases, that improved diet might achieve;
- identify specific categories of population for who such diet improvements is especially important; and
- increase the number of people who perceive that research in the area of functional foods and nutraceuticals is important

ii Definitions

‘Functional foods’ and ‘nutraceuticals’ can be defined as follows by Health Canada (1):

A ‘functional food’ is similar in appearance to, or may be, a conventional food, is consumed as part of a usual diet, and is demonstrated to have physiological benefits and/or reduce the risk of chronic disease beyond basic nutritional functions (Health Canada).

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

The above definitions for nutraceuticals and functional foods, while helpful, fail to appreciate and allow for the important roles that these can also play in retarding
disease progression, enhancing disease management, and offering effective risk factor modification in those with existing disease (as most Canadians have by their fifties).

Functional foods contain sufficient levels of natural extracts, dried powders, concentrates or purified natural nutraceutical ingredients which are isolated from natural food sources (or are known nutrients) which have a long history of being consumed as dietary components in different sectors of the world for decades (or generations) and which demonstrate health benefits including favourable modification of disease risk factors, prevention of disease, delay of disease onset, retardation of disease progression, as well as applications in disease/medical management in those who have pre-existing disease/disorders. The levels of intake of such nutraceutical ingredients are often higher than those consumed in a typical Canadian diet yet are within the range considered appropriate for general safety. In contrast to pharmaceutical agents (which represent novel and foreign chemicals to the human body when consumed), the human body has been exposed to nutraceutical components as dietary components for extended time periods in various jurisdictions without any significant evidence of notable untoward effects which may cause significant health risks.

iii Lifestyle-related disorders

Lifestyle-related chronic disorders (cardiovascular diseases, type 2 diabetes, many cancers, other) are major components of our present and mounting health care expenditures (2-17). This trend is expected to continue as our population ages. Canada is also facing an uncontrolled epidemic of diabetes (lifestyle-related type 2) which increases the prevalence and severity of premature cardiovascular disease, kidney failure, blindness, and gangrene of the legs. Diabetes is a common, growing, serious, costly, and potentially preventable public health problem in Canada. The prevalence of diabetes in our younger population (0 - 44 yr) sectors has risen by approximately 30% in the past 15 years; age-standardized diabetes prevalence rates amongst Aboriginal peoples being triple those found in the general population (18-20). By the time they reach the 55 – 64 yr age bracket, 50% of Canadian men and women will have developed one or more types of cardiovascular disease (21-23). Approximately 42% of men and 36% of women will develop some form of cancer in their lifetime with two-thirds of these dying from their disease (24,25). Cardiovascular disease and stroke (heart disease and stroke) continue to represent the leading cause of premature death in Canada followed by cancer. Approximately 50% of Canadians over the age of 30 have official ‘risk’ levels of circulating cholesterol with approximately 20% having ‘risk’ levels of blood triglyceride based on the ‘medical model’ for establishing such official cut-offs (26). In the case of blood pressures, 20% of Canadians (age 30 and over) are hypertensive with respect to systolic blood pressure using the ‘medical model’ cut-off of 140 mm mercury for hypertension.

iv Health expenditures in Canada
Total health expenditures in Canada are approximately $100 billion annually which is up 7% from the previous year (2,3,27). This expenditure represents approximately 10% of Canada’s gross domestic product being spent on health care. Health expenditures for seniors (age 65+) represented 42.7% of total health expenditures ($11,000 per capita) while they accounted for 12.5% of the total population. Expenditures for pharmaceutical drugs were second only to hospital costs and surpassed all other categories including physician costs (37-30). These record expenditures represent approximately $15 billion annually of which $12 billion is for prescribed drugs thereby representing one of the fastest growing categories of expenditure in both the public and private sectors. Provincial and Territorial drug expenditures in the year 2000 were up 82.3% from the 1990 level while those in the private sector were up 87.8%. It has been estimated (based on official clinical ‘cut-offs’ for blood cholesterol and triglyceride management) that 1-2 million Canadian adults should be receiving lipid-lowering drug treatment at a cost approaching $2-3 billion/yr (26). For the elderly, cholesterol-lowering medication is number two in prescription drug sales. Blood pressure-lowering drugs are the single most prescribed medication group accounting for over $1 billion sales in Canada annually. This surge in prescription drug expenditures is expected to continue now that massive advertising (TV, magazine, print, radio, etc.) directly to consumers is rampant by encouraging them to contact their doctor to provide various costly pharmaceutical agents thereby further stressing the health care costs for pharmaceutical agents. The previous approaches of leaving initiation of prescription drug therapy to the decision of the medical practitioner has now moved into the hands of the consumer as fueled by mass-marketing of such pharmaceutical agents directed to the consumer.

Disease and disorders related to diet

The proportion of disease onset attributable to diet has been estimated to be approximately 40 –50% for cardiovascular disorders (cardiovascular disease including risk factors – blood cholesterol, blood triglyceride, hypertension, others) and diabetes with 35-50% of all cancers being directly related to dietary factors (including colo-rectal, prostate, and breast cancers) (23,27,31-33). Approximately 20% of osteoporosis is diet-related (34,35). As well, the typical Western-style vs. the prudent diet (Mediterranean-type diet) can significantly alter the course of these chronic disorders although most people, despite dietary guidelines and recommendations from Health Canada and other professional groups, still adhere to the typical Western-style diet for various reasons including taste, convenience, busy lifestyles, etc (32, 36-42). Furthermore, most individuals continue to adhere to such chronic disease-promoting diets despite their recognition of health risks associated with such dietary patterns. In addition to playing a role in premature chronic disease appearance, dietary/nutritional components play a role in disease progression, morbidity (associated problems), and mortality (43-50). Functional foods containing efficacious and safe nutraceutical components can dramatically reduce the prevalence of chronic disease in Canada (cardiovascular disease, type diabetes, various cancers, etc) and provide dramatic savings in health care costs without overall dietary changes (31,32,51-66). These benefits (both personal and
financial) can be readily provided by the institution of functional foods in the marketplace. The Canadian public is suffering from premature chronic disease incidence and suffering as well as with excessive health care costs because functional foods/nutraceuticals as part of a primary agri-food approach in disease prevention/management have not been available to the Canadian public. As well, we have depended upon the ‘medical model’ which is usually initiated later in the person’s life when medical conditions have already developed and management with costly pharmaceutical agents and other medical strategies is the focus without offering hope of disease reversal. The scientific literature is overflowing with evidence-based information from numerous human/clinical trials to show the dramatic potential of functional foods/nutraceuticals to play a major role in chronic disease prevention and management. Essentially none of this literature and information is yet being directly applied (through product availability, health claims, marketplace availability, education on such products, etc.) to the Canadian public.

vi Rational for functional foods

There are numerous rationale for the immediate unleashing of bona-fide functional foods with appropriate health claims into the health care system in addition to a tremendous opportunity for disease prevention, risk factor management, and overall reduction in health care costs. In the case of cardiovascular disease development, people with more favourable cardiovascular risk profiles in their younger age (blood cholesterol, blood triglyceride, blood pressure) have much lower disease prevalence and associated medical costs in their older ages (67-69). Lower health care costs are associated with reduced prevalence of disease later in life and greater longevity. The current ‘medical model’ does not modify these critical risk factors early in the lives of Canadians. A significant portion of Canadians have ‘moderately’ elevated risk factors (cholesterol, triglyceride, blood pressure, others) which are not considered to be ‘at risk’ or of ‘clinical significance’ by the ‘official medical model’ (26,70). However, the official cut-offs in the medical model are much too permissive and fail to control for the moderate elevations in risk factors which the science clearly indicates are major risks for premature cardiovascular disease when allowed to go uncontrolled for 2-3 decades of life (21,39,67). These moderate elevations (considered not to be clinically significant) are indeed significant based on the published science showing that an individual in their early 20’s with blood cholesterol levels of 4.1 mmol/L are at much lower risk of developing heart disease later in life than those at or near the ‘official’ cut-off of 4.7 mmol/L (67). Furthermore, young population members with blood triglyceride levels of 0.80-0.94 mmol/L are at considerably lower risk for myocardial infarctions and coronary heart disease than those who meet the ‘official’ cut-off of 2.3 mmol/L (for young and old alike) (26,54,68). Similarly, blood pressures approaching 120/80 are highly preferred for disease prevention even though they are well below the ‘official’ cut-off of 140/90. In other words, the ‘medical model’ and corresponding cut-offs for risk of cardiovascular disease (cholesterol, triglyceride, blood pressures, others) do an injustice to the ‘preventive model’. The ‘preventive model’ requires that functional foods with moderate cholesterol-lowering and triglyceride-lowering and blood pressure-lowering, etc. features
be instituted into the health care system so that our young people (in their early 20s) will not progress in their risk factors and develop premature cardiovascular disease 20-30 years later.

vii The ‘preventive’ health-care model using functional foods

With the increased attention being paid to health and wellness by the general public, a preventative model (disease prevention via the early introduction of functional foods) now has the potential to provide some much needed relief to a heavily burdened health care system.

The current health care system offers medical intervention and dietary therapy to some individuals in an attempt to control their cardiovascular risk factors. However, reviews of numerous health care strategies employing dietitians for blood cholesterol control (via conventional dietary advice) have shown the net reduction in blood cholesterol to be only 0-4% after one year of interventions (71). A large portion of the Canadian population (including numerous young people) require blood cholesterol-lowering and triglyceride-lowering of 5-15% which will not be provided by conventional dietary advice and yet these are not large enough to warrant pharmaceutical/clinical interventions (which typically lower these parameters by 20-30%). The preventive model using functional foods would easily reduce these conventional risk factors by 5-15% and maintain such over a period of 20-30 years so most individuals would never develop disease or elevated levels requiring costly pharmaceutical interventions.

Although the Canadian public have long been advised by Health Canada to eat 5-10 servings of fruits and vegetables per day for health and cancer prevention, the majority of Canadian adults do not do so despite their acceptance that it would be a desirable practice (41). Furthermore, less than 15% of our children in grade schools eat sufficient servings of fruits and vegetables rich in natural antioxidants (phytochemicals), fibres, folic acid (an important B vitamin), etc (42). The functional food approach (51,52,58) allows for the removal of water (by freeze drying and other techniques) from fruits and vegetables (which are approximately 90% water) such that the dried powders (rich in antioxidants and cancer-preventing nutraceutical components) can be readily incorporated into the foods that our population and young people will and do eat (breads, beverages, various processed and fast foods, etc.). Thus, without compromising taste or shifting from the Western-style diet (which is infixed in our culture and may take decades to change), the cancer-preventing properties of such nutraceutical ingredients can be delivered to the Canadian public with reductions in cancer prevalence and associated medical cost. The public have clearly indicated a strong preference for preventing disease by the consumption of natural food-derived components which do not require shifts away from their current food preferences which are based on taste, convenience, reasonable prices, etc.
Savings in health-care costs

Functional foods containing efficacious natural nutraceutical components can serve a major role in reducing current health care costs associated with medical management (in addition to their disease ‘preventing’ effects) as detailed in the following report and attached appendix. As an example, it is comfortably estimated that 90% of the current usage of blood cholesterol-lowering and blood triglyceride-lowering prescription drugs could be eliminated from our health care system and replaced by less expensive nutraceutical ingredients (in functional foods) as alternative and similarly effective therapeutic options. They would find favour with consumers who would prefer to avoid the use of synthetic chemicals as medical agents if possible as evidenced by the ‘drop-out’ rates for lipid-lowering drugs of 40-65% within one year (72,73). The replacement of current cholesterol-lowering drugs by red yeast rice (a traditional Chinese health food) or a natural alcohol nutraceutical (from sugar cane wax), which each lower blood cholesterol levels by 20-25%, has the potential to save $2 billion/yr in drug treatment costs. Furthermore, omega-3 fatty acids from fish oil in functional foods can lower blood triglyceride levels (a risk factor for heart disease/heart attacks) as effectively (25-30%) as patented/imported pharmaceutical drugs (e.g., gemfibrozil) at one-fifth the cost thereby offering a potential savings of $2.72 billion/yr in medical management costs. Other cost savings arise from numerous functional foods which can either serve as alternative (and safe) therapeutics for several medical management applications and well as greatly improving the outcomes in patients who receive nutraceutical/functional foods as additional therapies on top of conventional medical treatment (e.g., post-heart attack, arthritis, certain psychiatric disorders, others).

The minimal savings in direct health case expenditures from the introduction of efficacious functional foods (containing fibres, plant sterols, omega-3 fatty acids from fish oils, etc.) into the public marketplace with associated health claims for the prevention of chronic diseases are estimated to be $19.5 billion (B)/yr ($6 B + $4 B + $8 B + $1 B + $0.5 B). These savings have been estimated from the information as provided in detail in the full report and appendix (attached herein). This ‘preventive’ total is partly accounted for by savings ($6 billion/yr) due to the reduced incidence of cardiovascular diseases/disorders via early control (at costs of 7-10 cents/day) of moderate elevations in well-established risk factors (blood cholesterol, blood triglyceride, blood pressure). The prevention of type 2 diabetes accounts for a savings of $4 billion in health costs/yr with additional savings coming from the nutraceutical/functional food-mediated reductions in total cancers ($8 billion/yr), kidney disorders ($1 billion/yr), osteoporosis ($500 million/yr). A 30-63% reduction in the annual incidence of colo-rectal and prostate cancer can be expected to be realized at a daily nutraceutical cost of 0.3 to 7 cents/day with savings in health care expenditures surpassing $1 billion/yr. The total estimated ‘preventive’ cost savings ($19.5 billion/yr) are considered minimal since numerous other nutraceutical/functional foods and risk factors which they favourably attenuate (e.g., non-conventional and important risk factors for cardiovascular disease such as thrombogenic (blood platelet reactivity), blood vessel dysfunctioning, heart arrhythmias, blood
homocysteine elevations, etc.) as well as other conditions which can be prevented have not been included.

ix A Canadian strategy

Canada needs to immediately formalize and initiate a strategy for the production of functional foods containing natural nutraceutical ingredients for disease prevention (including delaying disease onset and retarding disease progression) and disease management as well as risk factor control into the marketplace with associated and responsible health claims. Each month of delay in this overdue process is denying Canadians of chronic disease prevention while missing out on health care savings of at least $2 billion. The distinction between disease prevention and disease management should be abolished since most nutraceuticals that enhance disease management are also effective in disease prevention; the differences often pertain to the levels of the ingredients that may be desirable (i.e., oftentimes lower in disease-preventing vs. disease-managing foods). It is also noteworthy that the minority of Canadians are ‘disease-free’ by the time they reach the age of 50. Very early in life, most young Canadians are already beginning to acquire moderate risk factors for various chronic disorders, which, if allowed to progress over 2-3 decades, will result in overt disease and disorders (including pre-clinical disease).

x Shift of agri-food sectors from commodity to value-added perspective

Functional foods and nutraceuticals offer the opportunities for the agri-food sectors in Canada to become the ‘pharmacy for disease prevention’ as the pharmaceutical industry represents the pharmacy for disease management. The agri-food industry has been heavily criticized by the public and media for the GMO (genetically-engineered) developments; this issue would not apply to functional foods and nutraceuticals and would serve the agri-food sectors very well in being recognized as an ambassador for health in providing food as a vehicle for the delivery of disease-preventing and disease-managing properties. Both plant-derived and animal-derived food products can become major sources and delivery form of functional food components. Plant sources are rich in various phytochemicals (including antioxidants, fibres, and other nutraceutical ingredients) whereas animal-derived food products can be favourably modified to prevent and/or manage disease according to the type of animal feedstuffs used at the farm gate (e.g., feeding flax or fish oil to product omega-3 eggs, meats, etc.). Various plant products can be grown with altered mineral contents in the soils to develop them into very potent disease-preventing functional foods (e.g., selenium-enriched broccoli for cancer prevention, others). The agri-food sectors can move away from a generally ‘commodity-based’ industry (dollars peer bushel and acreage), having difficulty in competing with foreign products based on cheaper labour, more liberal pollution standards, etc., into a value-added functional food-directed industry offering better profit margins and providing for a massive reduction in health care costs. Functional foods can be a boom for the agri-food industry in Canada based on job creation, new product
developments, processing and production plants, penetration into foreign markets, etc. Furthermore, Canada is gifted with having a number of natural products (e.g., fish/fish oils, flaxseed, canola, soy, berries, oats, etc.) which can provide nutraceutical ingredients for food processing and functional food productions. Financial support and government leadership is needed for the agri-food sectors to fully capitalize on the functional food opportunity in terms of research support for nutraceutical processing and product formation, building of functional food production plants, support for marketing and penetration into the domestic and foreign markets. It is somewhat disturbing that Canada is capable of producing these various products yet, in many cases, such products have difficulty penetrating the shelves of our very own country. For example, a popular (imported) U.S. pancake mix is high in bad fats, low in good fats, and low in fibre in contrast to a tasty Canadian product (flax-based pancake mix) which cannot readily penetrate the shelves of the grocery stores in Canada due to financial barriers which our smaller producers cannot overcome alone. Also, there is a ready-to-use scrambled egg product in Canada which, as a functional food, can lower blood triglyceride levels (a risk factor for heart attacks) as effectively as the imported pharmaceutical drug known as gemfibrozil yet physicians in Canada continue to use gemfibrozil as a favourite triglyceride-lowering drug and not our home-grown functional food as an effective alternative. Canada’s health care system (federally and provincially) has to remove barriers which favour imported pharmaceuticals (at high costs) and blocks entry of low cost ‘home-grown’ functional foods into the forefront of our health care system for risk factor control plus disease prevention/management. Medical plans and coverages should offer the option to consumers of the use of evidence-based functional foods in their health care along with monitoring to ensure adequate efficacy.

Public perceptions and health professional’s attitudes, interest, and enthusiasm for the entry of nutraceuticals plus functional foods into the marketplace and health-care system are clearly apparent (28,80-84). They await government leadership on this important and critical opportunity for the service of all Canadians.

Canada should provide expanded funding sources to support ‘home-based’ entrepreneurial activities in the area of nutraceuticals and functional foods and offers many more opportunities for ‘structure-function’ and ‘health claims’ than provided in Canada. Our government needs to expand support for small Canadian companies with leading nutraceutical ingredients and functional foods. For example, Forbes Medi-Tech with plant sterols, Ocean Nutrition Canada with omega-3 fatty acid-containing fish oils, and many others across Canada could become global leaders in the functional food industry. Approval, support, and enthusiasm for ‘home-grown’ products (by our government) can enhance market opportunities and acceptance globally.

Functional foods and status in other countries

Japan and other countries have long had products in the marketplace under the category of functional foods and government policies that regulate them and the associated health claims. The legal status of functional foods in Japan translates into
FOSHU (Foods for Specialized Health Use) under the Nutrition Improvement Law of 1991 enacted by the Japanese Ministry of Health and Welfare (now renamed as Ministry of Health, Labour and Welfare). They have legislated the labelling of health claims of five groups of functional foods including foods that may improve specific health conditions (FOSHU). Clinically-proven products have been launched into the marketplace by various companies and many more companies are encouraged and plan on participating in the future because of the leadership and ‘friendly environment’ provided for such opportunities to the corporate sector (both small and large businesses) by the Japanese government. In view of the ongoing and future explosion in functional foods and the accelerated activity of multinational food companies worldwide in developing products and divisions dedicated to functional foods for disease prevention/management, it is of paramount importance for Canada to establish a research and business priority for funding agri-food activities in functional foods and nutraceuticals (production processed and facilities, support of businesses/markets, human trials on product-specific efficacy, etc.) so that Canada can be a major international player in this arena rather than a spectator importing such products from foreign countries with further internally-missed job/economic opportunities at home.

Health claims for functional foods

The establishment (legislation) for the labelling of health claims on brand-specific brand-name products at point of purchase and the allowance for responsible advertising and marketing of these products is essential if the massive potential reductions in chronic diseases and health care costs are to be provided for the Canadian public. Since the nutraceutical ingredients are from natural sources (usually long-consumed in the form of natural foods by various populations over generations), the health risks of nutraceutical ingredients are extremely small (and below that for many of the foods we now consume) in contrast to the significant prevalence of side effects observed in medical management with pharmaceutical agents, etc. Brand-specific health claims should require that specific products which are to be forwarded for health claim consideration have controlled human studies (nutritional/clinical trials) conducted to ensure that a reasonable serving size(s) of such products does provide a significant health effect (e.g., blood cholesterol-lowering, blood triglyceride-lowering, etc.) in order to qualify for such claims. Product-specific (brand-specific) human trials conducted within Canadian university settings are highly recommended as evidence for potential health claims for many reasons – they are not unreasonably expensive, each formulated product is a different food matrix which might influence bioavailability, efficacy, etc. of the functional nutraceuticals plus other issues. It is expected that many of these studies will require controlled experiments of a few weeks – few months in duration. It is expected that adverse effects on other risk factors would not be exhibited. Health claims need to cover numerous risk factors and disorders with respect to the areas of disease prevention and management without restriction to either one. The government should be encouraged to form a standing/rotating committee to consider health claim applications (before and after the necessary research has been conducted on specific products in human trials) since the government will normally lack sufficient expertise across the different nutraceutical/functional food and health
categories to appropriately evaluate such functional food-related health claims. Such a standing committee would consist of academics (with some input from medical and public (consumer) representation) from across Canada with expertise in nutrition/functional foods from a research and clinical perspective in relation to disease prevention/management and associated risk factors. Such a committee could also advise on the allowable levels of given nutraceutical components per food serving size to ensure safety and reasonable health claims based on efficacy. The standards which apply to the pharmaceutical industry (which involves the introduction of foreign chemicals into the human body) should not be applied to functional foods and nutraceutical-related health claims so as not to deny, or unreasonably delay, or place unwarranted restrictions on the delivery of functional foods and nutraceuticals into the Canadian health care system.

**xiii Shift in public policy**

The cost-effective and impact-effective strategy of using functional foods within the new ‘preventive model’ rather than the traditional ‘medical model’ requires new approaches (strategies, educational, diagnostic, professional) in the health care system and public policy. This ‘preventive strategy’ requires early and prolonged (years – few decades) control of moderately-elevated risk factors in otherwise healthy individuals as opposed to the ‘medical model’ which applies intensive therapy during latent stages for shorter time intervals in unhealthy people. Once established, most chronic diseases cannot be readily reversed. The major gains in reducing health care costs in human morbidity (suffering) and mortality will be derived by the ‘preventive model’. For cost-effectiveness, it is not appropriate to utilize highly trained physicians in the process of functional foods and disease prevention in healthy individuals. Physicians’ expertise and resources should be maintained for medical management and higher risk/disease individuals. The measurement, interpretation, and functional food use in public health care (normalization of abnormal risk factors such as cholesterol, triglyceride, blood pressure when moderately elevated) can readily be effected by the introduction of B.Sc. (life sciences/nutritional/nutraceutical majors) into our primary health care system as part of the preventive strategy. These individuals can readily be trained to interpret risk factor measures in healthy individuals, to recommend/utilize available functional food and nutraceuticals in a responsible manner to the public, and to monitor for appropriate improvement in the various risk factors at a fraction of the cost that would require a trained physician to so do. We are wasting and frustrating much of the highly educated personnel resources (e.g., B.Sc. grads in the life sciences) who want to enter the health care system in a responsible manner but soon realize that such an opportunity is primarily restricted to physicians and a few other select professional groups to which the vast majority of eager young university graduates compete for an insufficient number of positions. This ‘new professional’ dedicated to functional foods for risk factor management of healthy individuals and disease prevention would be a highly efficient utilization of our resources. Any considerably abnormal diagnostic results (e.g., risk factors) needing medical attention could immediately/readily be translated to a physician for referral and more aggressive management as required. This ‘new preventive professional’ using functional foods as their vehicles for health care would also utilize
more efficient, and widely-accepted measures of conventional risk factors. For example, there is equipment costing approximately $3000 which allows for accurate finger-prick measures of total cholesterol, LDL-cholesterol, HDL-cholesterol, triglyceride, glucose and other risk factors for cardiovascular disease and diabetes within 5 minutes of finger prick for a few drops of blood. Within minutes of giving such a small finger prick blood sample, the individual can be counseled immediately by this ‘new health professional’ in the appropriate use of functional foods and nutraceuticals for risk factor correction and subsequent follow up within a few weeks/months to ensure proper reduction in the various risk factors. The majority of the public sector can be expected to be fully appreciative of instantaneous results from such finger prick technology (at low cost to the health care system) and immediate on-site advice on correcting these factors with follow up in a few weeks to ensure correction of any observed moderate elevations. Such a strategy for ‘preventive’ health would be a win-win situation for consumers, for the public, and for young university graduates in the life sciences wishing to enter this new profession and the overall health care system.

xiv  Research funding

The traditional health funding agency in Canada (Medical Research Council of Canada) allocated only 0.82% of its research grant expenditures to nutrition based on its report for 1999-2000 (85). Almost none of this meager funding was devoted to nutraceuticals and functional foods for the prevention and management of human disease despite numerous globally-recognized experts in this field in academic and government institutions. The MRC funding for drug-related research (usually on patented drugs) is numerous-fold greater than that for nutrition (including functional foods) for disease prevention and management. Various countries (e.g., Italy’s huge support for human healthy nutraceuticals (polyphenols) in olive oil by academics and their agri-food sectors) understand how such research greatly benefits foreign market opportunities for their ‘home-produced’ foods. A major priority for research funding by the government (ranging from the nutraceutical components in plant, food, and animal produce through isolation, processing, production, marketing) is desperately needed. Agri-foods/products must become the ‘pharmacy’ for disease prevention and management via the ‘preventive model’ as patented drugs become the ‘pharmacy for disease treatment in the ‘medical model’.

xv  Educational programs

Educational programs and instruction are desperately needed on functional foods and nutraceuticals as therapeutic agents in various settings. For example, most physicians are interested in using such strategies in medical management (based on their potential to serve as alternative vehicles for medical management and also for enhancing conventional medical care when used on top of conventional medical strategies such as pharmaceutical agents). However, physicians, dietitians, naturopaths, chiropractors, and various other health professional groups are lacking in formal instruction in functional
food and nutraceutical therapeutics and therefore unqualified/untrained to provide such services. Certain universities in Canada (e.g., University of Guelph, others) have established formal academic programs at the undergraduate and graduate levels in the field of nutraceuticals and functional foods as therapeutic agents in disease prevention as well as medical management based on known products, dose, duration, and demonstrated evidence-based effects.

Immediate and long overdue government leadership is needed for the wide and responsible introduction of functional foods and nutraceuticals into the Canadian market place thereby reducing the risk, incidence, onset, and progression of various chronic disorders and as well enhancing disease management with major reductions (several $ billion/yr) in our health care costs. The public, food industry, academics and health professionals are all enthusiastically awaiting and anticipating such government leadership in functional foods.

xvi Concluding statements and recommendations

1. Diet-related chronic diseases and disorders (cardiovascular diseases, type 2 diabetes, many cancers, other) are of major and increasing prevalence in our population. These contribute to our present and accelerating health care expenditures with this trend continuing as our population ages.

2. Canadians have been denied access to functional foods with natural nutraceutical components for the prevention, delay of onset, retardation of disease, and disease management (including risk factor modification) despite overwhelming evidence-based published human studies showing their dramatic ability to be highly effective in these regards and to dramatically reduce health care costs.

3. The public have indicated their general unwillingness to significantly change the ‘western-style’ diet as now consumed. Functional foods and nutraceuticals can dramatically reduce disease incidence, severity, progression, etc. with or without any significant changes in overall dietary consumption patterns.

4. Health care costs in Canada can be reduced by a minimum of $20 billion/yr by early risk factor management and the accompanying disease prevention /retardation along with an additional minimal $10 billion savings for disease management applications.

5. The agri-food industry/sector needs extensive government support if it intends to be an international participant at the forefront of producing functional foods for disease prevention and management (along with the economic benefits to Canada that can be derived from such a prioritizing of resources, research, job creation, marketing opportunities, use of our natural agricultural resources, etc.). The gross under-funding of research in the area of functional foods for disease prevention in this country is in striking contrast to the past and previous research allocations.
given to drug-related research (usually on patented pharmaceuticals from non-Canadian sources). Canada is lagging well behind other countries in this important area.

6. A ‘preventive model’ using functional foods and not the regular ‘medical model’ needs to be established as soon as possible using a new breed of ‘preventive health specialists’ from our vast pool of eager, young, and underemployed B.Sc. graduates in life sciences from across Canada. The preventive model should focus on early detection and functional food-based control of ‘moderate’ risk factors in our younger population using the ‘preventive’ specialists without a dependency on physicians.

7. Education and training of various health specialists and professionals as well as the public in functional foods and natural nutraceuticals for the prevention and management of disease is also needed.

8. The public, food industry, academic plus government scientists, and various health specialists/professionals have indicated their enthusiastic interest and support for the early and broad-based entry of functional foods with appropriate health claims into the Canadian marketplace. Functional foods need to become the ‘pharmacy’ for disease prevention as well as management.

9. Government leadership in launching functional foods with natural nutraceutical components is desperately needed in Canada as soon as possible.
Related references


17. Salize HJ. [Costs of schizophrenia - what we know (not)?] Psychiatr Prax 2001 Jul;28 Suppl 1:S21-8

18. Canadian Diabetes Association. About diabetes www.diabetes.ca/about_diabetes 02/02/02

19. CDC Centers for Disease Control and Prevention, National Center for Health Statistics, CDC Diabetes Surveillance. 1999. www.cdc.gov/diabetes/statistics 02/02/02


26. Canadian Heart Health Surveys: A profile of cardiovascular risk. CMAJ, June 1, 1992


49. Martin RH. The role of nutrition and diet in rheumatoid arthritis. Proc Nutr Soc 1998;57(2):231-4


www.promarinternational.co


82. Greger JL. Dietary supplement use: consumer characteristics and interests. J Nutr 2001;131:S1339-43


II Introduction and Background

Health-care costs in Canada have increased markedly during the past several years. This trend is expected to further rise towards dramatic levels in the coming decade due to surges in health-care deliverables, lifestyle-related chronic disorders (cardiovascular diseases, diabetes, cancer, depression, etc.), numbers of elderly in the population, plus other factors. These costs include a plethora of approaches (pharmaceutical, risk-factor management, diagnostic, surgical, etc.) used to target the prevention, management, and treatment of chronic disorders and medical conditions. The wide availability and affordability of quality health care in Canada is highly cherished and demanded by the Canadian public. Furthermore, our current and anticipated (future) health-care costs and limited resources (personnel, infrastructure, expendables, etc.) are aimed at providing ‘satisfactory’ health-care in Canada but do and will fall far short of ‘optimal’ health-care unless dramatic changes are made.

Lifestyle-related chronic disorders (cardiovascular diseases, type 2 diabetes, many cancers, other) are major components of our present and mounting health-care expenditures. The aforementioned medical conditions account for the majority of the widespread and often early morbidity (physical and mental suffering, loss of quality of life including functional impairments, loss of independence, unemployability, poverty, psychiatric disorders, family and social discord, loss of self-esteem and hope, etc.) and subsequent mortality in Canada. The large body of scientific, medical, lifestyle, nutritional, and public health evidence as published in leading peer-reviewed journals provides overwhelming proof and support for lifestyle (‘modifiable’ or controllable) factors playing a predominant role in the development of chronic disorders and predisposing risk factors. The ‘modifiable’ lifestyle factors and personal choices include diet/nutrition, exercise, smoking and other addictive activities plus many other controllable factors which impinge upon health and disease.

Diet plays a major role in health and/or in promoting the development of chronic ‘lifestyle’ diseases and predisposing risk factors which plague Canadian society today. The types and amounts of foods consumed determine the ‘health risks’ associated with the diet as do the specific nutritional components (nutrients, non-nutrients) which are present therein. The multiple factors which can markedly influence the health ‘quality’ of the Canadian diet includes personal preferences including taste, price, marketing (including brand name establishment), convenience, perceived or actual nutritional value and health/disease implications, government-controlled food labelling, availability, etc.

The over-consumption of unhealthy diets/foods plus the under-consumption of health/protective nutritional components is an important contributor to the fact that the majority of Canadian adults acquire one or more risk factors for premature cardiovascular disease early in life. These tend to worsen with time and accumulate with other risk factors to culminate in chronic/overt disease needing costly medical interventions and therapeutics. Diabetes (type 2) plus lifestyle-related glucose-intolerance and associated cardiovascular disease are increasing at epidemic rates (both in the general population and among our native peoples). Young people (in their teens) are exhibiting alarmingly
high rates of diet-related fatty acid streaks (pre-clinical atherosclerosis) reflective of diet-induced elevations in blood cholesterol and other risk factors for cardiovascular disease. Rates of myocardial infarctions (heart attacks), diabetes, various types of cancers (gastrointestinal, breast, prostate) are dramatically higher amongst middle-aged Canadians as compared to corresponding age- and gender-matched populations in other countries where diets with markedly different compositions are consumed. Because of the poor nutritional quality of the diet consumed by lactating women, most breastfed infants in Canada are left consuming a ‘natural’ diet (breast milk) which has high levels of ‘bad’ fats (‘trans’ fatty acids) and insufficient levels of the physiologically-essential omega-3 fatty acid (known as DHA, docosahexaenoic acid) which is needed for optimal brain functioning and visual acuity. Furthermore, all infant formulae in Canada are devoid of this important nutrient known as DHA. Throughout the life-span, dietary modification is a critical lifestyle component for health as well as the prevention, delay/retardation, management, and mitigation (including reversal) of the major chronic diseases which eventually (sooner of later) afflict the vast majority of Canadians. The emphasis in our health-care system and costly expenditures in Canada has been directed towards the management of existing cardiovascular disease and associated risk factors later in life and not early modification of risk factors in ‘healthy’ individuals and disease prevention. Furthermore, the current ‘medical model’ is not a cost-effective model for controlling the excessive rates of lifestyle-related chronic diseases that exist in Canada today and which are predicted to climb steadily in the coming decade.

Despite the noble attempts and large expenditures of Health Canada (via Canada’s Food Guide, guidelines for healthy eating, etc) to promote altered food selections and eating patterns for health and disease prevention, the extremely high prevalence of non-compliance by the public to these recommendations is a major public health problem. The ‘nutrition gap’ between what the public should be eating for health and disease prevention plus management and their actual nutrient intakes are ever-widening. While the public has experienced much interest in consuming ‘healthier’ and more nutritious foods, the ever-appealing ‘taste’ factor in various processed and fast foods is a predominant barrier which most fail to overcome. The ‘nutrition gap’ is further compounded by issues of convenience in a society stressed by time.

Why the interest in ‘Nutraceuticals’ and ‘Functional Foods’? As will be elaborated upon in the following pages, enthusiastic government leadership and support for the development, production, widespread introduction, and use of valid (bona-fide) nutraceuticals and functional foods (along with valid and balanced ‘health claims’) can be expected to dramatically reduce our health-care costs by offering a new strategy (a ‘preventive strategy’) in Canada for the prevention of chronic diseases as well as aiding their management. Furthermore, the global opportunities for a nutraceutical and functional food industry based in Canada are immense in terms of job creation, export markets, etc. If Canada does not act quickly to establish itself in this area, we will be a ‘spectator’ and not a ‘player’ as we import these products in increasing numbers into Canada from other countries and non-Canadian based multi-national companies. While the public is clearly concerned and suspicious of ‘bio-engineered’ and ‘genetically-modified organisms’ (GMO), consumers and health professionals alike can be expected
to be enthusiastically supportive of nutraceuticals and functional foods offering safe and efficacious low-cost health care and disease prevention. Genetically-engineered (modified) organisms/foods are not considered in the present discussion of functional foods such that the present report is restricted to GMO-free functional foods and nutraceuticals. Also, non-food derived herbal products are not included in the present report since most of these do not have a history of being consumed in the diet as normal dietary components.

The following working definitions for ‘**Nutraceuticals**’ and ‘**Functional Foods**’ have been released by Health Canada:

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

The term ‘nutraceuticals’ as referred to herein refers to them as ‘healthful’ constituents of foods (natural or processed) with disease-preventing properties which are consumed in ‘food form’ rather than as a supplement (nutraceuticals can also be considered to include dietary or nutritional supplements which are consumed in capsule, tablet, or pill-like form but not in food form). For this report/discussion, the term ‘nutraceutical’ refers to the ‘nutraceutical ingredient’ in a so-called ‘functional food’. Functional foods (containing nutraceutical ingredients) provide complementary nutritional value as part of the whole diet whereas a nutritional or Nutraceutical supplement (capsule/tablet/pill-form) provides no additional nutritional value over and above that of the nutraceutical component.

A **functional food** is similar in appearance to, or may be, a conventional food, is consumed as part of a usual diet, and is demonstrated to have physiological benefits and/or reduce the risk of chronic disease beyond basic nutritional functions (Health Canada).

Thus, functional foods can serve as a nutritional vehicle for the delivery of healthy ‘natural’ nutraceutical ingredients in a food wherein they may or may not normally reside. For example, a nutraceutical ingredient (fraction) may be derived from a ‘healthy’ food source that people should but don’t eat and incorporated into one that they do enjoy eating. Also, nutraceutical ingredients can be readily introduced into functional foods at sufficiently-high levels to ensure their efficacy in disease prevention/management and the modification of important risk factors without risking consumer safety. These levels may be higher than are now normally consumed in the Canadian diet and such intakes are considered effective for health and disease prevention or management at these safe intake levels. In some jurisdictions, the term ‘functional foods’ may be phrases as ‘wellness foods’, ‘preventive foods’, ‘medical foods’, ‘pharma foods’, etc.
The above definitions for nutraceuticals and functional foods, while helpful, fail to appreciate and allow for the important roles that these can also play in retarding disease progression, enhancing disease management, and offering effective risk factor modification in those with existing disease (as most Canadians have by their fifties).

It is important to note that ‘herbal products’ (e.g., St. John’s Wort, Echinacea, etc.) do not come under the umbrella of ‘nutraceuticals’ and ‘functional foods’ and therefore will not be considered herein. Whereas herbal products are generally not constituents of human foods/diets, nutraceuticals are recognized as common constituents of foods/diets which have been consumed by various populations for decades or generations without evidence of any significant untoward effects. Also, the presence of genetically-modified (bio-engineered) organisms/foods (GMO products) are excluded from the functional foods and their natural nutraceutical components as presented and discussed in this report.
III Prevalence and Costs of Diet-Related Diseases in Canada

Canada has a very high prevalence of the major chronic diseases wherein lifestyle in general and diet in particular are known to play a major role. These include cardiovascular disease (CVD) and related disorders, diabetes, certain types of cancers, plus others. Chronic diseases are illnesses or conditions which are not generally considered to be directly transmitted from person to person in contrast to communicable diseases. Although genetics (family history) among other non-dietary factors can contribute to the risk of developing certain chronic diseases over time, dietary/nutritional factors represent a major vehicle influencing disease incidence, progression, morbidity (loss of quality of life) and mortality. In general, chronic diseases last for many years, tend to increase in prevalence and severity with aging, and are often incurable. Such diet-related chronic diseases have their origins early in the lives of numerous young Canadians who progressively develop modifiable risk factors for such diseases (e.g., moderately elevated blood cholesterol and/or triglyceride and/or glucose levels) which are left uncontrolled for years/decades until disease has developed.

i) Prevalence of Disease Burden, Risk Factors, and Diet-Related Diseases in Canada

The proportion of disease onset attributable to diet has been estimated to be 50% for arteriosclerosis, hypertension, stroke, and diabetes; 40% for coronary heart disease, and 20% for osteoporosis. The National Cancer Institute in the U.S. and other groups have estimated that at least 35-50% of all cancers are directly related to dietary factors (incl. the incidence of colonic/rectal, prostate, and breast cancers). They have also estimated that diet plays a role in 80% of cancer deaths (by influencing susceptibility and incidence, progression, metastases, and/or nutritional interactions with medical treatment including chemotherapeutic agents and cachexia).

Specific information on the number of people with chronic diseases in Canada is very incomplete due to the lack of a comprehensive centralized system coupled to the diagnoses and registration of disease events. The information provided herein in abbreviated form is based on Canadian data where available and extrapolation to Canada from U.S. statistics where necessary based on the population differences between the countries (284.8 M in U.S. and 31.1 M in Canada as of 2001). More extensive and detailed information plus references are available in the appendix to this section.

Cardiovascular disease and stroke (heart disease and stroke) continue to represent the leading cause of premature death in Canada followed by cancer. Whereas annual all-cause mortality rate per 100,000 in the Canadian population is approximately 660, the corresponding figures for diseases of the heart and cerebrovascular disease = 221, diabetes = 17, and cancers = 182. Globally, cardiovascular disease contributes to a third of total deaths and is estimated to be the leading cause of death in developing countries by the year 2010. Heart disease has no gender, geographic, or socio-economic barriers. The prevalence of cardiovascular disease, diabetes, and cancer is alarmingly high in the Canadian population. By the time they reach the 55-64 year age bracket, 50% of
Canadian men and women will have developed one or more types of cardiovascular
disease. The number of Canadians aged 12 and over with diabetes (90-95% of which is
lifestyle-related type 2 diabetes) is estimated to be 5-6% of the population with
approximately 40% of these cases being undiagnosed. Furthermore, many more people
(approx. double those with diabetes) exhibit ‘impaired glucose tolerance’ (IGT) which is
the pre-diabetic state or the transition time period progressing past normalcy to overt
diabetes. Approximately 30-55% of individuals (age of 45-55 yr) with IGT can be
expected to progress to overt diabetes within 5 years. Thus, approximately 18% of our
population over the age of 12 years have either IGT or diabetes. Among Aboriginal
peoples, age-standardized diabetes prevalence rates are triple those found in the general
population. The future outlook is rather ominous when consideration is given to the rise
in the prevalence of diabetes in the younger population (0-44 yr) sectors by
approximately 30% in the past 15 years. The complications of type 2 diabetes include
markedly higher rates of accompanying cardiovascular disease (incl. stroke and
hypertension), blindness (leading cause in Canada), kidney disease and failure (requiring
dialysis or transplantation), nervous system damage, gangrene with amputations, and
pregnancy complications. On first diagnosis, diabetics already exhibit a much higher
severity of cardiovascular disease risk factors and a much poorer prognosis both before
and after an acute myocardial infarction (heart attack). A recent report from the
Canadian Heart & Stroke Foundation indicates that the prevalence of type 2 diabetes is
increasing rapidly within the 9-12 year age group which puts them in the “fast lane” for
developing heart disease and stroke by the time they reach 30 years of age.

One-third of the Canadian population aged 35-64 yr is overweight (body mass
index (BMI) > 27) including those who are obese (BMI > 30). Such groups are much
more prone for a greater prevalence of various cardiovascular disease risk factors,
cardiovascular events (heart attacks, etc.), progression to diabetes, and others (incl. a
greater risk for colo-rectal cancer, breast cancer in women, etc.).

Cancer statistics for Canada indicate that 42% of men and 36% of women will
develop some form of cancer in their lifetime with two-thirds of these dying of cancer.
The cancers which have shown a dietary/nutritional relationship (either detrimental or
beneficial) include prostate cancer (affecting 13% of men in their lifetime), breast cancer
(affecting 11% of women in their lifetime), colorectal cancer (affecting 6% of Canadians
in their lifetime), plus other cancers.

Prior to the development of overt chronic diseases (cardiovascular, diabetes,
certain cancers, other conditions), there is often a prolonged period (many years – few
decades); beginning in youth, where one or more risk factors, which predispose to the
disease condition, are left uncontrolled by the current health care system. For example, a
comparison of the desired (target) cutoff points for total blood cholesterol and LDL-
cholesterol (risk for cardiovascular disease) with the distribution found in the population
indicates that approximately 25% of our younger population (18-29 yrs) and 45-50% of
those over the age of 30 yrs have official ‘risk’ levels of circulating cholesterol. It should
also be noted that the ‘official’ clinical cutoffs for risk management based on the clinical
(disease) or ‘medical model’ of health care are not ‘ideal’ cutoffs for a ‘health’ or
preventive model’. The cut-offs in the ‘medical model’ as used in Canada are much too liberal for a ‘preventive’ health strategy. The ‘preventive model’, using evidence-based or ‘optimal’ cutoffs from the literature, would leave approximately 75% of the Canadian population (18 and over in age) at risk (moderate-high) for cardiovascular disease based on their blood cholesterol levels. Similarly, the ‘medical model’ using the official liberal cutoff for blood triglyceride levels (an important risk factor for cardiovascular disease and heart attacks) as used by clinicians in Canada indicates 17% of those over the age of 30 to be at high risk (based on a cut-off of 2.3 mmol/L) with approximately 70% at risk (moderate-high) using the ‘preventive model’ cutoff of 1.15 mmol/L. In the case of blood pressures, 20% of Canadians (age 30 and over) are hypertensive with respect to systolic blood pressures using the ‘medical model’ cutoff of 140 mm mercury whereas the ‘preventive model’ (systolic pressure > 120 mm mercury) shows 59% to be at risk (moderate-high). Further, the ‘preventive model’ cutoff shows 35% of our young people (aged 18-29 yr) to be at risk and yet left largely unprotected.

Other dietary-related chronic disorders (where diet or nutraceuticals can prevent, delay, or retard progression of disease) include kidney (renal) diseases and disorders (including kidney failures (needing dialysis or transplantation) and kidney stone formations), osteoporosis, rheumatoid arthritis, psychiatric disorders, genetic conditions, communicable diseases, and others. Osteoporosis affects approximately 1 million Canadians (particularly post-menopausal women). An estimated 10% of Canadians will have kidney stone formation at some point in their life. The probability of a 50 year old having a hip fracture during his or her lifetime is 14% for women and 5-6% for men (with 1 in 5 patients no longer living 1 year later after having sustained an osteoporotic hip fracture). Approximately 3-4 million Canadians suffer from some form of arthritis (rheumatoid arthritis or osteoarthritis). The Canadian population (and globally) is anticipated to experience a continuous surge in the prevalence of depressive illness and other psychiatric disorders including dementia/Alzheimer’s disease with the aging population.

ii) Costs of Diet-Related Risk Factors and Diseases in Canada

Total health expenditures in Canada for the year 2000 were $98 billion which was up 7.2% from the previous year. This expenditure represents approximately 10% of Canada’s gross domestic product which is spent on health care. The per capita total health expenditures in the population for the year 2000 were $3,174. It is noteworthy that the total health expenditures for seniors (age 65+) represented 42.7% of total health expenditures ($10,834 per capita) while they accounted for 12.5% of the total population. Approximately 70% of health expenditures were accounted for by provincial plus territorial governments and 30% by the private sector.

With respect to category of total health expenditures, drug costs per capita ($467), representing approximately 15% of total health expenditures, were second only to hospital costs ($986) and surpassed all other categories including physician costs ($417). Drug expenditures include prescribed drugs, non-prescribed drugs (over-the-counter medications) and personal health supplies with prescribed drugs representing
approximately 78% of total drug expenditures. Drug expenditures (approximately $15 billion annually of which $11.5 billion is for prescribed drugs) represented one of the fastest growing categories of expenditure in both the public and private sectors. Provincial and territorial government drug expenditures in the year 2000 were up 82.3% from the 1990 level while drug expenditures were up 87.8% in the private sector over this interval.

As mentioned previously and elaborated upon later, dietary intakes play a major role in the incidence and progression of the lifestyle-related chronic diseases including cardiovascular disorders, type 2 diabetes, and certain cancers (colo-rectal, prostate, others). It can be estimated that the total Canadian economic burden for diet-related diseases ranges from $35-$45 billion per year. The total direct costs for the combination of cardiovascular disease, coronary heart disease, and stroke account for approximately $13 billion annually with even more for total indirect costs. The aforementioned cardiovascular-related disorders cost approximately $3 billion per year for cardiovascular/heart-related drug expenses. Anti-hypertensive drugs (ACE-inhibitors, calcium antagonists, etc.) are the single most prescribed medication group accounting for over $1 billion sales in Canada annually. It has been established (based on guidelines for blood cholesterol and triglyceride management) that 1-2 million Canadian adults should be receiving lipid-lowering drug treatment at a cost of $2-$3 billion/yr (which is being approached as identification of these at risk is being increased). For the elderly, cholesterol-lowering medication is number two in prescription drug sales. Total health expenditures (including direct and indirect costs) for type 2 diabetes is now considerably greater than $10 billion annually. It should be further noted that the per capita health costs for a diabetic is approximately 4 times those for a non-diabetic. It is estimated that the overall annual costs for cancer in Canada are approximately $20 billion with the diet-related cancers such as colonic/rectal, prostate and breast cancer accounting for approximately $2 billion, $1 billion, and $500 million, respectively. Other cancers (stomach cancer, etc.) also have a significant dietary component.

Chronic renal (kidney) disorders account for approximately $3 billion in health care costs annually in Canada. The cost of arthritis (incl. rheumatoid arthritis) is estimated at $11 billion/yr in medical care and $11 billion/yr in indirect costs (lost wages). Psychiatric disorders place a considerable financial burden in Canada. For example, schizophrenia is regarded as one of the more costly mental illnesses because of its specific symptoms and characteristics. The total economic burden is approximately $3 billion/yr with $1.5 billion for direct health care and non-health care cost plus $1.5 billion in lost productivity. Dementia accounts for a national annual cost of approximately $5-6 billion/yr. Alzheimer’s disease imposes an increasingly high economic burden with the aging population.
IV   Evidence for Dietary Factors and Nutraceuticals/Functional Foods in Risk Factor Modification, Prevention, and Management of Disease

There is overwhelming science-based evidence from epidemiological (population) studies, case-control studies, and controlled dietary/nutritional trials (interventional/clinical trials) to show the critical and often predominant role that dietary components play in both the prevention and retardation as well as the causation/promotion of chronic diseases (cardiovascular, diabetes, certain cancers, other). The dietary differences between North America (Canada, U.S.) relative to other countries (e.g., Japan) is considered to account for a large portion of the lower chronic disease-free life expectancy in Japan as compared to Canada. World Health Organization statistics show that Canadian males exhibit death rates (per 100,000) from acute myocardial infarctions plus other ischemic heart diseases which are 160% higher than that for Japan (females being higher by 150%). Death rates from atherosclerosis in Canada (both genders) are 5 times those in Japan. Diabetes-related mortality rates (both genders) in Canada are double those in Japan. Breast cancer rates in Canada and the U.S. are 140% higher (or 2.4 times) the rates in Japan. Prostate cancer rates in Canada and the U.S. are 143% (or 2.4 times) the rates in Japan. Numerous carefully controlled dietary studies (retrospective, interventional/clinical, etc.) using modified nutritional compositions (including ‘nutraceuticals’ and ‘functional foods’) have demonstrated the ability of such ‘non-medical’ strategies to effectively modify risk factors for chronic disease, prevent or delay the onset of disease, retard or stop disease progression, reverse disease, complement needed medical interventions, and to reduce morbidity and mortality with little or no side effects.

There is overwhelming data based on epidemiological (population) studies as well as carefully controlled interventional studies to indicate that certain dietary patterns can promote the development of risk factors for cardiovascular disease (CVD) and accelerate the development of CVD and its various complications (hypertension, ischemic heart disease including angina, impaired exercise capacity, prevalence of premature myocardial infarctions leading to increased morbidity and mortality, increased prevalence of strokes and disability resulting therefrom, etc.). There is also excellent evidence-based publications in the medical and nutritional literature to indicate that certain nutraceutical ingredients consumed as such or in the form of functional foods can markedly attenuate risk factors for CVD and stroke, reduce the prevalence and progression of disease, as well as play an important role in providing alternatives to conventional medical/pharmaceutical therapy as well as complementing (improving) the patient outlook when imposed on top of conventional medical/pharmaceutical therapeutics.

A ‘western-type’ dietary pattern (characterized by higher intakes of red and processed meat, sweets and desserts, French fries, refined grains, etc.) when compared with a ‘prudent’ diet (rich in fruits, vegetables, whole grains, legumes, poultry, fish, etc.) showed the latter to significantly lower the risk of CVD. Higher consumptions of fruit and vegetables plus whole grains have been found to be protective against the risk for coronary heart disease as well as ischemic strokes. Some of the important components of
the western diet which appear to promote CVD include high intakes of trans fatty acids (in hydrogenated vegetable oils and vegetable shortenings as found in fast and processed foods), high intakes of saturated fats (in fatty meats and full-fat dairy products), along with a low intake of fruit/vegetable-derived antioxidants, low fibre intakes from cereal and other sources, low intakes of folic acid (a B vitamin), low intakes of omega-3 fatty acids, and other dietary components. In addition to preventing coronary heart disease, the so-called ‘Mediterranean diet’ (offering increased intakes of omega-3 fatty acids, monounsaturated fatty acids, decreased intakes of omega-6 fatty acid, lower intakes of trans and saturated fatty acids, higher intakes of antioxidants and folic acid, lower salt intakes, etc.) has been shown to also markedly reduce secondary mortality following a heart attack by 60%. It is noteworthy that the various nutritional/nutraceutical components which are considered to be cardioprotective in the Mediterranean diet exert their protection by blood cholesterol-lowering but also by non-blood cholesterol-lowering effects which are of utmost importance (reduced thrombogenic risk, lowering of circulating homocysteine, antiarrhythmic effects, reductions in vascular dysfunctioning, etc.).

Dietary supplementation with natural nutraceuticals (often at levels which are much higher than those consumed in a typical North American diet) has been found to favourably attenuate various risk factors for cardiovascular disease including cholesterol-lowering with various fibres, plant sterols, ‘natural statins’, natural aliphatic alcohols, etc. Furthermore, the B vitamin folic acid has been found in numerous studies to significantly lower the circulating levels of blood homocysteine, a significant risk factor for CVD. Increasing blood pressure and hypertension correspondingly increases the risk for cardiovascular disease; there are very taste-acceptable salt substitutes (e.g., a sodium-reduced, potassium/magnesium/lysine-enriched mineral salt) which can significantly lower blood pressure. Such functional food ingredients offer powerful protection against the harmful effects of sodium chloride (common salt). Also, such blood pressure-lowering nutraceuticals can reduce the risk for diabetic complications, enhance the cardiovascular effects of hypertensive medications, etc. Omega-3 fatty acids from fish and fish oils (or consumed in the form of functional foods) have been found to favourably influence numerous risk factors for cardiovascular disease and myocardial infarctions via mechanisms which operate independently of blood cholesterol-lowering including reduced blood platelet reactivity (anti-thrombogenic effect), improved vascular functioning, lowering of blood fat as triglycerides, antiarrhythmic effects, reduced blood viscosity, plus others. Furthermore, consuming omega-3 fatty acids from fish/fish oils at levels which are significantly higher than those consumed in a typical North American diet have been found to also retard the progression of pre-existing atherosclerosis (as measured by clinical angiography) and to markedly reduce sudden cardiac death rates (by 35%) in individuals receiving supplementary intakes of omega-3 fatty acids from fish and fish oils following a myocardial infarction despite the fact that such patients were given aggressive and modern medical therapy (including various pharmaceutical agents) plus being placed on a cardio-friendly diet (the so-called Mediterranean diet). These and other studies clearly indicate that, in the presence of a typical western-type diet, or in the presence of a prudent-type diet (such as the Mediterranean diet), increased intakes of omega-3 fatty acids from fish oils can significantly attenuate various risk factors for...
Disease, retard disease progression, and reduce subsequent morbidity and mortality in those who have suffered their first heart attack.

Dietary components (e.g., diets high in processed and fast foods containing ‘trans’ fatty acids, high fat dairy and meat products rich in saturated fats, high sugar and salt diets, several others) are known to be key dietary factors which adversely influence conventional risk factors for cardiovascular disease (by elevating circulating levels of cholesterol, triglyceride, glucose, and blood pressures, plus others). Other dietary factors and nutritional components (fibres, mono-/poly-unsaturated fats, salt replacers, etc.) plus numerous nutraceutical components can markedly suppress these same conventional risk factors. Furthermore, many of the blood cholesterol-independent and important risk factors for cardiovascular disease and myocardial infarctions (heart attacks), not measured (diagnostically) in the current health care system (thrombogenic factors, elevated homocysteine levels, postprandial lipemia, endothelial dysfunction, heart rate variability, etc.), can be favourably modified by many low-cost nutraceutical candidates (omega-3 fatty acids, antioxidants, the vitamin folic acid, others).

A very large and recent prospective study in the U.S., with a 12-yr follow-up, has shown that a ‘western dietary pattern’ (characterized by a high consumption of red meat, processed meat, French fries, refined grains, sweets and desserts and a low intake of whole grains, fibres, magnesium, etc.) was associated with a substantially increased risk for type 2 diabetes. Previous studies have shown that a dietary pattern characterized by a high consumption of fruits and vegetables and a low consumption of processed meat and fried foods was associated with a low incidence of type 2 diabetes. A study on Native Canadians demonstrated that a “junk food” pattern was associated with a higher prevalence of impaired glucose tolerance and type 2 diabetes. Dietary/nutritional changes alone have been found to significantly reduce (by 35%) the progression to type 2 diabetes in individuals with impaired glucose tolerance (the pre-diabetic state). Also, significant improvements in blood insulin levels and various risk factors for cardiovascular disease were found in diabetic patients (with non-insulin-dependent diabetes mellitus). Konjac-mannan fibre and the nutraceutical components in ginseng have been found to favourably attenuate metabolic control in type 2 diabetic patients as measured by postprandial glycemia, lipidemia, and blood pressures. Thus, dietary and nutraceutical/functional foods can contribute importantly to both the prevention and management of type 2 diabetes. Dietary/nutritional changes alone have been found to significantly reduce (by 35%) the progression to type 2 diabetes in individuals with impaired glucose tolerance (the pre-diabetic state). Also, significant improvements in blood insulin levels and various risk factors for cardiovascular disease have been found in diabetic patients (with non-insulin-dependent diabetes mellitus). Konjac-mannan fibre and the nutraceutical components in ginseng have been found to favourably attenuate metabolic control in type 2 diabetic patients as measured by postprandial glycemia, lipidemia, and blood pressure. Thus dietary and nutraceuticals/functional foods can contribute importantly to both the prevention and management of type 2 diabetes.

Numerous human epidemiological studies have shown very strong associations between several foods and various types of cancers (including colorectal, prostate, and
breast cancer). The components in fruits and vegetables which provide for chemoprotection include some of the classical micronutrients (incl. selenium, the antioxidant vitamins E and C, folic acid, etc.) plus numerous antioxidant phytochemicals (bioflavonoids – numbering over 4,000 in various mixed fruits and vegetables). Furthermore, supplementation with natural nutraceuticals (incl. selected nutrients) at levels above that which the majority of the population generally consumes in a typical Canadian diet has been found to both prevent certain cancers and/or to retard their progression. For example, some human studies have shown that nutraceutical enrichment of the diet can reduce total cancer mortality by 50% and reduce total cancer incidence by 37% without any dietary changes.

Colon and rectal cancer risk is increased with a typical “Western” dietary pattern as compared to a more “healthy” dietary pattern. The nutraceutical components found in plant foods (fruits, vegetables, or whole grains) are considered to provide the reduced risk of developing colon cancer as observed with such foods in epidemiological studies. Dietary supplementation with calcium carbonate (at 3 g/day or 1.2 g of elemental calcium) was found to significantly prevent the formation of colorectal adenomas (by 15%) in the Calcium Polyp Prevention Study Group. Higher folic acid (folate) intakes have been found to be protective against colon cancer (e.g., 0.4 mg/day of folic acid provided a 30% reduction in the risk of colon cancer and a 35% reduction in the risk of colorectal adenomas). Selenium supplementation at 200 ug/day was found to reduce mortality from all cancers including colorectal cancer (by 58%) with no observed cases of selenium toxicity. Recent observations in humans have provided evidence that the intake of omega-3 fatty acids from fish/fish oils are protective against colon cancer as are natural sulphur-containing ingredients in garlic.

Prostate cancer appears to be an ideal candidate for chemoprevention by altered nutritional practices and an increased consumption of nutritional and nutraceutical components which can markedly reduce the incidence of this cancer. In view of the predominant role that nutritional components play in the initiation/progression and (or) prevention against cancer of the prostate, this cancer is often referred to as a ‘nutritional disease’. An elevated risk for metastatic prostate cancer has been observed with higher intakes of red meats as well as processed meats (bacon, beef, pork and lamb products). Several double-blind placebo-controlled clinical trials have shown that supplementation with selenium as a nutraceutical component can markedly reduce prostate cancer. Consuming 200 ug/day of supplementary selenium (over and above the levels normally obtained by the majority with a typical North American diet) was found to produce a very dramatic reduction (63%) in prostate cancer incidence in U.S. men. The results of epidemiological (population) and animal studies support the role for supplementation with omega-3 fatty acids contained in fish oils in preventing the development and progression of prostate cancer. The consumption of fatty fish containing omega-3 fatty acids showed an inverse relationship to the risk of developing prostate cancer. Other studies have indicated that various antioxidants may play protective roles (including vitamin E and other tocopherols, possibly lycopene from tomato paste, others). Also, there is population-based evidence to support the possibility that soy-based products and
their constituents (primarily the isoflavones or phytoestrogens) may have a protective role against prostate cancer.

A number of nutritional and nutraceutical components found in natural human foods and diets appear to offer protection against breast cancer when consumed at levels which are generally higher than those present in a typical Canadian diet. Population studies have indicated a protective role for dietary folic acid (a B vitamin) which appears to be particularly pronounced in women consuming high levels of co-factors (enhancers) for folic acid metabolism and function including methionine (an amino acid) as well as specific B vitamins (namely, vitamin B\textsubscript{12} and vitamin B\textsubscript{6}). Recent observations in humans and previously in animal models have provided evidence that a high intake of omega-3 polyunsaturated fatty acids (from fish/fish oils) appear to be protective against mammary cancer. The evidence regarding the protective effects of phytoestrogens from soy against breast cancer are equivocal at the present time. Recent studies have indicated the potential of high-selenium broccoli to protect against mammary cancer (plus other cancers) based on animal studies. There is currently much interest in the evaluation of an organic form of selenium (specifically, selenium-methylselenocysteine) as a potentially effective chemopreventive nutraceutical agent against breast cancer.

There are a number of other chronic conditions which burden (both personally and financially) the health care system in Canada which have a strong dietary component. Consuming higher levels of natural nutraceutical ingredients than are normally present in the food supply in Canada appears to provide significant protective effects as well as opportunities for retarding the progression of these disorders. Dietary factors which are generally regarded as protective against osteoporosis include a diet more enriched in plant-derived protein/food sources (e.g., soy-based) plus supplementation with calcium and vitamin D. There is currently much research investigation directed towards the possibility that soy-derived phytoestrogens may possibly have protective effects in osteoporosis amongst post-menopausal women. Dietary factors are known to play a significant role in the development of various kidney disorders (chronic renal diseases plus kidney stone formation). With respect to chronic renal disorders (in many cases eventually progressing to end-stage kidney disease requiring dialysis and/or transplantation), there is considerable evidence to indicate that replacement of a high protein diet (as typically consumed in Canada) with functional foods containing low-protein substitute constituents (e.g., rice and potato flour as substitutes for wheat flour in bread, pastas, other products) can significantly slow down the progression of chronic renal disease (by about 40%) therefore delaying by years the time interval before end-stage kidney disease is reached. Other studies have shown that simply increasing the intake of omega-3 fatty acids from fish oil supplementation in patients with IgA nephropathy can markedly retard the progression of this serious kidney disease therefore delaying by years the time to end-stage kidney failure requiring dialysis or transplantation. Such dietary supplementation has shown also to greatly improve the treatment of diseased patients (better results with shunts for vascular access in dialysis, etc.). Supplementation of potassium citrate (as a nutraceutical constituent) has been found to markedly reduce the incidence of kidney stone formation (calcium nephrolithiasis) as well as significantly improving the treatment of urinary stones in
individuals with this condition. There is extensive literature to indicate that various nutraceuticals and functional foods can significantly attenuate the severity of chronic disorders common to the Canadian population such as rheumatoid arthritis. Evidence-based studies have shown significant beneficial effects of natural nutraceuticals including glucosamine, omega-3 fatty acids from fish oil, others. In addition to alleviating joint pain, stiffness, etc. in those on arthritis medications, some patients given supplementary fish oil were able to discontinue the need for their prescription medications entirely without experiencing a disease flare. A beneficial effect in the reduction of pain has been shown using dietary supplementation with vitamin E in rheumatoid diseases. Inflammatory bowel disorders and skin disorders have also shown marked improvements when certain nutraceuticals have been added to conventional medical therapy as part of the health care regimen. An oral fish oil preparation was found to be effective in reducing the rate of relapse when given to Crohn’s patients in remission. A number of psychiatric disorders have been found to respond favourably to various natural nutraceuticals. For example, omega-3 fatty acids were very well tolerated and improved the course of illness in a double-blind placebo-controlled study in patients with bipolar disorder. Promising studies have been reported with subsets of schizophrenic patients given dietary supplementation with antioxidants and omega-3 fatty acids. Higher intakes of folic acid (a natural B vitamin) have also been associated with a significantly reduced risk of developing Alzheimer’s disease later in life by lowering blood homocysteine levels.

The aforementioned and numerous other non-mentioned chronic disorders which predominate in Canadian society have the potential to be greatly reduced in prevalence, severity, progression, etc. by the use of nutraceutical components in functional foods targeted at benefiting wide sectors of the population with these disorders and dramatically lowering health care costs in Canada.
V Rationale for the Potential for Functional Foods containing Natural Nutraceutical Components to Significantly Reduce the Prevalence of Chronic Diseases, Predisposing Risk Factors, and Associated Conditions in Canada as well as Lowering Corresponding Health Care Costs

1) A large portion of the staggering and ever-increasing economic burden for health care in Canada is associated with dietary-related chronic disorders (including cardiovascular risk factors and diseases, type 2 diabetes, certain cancers, etc.). Current approaches in the Canadian health care system essentially exclude the utilization of safe and effective functional foods for modifying risk factors for chronic diseases as well as disease prevention/management despite the voluminous literature indicating their potential to immediately play a major role in reducing disease prevalence, progression, and greatly facilitating disease management. In addition to prevention of disease, delaying disease onset, or retarding the progression of dietary/lifestyle-related diseases, functional foods can also play an important role in the management of diseases which do not have a dietary component per se (e.g., various genetic disorders).

2) Natural nutraceutical ingredients which are incorporated into functional foods are those which have a long history (over decades or generations) of being consumed as natural components in the diets of various populations and sub-groups throughout the world. Therefore, the nutraceuticals so consumed in food form have a long standing history of being natural components of the diet in various sectors and do not represent the introduction of novel chemical compounds into the body as foreign agents (such as is the case with pharmaceutical agents used in the medical system). Thus, the side effects and risks associated with the use of certain pharmaceutical agents can be expected to be rare.

3) Most chronic disorders (e.g., cardiovascular, type 2 diabetes, etc.) evolve from a disease-free state early in life through a multi-year period (often 2-3 decades) of gradually-increasing risk factors for disease at a moderate level (e.g., blood cholesterol and blood triglyceride levels, blood pressures) which are moderately elevated (i.e., risk levels which can predispose towards eventual disease but which do not meet the official clinic cutoffs for medical intervention). Furthermore, these moderately-elevated levels are not only unmanaged but are oftentimes unrecognized. Subsequently, the individual progresses to having risk factors which are sufficiently high enough to require medical intervention if diagnosed and/or will have developed a chronic disease (early/mid/late end stage) which will require extensive medical management. For every individual receiving costly medical therapy for elevated blood cholesterol (as an example) or treatment for cardiovascular disease, there are many more who have moderately-elevated cholesterol levels which predispose them to a subsequent disease situation. The introduction of functional foods containing natural cholesterol-lowering components (as an example) early in an individual’s life would either prevent the development of moderately-elevated cholesterol levels or would reduce the moderately-elevated cholesterol levels to normal (low/safe) levels which would
totally eliminate (or greatly reduce) their subsequent need for costly cholesterol-
pharmaceutical therapy and/or extensive medical management (surgery, etc.) for
premature cardiovascular disease. The savings to the health care system using
such a ‘preventive model’ with functional foods containing cholesterol-lowering
nutraceutical rather than relying upon the subsequent ‘medical model’ for
intervention would be of enormous personal/humanitarian as well as financial
benefit to Canada.

4) In addition to having a tremendous potential to prevent, delay, or manage chronic
diseases, functional foods containing natural bioactive nutraceutical components
(derived from natural food sources) can also serve as alternatives or
complementary strategies for those undergoing necessary medical management
(pharmaceutical, surgical, others). For example, there are natural nutraceutical
ingredients available for inclusion into functional foods which can lower blood
cholesterol levels as effectively as the commonly-used cholesterol-lowering drugs
(e.g., statin drugs). These natural cholesterol-lowering ingredients could be
employed immediately in our health care system at a much lower cost than the
currently used pharmaceutical agents. Again, the risk of their usage is essentially
minimal or non-existent as these are natural ingredients which have been
consumed in the form of natural foods for decades or generations in various
population sectors. Certain nutraceutical ingredients consumed as functional
foods with more moderate blood cholesterol-lowering ability would serve in the
‘preventive model’ for those with moderately-elevated cholesterol levels which
develop early in life while other nutraceutical components with more potent blood
cholesterol-lowering ability could be readily applied as alternative ‘natural’
therapeutic agents to the imported pharmaceuticals (drugs). In addition,
functional foods can also play a complementary role in health care when the
‘medical model’ is used since many of these have been found to provide added
beneficial effects (e.g., in cardiovascular care, diabetes, etc.) when added on top
of the medical/pharmaceutical regimen which is currently employed for such
individuals. Essentially all Canadians are currently being deprived of
opportunities and access to safe and efficacious functional foods for disease
prevention and management within our current health care system.

5) The health care system does provide for payments for health professions other
than physicians who can provide dietary counseling to individuals at risk of or
having chronic disorders (e.g., elevated blood cholesterol levels in the case of
cardiovascular disease). Oftentimes, physicians will refer such
individuals/patients to registered dietitians for a trial period of dietary advise
which, if unsuccessful in normalizing the blood lipid values, will often result in
the physicians prescribing a blood cholesterol-lowering medication. Published
reports in the literature on the impact of dietitians’ advise in the health care
system to drop blood cholesterol levels (e.g., net impact after 1 year) have shown
net reductions ranging from 0 to 4%, 0.6 to 2%, and no more than a 6% reduction
in a few studies. While even small reductions on blood cholesterol should not be
regarded as unimportant, this degree of cholesterol-lowering would be considered
as very modest when compared to the potential for functional food. Numerous natural nutraceutical ingredients and functional food are available at the present time which can readily lower blood cholesterol levels by 5-25% as part of an overall diet with or without the involvement of health care professionals on a regular basis. The current strategy in our health care system of offering dietary advise (changes in food selections) and, if unsuccessful, the use of medical intervention denies Canadians of the opportunities to consume highly efficacious functional foods for risk factor management and disease prevention which can be expected to dramatically lower our health care cost. The ‘diet and if necessary medical intervention’ scenario needs to be replaced immediately by a ‘dietary plus nutraceutical/functional food strategy plus subsequent medical intervention if/as necessary’.

6) Canada’s Food Guide and Nutritional Recommendations and associated public information vehicles (food labelling, etc.) are directed towards (for the most part) the consumption of the so-called ‘essential nutrients’ to prevent specific nutritional-deficiency syndromes and conditions. However, very few Canadians ever die or suffer from vitamin C deficiency, vitamin A deficiency, etc. While respecting the need for sufficient intake of these important nutrients, the vast majority of Canadians will continue to die prematurely of chronic diseases. This country desperately needs dietary advice directed towards the prevention and management of chronic disorders (cardiovascular, diabetes, certain cancers) which will sometimes include advice on the so-called traditional nutrients as well as a whole range of dietary components which can play an major role in disease prevention/management despite the fact that they are not included in the so-called ‘traditional’ nutrient categories. Furthermore, future food guides and corresponding health-related advice for disease prevention in this country need to aggressively support the use of efficacious, safe, and cost-effective functional foods with diverse natural components (both nutrients and non-nutrients) for the prevention and management of chronic disorders.

7) Canadian dietary recommendations (including Canada’s Food Guide) have appropriately recommended that Canadians consume 5-10 servings of fruits and vegetables each day for health. However, for taste, convenience, time constraints, etc., a large portion of the population (young and old alike) are failing to comply with these recommendations despite appropriate educational programs on such and the awareness of the public that such dietary practices would be to their overall health benefit. Recent surveys have indicated that the majority of Canadians are not meeting Health Canada’s recommendations in Canada’s Food Guide to Health Eating which recommends 5-10 servings of fruits and vegetables per day. Over 50% of adult Canadians (18-65 years of age) are failing to meet the recommended minimal intake of 5 portions per day. Recently, the Canadian Heart & Stroke Foundation report indicated that only 14% of children aged 9-12 years were consuming sufficient amounts of fruits and vegetables. These findings are even more startling when consideration is given to the official inclusion of fast-food ‘French fries’ in the fruit and vegetable category in such surveys. The
greatly insufficient intakes of the various nutrients and healthy/natural non-nutrient components in fruits and vegetables could readily be enhanced dramatically in the population (with chronic disease prevention opportunities) by including dried (nutraceutical) preparations of various fruits and vegetables into foods which the population (young and old alike) prefer to eat for taste, convenience, other reasons. Such functional foods could readily deliver the 5-10 serving equivalents of the natural nutraceutical ingredients in fruits and vegetables. Such functional foods could have a major impact in the prevention of cardiovascular disorders, certain cancers, other disorders.

8) The availability of effective and safe functional foods with associated health claims would serve as new and effective vehicles for usage by both the public and health professionals (physicians, dietitians, nurses, naturopaths, nutritionists, other health professionals) for the prevention and management of various chronic disorders. Such would greatly surpass the physiological benefits offered by conventional dietary advice. The introduction of natural nutraceutical ingredients in functional foods could be a major boost in reducing Canada’s health care cost for chronic diseases.

9) In addition to diet-related chronic disorders, there is overwhelming evidence that many chronic disorders/diseases which are not generally considered to be related to diet (e.g., genetic disorders, kidney or renal diseases, inflammatory disorders including arthritis, skin conditions, bowel disorders, as well as medical complications such as impediments to vascular access in dialysis patients, depression and certain psychiatric disorders, urinary tract disorders, plus many others) can be markedly improved clinically by the use of functional foods or appropriate levels of natural nutraceutical components based on the voluminous evidence-based literature in leading medical and nutritional journals. Currently, almost all patients in Canada with these latter conditions are being deprived of efficacious, safe, and inexpensive functional food therapeutics to alleviate their medical conditions.

10) The consumption of bioactive plus natural nutraceutical components in functional foods provides for their intake by dietary means as a food commodity which greatly reduces the potential for over-consumption of such foods and ingredients in contrast to what can occur with pharmaceutical agents and certain nutritional supplements taken at high doses and in encapsulated or tablet form.

11) In contrast to their current negative attitudes towards bio-engineered foods (genetically-modified organisms and foods), the public can be fully expected to enthusiastically embrace functional foods with natural nutraceutical ingredients as part of their health care. A report released by the National Institute of Nutrition indicates that 80% of respondents believe that food and nutrition play a great role in improving overall health and the majority agree that certain foods have health benefits that go beyond basic nutrition and have the potential to reduce the risk of disease or other health concerns. Consumers have indicated their acceptance of
the benefits of nutraceuticals despite lack of leadership from the health care system in this regard. Approximately half of all North American adults when surveyed reported taking some type of non-prescription vitamin, dietary, or mineral supplements on a regular basis for health and protection against chronic disorders for management of the latter. The public are most interested in taking as much responsibility as possible for their own personal health. A recent American survey indicated that, 49% took vitamin or mineral supplements on a daily basis, 82% took such supplements on various occasions, while only 12% used herbal supplements daily. These data indicate the greater interest of the public with respect to the health benefits of nutritional and nutraceutical components as compared to non-food-derived components as found in herbal supplements. This possibly reflects the concern that herbal supplements are not derived from natural food sources whereas nutraceutical components are derived from natural foods which have been consumed by various sectors of the population for decades or generations without any apparent untoward effects.

The entry of functional foods in the health care system would also allow the introduction of natural nutraceuticals into various food forms at levels which could be adjusted to sufficiently high levels to ensure clinical efficacy without any significant risk of even minor side effects.

12) Various health professional groups (physicians, dietitians, nutritionists, naturopaths, osteopaths, nurses, academics, etc.) have exhibited a marked surge in interest in functional foods and their entry into the health care system. The near absence of educational programs in universities and the curriculae which trains such professionals has also been a deterrent in moving functional foods to the forefront of health care in Canada as part of the new ‘preventive model’. However, Canada is now training, through academic courses and programs, highly qualified B.Sc. graduates with expert knowledge in various facets of nutraceuticals and functional foods. The first programs along these lines were developed a few years ago at the University of Guelph and other universities in Canada are currently developing and beginning to offer similar programs. When evidence-based courses and instruction on nutraceuticals and functional foods as preventive agents for chronic disease and therapeutic agents for disease management (by dose, duration, and expected effects for various conditions) spread, the interest of health professionals will surge even further. Numerous countries worldwide are offering functional foods containing natural nutraceutical ingredients with responsible health claims at the forefront of their health care systems. The high prevalence of preventable and manageable disorders, staggering health care costs, the aging population, and other factors have led their governments to show leadership in advocating and supporting functional foods.

13) Numerous multinational companies (and smaller companies) globally have established corporate divisions entitled Nutraceuticals and Functional Foods and are establishing research and development in this area as targeted priorities. Functional food sales have begun to surge dramatically and the market share for
such products is expected to reach staggering proportions in the coming few years. If Canada wishes to be a developer and leader in this area rather than a spectator who imports such products from abroad, it is very timely and urgent that consideration be given in making a full and firm commitment to this important vehicle for low cost health care which will be enthusiastically embraced by the public and health professionals alike.

14) The agri-food/farming sectors in Canada have generally been commodity-based while now facing severe competition from other countries which is fuelled by low-cost labour, lower energy cost, willingness to accept higher environmental pollution indices, etc. The transition of the Canadian agri-food/farming sectors towards a functional food (value-added/wellness food) base could provide both economic opportunities and marketing directives towards health and disease prevention/management at both the domestic and export levels. Canada could become a major centre for the processing, production, and distribution of functional foods including the use of Canada’s raw resources as sources for nutraceutical components in such food products. In addition to food processing, altered feeding regimens with selected nutraceutical components in domestic feed rations can markedly and favourably modify the health and wellness positioning and marketing of dairy, meat, egg, and poultry produce.
VI Attitudes of Public and Health Professionals to Functional Foods and Nutraceuticals

The public have traditionally consumed and selected foods while often regarding these as a source of important nutrients for playing a role in maintaining or improving overall health. However, consumers have now begun to be concerned with the increasing prevalence of diet-related chronic diseases including cardiovascular disorders, diabetes, cancer, plus others. Surveys have indicated that the North American consumer wishes to go far beyond having foods as providing only basic nutrition but are interested in them as vehicles for reducing risk factors for chronic disease, preventing disease, or delaying its onset, as well as reducing the severity of the disease and its management. Previous concerns regarding consuming various nutrients for the prevention of disease-specific conditions (e.g., consuming vitamin C to prevent scurvy, consuming thiamine to prevent beri-beri, etc.) are not of concern as the public realizes that premature morbidity and mortality rates from the lifestyle-related chronic diseases are alarmingly high in Canada. Consumers also realize that dietary recommendations and ‘official’ nutrient requirements as advocated by Health Canada and other agencies are not targeted towards the intake of nutrients and nutraceutical components at levels which scientific studies (as revealed to consumer and media and press report) have indicated can prevent and manage various diseases. Consequently, consumers have become impatient in waiting for the health care system to ‘catch up’ with the scientific information as provided for the consumers by the media/press and have begun to take their health into their own hands using dietary nutritional supplements as well as nutraceuticals and what few functional foods are available. Approximately half of all North Americans use vitamin and mineral supplements on a daily basis with 7, 3, and 23% using such supplements on a weekly, monthly, and occasional basis, respectively. Less than 20% of North American consumers do not consume such supplements on an annual basis. The use of herbals (which are not regarded as natural nutraceuticals and functional food ingredients) is relatively low with over 60% of consumers indicating that they have not used such products in the past year.

A report as published by the National Institute of Nutrition indicates that 63% of consumers strongly believe that some foods can provide health benefits beyond basic nutrition and disease prevention/management. Further, the majority of consumers are capable of naming at least one nutraceutical component which they believe to be associated with the prevention of heart disease and cancer. Many consumers regard the use of nutritional supplements including nutraceuticals/functional foods as ‘insurance policies’ which reflects their concerns regarding their dietary habits. For example, numerous surveys in Canada and elsewhere in North America have shown that despite recommendations to consume 5-10 servings of fruits and vegetables per day (Health Canada Guidelines) the majority of adult Canadians and less than 15% of young children are complying with such reasonable dietary recommendations as a source of important nutrient and nutraceutical ingredients for health and disease prevention. Issues such as taste, convenience, limited time constraints, etc. are responsible for this poor performance towards healthy eating despite appropriate government recommendations as well as the
knowledge of consumers that this would be a desirable lifestyle for them to adopt yet the majority fail to do so. Approximately 90% of consumers have expressed interest in learning more information about functional foods which they derive at the present time (to a very limited extent) from health associations, various health professionals, physicians, pharmacists, dietitians, naturopaths, chiropractors, others, plus health agencies/local health units as well as various government agencies. Essentially all the aforementioned have been received insufficient or no training on the topic.

The interest in nutritional supplements, nutraceuticals, plus functional foods is also becoming a priority issue for health professionals (physicians, dietitians, naturopaths, nutritionists, chiropractors, nurses, others) for various reasons. This area is becoming consumer-driven such that the public are requesting information on appropriate nutraceuticals and functional foods to apply to their particular medical condition and concerns when visiting their physician or other health professional. Both the consumer and health professionals are interested in these alternative strategies (if evidence-based) since many consumers will often not comply with their prescribed medications out of concern for side effects, excessive cost, other factors. The availability of efficacious, safe, and cost-effective natural nutraceuticals and functional foods which can attenuate risk factors for disease, and prevent or assist in disease management are of concern to the public and health professionals alike. The public are beginning to appreciate, as are many health professionals, the fact that the consumption of nutraceuticals and functional foods in the presence or absence of major dietary changes can often provide much more dramatic improvements in risk factors for disease (including disease prevention) than standard dietary advice that the health care system provides. For example, various published studies have shown that, for patients who have elevated blood cholesterol and are referred to a dietitian for dietary management in managing their conditions, the average blood cholesterol-lowering delivered by such current health care strategies in North America often amount to a net lowering of between 0 and 5% after a period of approximately 12 months. A recent review of 11 studies indicated that participants receiving advice from dietitians experienced a moderate reduction in lowering blood cholesterol in the short to medium term (by approximately 4%) which was somewhat greater than those receiving dietary advice only from physicians. However, there was no evidence that the degree of cholesterol-lowering was any difference than those provided from nurses nor were they better than self-help consumer resources. In contrast, there are numerous natural nutraceutical ingredients available to the consumer which can readily lower blood cholesterol levels by 5 to 20% within a few weeks with little effort or lifestyle change by the consumer. Furthermore, nutraceuticals consumed at levels which are safe yet higher than those present in the standard Canadian diet have the potential to markedly reduce morbidity and mortality for a wide range of chronic disorders for minimal cost to the health care system.

Various published studies have indicated the considerable interest that physicians, dietitians, nurses, naturopaths, chiropractors, and other health professionals have in functional foods for disease prevention and management. However, these studies indicate that many of the same health professionals (e.g., physicians, dietitians, etc.) have not received any formal academic training (through academic courses in universities)
directed specifically to the use of science-based functional foods in the prevention and management of various chronic disorders. These same professionals are essentially ignorant of the dose, duration, and expected effects that such functional food-based strategies can offer in health care. Some universities in Canada (e.g., University of Guelph) began offering formal academic courses and academic streams in functional foods and nutraceuticals where the student body consists mainly of students in nutritional sciences or food sciences. It is anticipated that other universities in Canada will begin to offer formal academic training in functional foods and nutraceuticals such that the professional who is interested in using functional foods in practice will be properly trained on the topic.
VII Estimates of Reductions in Health Care Costs from Introduction of Functional Foods containing Natural Nutraceuticals in Canada

The estimates for the reduction in health-care costs by the introduction of functional foods containing nutraceuticals into the Canadian marketplace are impressive. These estimates can be determined by simplistic or more refined approaches. Simplistically, one can predict that, based on the degree to which various chronic disorders are diet-related and the current costs of direct medical costs of these disorders, the potential annual savings would be in the order of $6 billion/yr (direct costs) for cardiovascular disease (including atherosclerosis, hypertension, stroke, etc.) and another $12 billion savings for indirect costs. The savings for diabetes (type 2) are estimated at $4 billion per year, for all cancers (savings of $8 billion/yr), and osteoporosis (savings of $500 million/yr). The aforementioned savings alone amount to approximately $20 billion/yr (excluding indirect costs) in health care costs are considered minimal since they don’t include savings from numerous other chronic conditions where nutraceuticals/functional foods have been found to offer considerable benefit in managing such conditions (e.g., rheumatoid arthritis, inflammatory bowel disorders, certain psychiatric conditions, others).

The above simplistic approach assumes that extensive dietary changes will be made (change from the typical ‘western-style’ to the ‘prudent’ diet) to bring about the predicted reductions in disease prevalence and associated savings in health care costs. However, as discussed elsewhere in this report, Canadians are rather resistant for various reasons (taste, convenience, time constraints, etc.) to make major dietary changes. This is evidenced by the majority failing to comply with the recommended 5-10 servings of fruits and vegetables per day amongst other factors. A ‘functional food/nutraceutical’ approach to estimating the potential for reductions in health care costs is more reliable and realistic since it is evidence-based (from published human studies) and doesn’t require any change in the overall dietary patterns or habits as fixed in our present culture and established by the food industry as a whole in the marketplace. The mere consumption of 1-2 servings/day of particular ‘functional foods’ can have a major impact on reducing disease prevalence (plus disease management) with or without any significant shifts in overall dietary patterns.

More direct approaches in estimating the savings in health care costs via functional foods containing nutraceuticals can be obtained from the peer-reviewed scientific literature (human/clinical studies) showing efficacy and safety in disease prevention, disease management, and favorable risk factor modification. This cost effectiveness and dramatic savings to the health care system can then be calculated/estimated form the wholesale costs of the corresponding natural nutraceutical components and amounts needed to produce the beneficial effect as reported (see below and Tables 1, 2, and 3).

Tables 1 and 2 as examples provide a realistic indication of the remarkable savings in health care costs that can readily be produced by the use of moderate lipid-
lowering functional food strategies which provide an 8% lowering of 15% in blood cholesterol or blood triglyceride early in the lives of our younger populations when they are still healthy and free of cardiovascular disease. The principle here is based on the fact that a significant portion of our population have ‘moderately’ elevated levels of blood lipids (cholesterol and triglyceride) which are well below levels calling for drug therapy (which is typically reserved for those, usually older, needing lipid lowering of 20-25%). Younger disease-free individuals (in their twenties) with moderately elevated blood lipids in their youth have been shown to be those who are most likely to progress over the next 25-30 years to early development of cardiovascular disease as their blood lipids slowly but steadily rise over this time-frame. The wide availability of functional foods offering moderate lipid-lowering nutraceutical ingredients would flatten the progress curve thereby drastically lowering the subsequent dependency on costly lipid-lowering drugs as well as greatly lowering the risk of developing cardiovascular disease in their forties and fifties. It should also be noted that published review articles have indicated that dietitians (using conventional foods and dietary advice) can only realize blood cholesterol reductions of 1-4% after one year of management. The large numbers of younger Canadians needing blood cholesterol-lowering of approximately 8% (5-10%) would not generally attain the lowering required by conventional dietary advise (1-4%) and yet would not be given drug therapy (providing reductions of 20-25%). Thus, the 5-10% or

<table>
<thead>
<tr>
<th>Nutraceutical Ingredient</th>
<th>Wholesale Cost of Daily Ingredient to Lower Cholesterol (by 8%)</th>
<th>Expected % Decrease in Disease Risk</th>
<th>Reduced Expenditure for Heart Disease per year *</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Selected Food Fibres</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>i) Citrus Pectins</td>
<td>8 cents/day (yearly cost = $29)</td>
<td>20%</td>
<td>$3.26 billion</td>
</tr>
<tr>
<td>ii) Guar Gum</td>
<td>7 cents/day (yearly cost = $26)</td>
<td>20%</td>
<td>$3.26 billion</td>
</tr>
<tr>
<td>b) Plant Sterol</td>
<td>20 cents/day (yearly cost = $73)</td>
<td>20%</td>
<td>$3.26 billion</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Nutraceutical Ingredient</th>
<th>Wholesale Cost of Daily Ingredient to Lower Triglyceride (by 15%)</th>
<th>Expected % Decrease in Disease Risk</th>
<th>Reduced Expenditure for Heart Disease per year *</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omega-3 Fatty Acids (EPA/DHA)</td>
<td>13 cents/day (yearly cost = $47)</td>
<td>20% (in women) 7.5% (in men)</td>
<td>$2.70 billion (both genders)</td>
</tr>
</tbody>
</table>

* Includes both reduced dependency on costly cholesterol- or triglyceride-lowering drugs later in life and the reduced risk for later disease development needing costly medical treatment. Expected decreases (%) in disease risk are based on published literature giving blood lipid changes in relation to disease risk. Higher intakes of nutraceutical ingredients in functional foods will give a corresponding lower decrease in later diseases and greater cost savings.
10-15% cholesterol- or triglyceride-lowering required for significantly reducing disease risk could easily, inexpensively, safely, and readily be provided by lipid-lowering functional foods.

Table 2  Estimates of Savings in Clinical Care in Canada by Managing Elevations in Blood Cholesterol Levels (≥ 6.2 mmol/L) or Blood Triglyceride Levels (≥ 2.3 mmol/L) using Functional Foods with Nutraceuticals rather than Pharmaceuticals for Lipid-Lowering

<table>
<thead>
<tr>
<th>A) Elevated Cholesterol (≥ 6.2 mmol/L)</th>
<th>Cost/day</th>
<th>Cost/yr</th>
<th>Target Population Cost/yr</th>
<th>Net Savings/yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>i) Pharmaceutical (e.g., Lipitor as statin drug)</td>
<td>$2.50</td>
<td>$913</td>
<td>$4.97 billion</td>
<td>__</td>
</tr>
<tr>
<td>ii) Nutraceutical</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) Red yeast rice, traditional Chinese health food</td>
<td>$1.50</td>
<td>$548</td>
<td>$2.98 billion</td>
<td>$2.0 billion</td>
</tr>
<tr>
<td>b) Policosanol (from sugar cane wax)</td>
<td>$1.50</td>
<td>$548</td>
<td>$2.98 billion</td>
<td>$2.0 billion</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>B) Elevated Triglyceride (≥ 2.3 mmol/L)</th>
<th>Cost/day</th>
<th>Cost/yr</th>
<th>Target Population Cost/yr</th>
<th>Net Savings/yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>i) Pharmaceutical (e.g., gemfibrozil)</td>
<td>$1.70</td>
<td>$621</td>
<td>$3.38 billion</td>
<td>__</td>
</tr>
<tr>
<td>ii) Nutraceutical (e.g., omega-3 fatty acids (EPA/DHA) from fish oils)</td>
<td>$0.30</td>
<td>$110</td>
<td>$0.66 billion</td>
<td>$2.72 billion</td>
</tr>
</tbody>
</table>

Note: Based on amounts needed to give either a 20-25% reduction in cholesterol or a 25-30% reduction in triglyceride levels and number in Canadian population with cholesterol levels ≥ 6.2 mmol/L or triglyceride levels ≥ 2.3 mmol/L who qualify for drug treatment.

Table 1 gives the estimated savings in direct healthcare costs per year in Canada by simply introducing functional foods (with appropriate levels of blood cholesterol-lowering nutraceutical components) early in the lives of young adult Canadians for moderate cholesterol-lowering (by approximately 8%) and reductions in subsequent prevalence (by 20%) can be expected to provide $3.26 billion/yr savings in health care costs at an individual cost of $26 to $73/yr. Even if 75% of Canadians were consuming such nutraceutical ingredients, the annual cost to the country per year would be $606 to $676 million/yr for food fibre-based functional foods with a net savings of $2.58 to $2.65 billion/yr ($3.26 billion - $606 million or $676 million) or a net savings of $1.56 billion/yr for plant sterol-based functional foods ($3.26 billion - $1.70 billion). In the case of omega-3 fatty acids (eicosapentaenoic acid, EPA, plus docosahexaenoic acid,
DHA) from fish oils as nutraceutical components in functional foods for early control of blood triglyceride levels (an important risk factor for heart disease and attacks). Table 1 indicates a savings to the health care system (with a blood triglyceride-lowering of 15%) of $2.7 billion for an individual cost of 13 cents/day or $47/yr. The net savings in this case (omega-3 fatty acids for triglyceride-lowering for heart disease reduction), if 75% of Canadians were to consume this nutraceutical component regularly, would be $1.6 billion/yr ($2.70 billion - $1.10). These net savings do not include the many other health benefits associated with increased consumption of omega-3 fatty acids.

Although not shown in table form, it should also be noted that low-cost salt substitutes (with excellent taste equivalency to regular table and cooking salt (blood pressure-raising)) for functional foods (e.g., a potassium/lysine complex) have been shown to produce significant lowering of blood pressures (4-9%) including alleviation or elimination of borderline hypertension. Considering the importance of blood pressure as a risk factor for cardiovascular disease and the high prevalence of undesirable/elevated blood pressure in our population (30% of all Canadians have systolic blood pressures ≥ 130 mm mercury), the early introduction of such blood pressure-controlling functional foods prior to the development of overt hypertension requiring costly pharmaceutical therapy can be calculated to reduce health care costs for blood pressure control (using pharmaceutical agents) and the treatment of disease by $1.4 billion/yr. These savings do not include the reduced risk/costs for developing kidney disease, etc.

Table 2 indicates the potential in medical management for certain natural nutraceutical components to markedly reduce health care costs by their use as alternative treatments (to more costly pharmaceutical agents) for blood lipid-lowering. It is estimated that 90% of the current usage and health care costs for lipid-lowering drugs

<table>
<thead>
<tr>
<th>Type of Cancer</th>
<th>Nutraceutical Ingredient (amt/day)</th>
<th>Cost of Protective Nutraceutical per day</th>
<th>Expected % Decrease in Cancer</th>
<th>Cost of Protective Nutraceutical per year</th>
<th>Reduced Cancer Expenditure per year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colo-rectal</td>
<td>1) Calcium (1.2 g)</td>
<td>7 cents</td>
<td>15% red’n in colorectal adenomas</td>
<td>$26</td>
<td>$300 million</td>
</tr>
<tr>
<td></td>
<td>2) Selenium (0.2 mg)</td>
<td>5 cents</td>
<td>58 % red’n in colorectal cancer</td>
<td>$18</td>
<td>$1.2 billion</td>
</tr>
<tr>
<td></td>
<td>3) Folic acid (0.4 mg)</td>
<td>0.3 cents</td>
<td>30% red’n in colorectal cancer</td>
<td>$1</td>
<td>$600 million</td>
</tr>
<tr>
<td>Prostate</td>
<td>Selenium (0.2 mg)</td>
<td>5 cents</td>
<td>63% red’n in prostate cancer</td>
<td>$18</td>
<td>$315 million</td>
</tr>
</tbody>
</table>

*Based on wholesale prices for nutraceutical ingredients and published human studies showing cancer reductions with given levels of nutraceutical/day.
could be totally abandoned in Canada. Functional foods can provide blood cholesterol-lowering with these nutraceutical ingredients (e.g., red yeast rice with ‘natural’ statin, policosanol from sugar cane wax) in the range of 20-25% which is similar to that provided by synthetic pharmaceutical drugs (e.g., synthetic statins). In addition to lowering cholesterol medication costs (potential net savings of $2.0 billion/yr), there will be better long-term compliance by the consumer since they have concerns regarding synthetic drugs (‘drop-out’ rates of 40-50% at 1 year). Most consumers would prefer evidence-based ‘natural’ rather than ‘synthetic drug’ strategies for cholesterol-lowering if offered a choice.

As seen also in Table 2, clinical management of elevated blood triglyceride levels can be effected using omega-3 fatty acids (EPA/DHA) from fish oils at the intake levels which yield the same degree of blood-triglyceride lowering as provided by synthetic drugs (e.g., gemfibrozil). It is noteworthy that ‘drop-out’ rates of 65% are commonplace with gemfibrozil. The daily cost of omega-3 therapy at approximately 30 cents/day is about one-fifth of the drug providing net potential savings of $2.72 billion per yr. Such a nutraceutical (omega-3 fatty acids from fish oil) also offer many other cardioprotective effects in addition to blood triglyceride-lowering.

Table 3 indicates the dramatic expected reductions for cancer-related health care costs that can be expected from a few natural nutraceuticals when consumed in functional food form at levels which have shown considerable reductions in colo-rectal and prostate cancers. For examples, at annual costs of $1 - $26 per person/yr (calcium, selenium, folic acid), each of these can be estimated to save $300 million, $1.2 billion, and $600 million, respectively, annually based on reductions in colo-rectal cancer. At a cost of $18 for selenium per person/yr, a $315 million reduced expenditure for prostate cancer is estimated.

Numerous nutraceutical ingredients (not mentioned above) have been shown to significantly enhance the medical management of various chronic conditions (arthritis, inflammatory bowel disorders, certain psychiatric disorders, etc.) with a high benefit:cost ratio. The numerous benefits and health-care cost savings of functional foods with efficacious nutraceutical components are realized with little or no minor side effects, high patient approval and compliance, little risk of over-consumption (as they are consumed in the form of full foods), along with other attractive features.
VIII Policies and Health Claims for Functional Foods and Nutraceuticals in other Global Jurisdictions

Health Canada is striving towards a regulatory framework which will provide for health claims associated with functional foods containing nutraceutical ingredients. A number of countries have already established or are in the process of establishing regulatory guidelines relating to the sales of functional foods in the marketplace along with associated health claims. Such countries include Japan, China, Australia, Nigeria, Malaysia, Singapore, Thailand, as well as North America. In general, the U.S. and Canada have lagged well behind development in other countries. For example, legal approval procedures for foods commonly referred to as ‘functional foods’ began in Japan in 1991 with the first legal control of functional foods in the world. In the eastern hemisphere (especially in such nations as China and India), these cultures have a history wherein traditional medical science considered it more important to promote health and avoid illness through proper dietary practices (a preventive strategy) rather than to treat the sick via the medical model which predominates in North America. Despite its long history, only approximately 10% amongst the Japanese public are familiar with the term functional foods (their legal name for such food products with specified health use). This low level of consumer recognition appears to be a result of insufficient advertisement/information programs, unique legal name, a complicated approval system, and the strict restriction of claims on foods labels. In November of 1990; the Committee for Functional Foods organized by the Ministry of Health and Welfare in Japan recommended that the ministry establish a labelling system for foods for specified health use and proposed requirements for licensing. In July of 1991, the ministry partially amended the administrative ordinance of the Nutrition Improvement Law. With the new regulation, foods for specified health use are classified in the framework of foods for special dietary uses and licensed to bear a label claiming appropriate health promotion benefits. The Ministry of Health and Welfare has released a number of recommendations which a food must meet including that the health benefit of the food or its relevant components should have a medical or a nutritional basis. Also, an appropriate level of consumption of the food or its relevant nutraceutical ingredient should be definable. The products should also appear in the form of an ordinary food and detailed instructions for use, when necessary, should be expressed on the label. Several dozen foods have been approved as foods for specified health use for the prevention/management of blood cholesterol levels, blood pressure, gastrointestinal performance, kidney disease, various allergies, dental caries, plus several others. The Japanese position and that of other countries is that such development in functional foods will lead to healthier lives for people throughout the world.

Japan and other countries have long had products in the marketplace under the category of functional foods and government policies that regulate them and the associated health claims. The legal status of functional foods in Japan translates into FOSHU (Foods for Specialized Health Use) under the Nutrition Improvement Law of 1991 enacted by the Japanese Ministry of Health and Welfare (now renamed as Ministry of Health, Labour and Welfare). They have legislated the labelling of health claims of
five groups of functional foods including foods that may improve specific health conditions (FOSHU). Clinically-proven products have been launched into the marketplace by various companies and many more companies are encouraged and plan on participating in the future because of the leadership and ‘friendly environment’ provided for such opportunities to the corporate sector (both small and large businesses) by the Japanese government.

The Australian/New Zealand Food Authority have developed regulations through an open consultative process in which matters are assessed within an agreed, transparent policy framework. This process allows for the ability to draw out community views and to explore ways by which everyone’s needs can be met. It is generally considered that such group participation is an important component in a true regulatory analysis of a framework for regulatory control of functional foods in a responsible and fair manner. The appendix contains documentations and references from several other countries regarding their past, present, and ongoing discussions regarding regulatory aspects of functional food. Input from consumers, a wide range of health professionals, industry, consumer groups and government are important in this regard. Meeting this challenge by the scientific community (including nutritional, food, medical representation), health authorities, the food industry, and the public are needed to effectively bring functional foods to the Canadian public in a responsible manner and in as short a time as possible.
The nutrition industry in the U.S. was 68 billion (Canadian dollars) in the year 2000 with dietary supplement sales reaching $25 billion in that year. Rising sales and profits are commonplace and projected for the functional food industry with functional foods outstripping the overall 7% annual increase in the total U.S. nutrition industry. Whereas consumers previously relied upon drugstores as a major source of dietary (nutritional) supplements, there is a shift in the marketplace towards traditional grocery stores offering expanded shelf space for natural products including nutraceuticals and functional food. Conventional supermarkets are now becoming the primary shopping channel for functional foods across the various food sectors. Last year, half the shoppers who entered a grocery store in the U.S. asked for health and nutrition information. The desire to ensure overall good health and chronic disease protection rather than balanced nutrition is a primary motivator for the aging baby boomers who are expected to dominate the North American functional food segment in the coming decades. Within the next few years, the 50-64 year old boomer age group is expected to experience a marked increase in incidence of high blood pressure, elevated cholesterol and triglyceride levels, heart disease, cancer (especially prostate), and anxiety/depressive illnesses. Education by the media and the press about the latest medical opportunities for disease prevention and management associated with nutraceutical ingredients in functional foods has contributed greatly to the growth and enthusiasm for this segment of the food market. Existing and future health claims by the Food and Drug Administration is expected to accelerate access to major markets in the functional food arena by the multinational food conglomerates. A listing of the top 18 U.S. functional food companies (see Appendix) shows functional foods to represent 2-100% of their total food sales (an average of 4% of total sales for the top 18 companies) with this proportion devoted to functional foods expected to show a dramatic increase in the coming few years. Consumer concerns regarding genetically-engineered foods is providing a watershed opportunity for functional foods which also qualify as ‘organic’ products.

In addition to major food companies, various agri-food sectors are entering the growing functional food market with ‘wellness foods’ and disease preventing/managing food products. In addition to processed foods where natural nutraceutical ingredients can be added at effective levels for disease prevention and management with safety assurances, the animal industry is beginning to successfully produce and market animal-derived products with nutraceutical components based on the natural feeding regimens employed. For example, the inclusion of flax as a source of omega-3 fatty acid has led to the successful launch in Canada and the U.S. of omega-3 fatty acid-containing eggs which have captured a significant share of the food market for the health-conscious consumer. Functional food products are available in the U.S. and to a more limited extent in Canada which can lower blood cholesterol levels, lower blood triglyceride levels, lower blood pressure, lower the glycemic index in diabetics or those who are glucose intolerant, as well as preventing disease, delaying disease onset, reducing progression and severity, and playing a critical role in overall disease management. Global sales of functional foods are expected to show a very steady increase as health
care costs soar and the populations in various countries ages with the development of various chronic disorders in increasing prevalence. Whereas consumers typically had to shop at health food stores in the past to seek out so-called ‘healthy products’, grocery stores are now routinely stocking products in the functional food category in the U.S. (and to a very limited extent in Canada) devoted towards the prevention and management of chronic disorders and associated risk factors. An ‘ideal’ supermarket is regarded to be one that will offer whole-health solutions including the offering of functional foods as well as staffing with knowledgeable personnel who can answer questions on health/nutrition and corresponding disease prevention/management. Scientific/trade journals entitled ‘wellness foods’, ‘medical foods’, ‘medicinal foods’, etc. are now appearing in both the food industry and academic sectors.
X Research Issues regarding Functional Foods and Nutraceuticals – Past, Present and Future Needs

The Canadian government and its grant-dispersing bodies (primarily the Medical Research Council of Canada (MRC of Canada) and the National Sciences and Engineering Research Council (NSERC)) have largely neglected the nutrition (including nutraceutical and functional food) sector which, if properly funded during the past couple of decades, could have a major impact in reducing disease prevalence in Canada and health care costs. For example, the official report from MRC for 1999-2000 indicates that only 1.1% of all research grants and only 0.82% of total funding provided by the Medical Research Council of Canada was devoted to nutrition. Furthermore, only a minor portion of this 0.82% was for nutrition research (nutraceuticals and functional foods) for the prevention and management of human diseases despite the many scientists (and their students) with globally-recognized expertise in the area. This poor funding record is in striking contrast to the reality where nutrition plays a major role (up to 40-60%) of the various chronic diseases which predominate in our society along with the accompanying/excessive health care cost. In contrast, drug research received several times more funding for research from the public (tax payer) from MRC than did nutrition-related research despite the fact that, if the public were to be polled, it can be expected that they would much prefer to see research on nutrition and disease prevention receiving a much greater share of the funds offered to date. Research on ‘genetics’ received eight times more funding than nutrition despite the potential for nutrition research to offer immediate protection against chronic diseases in contrast to research in other areas. This great under funding of nutrition-disease prevention research is contrary to what is provided in numerous other countries. This paucity of research likely reflects the predominance of the ‘medical model’ in our health care system and research funding control, rather than a ‘preventive model’, such that MRC policies, committee members, executive members are often dominated by those individuals who emphasize the medical model as opposed to lifestyle-oriented units which emphasize health and disease prevention. Very few faculty and representatives from lifestyle-oriented programs and schools are invited to ever become involved to set policy for the medical funding establishment in Canada or to serve as influential members of their various committees. Public involvement in the process would further aid the shifting of resources into nutrition and nutraceuticals/functional foods being allocated towards disease prevention and management. NSERC, which funds research in many of the non-medical school-based institutions, does not have a committee devoted human health or disease prevention and, in fact, it is usually most difficult for individuals with research proposals in the nutrition-disease preventive area to receive funding through NSERC. There is a great need for a shifting of resources from our national granting counsels, such as CIHR, towards functional foods and nutraceuticals by emphasizing food processing, production of nutraceutical ingredients, research and development into the production of functional foods, their human health potential and their marketing/penetration into the marketplace. Also, research dollars are needed for the agri-food sectors to further develop/expand these activities in Canada as well as the need for research dollars allocated to universities for conducting research trials on functional foods and nutraceuticals in Canada for eventual health claims as well as training of future researchers. It is important to note
that many countries support research on nutraceutical/functional foods with the intention of using this health-based research to market their country’s products globally. For example, extensive funding is provided by Italy into the polyphenols (antioxidants) found in olive oil, red wine, etc. to ‘sell’ and market their products based on the apparent health effects/disease preventing-properties of such foods and their natural nutraceutical ingredients. Canada needs to perform in the same way as other leading countries if they want to compete at the global level for market share in functional foods and nutraceuticals which are ‘home grown’. There is also a need to have individuals with expertise in functional foods and nutraceuticals interacting on a regular basis (formally by cross-appointments and informally) health-oriented and clinical research units so that functional foods can be brought to the forefront in our health care system for disease prevention and disease management.
**Summary of Characteristics of a Successful Functional Food**

In general, a successful functional food should be a brand-name product which contains sufficient levels of a natural nutraceutical ingredient(s), either in purified or crude form (e.g., dried powders, concentrates, etc.), such that a reasonable serving of this food product has been found in a controlled human trial(s) to deliver one or more health effects which qualify for health claims. The nutraceutical components within the functional food should be derived from natural (edible) sources which have been consumed in some sectors of the population globally over many years or decades without any apparent untoward effects. The levels of such nutraceutical components in a functional food can be near the upper limits (e.g., quintile) of population intakes as occurs in certain sectors (countries) and not significantly above the highest intake in such populations. For the present time, functional food should be GMO-free and not include herbal ingredients which have no history of being consumed as foodstuffs in certain populations. The successful functional food should be capable of demonstrating (over a few weeks or months of experimentation in controlled studies) a significant reduction (even if moderate) in one or more risk factors for cardiovascular disease, diabetes, cancer, or any one of a number of other chronic disorders. A successful functional food may be found to reduce the risk of disease, delay the onset of disease, retard disease progression, as well as serving a role in managing various diseases and disorders as alternative treatment to conventional medical/pharmaceutical treatment or by improving the expected prognosis and outcomes in patients on conventional medical treatment (i.e., a functional food on top of conventional medical treatment is more efficacious than medical treatment alone). Since patent positions on nutraceutical components are not possible (because of their natural origins/nature), in contrast to costly synthetic pharmaceutical agents, it is expected that many functional foods will be equal to or, more often than not, much more cost effective than medical strategies when corresponding beneficial effects are compared. The consumer is expected to be attracted to functional foods for self health preservation. The risk of ‘over dosing’ on a functional food is almost non-existant; also, adherence should be better than found for drugs. Many successful functional foods will be introduced early into an individual’s dietary habits to reduce moderately-elevated but not drug-dependent risk factors with success over extended time periods and with essentially no side effects plus a high level of confidence and compliance by the consumer.
XII Methodology

This report was commissioned by Agriculture and Agri-Food Canada (Market and Industry Services Branch). The writing in this report was performed by Professor Bruce J. Holub (Department of Human Biology & Nutritional Science, University of Guelph, Guelph, Ontario, Canada, N1G 2W1). Professor Holub recruited and personally paid a stipend to Mr. Colin Kay (graduate student within the Department of Human Biology & Nutritional Science, University of Guelph) to help collect the relevant published literature and to assist in preparing the material (references) and supportive information (for the Appendix). Some text material was provided to Professor Holub from Agri-Food Canada upon initiating this report. As well, extensive searching of the relevant literature (peer-reviewed journal articles, etc.) on the various topics covered was conducted and such material was carefully consulted in preparing the report found herein. There are over 200 references cited which include the listing of many of the referred literature that was consulted.
XIII  Concluding Statements and Recommendations

10. Diet-related chronic diseases and disorders (cardiovascular diseases, type 2 diabetes, many cancers, other) are of major and increasing prevalence in our population. These contribute to our present and accelerating health care expenditures with this trend continuing as our population ages.

11. Canadians have been denied access to functional foods with natural nutraceutical components for the prevention, delay of onset, retardation of disease, and disease management (including risk factor modification) despite overwhelming evidence-based published human studies showing their dramatic ability to be highly effective in these regards and to dramatically reduce health care costs.

12. The public have indicated their general unwillingness to significantly change the ‘western-style’ diet as now consumed. Functional foods and nutraceuticals can dramatically reduce disease incidence, severity, progression, etc. with or without any significant changes in overall dietary consumption patterns.

13. Health care costs in Canada can be reduced by a minimum of $20 billion/yr by early risk factor management and the accompanying disease prevention /retardation along with an additional minimal $10 billion savings for disease management applications.

14. The agri-food industry/sector needs extensive government support if it intends to be an international participant at the forefront of producing functional foods for disease prevention and management (along with the economic benefits to Canada that can be derived from such a prioritizing of resources, research, job creation, marketing opportunities, use of our natural agricultural resources, etc.). The gross under-funding of research in the area of functional foods for disease prevention in this country is in striking contrast to the past and previous research allocations given to drug-related research (usually on patented pharmaceuticals from non-Canadian sources). Canada is lagging well behind other countries in this important area.

15. A ‘preventive model’ using functional foods and not the regular ‘medical model’ needs to be established as soon as possible using a new breed of ‘preventive health specialists’ from our vast pool of eager, young, and underemployed B.Sc. graduates in life sciences from across Canada. The preventive model should focus on early detection and functional food-based control of ‘moderate’ risk factors in our younger population using the ‘preventive’ specialists without a dependency on physicians.

16. Education and training of various health specialists and professionals as well as the public in functional foods and natural nutraceuticals for the prevention and management of disease is also needed.
17. The public, food industry, academic plus government scientists, and various health specialists/professionals have indicated their enthusiastic interest and support for the early and broad-based entry of functional foods with appropriate health claims into the Canadian marketplace. Functional foods need to become the ‘pharmacy’ for disease prevention as well as management.

18. Government leadership in launching functional foods with natural nutraceutical components is desperately needed in Canada as soon as possible.