

Coordination of Natural Health Product Research in Canada

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The opinions expressed in this report are a synthesis of citizen input garnered through a series of stakeholders consultations and do not necessarily represent the opinions of Health Canada, Mage Consulting, or the authors.

Coordination of NHP Research in Canada

Executive Summary

Over the past five years, the Natural Health Product Directorate (NHPD, Health Canada) conducted an extensive series of consultations on Natural Health Product (NHP) research priorities. One of the major themes that emerged from these consultations was the need for an infrastructure to coordinate research, and facilitate stakeholder communication and knowledge transfer. The discussions surrounding this concept invariably involved the formation of some type of national research network to develop and carry-out a strategically planned research program. While there was a strong consensus amongst all stakeholders regarding the need for a network and a national strategic plan for NHP research, there was a wide array of concepts as to their constitution, scope and objectives.

The purpose of this project was to identify key issues and elements for a strategic plan, and the next steps required to advance the development of such a strategic plan. The consultative process took place over a period of six months and involved not only academic scientists but also research stakeholders from industry, funding agencies, and government. Several new themes and issues emerged, along with some new perspectives on the re-occurring themes of databases, networks, and product quality. Although these threads were intricately interwoven, they generally may be summarized as follows:

- Functional Foods and Nutraceuticals (FFNs) vs. Natural Health Products (NHPs)
- NHP Research Database
- Current Research Capacity
- Networks and Networking
- Coordination of NHP Research in Canada

There is considerable confusion surrounding the differentiation between Functional Foods and Nutraceuticals (FFNs) and Natural Health Products (NHPs). Although nutraceuticals are now regulated as NHPs, nutraceutical stakeholders are largely unaware of this shift. In academia, industry, and government, there appears to be a significant disjunct between FFN and NHP stakeholders, and this lack of linkages was identified as a key factor impacting upon the development of a strategic plan for research. It was recognized that considerable work needed to be done to bridge these gaps and that a concerted effort should be made to more actively engage nutraceutical FFN stakeholders in the national NHP dialogue, including federal and provincial government agencies, industry associations, and research institutes.

There was a strong consensus that the NHP Research database should be up-dated and expanded to include NHP research expertise and capabilities. This process should specifically target the inclusion of nutraceutical researchers and attempt to identify researchers interested in animal bioactives, cultural medicines and homeopathy in collaboration with relevant industry, professional, and special interest groups.

Canada has considerable current capacity in biomedical research and there are several institutions that conduct research in the field of NHP and FFN including government, university, and contract research organizations. It is estimated that there are roughly 200 NHP researchers in Canada but the only formally funded institutes are focused on FFN research. There are a few emerging nodes of NHP research and a number of informal collaborative networks across the country, mainly in the areas of probiotics, essential fatty acids, and botanicals.

There appears to be significant research gaps in the fields of animal-based NHPs, cultural/traditional medicines, homeopathy, and product quality. However, there are a number of industry, professional, and special interest groups who are interested in promoting research in these areas. A concerted effort needs to be made to integrate these stakeholders into the research community and facilitate capacity building. Appropriate peer-review, perceived institutional biases against NHPs, and the growing funding emphasis on intellectual property (IP) value and commercial potential were commonly identified as the most significant barriers to NHP research funding.

A consensus has developed that there is a need for two forms of infrastructure to coordinate and promote NHP research in Canada: highly focused research networks that could be funded through the Natural Sciences and Engineering Research Council (NSERC) Network program, and a broader policy and coordination body to develop and implement long-term strategic planning.

There are several nascent clusters of NHP research expertise which have the potential to carry-out coordinated research programs, especially in the fields of product quality and aboriginal traditional medicines. An action plan for facilitating the formation of a quality network and a strategy for the creation of a traditional medicine network were developed. The most substantial obstacle impeding the formation of these networks was identified as the lack of infrastructure support to carry out the necessary planning and stakeholder coordination. In this regard, the NHPD could play a key catalytic role in fostering the development of these traditional medicine and product quality networks.

It was widely recognized that there is a need for a broader-based network to provide overall coordination, communication, and strategy implementation, and that this mandate is beyond the scope of a highly focused NSERC research network. A pivotal, priority role for this national coordinating body is building cohesion between the various research sectors, government agencies and key stakeholder groups. The NHP research database was repeatedly identified as an essential tool for accomplishing this objective. To effectively build cohesion amongst the diverse range of NHP research stakeholders, it is essential that a comprehensive communication plan be developed with customized strategies for each sector.

Throughout the national dialogue on NHP research, there has been a number of other policy issues which have repeatedly arose. The most prominent of which were research funding and appropriate peer-review, along with the associated issues of perceived institutional bias against funding NHP research, the lack of patent protection for many NHPs, negative perceptions of NHPs as lacking commercial potential and IP value, the need for greater clarity regarding the nature and extent of scientific evidence required to support claims, and research capacity building.

In the past, the NHPD has been perceived as the sole champion of NHP research in Canada and stakeholders have invariably recommended that the NHPD should assume responsibility and/or concerted work towards major policy changes. However, this perspective has started to shift and it is extremely encouraging that stakeholders are taking a more pro-active role, seeking alternatives to complete reliance on government and discussing collaborative solutions. Consequently, many of the ideas and suggestions involved actions and initiatives that could be carried out by NHP research stakeholders and the NHPD.

A pivotal recommendation in this regard was the formation of a policy committee under the national coordinating body to formulate general and customized strategies for building support for NHP research amongst consumers and other key national and international stakeholders. Each of these customized strategies should effectively address the issues of IP, health claims, product quality and research for the public good. Other key policy committees identified were Peer-review and Industry Liaison, Standard of Evidence, Quality Standards, and Policy Communication.

From the time of the first NHPD research consultation in 1999 up to the present, stakeholders have consistently identified the priority need for an infrastructure to coordinate NHP research and communications, and to devise and implement strategies for advancing NHP research. Focused NHP research networks funded under the conventional scientific grant programs could contribute towards but could not fulfill many of the needs that have been identified in this report. It was also recognized that no one government, academic, or industry stakeholder group could satisfactorily address these needs by working in isolation.

All of these stakeholder groups have an important role to play in the development of a national strategic plan for NHP research and the coordination of NHP research in Canada. However, it will be important for one organization to take a lead role to facilitate collaboration and cooperation on a national level. To undertake many of the recommendations identified in this report, a focused and dedicated approach will be required by a national coordinating body that has the capacity to build cohesion, coordinate strategic planning and promote NHP research. The mandate and activities of the national coordinating body should mirror as closely as possible with the needs for advancing NHP research. This alignment will help to maximize efficiencies and minimize potential duplication with other organizations. Key attributes of this organization will include the capability to undertake and manage the policy and communication initiatives recommended by stakeholders.

Summary of Recommendations

The extremely valuable role the NHPD has played in building cohesion amongst research stakeholders is widely recognized. The NHPD is encouraged to:

- Continue to work collaboratively with stakeholders to further clarify regulatory boundaries and the attendant levels of evidence required to support the safety and efficacy of products.
- Strive to more actively engage with key FFN representatives and policy-makers to raise awareness regarding NHP research.
- Up-date and expand the NHP research environmental scan (ES).
- Take a lead advocacy and coordination role in building support for an NHP literature database collaboratively funded by government and non-governmental organizations.
- Establish a standard of evidence committee comprised of experts in the critical evaluation of scientific evidence and research methodology, to further delineate standards of evidence.
- Champion public funding and prioritize NHPRP support for generic NHP research and other potentially beneficial projects which lack direct IP value.
- Take an active role in promoting and facilitating product quality research as there is a clear consensus that this is a leading national priority.
- Establish a “virtual” WHO Collaborating Centre for Traditional Medicine that builds upon existing nodes of expertise and fosters the development of new research clusters.
- Develop a comprehensive communication plan for building cohesion amongst NHP research stakeholders, with customized strategies for each sector.
- Establish a NHP Research Policy Committee under the national coordinating body to develop customized strategies for building support for NHP research.
- Establish a Peer-review Advisory Committee under the national coordinating body to facilitate appropriate peer-review and act as an industry liaison.
- Develop a policy communication plan, to coordinate strategic input on policy development and ensure consistent delivery of key messages and content to build support for research.
- Establish an expert Product Quality Standards Committee to further develop more detailed product quality standards.
- Identify and support a lead organization that can provide national coordination for NHP research. This organization should have the capability to undertake and manage the policy and communication initiatives recommended by stakeholders.

1. Background and Introduction

Over the past five years, the Natural Health Product Directorate (NHPD, Health Canada) conducted an extensive series of consultations on Natural Health Product (NHP) research priorities. One of the major themes that emerged from these consultations was the need for an infrastructure to coordinate research, and facilitate stakeholder communication and knowledge transfer. The discussions surrounding this concept invariably involved the formation of some type of national research network to develop and carry-out a strategically planned research program. While there was a strong consensus amongst all stakeholders regarding the need for a network and a national strategic plan for NHP research, there was a wide array of concepts as to their constitution, scope and objectives.

The purpose of this project was to identify key issues and elements for a strategic plan, and the next steps required to advance the development of such a strategic plan. To accomplish this, a series of consultations were conducted. The consultative process took place over a period of six months and involved not only academic scientists but also research stakeholders from industry and government. A wide range of mediums were employed including in-person meetings, telephone, email, and fax. The consultations also ranged considerably in size from one-on-one discussions to group meetings

To initiate this dialogue, a small working group composed of academic and industry stakeholders drafted a discussion document, outlining potential elements of a scientific framework for NHP research. This entailed a two-day meeting, teleconferences, and email discussions. The document was then circulated to all potential participants to provide a starting point for the discussions. The largest in-person consultation was held in Montreal on February 22-23, 2004 following the landmark First NHP Research Conference and involved stakeholders from academia, industry and practitioner associations, government, funding agencies, and individual companies. This dialogue was subsequently continued via email, telephone and in-person meetings over the following four months.

During the Montreal consultation, several new themes and issues emerged, along with some new perspectives on the re-occurring themes of databases, networks, and product quality. Appendix 1 provides a summary of these discussions. Although these threads were intricately interwoven, they generally may be summarized as follows:

- Functional Foods and Nutraceuticals (FFNs) vs. Natural Health Products (NHPs)
- NHP Research Database
- Current Research Capacity
- Networks and Networking
- Coordination of NHP research

These topics formed the focal points of subsequent consultations and were used to frame the contents of this report.

2. Functional Foods and Nutraceuticals (FFNs) and Natural Health Products (NHPs)

Background

The lack of linkages between functional food and nutraceutical (FFN) and NHP stakeholders was identified as a key factor impacting upon the development of a strategic plan for research. It was pointed out that this disjunct between FFNs and NHPs was not just a matter of semantics or legal definitions, although both factors also impact on NHP research.

In industrialized countries around the world, “FFN” has become a vernacular term used to describe foods/natural products and/or their constituent(s) that convey health benefits over and above their nutritional value. The term NHP has more recent antecedents and is unique to the Canadian idiom. In 1998, the Natural Health Product Directorate was established within Health Canada and given initial mandate to develop a new regulatory framework for NHPs. That same year, Health Canada also proposed the following definitions for the terms “functional food” and “nutraceutical”.¹

A **functional food** is “... similar in appearance to a conventional food, consumed as part of the usual diet, with demonstrated physiological benefits, and/or to reduce the risk of chronic disease beyond basic nutritional functions”.

A **nutraceutical** is “a product that has been isolated or purified from foods and generally sold in medicinal forms not usually associated with food. Nutraceuticals have been shown to exhibit a physiological benefit or provide protection against chronic disease”.

While these terms (FFNs) are not recognized in Canadian law, they have been widely adopted by other federal, regional, and provincial agencies. Amendments to the Food and Drug Act (FDA) enacted in 2003 now permit five *generic* structure/function health claims for foods though.² Health Canada has also proposed a regulatory framework for *specific* health claims for foods which would not require additional FDA amendments³ and has published an interim guidance document which describes the standards of evidence for evaluating health claims for foods.⁴

With the enactment of the Natural Health Product Regulations in January 2004, the NHP category is now legally recognized within the Canada Food and Drug Act⁵ as a special sub-section of drugs. Natural health products (NHPs) are defined in the Regulations as vitamins and minerals, herbal remedies, homeopathic medicines, traditional medicines, probiotics, and other products like amino acids and essential fatty acids.⁶ Consequently “nutraceuticals” as earlier defined by Health Canada are now classified and regulated as NHPs. The NHPD has published guidance documents on the standards of evidence for evaluating NHPs, which differ from the standards for foods.⁷

Many stakeholders maintained that there are other fundamental differences between FFNs and NHPs that have very significant implications for research in Canada, beyond the levels of evidence required for the different regulatory categories. The key themes underlying these perceived distinctions were differences in scientific objectives, philosophical approach, and at the core, the national research agenda and funding priorities. The varying perspectives of research, industry and government stakeholders on these issues are summarized below.

Researcher perspectives

Scientists who self-identify themselves as FFN researchers appear to predominantly follow the drug discovery model, focusing on the isolation, characterization, and concentration of novel bio-actives. They generally consider that the FFN term includes NHPs and typically perceive “NHP” researchers as those scientists working on herbal medicines/cultural medicines and/or “dietary supplements” rather than crops or food ingredients that may be marketed in both food and medicinal dosage forms. Most FFN workers have a food and/or agriculture background, and are well-grounded in the economics of food production, which they perceive as one of the primary drivers of the national research agenda. Their targeted research outcomes are very practical, with the dual goals of developing new products that improve health and provide new commercial opportunities, predominantly in the value-added agriculture and biotechnology sectors.

Although many academic and government FFN scientists engage in basic science or “discovery” research, patentability and/or commercial potential appear to be fundamental prerequisites in the selection of FFN research projects. This is generally attributed to the growing emphasis on intellectual property (IP), knowledge/technology transfer, and industry partnerships as public funding priorities. The rising prominence of patents as career advancement criteria, the down-sizing (or in some cases the elimination) of direct funding and 100% grant programs over the past decade, together with the increasing number of partnership programs and their higher funding success rate compared to investigator-initiated grants, were commonly cited as evidence of this shift in research priorities.

In contrast, scientists who self-identify themselves as NHP researchers tend to dissociate and differentiate themselves from the FFN field, perceiving a fundamental philosophical difference in both their perception of the research questions and their research approach/methodology. The majority of self-identified NHP researchers work with whole organisms or their products; I.e. animals, botanicals, fungi, insects, and complex combination traditional medicines or natural products such as animal and insect venoms, elk velvet, royal jelly, etc.). They describe their primary research focus as the evaluation of the properties and effects of the whole or intact NHP, not its isolated components. According to some, this higher level of complexity also differentiates NHPs from FFNs which are often isolated chemical entities. As whole natural entities, these NHP research materials usually cannot be patented and hence have more limited commercial potential compared to many FFNs.

Targeted NHP research outcomes are usually for the “common good”; improved consumer health, reduced health care costs, reduced health risks. Outside of research to ensure product consistency and/or to improve product quality/potency, commercial potential is rarely a primary consideration in the selection of research projects. Rather, product popularity, disease population frequency/burden of illness (Eg. Cancer, diabetes), and/or scientific curiosity are most commonly cited as selection criteria. These researchers report that their work is typically supported by investigator-initiated grants. Compared to FFN research, there appear to be significantly fewer industry partnerships and they most often are fairly modest in terms of corporate investment.

It was apparent at the 2004 NHP Research Conference that this meeting was one of the first times that a significant number from these two stakeholder groups attended the same event. Many FFN delegates remarked on their prior lack of awareness of the identity of “NHP” researchers and the

scope of their research; and vice versa. Similarly, the subsequent Montreal consultation was the first time that a number of scientists who self-identified themselves as “FFN” researchers participated in the national dialogue on NHP research. Identifying this disjunct between FFN and NHP research as an important issue impacting on the development of a strategic plan, there was ready agreement that continuing interaction and dialogue should be actively promoted and facilitated.

Industry Perspectives

It was observed that this disjunction between the FFN and NHP spheres was not just restricted to researchers but was perhaps even more pronounced amongst industry and government stakeholders. FFN representatives emphasized that FFN industry members have very little awareness of the NHP category and that nutraceutical stakeholders in particular did not associate themselves with the NHP category; many do not even appreciate that their “nutraceutical” ingredients are now regulated as NHPs in Canada. This regulatory change has had little impact on their research agenda as, given Canada’s relatively small market size, most companies focus on the larger international markets as their sales targets. FFN industry research priorities are to discover and develop novel ingredients and product formulations for the global market, and to prove the health benefits of these products. Significant intellectual property (IP) and/or commercial potential are fundamental prerequisites for industry research investment.

Alternatively, the NHP industry generally does not identify itself with the FFN category, and in fact, stakeholders are often quite emphatic in dissociating their companies from this label. In subsequent interviews, NHP industry members repeatedly pointed out that “natural” was the critical essence of their products; that consumers buy their products because they are natural substances that have not been scientifically manipulated. The term FFNs was perceived to have negative connotations associated with the pharmaceutical industry, biotech, and genetic engineering. While consumers were thought to largely welcome scientific evidence of efficacy and quality, they were perceived as being very sensitive about “scientific engineering” of the product contents. It was observed that there is delicate balance to strike between assuring customers that products are natural and healthy, and yet of high quality and efficacious.

This distinction has significant impact on the NHP industry’s research agenda and priorities. While FFN stakeholders did not consider “product quality” to be an issue, it was unquestionably a priority issue for NHP stakeholders and virtually all companies invest in quality research, albeit to varying degrees. Compared to the FFN industry, there appears to be relatively few NHP companies which invest in scientific research outside of the product quality arena. Those which do have focused primarily upon developing and/or maximizing the effectiveness of proprietary processes or formulations, and proving the (superior) efficacy of these products. For NHP companies, the commercial value of investing in research is contingent upon branding and market protection of health claims for their proprietary formulas. Given the generic nature of most NHPs, industry stakeholders have repeatedly emphasized that clearly delineated regulatory assurances of protection for proprietary health claims is required in order to stimulate research investment.

One perceived impediment to research common to both FFN and NHP industry stakeholders was the lack of clarity surrounding “how much” evidence was sufficient to support safety and efficacy claims. Without this knowledge, companies cannot accurately assess whether the research required

to bring a product to market is economically feasible. Consequently, many are highly reluctant to take the financial gamble of investing in research programs where there is no clear endpoint and costs may continue to escalate indefinitely. In addition, there is still some confusion regarding products which can “cross over” from the NHP (or nutraceutical) category into the food arena, in terms of the definition criteria and the levels of evidence required for ingredients sold in therapeutic dosage levels versus those used as flavouring, food additives, or ingredients.

Other perspectives

Outside of Health Canada, the term FFN is used almost exclusively by public officials to describe the range of foods and natural substances with health benefits, including herbal medicines and other NHPs. Even those agents who are very familiar with the term NHPs, most often tend to consider them to be a subset of FFNs.

Innovation Canada, Industry Canada (including NRC and IRAP), Agriculture and Agri-Food Canada (AAFC), Natural Sciences and Engineering Research Council (NSERC) and Western Economic Diversification (WED) have all recognized FFNs as a priority area for research and innovation. When representatives from these agencies were queried as to where NHPs “fit” under their program classifications, FFN was virtually the universal response.

This perception of NHPs as a sub-category of FFNs and the recognition of FFNs as a priority area for research presents both advantages and disadvantages. Many NHP stakeholders felt that at present, any potential benefits were largely negated by the perception that NHPs lack economically significant IP/commercial potential. They felt that concerted liaison and education would be needed to raise awareness of both the unique challenges and benefits of NHP research. It was pointed out that factual evidence supporting these potential benefits (Eg. pilot study on socio-economic benefits of a particular NHP) would provide considerable leverage.

Comparison of FFNs versus NHPs

The following table summarizes the major points of differentiation between FFN and NHP which were identified by stakeholders.

Research

FFN	NHP
- Generally aligned with food, general nutrition and agriculture	- Generally aligned with basic science (pharmacology) and clinical medicine
- Within these sectors, FFNs are very much part of the popular trend towards high tech/biotech innovations	- Research orphans accorded little credibility, negative peer bias against scientific/socioeconomic value
- Research focus on novel compounds and/or processes, new claims for known constituents or enhancement of conventional crops	- Focus largely on potential efficacy and/or safety; agronomy, processing, and quality to a much lesser extent

<ul style="list-style-type: none"> - Research driven by both market and health potentials - Scientists fairly knowledgeable of the industry and its socioeconomic drivers; aware of industry and government priorities - No specific funds earmarked for FFN but official recognition well-documented; designated research priority by AAFF, NSERC, IRAP, WD, and various provincial agencies - Compete against other bioproduct (non-agrihealth, genomic/biotech proposals) - Relatively large and well-known pool of peer-reviewers with appropriate expertise in agriculture, nutrition, and clinical research. - Average to slightly above average funding rate, especially for projects emphasizing commercial potential - Greater industry support for research with matching cash, as well as in-kind contributions - Investigator-initiated proposals usually discovery (basic and applied) and proof of concept research, industry partnership projects span all phases of product development - Substantial linkages between stakeholders, especially industry and agriculture researchers - Established infrastructure to facilitate research-industry partnerships, expertise databases, etc. - Researchers fairly well-connected within the larger agriculture/food /nutrition communities, good market knowledge, frequent interactions via professional and government initiatives - Several government stakeholders but agencies do not have clear mandates, and no formal mechanism for interdepartmental coordination, resulting in significant overlaps and gaps 	<ul style="list-style-type: none"> - Research for the “common good”, consumer health - Scientists typically have little/isolated knowledge of the industry; not attuned to industry and government priorities - No dedicated funds outside of NHPD, do not register on political radar; don’t fit well under existing categories/funding priorities except as FFNs lacking IP value - Must compete with conventional natural science and biomedical research - Very small and relatively unknown cohort of qualified peer-reviewers, expertise in quality/ methodology especially rare. - Funding success rate well below average unless described as “novel natural products” (FFNs) - Partnership grant proposals rare, mostly in-kind support rather than cash - Investigator-initiated projects span the entire range from basic to clinical, industry partnerships mostly for product quality, processing or more rarely efficacy testing - Linkages between stakeholders, especially industry and researchers very poor - Little infrastructure, difficult to identify partners, determine level of expertise - Researchers largely isolated from each other and from industry, contact often limited to 1 company; knowledge of market, government and industry needs often lacking - Disjunct between government agencies; disparate mandates, interaction rare, few lines of communication, and coordination is markedly lacking
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Intellectual Property

FFN	NHP
<ul style="list-style-type: none"> - Significant IP and potential commercial value in discovery of novel compounds, products and/or processes; new crops, crop uses or crop enhancements can also be of value in large scale agriculture - Strong patent protection for novel compounds/ingredients, some protection for novel formulations and processes, weakest form plant breeders rights - IP and commercial potential increasingly critical key to obtaining funding; patent protection essential factor to secure private research investment - Timing between patent filing and product launches critical as patent life-span limited to 7 years; lack of clear regulatory process significant risk factor 	<ul style="list-style-type: none"> - Little or no IP value as based largely on public domain knowledge: known compounds (Vit. C), historical usage, non-patentable organisms (botanicals, probiotics, animal products) - Significantly weaker patent protection for new formulations and processes; very limited value in the marketplace (NHPs generally perceived as generic products) - Lack of IP and/or commercial potential significant detraction to public funders; lack of patent protection barrier to private investment - Market benefits of proprietary research generally small and have very short life-span (typically months till introduction of “comparable” competitive product)

Safety and Quality

FFN	NHP
<ul style="list-style-type: none"> - Mostly “generic” products wherein safety and quality rarely at issue; FFNs typically well-defined and structurally characterized entities derived from common foods and/or GRAS substances in licensed food/pharma GMP facilities with robust QC programs 	<ul style="list-style-type: none"> - Potential safety concerns arising from multiple sources: non-GRAS/toxic materials, contraindications, drug interactions, poor quality (misidentification, impurities, adulterants, inconsistent potency) - Products not generic in their composition. Research materials must be fully characterized and standardized to ensure reproducible results - Product safety and quality difficult to assess due to complex make-up, lack of quality standard, reference materials and validated methods

Product Development

FFN	NHP
<ul style="list-style-type: none"> - Product development almost exclusively based upon science and/or technology innovation - Primary commercial development supported through pilot processing plants, AAFC research stations, business incubators, and other federal and/or regional government programs – mostly in the agriculture area. Secondary development via spin-off companies, venture capital, and government programs - Growing industry primarily supported by agricultural incentives - Venture and angel capital exists for research and product development, although challenging to find appropriate strategic partners in the food industry, which tends to be quite conservative and risk adverse 	<ul style="list-style-type: none"> - Consists largely of “new” ingredient combinations and introduction of “new” traditional medicines - Small, heterogeneous and isolated industry members that are very competitive. Lack awareness of pilot processing resources and/or cost of new product development often prohibitive. Little primary or secondary support for products which are not innovative. - Research incentives lacking, less support from agriculture sector - Very difficult to secure venture capital because of IP issues, biases within financial circles, and uncertainties surrounding new regulatory regime.

Summary

The key features associated with FFN were food products, biotechnology and innovation, intellectual property, and significant potential economic benefits. Few FFN stakeholders participated in the development of the NHP Regulations and many of these stakeholders still do not recognize nutraceuticals as NHPs. NHPs were perceived as health products, naturally-occurring substances that have not been significantly modified chemically and/or through biotechnology, generally with little IP value and/or non-patentable, significant socio-economic benefits in terms of their contributions to the health of Canadians but only modest direct benefits to the Canadian economy.

In academia, industry, and government, there appears to be a significant disjunct between FFN and NHP stakeholders. Recognizing the considerable overlap between these two categories, most especially in regards to “nutraceuticals”, there was a general agreement that a concerted effort needed to be made in order to bridge these gaps. Specifically in terms of developing a strategic plan for NHP research, there was a consensus that FFN* stakeholders should be included in the national dialogue, including federal and provincial government agencies, industry associations, and research institutes.

* For brevity, the acronym FFN is used hereafter to refer to nutraceutical stakeholders who self-identify with the FFN category.

Recommendation:

Regulators and stakeholders continue to work together on clarifying the definition boundaries for FFN and NHPs, and the attendant levels of evidence required for each.

Recommendation:

Strive to more actively engage key FFN representatives and policy-makers in the national dialogue on NHP research, and raise awareness regarding the definition of NHPs, unique challenges in NHP research, and the potential socio-economic benefits of NHP research.

Next Steps:

- Identify key FFN representatives and policy-makers.
- Develop briefing documents and presentations regarding NHP research, NHPs and FFNs definitions, etc.
- Host virtual, in-person and/or consultative meetings starting with key FFN representatives, and building up the administrative chain.

Recommendation:

Invite and encourage FFN associations and research institutes to more actively engage in the NHP research dialogue. A clearer picture of the objectives and parameters of the research programs at the existing FFN institutes is needed in order to develop a comprehensive strategic plan. The FFN industry does not have a unified national voice and most associations do not have a formal policy position on research, yet they are well-situated to solicit and focus industry input.

Next steps:

- Initiate a dialogue with FFN research institutes to explore their research objectives and the parameters of their research programs, and to identify points of commonality and divergence in relation to NHP research, potential research barriers and champions.
- Initiate a dialogue with FFN associations to identify their organizational objectives and activities, and their potential role in the development of the strategic plan for their sector.
- Host a strategic planning meeting with these stakeholders to obtain focused input and build consensus on the strategic plan for nutraceutical research.

3. NHP Research Database

Background

The critical need for a NHP researcher database was recognized from the outset at the first NHP Priority Setting conference in 1999.⁸ It was frequently identified as a priority issue in the subsequent consultations, with stakeholder recommendations that the NHPD should take a lead role in initiating the development of such a database.⁹

The underlying rationale was that the NHP research community was very fragmented and isolated, and a tool was needed to identify these researchers and their areas of expertise. The database was envisioned as primarily a tool for the NHPD and to a lesser extent, NHP researchers. It was frequently suggested the NHPD should share the information amassed in the database with granting agencies to assist in the identification of appropriate peer-reviewers.

Following up on these recommendations, the NHPD commissioned an NHP Research Environmental Scan (ES), which was completed in 2003. This survey captured the majority of Canadian NHP researchers but was not exhaustive due to the project's short time frame. In particular, a number of nutraceutical researchers from the FFN community did not participate in the survey. The ES did not include any information on the technical resources and research capacity of these scientists. Shortly following the completion of the ES, participants at the NHPD Invitational Roundtable of Natural Health Products Research Priority Setting Conference in Winnipeg recommended that this database be maintained (up-dated), and expanded to include infrastructure and research capacity.¹⁰

During this project, the need for an up-dated NHP research database again emerged as a key priority, albeit with several new perspectives on the issue from industry, funders and researchers.

Industry

Industry stakeholders identified a researcher database as an essential tool to enable compliance with the new regulations. There are few linkages between the NHP industry and the research community, and consequently many industry members do not know who the researchers are or how to identify them. In some cases, they may not know exactly what type(s) of expertise and research capacity they require to fulfill their needs. Of equal importance, once a potential collaborator has been identified, it is very difficult for industry stakeholders to objectively evaluate the researcher's level of expertise, the scientific merit of their work, and/or the relative strength/weight of difference types of scientific evidence.

It was pointed out that while there are some databases/directories available, these are of limited utility because they have been compiled through voluntary self-reporting. I.e. They tend to contain a high proportion of consultants, contract research organizations, and allied service industries - and relatively few academic researchers. Another shortcoming is that existing directories do not provide details on areas of expertise or research capabilities.

There was a strong consensus that a searchable database on bona fide NHP researchers was a top priority. Specific areas of bio-medical and NHP expertise, research capacity, and scientific credibility were identified as essential features. I.e. The database should be designed to facilitate

searches for researchers with specific types of expertise (Eg. Acute toxicity, breast cancer, chemical analysis, drying methods, echinacea, etc.) and research capabilities (Eg. in vitro anti-herpes virus testing, chronic toxicity studies in mice, human pharmacokinetic studies, etc.).

It was recommended that the survey template be developed in consultation with industry to determine the most useful and user-friendly classification hierarchy. Some envisioned this database as an internet resource while others indicated a preference for a human interface through a professional organization that could provide objective recommendations. It was generally agreed that there was a need for both an electronic database and expert guidance.

Funding Agencies

These stakeholders also emphasized the great utility of an NHP research database and stressed the importance of peer-review and third-party validation of NHP expertise. It was suggested that such a database would have much greater credibility and value to funders if it included objective evaluation criteria, precise scientific/medical expertise and NHP expertise classifications; and that this data was vetted by a credible arms-length agency.

Researchers

Researchers echoed many of the same sentiments, also stressing the importance of differentiating between scientific expertise and NHP expertise, and objective third-party validation. This data was deemed essential to objectively assess which areas currently have the greatest critical mass of research projects and NHP expertise. As with industry stakeholders, researchers also saw such a database as a very valuable tool for facilitating new collaborations. The inclusion of data on nutraceutical researchers, infrastructure and research capacity were identified as key objectives.

Summary

A peer-reviewed, searchable database of NHP researchers was identified as a top priority by all stakeholders. There was a clear consensus that the ES should be up-dated and expanded to include nutraceutical researchers, research expertise sub-classifications and research capacity data. The ES template should retain objective criteria for evaluating NHP expertise and the veracity of this information should be authenticated through peer-review. Considering that this is a relatively new field with unique challenges that are not generally well-known, stakeholders felt that a human interface was also essential for the appropriate matching of expertise. It was recognized that the recently enacted privacy legislation introduced another layer of complexity and expense, and that the revised ES template must be designed specifically with these constraints in mind.

Recommendation:

Up-date and expand the ES to include nutraceutical researchers, research expertise sub-classifications and research capacity data. The ES template should retain objective criteria for evaluating NHP expertise and the veracity of this information should be validated through peer-review.

Literature Database

Another widely recognized need is an NHP literature database compiling existing scientific evidence on NHPs and providing critical reviews and synthesis of this data. Although all stakeholders agree on the need for such as database, this type of work is usually not supported by the scientific funding agencies. However, it was pointed out that many other health oriented non-governmental organizations (NGOs) also have a need for objective information on NHPs. The Canadian Breast Cancer Society and Reseau Proteus were cited as two examples of NGOs which have supported critical NHP literature reviews. It was also noted that the non-profit organization Reseau Proteus has already compiled considerable data in French and recently entered into an agreement with the NHP Research Society to facilitate the production of English language systematic reviews.

While the task of compiling a comprehensive NHP literature database is too large for any one association to fund individually, many of these organizations have a vested interest in NHPs and may be open to a collaborative project. An initial commitment of secure seed monies from one or two well-recognized agencies would provide strong funding leverage with other organizations. It was suggested that the NHPD could play a critical “matchmaker” role in building funding support amongst Canadian government and NGOs for a national project.

Recommendation:

Take a lead advocacy and coordination role in building support for an NHP literature database collaboratively funded by government and non-governmental organizations.

4. Current Capacity for NHP Research

The Canadian Research and Development Community

Initially research in the FFN area was located almost exclusively in the domain of agriculture. However, due to the significant attention paid to the industry within the last decade, FFN research has attracted interest from the “traditional” food sector as well as from departments of nutrition, pharmacology and medicine. In comparison, NHP research began with, and continues to have, basic science (pharmacology) and clinical medicine as its root and foci.

The imprecision in the definitions of FFN and NHP preclude exact numbers but it is estimated that there are roughly 200 scientists currently working on funded FFN/NHP research projects in Canada. The NHP Research Environmental Scan identified over 160 Canadian researchers, the majority of which were academic researchers in agriculture, basic science, medicine and nutrition. Approximately two-thirds of these scientists reported that herbal or traditional medicines were their primary research focus. The interests of the remaining one-third encompassed the entire array of NHPs, the most predominant of which were (in descending order) “all NHPs” and CAM.

There are a number of natural health products/ingredients that are currently being studied in Canada including, but not limited to:

- Antioxidants (lutein, zeaxanthin, lycopene, polyphenols, flavonoids, etc)
- Botanicals and fungi
- Conjugated linoleic acid – plant and animal derived
- Essential fatty acids – fish and plant derived
- Flax lignans
- Glucosamine and chondroitin
- Glucosinolates
- Lecithin and other phospholipids
- Peptides and proteins (most commonly oilseed proteins from canola, flax, hemp, and soy)
- Phytosterols
- Pre and probiotics
- Saponins
- Soluble fibers (β -glucan, galactomannans, mucilage, pectins)
- Soy isoflavones
- Vitamins and minerals

The Canadian Industry

It is currently believed that the demand for nutraceuticals and functional foods in Canada is in the \$1-2 billion range (CDN).¹¹ In 2003, Statistics Canada published the first-ever information on the Canadian FFN/NHP industry.¹² The FFN survey was sponsored by Agriculture and Agri-food Canada, and employed the FFN definitions previously published by Health Canada. Therefore NHPs were included under the nutraceutical category in this survey.

A total of 146 respondents indicated involvement in FFN activities. One-quarter were involved in both functional food and nutraceutical activities, while around 28% were in FF only and 48% were in nutraceuticals only. In terms of the source origin of FFN ingredients (I.e. raw materials), herbs and spices predominated at 36.6%, followed by oil seeds (32.6%), and grains and cereals (28.7%). In descending order, the health categories with the greatest number of products and greatest revenue generation were: general well-being, cardiovascular, immune, and energy.

Product development and scientific research and development (R&D) were two of the four main areas that FFN companies were most likely to be engaged in, with almost 40% of nutraceutical companies reporting product development and 36% R&D participation. However, over one-half of these companies (54%) spent less than \$50,000 and another 35% spent less than \$500,000 on R&D in 2002.

Existing and Emerging Research Nodes

There are several institutions that conduct research in the field of NHP and FFN including government, university, and contract research organizations. Overview summaries of the current capacity of these agencies, as well as some key networks and supporting stakeholder associations are given in Appendix 2. In addition to these formal groups, there a number of informal collaborative networks and emerging nodes across the country, mainly in the areas of FFNs, probiotics, essential fatty acids (flax and marine), botanicals (especially First Nations Traditional Medicines and to a lesser degree Traditional Chinese Herbal Medicines), and product quality.

Research Gaps

There are a number of NHP sub-categories though, where there appears to be very little, if any, funded research. Often referred to as “research orphans”, common features of these research gaps are that they do not easily fit within established scientific specialities, and they lack champion(s), and financial support. In areas such as animal-based NHPs, cultural/traditional medicines such as Ayurveda, and homeopathy, whilst there are some highly interested individual and group stakeholders, as yet there are no nascent research nodes or even recognized research champions to foster development. In the quality field, there are a number of experienced researchers but they report that they cannot obtain Canadian funding for quality research projects which have been identified as national priorities.

Animal-based NHPs (Eg. elk velvet, emu oil, animal and insect venom)

Although commonly referred to as “animal-based” NHPs, this category might be more accurately described as non-plant NHPs as it encompasses a range of products derived from birds, fish, insects, mammals, reptiles, etc.. This area has several very small industry based associations for some products (elk velvet, emu oil) but not others. Moreover, there are no unifying national organizations or research groups. There are individual scientists across the country with an interest these “animal-based” NHPs, some of whom may be captured under the FFN/bioactive category but the remainder are widely scattered across the bio-medical spectrum and tend to work in isolation. Many report that their work on animal-based NHPs is carried out as a small, unfunded adjunct to their conventional research projects.

Homeopathy

While there are some practitioners (both homeopathic and conventional) with an interest in this

field, there is little if any funded research in this area. During the course of this project, no Canadian researchers with experience in the scientific evaluation of homeopathic medicines were identified. Although research expertise and infrastructure support is lacking, key associations and companies have indicated a strong interest and willingness to work together to develop research capacity.

Stakeholders have emphasized the importance of integration as opposed to segregation as an “under-developed” research area. I.e. Homeopathic stakeholders should be invited and actively encouraged to participate in the NHP/Complementary and Alternative Medicine (CAM) research community, attend meetings, conferences, etc. It has been suggested that an exploratory workshop that brought together homeopathic stakeholders, interested conventional practitioners, and experts in research methodology could provide an important first step towards building cohesion and research capacity.

Traditional/Cultural Medicines

Outside of the emerging clusters in First Nations and TCM, there are no apparent research clusters or champions for other traditional/cultural medicines although there are interested researchers scattered across Canada. There are a number of cultural and/or practitioner/professional organizations with an active interest in traditional medicine research. However, even within a particular cultural context, these groups tend to be diffuse and often lack a unifying national infrastructure that could link traditional practitioners, conventional health professionals and researchers.

Recommendation:

There are significant research gaps in the NHP sub-categories of animal-based bioactives, homeopathy, traditional/cultural medicines, and product quality. Industry, professional, and scientific associations can play lead roles in identifying current and potential researchers, strategic planning, and research capacity building. Capacity building strategies should focus on fostering the integration of these “orphans” into the larger research community and building cohesion, rather than segregating them as special needs areas.

Next steps:

- Identify and survey stakeholder organizations regarding their vision, objectives, and resources for research.
- Invite their participation in national dialogue on strategic planning for NHP research.
- Foster and promote interaction with the larger community, especially inter-disciplinary meetings, workshops, and conferences to disseminate research skills.

Product Quality

One of the few issues that consumer, industry, government, and scientific stakeholders are universally agreed upon is that product quality is a top priority. Canada has the basic capacity required for quality research but there is a quite marked gap in quality research funding and personnel training. A few post-secondary courses have very recently been introduced but there are no undergraduate or graduate training programs in Canada. There is a small core group of experienced workers, a few of whom are internationally-recognized experts and participants in

various global initiatives, but their funding is largely from international sources.

Product quality is generally not perceived as a legitimate field of research in and of itself. Projects that have been recognized as top priorities (Eg. quality standards, reference materials, method development and validation) both in Canada¹³ and abroad, typically are not considered to be original research by the research funding agencies and their peer-reviewers. While quality research generally has little intellectual property (IP) or commercial value, it does convey highly significant benefits for the health of Canadians and the Canadian NHP industry.

Recommendation:

The government is strongly encouraged to take an active role in promoting, facilitating, and supporting product quality research as there is a clear consensus that this is a top national priority. (see also section 5 for further recommendations)

Research Funding

Common Canadian funding sources for FFN and NHP research are listed in Appendix 2.3. Outside of the NHPD, none of these organizations have dedicated NHP research competitions, programs or research themes. However, a number of these agencies have identified FFNs as a priority funding theme and generally classify NHPs as falling within the FFN category.

Appropriate peer-review, perceived institutional biases against NHPs, and the growing emphasis on intellectual property (IP) value and commercial spin-off potential were commonly identified as the most significant barriers to NHP research funding.

For the most part, NHP applicants must compete with conventional biomedical researchers for scarce funding resources. Relative to other biomedical fields, the Canadian pool of NHP research expertise is quite small and very few of these experts serve on grant review committees. This means that NHP applications are often reviewed by conventional scientists with little or no NHP expertise. As the potential benefits of most NHPs are related to wellness and prevention rather than disease treatment or cure, both the scientific and socio-economic value of NHP research is often perceived to rank below that of conventional disease-related projects. In addition, mainstream researchers are often unaware of the special challenges and issues in NHP research.

Protection of intellectual property (IP) rights to health claims was identified as one of the most crucial factors influencing public and private support for NHP research. In the public arena, changing priorities and budget allocations have produced a new funding agenda, which has a strong commercialization and cluster focus. These new priorities have significantly influenced the evaluation criteria for basic research grants and decidedly shifted the funding emphasis in favour of partnership (private/public support) programs. As a result, a much higher percentage of research funding is now dedicated towards the support of ‘priority’ sectors or economic clusters for the development of patented products and processes that have a strong commercialization potential.

To secure private funding, corporate management or potential investors must be convinced that their investment will be profitable and profitability is largely contingent upon the ability to protect good ideas through adequate intellectual property rights. For the vast majority of decision-makers,

patents or very strong patent potential are an essential prerequisite for research investment.

However, patent protection is generally weak or non-existent for the majority of NHPs, as they are composed of non-patentable organisms (Eg. microorganisms; animal, fungi, or plant material) or well-known substances such as vitamins and minerals (I.e. not novel compounds, public domain knowledge). Therefore, it has become increasingly difficult to secure private or public funding for NHP research because it rarely results in strong IP.

One of the means that the NHP sector does have to attract interest from the very limited public and private funding pool that does not necessarily require IP is through its ability to make health claims. However, predictability about process, costs and timing is essential to secure this potential investor interest. A priori definitions of ‘how much’ and ‘what kind’ of evidence is required to make claims are pivotal factors in providing this predictability. At present, guidelines appear to be very fluid and both detailed criteria and case precedents are lacking. Consequently, funding stakeholders are withholding or minimizing investments in NHP research.

In this regard, regulators hold a pivotal role in promoting NHP research in Canada, as a clearer delineation of the evidence required to support proprietary claims would contribute significantly towards attracting both private and public financing. An appropriate balance between flexibility and prescriptiveness could be struck by expanding the standard of evidence guidelines to include maximum and minimum evidence levels, algorithms for equating different levels of evidence, and case examples.

In addition to knowing how much and what type of evidence is required to support claims, it is equally, if not more crucial, that stakeholders have a firm legal assurance that proprietary claims will be protected. Given the generic nature of most NHPs, explicit written guidelines regarding the evidence requirements for *establishing* a proprietary claim and for *proving generic product phytoequivalence* are essential prerequisites for research investment, especially from the private sector.

Recommendation:

Establish a Standard of Evidence Committee comprised of experts in the critical evaluation of scientific evidence and research methodology, to advise on the further delineation of more detailed standards of evidence, including:

- maximum and minimum levels of safety evidence for each risk category,
- maximum and minimum evidence requirements for each level of efficacy claims
- nature and degree of evidence required to establish proprietary claims,
- nature and degree of evidence required to establish generic product phytoequivalence,
- algorithms for equating different levels of evidence, and
- case examples.

There is also a strong need to champion NHP research for the public good. The growing funding emphasis on knowledge transfer to industry, commercial spin-offs from research, and industry

partnerships makes it increasingly difficult to access funding for NHP research, especially for generic products which have little IP value. In order to effectively argue the case for NHP research for the public good, hard data on potential socio-economic benefits of NHP usage is urgently needed. By funding a pilot project evaluating the socio-economic benefits of exemplary NHPs, the NHPD could significantly contribute towards the future competitiveness of NHP research projects.

As the only dedicated source of Canadian NHP research funding, stakeholders felt that NHPRP grants and contributions should not be used to support projects with IP value or commercial potential, as these projects should be competitive in the general biomedical grant arena. It was recommended that the NHPRP funding criteria include a priority for projects which potentially provide significant socio-economic benefits for Canadians but lack IP or commercial potential.

Recommendation:

Champion public funding and prioritize NHPRP support for generic NHP research and other potentially beneficial projects which lack direct IP value. The NHPD is encouraged to provide seed funding for a pilot study on the socio-economic benefits of exemplary NHPs (Eg. vitamin, amino acid, essential fatty acid, herb, etc.).

International Capacity

Based upon a synthesis of official documents, internet search results, expert input, and the authors' professional experience, overviews and analyses of the core strengths and weaknesses in other countries were compiled and are given in Appendix 3.

SWOT Analysis of NHP Research Capacity in Canada

This analysis of the strengths, weaknesses, opportunities and threats (SWOT) regarding NHP research is based upon a synthesis of the data amassed in the foregoing sections (4.1-4.5) and stakeholder input.

Strengths

- Conventional bio-medical research infrastructure and technological capability, and
- Comparatively strong research infrastructure in crop development and processing areas
- Government has developed an appropriate regulatory climate for NHPs, increasing the incentive for industry investment in research
- Canada has strong scientific and technical expertise in universities and research institutions, and cost-effective research capability
- Several institutions have teams in place working on various aspects of the fundamental “research to product development” continuum
- Governments, universities, health institutions and industry have some collaboration
- Research community organizing through national and provincial networks and associations
- Several federal and provincial agencies have identified FFN/NHP as priority area

Weaknesses

- Lack of cohesion and coordination amongst the research community
- Lack of communication, linkages between NHP sectors and stakeholders

- Reluctance of the medical community to be involved in NHP research; lack of awareness of NHP research findings and/or sceptical of their scientific validity.
- Limited financial resources for research; falls between “agriculture and medicine” and/or “food and drug”
- NHPs appear to carry a stigma within many of the funding agencies
- Very limited financial assistance specifically for product R& D, proof of concept, and background research (Eg. agronomics, stability, etc.)
- Lack of focused government support for NHP research. Role needs to be defined as several agencies are involved without clear mandates and with much overlap
- No obvious champions exist on a national level
- Significant need for highly qualified personnel
- Lack of clarity surrounding levels of evidence required and FFN/NHP boundaries
- Research costs to support claims for generic products prohibitive for most companies
- Industry is fragmented and most players work independently. No clear leadership exists at national level despite multitude of organizations
- Lack of IP, patent-protection, and/or commercial potential
- NHP research sectors are at different levels of sophistication and evolution.
- Have not identified all of the associations and partners that can help move the research agenda forward.

Opportunities

- Canada has the potential to assume a leadership role and establish unique research niches in specific areas that can be chosen based on national and consumer priorities
- Significant socio-economic benefits nationally and internationally, especially
- Potential to significantly lower health care costs and improve quality of life
- Potential to leverage support and funding by building linkages with other major federal initiatives and priority themes such as the new Agriculture Policy Framework (quality, safety and traceability), Industry Canada (quality, safety and efficacy, marketability and innovation), Forestry (sustainable non-timber forest products or NTFPs), etc.
- Potential to influence and build a “Genome Canada” type of scenario for NHP research based upon a strong business case rationale.
- EU regulatory regime substantially lags that of Canada.

Threats

- Severe competition for scarce health research dollars
- Increasing emphasis on IP value, commercial potential and industry partnership funding
- Some other regulatory regimes are more liberal and/or further developed in defining product categories and permissible health claims for nutraceuticals and NHPs
- US, EU and Japan commit significantly more funding towards NHP research (Eg. In the U.S., ~ 50% of NCCAM’s \$110 M annual budget goes towards NHP research)
- US in particular commits substantially more dedicated funding for NHP research, with 4 established research centres and several more under development funded @ \$10 M each

5. Networks and Networking

Background

One of the major themes that emerged from the NHPD consultations was the need for an infrastructure to coordinate research, and facilitate stakeholder communication and knowledge transfer. The discussions surrounding this concept invariably involved the formation of some type of national research network to develop and carry-out a strategically planned research program. The most commonly cited purposes for the network were coordination and collaboration, resource sharing, capacity building, and the development of policy and standards.¹⁴ While there was a strong consensus amongst all stakeholders regarding the need for unifying national infrastructure, there was a wide array of concepts as to its constitution, scope and objectives.

In March 2003, the NHPD hosted a final research roundtable in Winnipeg to develop a strategy for advancing the national research priorities (Invitational Roundtable of Natural Health Products Research Priority Setting Conference.¹⁵) The need for infrastructure and the creation of a national network were again a major theme in these discussions. Acknowledging the need for a research network, the participants recognized that considerable groundwork would first need to be done to develop a strategic plan, formulate a scientific framework, and build funding support for a network.

A consensus was developed that the NHPD should support the formation of a non-profit society to provide organizational infrastructure for the advancement of Canada's NHP research priorities. It was agreed that the society's first initiative should be the hosting of a national research conference to provide a communication forum for all stakeholders, facilitate collaborations, and to foster networking to build cohesion within this sector. It was recommended that the NHPD provide seed funding for the conference and fund various activities of the Society including the costs of establishment.¹⁶ [N.B. Based upon these recommendations, the Natural Health Product Research Society of Canada was founded as a not-for-profit organization and was granted federal Letters Patent on August 26, 2003. The society subsequently organized the "First NHP Research Conference: Linking Researchers, Industry and Government" held on February 20-22, 2004 in Montreal.¹⁷]

Following the conference, it was recommended that additional discussions/meetings be held to further the development of a national research network, the scientific framework for NHP research, and a strategic plan for NHP research in Canada. Inclusive consultations with all NHP research stakeholders and consensus building on these plans were identified as critical factors in this process. One of the objectives of this project was to advance this recommendation in regards to the formation of a national NHP research network.

Two very distinct perspectives on networks and networking emerged during the Montreal consultation, and these viewpoints persisted throughout subsequent dialogues. Some stakeholders approached the subject of networking from an extremely pragmatic point of view, focusing on what was realistically possible within the constraint of current funding opportunities in Canada. Others approached the issue from a more theoretical perspective, focusing first on the conceptual elements and objectives.

Pragmatic Approach: Focused NHP Research Networks

Based upon a review of existing Canadian programs, it was concluded that research “network” funding opportunities are extremely limited at the present time. As no National Centres of Excellence (NCE) Network competitions have been announced since 2003, the general consensus was that the Natural Sciences and Engineering Research Council (NSERC) Network grant program constituted the best available opportunity for network funding currently available. The NSERC Network program is designed to support highly focused research projects that require inter-disciplinary collaboration. In addition to scientific excellence and the involvement of recognized leaders in research, the NSERC program emphasizes innovation, strong industry participation and support, and a robust business plan that addresses intellectual property issues and effective technology transfer.¹⁸

It was recognized that “NHPs” constituted too broad of a research focus for an NSERC Network, considering the program criteria, the scope of networks funded to date, and criticisms of a previous unsuccessful herbal network application. A number of more tightly focused research themes for an NSERC Network application were identified including traditional medicines, product quality, and botanicals. During the Montreal meeting, many participants chose to concentrate on elaborating a framework for a botanical network, as they felt that this field had the greatest critical mass of expertise.

Botanical Research Network

Cognisant of the need for a highly focused research program, initial discussions centered round the delineation of specific research areas and themes. There was ready agreement that product quality was an essential cross-cutting theme and that the employment of well-characterized, standardized botanical material was a fundamental prerequisite for any network project. The importance of multi-disciplinary teams, collaborating with existing groups, and training of highly qualified personnel were also identified as over-arching principles.

There was a general agreement that quality from the crop to the consumer and clinician was a good unifying theme that emphasized our Canadian advantages. The network’s research approach should be to develop reproducible research protocols from the ground up; from production and processing through to pre-clinical studies. To ensure maximum relevance to Canadians, priority should be given to top-selling products and those which pose the greatest potential risks/benefits. After considerable discussion and winnowing, the research areas with the strongest critical mass of existing expertise were identified as:

- Cancer
- Diabetes and metabolism
- Ethnopharmacology (traditional medicines)
- Infection, Immunity, and Inflammation
- Pharmacology and toxicology
- Production, processing, and product quality (pharmacognosy)

Node leaders and key contributors were identified in each of these areas, and these participants agreed to collaborate on further developing this framework, fleshing out the six research areas and developing a management plan, with the objective of submitting an NSERC network application.

In subsequent discussions, some reservations were expressed that while this framework focused on existing research strengths, it might still be deemed as being too broad in scope for an NSERC network. To be successful, it may be necessary to focus the proposed research program more tightly under the heading of “pharmacology and toxicology” research, or restrict the program to only a few of these areas. Product quality was identified as the core prerequisite for either approach.

Product Quality

Product quality has variously been identified as a national priority, an essential cross-cutting theme, a research orphan, and the potential focus for a research network. During the Montreal consultation, it was observed that most of the necessary elements for a quality research network were already in place. A consensus has been developed on the top priority research areas, the key national and international players have been identified, and a preliminary NRC/NSERC grant proposal has been framed. There is strong industry support for quality research in principle, although there is little financial incentive for individual companies to invest in projects which are essentially for the greater good of the industry and Canadian consumers.

The perception that quality research is not “real” scientific research and/or not appropriate for public grant funding was identified as one of the most substantial barriers. It was suggested that this obstacle could be potentially overcome if it was apparent that there was very strong industry and government support. The University of Toronto Food Safety Program was cited as an example of how such a project could be successfully mounted. A national check-off system was also mentioned as a potential funding mechanism.

There was agreement that efforts should now be focused on the development of a concrete business plan and management strategy with industry stakeholders. To accomplish this, it was recommended that an advisory committee consisting of industry stakeholders (associations and lead company representatives) and a few key researchers be formed and a business consultant with experience in public funding hired to guide the development of the business plan. At the appropriate stage(s), grant officer(s)/advisors should also be involved in these discussions. Once a consensus was reached on an acceptable funding formula and management plan, this committee should continue to function on an ongoing basis as an oversight body, responsible for identifying the specific NHP priorities and ensuring optimum relevance of the research program.

The presence of an effective catalyst/facilitator for this matchmaking process was identified as a critical missing element. Individual researchers do not have sufficient time or resources to devote and similarly the NHPRS does not have the manpower to advance this agenda even though it is one of the organizations key objectives.

Recommendation:

Considering that product quality has been consistently identified as a top priority for the NHPD, there was a general consensus that it would be highly appropriate for the NHPD to take an active role in facilitating this process and in providing seed funding.

Next Steps:

- Form an advisory committee consisting of representatives from industry associations, individual lead companies, BCIT, NRC, NSERC, ODS, and the NHPRS with an initial mandate to create a business plan for the quality program. The NRC/NSERC framework could be circulated to the committee members as a starting place for these discussions.
- Contract a business consultant with experience in public funding to guide the development of the plan. Drawing upon their experience and input from the committee members, the consultant should draft and circulate a plan outlining the most promising management and funding structures.
- Host an advisory committee meeting to develop a firm consensus on the business plan and timeline for its implementation.

Traditional Medicines

Under the auspices of the World Health Organization (WHO) Traditional Medicine program, 19 WHO Collaborating Centres for Traditional Medicine (CCTM) have been established around the globe.¹⁹ At the 2003 WHO Traditional Medicine meeting, the concept of establishing a Canadian WHO Collaborating Centre for Traditional Medicine (CCTM) was apparently positively received and the NHPD was identified as the lead Canadian agency for further discussions. The priority objectives of the WHO Traditional Medicine (TM) program are TM policy and promoting the safety, efficacy, and quality of TMs.²⁰ The research carried out at the various CCTMs focuses largely on phytochemical and pharmacological studies on traditional remedies.²¹

At the Montreal consultation, the notion of a Canadian CCTM was also well-received. The consensus was that a more diffuse, virtual network approach would be a more appropriate format for Canada though, rather than “bricks and mortar” institution. Acknowledging the practical limitations in terms of financial resources and research capacity, there was generally agreement that initial efforts should focus on developing infrastructure for the existing nodes of traditional medicine research expertise. A number of potential collaborating institutions were identified as having a core of experienced researchers, established codes of ethics for aboriginal research collaborations, and First Nations advisory committees, as well as strong linkages with aboriginal communities.²² Participants felt that there is a tremendous opportunity to formally link these clusters to create a coordinated national research program.

Three potential funding avenues were thought to merit serious consideration and further exploration: the NCCAM Developmental Centres for Research on Complementary and Alternative Medicine (DCRC) program, NSERC, and CIHR – Institute for Aboriginal Peoples Health (IAPH) as traditional medicines is one of its priority research areas.

The Institute of Aboriginal People's Health (IAPH), Canadian Institutes of Health Research (CIHR) recently partnered with the NHPD's Natural Health Products Research Program to fund a “New Emerging Team” investigating the use of herbal medicines for diabetes amongst the Cree nation²³. It was suggested that the IAPH might be willing to consider a larger project in this area. It was pointed out though, that sustainability, ecological and environmental issues were an integral part of traditional medicine research and that it was very unlikely that CIHR would fund this type of work. This gave rise to the idea of a complementary NSERC proposal to address these aspects,

as they fell under the natural sciences mandate.

Another limitation of conventional grant programs is the prerequisite for academic credentials, which precludes the involvement of many natives/native communities as recognized research collaborators and/or project leaders. It was stressed that traditional medicine research must be based upon equitable, respectful and mutually-beneficial partnerships wherein native peoples are not only accorded an active role but also leadership in the determination of priorities and decision-making.

The U.S. National Centre for Complementary and Alternative Medicine (NCCAM) within the NIH (National Institutes of Health) was also identified as a potential avenue for funding. In particular, the NCCAM Developmental Centres for Research on CAM (DCRC) program was identified as a promising funding program which was open to international applicants. The purpose of the DCRC program “is to promote innovative, high quality, multidisciplinary basic through clinical exploratory/developmental projects in the area of CAM.” The DCRC provides an infrastructure and environment to make it possible to build and stabilize the collaborative research capabilities.”²⁴ It was felt that a very strong argument could be made for a center to tackle the unique challenges involved in aboriginal traditional medicine.

Throughout the subsequent consultations, the concept of a Canadian traditional medicine research network was broadly supported. The importance of a well-grounded, grass roots approach building upon existing strengths was repeatedly stressed. It was generally felt that Canada already has a strong research capacity in this area and the only major obstacle was the lack of a dedicated organizational facilitator.

Recommendation:

Establish a “virtual” Canadian WHO Collaborating Centre for Traditional Medicine that builds upon existing nodes of expertise and fosters the development of new research clusters. The NHPD is encouraged to work collaboratively with research stakeholders to realize this goal.

Next Steps:

- Form a scientific committee consisting of ethnopharmacology researchers to fully develop a national traditional medicine research plan, in consultation with their extended collaborative networks. This plan should build incrementally upon existing projects and expertise to create a cohesive program that encompasses both health and natural sciences. I.e. The initial focus should be on filling the most critical research and infrastructure gaps, followed by small steps of planned growth and development in priority areas.
- Identify the infrastructure required to implement this plan and develop a funding strategy to address these needs.
- Appoint a program administrator to carry out the funding strategy and coordinate the initial organization of the network.
- Appoint a scientific director and form a larger, standing advisory committee consisting of First Nations traditional medicine stakeholders and researchers to review and direct the research program. In forming this committee, explore the possibility of drawing

upon existing institutional advisory committees to minimize duplication and facilitate coordination of efforts.

- Create a network planning and development sub-division to foster capacity building in other areas of traditional medicine research.

6. Conceptual Framework for the Coordination of NHP Research

It was widely recognized that there is a need for a broader-based network to provide overall coordination, communication, and strategy implementation, and that this mandate is beyond the scope of a highly focused NSERC research network. In previous consultations, this body was variously envisioned as a network of networks, a stakeholder consortium, or a representative working group/central planning/advisory committee with multiple sub-committees/nodes.²⁵

A pivotal, priority role for this national coordinating body is building cohesion between the various research sectors, government agencies and key stakeholder groups. The NHP research database was repeatedly identified as an essential tool for accomplishing this objective. In order to ensure that all stakeholders were identified, two strategies were suggested. For established sectors such as FFN, nutraceutical researchers may be identified and contacted through the existing research institutes and industry associations. The latter was recommended as a particularly valuable resource for identifying industry researchers employed by private companies. In the more diffuse areas that lack unifying research centers (Eg. animal bioactives, homeopathy, etc.), interested researchers may identified through scientific and industry associations, special interest groups, and conventional and alternative/traditional health professional organizations.

The interaction with these stakeholder groups should include an assessment of their objectives, needs and goals. (Note that while various association representatives have participated in many previous consultations, a global assessment of the associations' research positions has not been conducted.) Wherever possible, the primary interaction should be with the highest hierarchal level within any given cluster/node (Eg. National association representing provincial groups).

This process will constitute an important step towards building cohesion both within and between interest nodes/clusters. As appropriate for each node, this should be followed up with ongoing contact to develop a consensus strategic plan for that sector that addresses the needs and goals of all stakeholders. (eg. Bring together all FFN associations to work on overall strategic plan for the nutraceutical sector.) Although networking may be facilitated via a number of mediums, in-person meetings were thought to be the most productive communication forum.

An annual, national research conference was identified as an essential tool for stimulating and fostering the development of intra-node cohesion, higher level linkages between cluster/node members, and building research capacity. There was a consensus that the conference should be a high organizational priority. It was also recommended that the connections and networking fostered by the conference should be further nurtured by interim regional and node meetings.

To effectively build cohesion amongst the diverse range of NHP research stakeholders, it is essential that a comprehensive communication plan be developed. As this will involve working with different lead agencies in each sector and stakeholder groups with varying degrees of infrastructure and capacity building needs, customized strategies need to be devised for each area. The development of master communication plan to coordinate and integrate these strategies is therefore critical. The annual national conference will provide an important cornerstone for this coordinated plan. As both the NHPD and the national coordinating body should have lead roles, it was recommended that this communication plan be developed collaboratively.

Recommendation:

Develop a comprehensive communication plan for building cohesion amongst NHP research stakeholders, with customized strategies for each sector. Key elements of this plan will include the following:

1. Identify and solicit input from scientific, professional, industry, and consumer groups interested in NHP research (especially the FFN, animal bio-actives, cultural/traditional medicine, and homeopathy sectors) in regards to:
 - NHP/nutraceutical researchers to be included in the database
 - Their organizational goals, objectives, and needs in relation to NHP research
 - Establishing effective two-way communication, and
 - Development of a strategic plan for research in their sector.
2. Design and build consensus on the communication processes and timelines for developing sector strategic plans.
3. Organize and host national research conference and regional meetings to facilitate strategic planning, networking, and research capacity building.

Policy Development and Dissemination

Throughout the national dialogue on NHP research, there have been a number of other policy issues which have repeatedly arisen. For researchers, funding and appropriate peer-review in particular have been the most prominent of these, but these topics are intricately interrelated with the associated issues of perceived institutional bias against funding NHP research, the lack of patent protection for many NHPs, negative perceptions of NHPs as lacking commercial potential and IP value, confusion surrounding the differentiation of FFNs and NHPs, and the levels of evidence required to support health claims. The latter is also a prominent concern for industry stakeholders, especially the need for greater clarity regarding the nature and extent of scientific evidence required to support claims. Homeopathic and traditional medicine stakeholders also have concerns surrounding the nature and extent of evidence and research methodology, as well as research capacity building.

During this project, policy discussions were focused on identifying the practical steps that should be taken to address these issues. In the past, the NHPD has been perceived as the sole champion of NHP research in Canada and stakeholders have invariably recommended that the NHPD should assume responsibility and/or actively work towards major policy changes. However, this perspective has started to shift as stakeholders have begun to take a more pro-active role. Consequently, many of the ideas and suggestions involved actions and initiatives that could be carried out by NHP research stakeholders and the NHPD. A pivotal recommendation in this regard was the formation of a policy committee under the national coordinating body to develop and implement the policy initiatives discussed below.

Recommendation:

Establish an NHP Research Policy Committee under the national coordinating body to develop and implement policy initiatives.

Peer-review

An up-dated and expanded version of the NHP research database was identified as an essential tool for improving and promoting more appropriate peer-review. Even with the objective criteria built into the survey template, it was generally felt that a self-reporting system would not be sufficient to meet the need for fair and appropriate selection of peer-reviewers. Both research and funding stakeholder emphasized the importance of professional oversight to ensure the veracity of the information and the most accurate interpretation of the data. It was recommended that the primary interface with granting agencies should be through an expert committee that reviewed the agency's requirements, searched the database, and provided short lists of appropriate peer-reviewers. This committee should also facilitate industry liaison with the research community.

Given the extremely wide range of potential research proposals, it was suggested that a realistic short-term goal should be to the appointment of NHP experts to as many standing grant review committees as possible. Stakeholders should try to identify the specific peer-review committees that would be most open to NHP research and encourage the appointment of NHP experts on these review committees. The longer term goal would be to have NHP experts as internal reviewers (not category specific) in the funding agencies.

Recommendation:

Establish a Peer-review Advisory Committee under the national coordinating body to facilitate appropriate peer-review and act as an industry liaison. This committee should be comprised of NHP research experts with proportional representation of NHP sub-sectors.

Raising the Profile of NHP Research in Canada

A number of concrete recommendations were made regarding the creation of a more positive profile for NHP research in Canada and increased funding support. Developing strategies to link NHP research and national initiatives such as Innovation Canada, Health Innovation, Bio-products and the Agriculture Policy Framework was identified as a key step in this process. The need to expand these linkages to embrace international partnerships was also recognized. Intellectual property, health claims, product quality and research for the public good were identified as pivotal policy issues which must be addressed. Acknowledging the wide range of stakeholder perspectives and priorities, there was a consensus that in addition to general policy positions on these issues, customized strategies should be developed in order to effectively build support for NHP research.

The critical importance of developing a strategy to mobilize consumer support was also emphasized. It was pointed out that the strong growth in American funding of NHP research over the past decade has been driven by public demand. Canadian consumers also have a high interest in NHPs, as demonstrated by numerous public opinion surveys and the high degree of citizen input to the parliament's Standing Committee on Health hearings on natural health products. However, the populace is largely unaware of the considerable work which has been done by the NHPD to identify national research priorities, and generally has little knowledge of the research

funding system. It was recognized that there was a strong need to develop an effective strategy to promote public awareness, mobilize and help direct consumer support for NHP research.

It was recommended that a policy committee be established under the auspices of the national coordinating body to formulate general and customized strategies for building support for NHP research amongst consumers and other key national and international stakeholders. Each of these customized strategies should effectively address the issues of IP, health claims, product quality and research for the public good, from the perspective of the target audience. The national coordinating body would facilitate strategic input from other national and regional associations to this committee.

Recommendation:

Establish a NHP Research Policy Committee under the national coordinating body to develop customized strategies for building support for NHP research amongst consumers and other key national and international stakeholders. These strategies should effectively address the issues of IP, health claims, product quality and research for the public good, from the perspective of the target audience.

Once the strategies have been developed, short summaries (briefing notes) and professional position/policy papers should be created. These should be very concise, professional documents with two or three clear talking points. Potential internal champions in the relevant agencies and their key individuals who interact with industry should be identified. The involvement and support of as many stakeholder groups as possible should be sought, and they should be kept up-to-date and actively involved regarding these initiatives.

To accomplish this, a strong policy communication plan should be developed under the national coordinating body, to facilitate strategic input on policy development from stakeholders, and ensure consistent delivery of key messages and content. Key components of this plan would include raising awareness and building support with a number of different target audiences including consumers, industry, other researchers and government. Media relations and the development of communications tools such as websites, and educational materials would also be considered.

Recommendation:

Develop a policy communication plan for the national coordinating body, to coordinate internal and external strategic input on policy development and ensure consistent delivery of key messages and content aimed at raising awareness and building support for NHP research.

Standards of Evidence and Product Quality Standards

Two specific areas wherein stakeholders identified a strong need for policy development and coordination were NHP standards of evidence and product quality standards. As discussed in section 4, it was recommended that an expert standard of evidence committee be established, to further develop a more detailed scientific framework for the evaluation of NHP research evidence. This committee could also serve as an expert adjudicator of evidence assessments.

Independent of the quality research agenda, a strong need for an expert scientific committee to further develop more detailed product quality standards was identified. Four specific areas of immediate concern were identified:

- Designation of official analytical methods for the assessment of product identity, purity, and strength parameters.
- Purity specifications which take into account processing, end-use, and duration of use.
- Exemptions, exemption limits and procedures for special products.
- Laboratory competence and accreditation.

Ideally, this expert committee would ultimately be responsible for the development of pharmacopoeial standards for all NHPs. As NHP quality is a global concern currently being addressed by a number of jurisdictions, harmonization is also a key factor and considerable economies of scale could be realized through international collaboration in the development of these standards. Already recognized world-wide as an innovator in NHP regulation, Canada is well-positioned to take a lead role in the development and coordination of global NHP quality standards. This strategy would provide a considerable competitive advantage for Canadian industry and substantially benefit Canadian consumers.

To be effective and credible, pharmacopoeial commissions must function as autonomous or at least semi-autonomous agencies and there are considerable legal precedents for legislative recognition and support of such bodies. The formation of these expert committees under the auspices of the national coordinating body provides several advantages, the foremost of which are greater scientific credibility and greater credibility amongst stakeholders as an impartial expert committee. While there are undoubtedly administrative and legal rationales for the establishment of these committees under the aegis of the government, it was recommended that the NHPD facilitate the establishment of these committees as arms-length agencies.

Recommendation:

1. Establish an expert committee to further develop a more detailed scientific framework for the evaluation of NHP research evidence.
2. Establish an expert Product Quality Standards Committee to further develop more detailed product quality standards. The scientific committee should include experts from Canada and abroad, and conduct its work in close cooperation with parallel foreign initiatives.

National Coordinating Body

To undertake many of the recommendations identified in this report, a focused and dedicated approach will be required by a national coordinating body that has the capacity to build cohesion, coordinate strategic planning and promote NHP research. The mandate and activities of the national coordinating body should mirror as closely as possible with the needs for advancing NHP research as well as having a product research focus (versus a service focus). This alignment will help to maximize efficiencies and minimize potential duplication with other organizations. Key attributes of this organization will include the capability to undertake and manage the policy and communication initiatives recommended by stakeholders.

Recommendation:

Identify and support a lead organization that can provide national coordination for NHP research. This organization should have the capability to undertake and manage a number of activities including the following:

- Establishing and managing a NHP Research Policy Committee to develop strategies to build support for NHP research.
- Establishing a NHP Research Communications Committee to develop a strategy and implementation plan for facilitating communication amongst NHP stakeholders and public relations to raise awareness and build support for NHP research.
- Establishing and managing a NHP Peer-review and Industry Liaison Committee.
- Establishing and managing a Standard of Evidence Expert Committee further develop a more detailed scientific framework for NHP research evidence.
- Establishing and managing a Quality Standards Expert Committee to further develop more detailed product quality standards.
- Have the capability to undertake educational activities and events to raise awareness and support for NHP research among a diverse group of stakeholders.
- Act as a focal point to build a strong NHP research network and facilitate collaboration and partnerships.

More specifically, organizational communication and policy tasks identified by various stakeholders under this coordinating body include the following:

- Identify and solicit input from scientific, professional, industry and consumer groups interested in NHPs.
- Up-date and expand the NHP research database.
- Organize and host national research conference and regional meetings to facilitate strategic planning, networking, and research capacity building.
- Facilitate and foster the development of successful focused research networks.
- Develop strong linkages and partnerships with other national and regional associations involved in the NHP sector as well as with other stakeholder groups that have an interest in the advancement of NHP research.

It is extremely encouraging that stakeholders are seeking alternatives to complete reliance on government and are actively discussing collaborative solutions. Throughout various discussions, clear recognition has been given that no single government, academic, or industry stakeholder group is in a position to satisfactorily address needs as outlined in this report. The concept of establishing a “network of networks” comprised of representatives from all of these stakeholder groups was generally not well-received either. Appendix 2 lists some stakeholder groups that play important roles in the NHP sector and have an interest in the advancement of NHP research.

There are a number of national industry associations, many of whom participated in previous

NHPD consultations and in this project. While these industry groups indicated an interest in contributing to the ongoing development of research strategic planning and coordination, this is one of many diverse areas in which they represent their members' interests and not necessarily their primary focus. Similarly, a number of CAM stakeholder groups have signalled a strong interest in helping to advance NHP research but for most of these groups, research is only one of multiple organizational objectives and not necessarily a top priority.

There are numerous scientific associations and research institutes whose members are interested in NHP research but only a very few of these groups have identified NHP research as a priority issue. As described in Appendix 2, most government and academic research groups are dedicated to conducting research and do not have an organizational mandate or infrastructure for policy development.

From the national research capacity assessment, three network groups exist that have identified national NHP research policy and/or coordination as one of their organizational objectives: the Canadian Advanced Foods and Biomaterials Network (CAFBN), the Integrated Network for Complementary and Alternative Medicine (IN-CAM), and the NHP Research Society (NHPRS). CAFBN and IN-CAM are academic programs funded by research grants from the National Centres of Excellence Network program and the Canadian Institutes for Health Research respectively. The NHPRS is a non-profit organization funded through membership contributions. The mission and objectives of these groups are detailed in Appendix 2 but may be briefly summarized as follows.

CAFBN provides infrastructure for advanced foods and bio-materials research to develop commercially viable, socially acceptable value-added products and processes. One of the network's sub-themes is the research and development of FFN products. The CAFBN research program is very broad, encompassing not only advanced foods and bio-materials, but also research related to the wide array of genetic, social, ethical, policy, and legal issues which impact on these theme areas. Training of highly qualified personnel is also a priority criteria for CAFBN funding.

IN-CAM facilitates and supports high quality collaborative CAM research from a health services and policy perspective. It was established to create a sustainable, well-connected, highly trained CAM research community that encompasses both complementary and conventional practitioners, as well as CAM researchers. Network objectives include building CAM research capacity, developing CAM research priorities and a research agenda, promoting knowledge transfer and linking with relevant networks, organizations, and educational institutions to develop partnerships that further the Network's goals.

The extensive consultations on NHP research conducted by the NHPD culminated in the stakeholder recommendation that the NHPRS be established to advance NHP research in Canada.²⁶ Identified as a critical gap not met by any other organization, the purpose of the society is to provide the infrastructure needed to coordinate and promote NHP research. Developed through stakeholder consensus, NHPRS objectives reflect the national priorities in NHP research including facilitation of networking and collaboration, policy development, research funding, peer-review, communications, NHP quality and standards.²⁷

The objectives of these three groups are highly complimentary, as CAFBN and IN-CAM address the needs of two very important outlying NHP sectors, while the NHPRS addresses overall coordination and communication. CAFBN, together with the regional FFN institutes, are key focal points for strategic planning and coordination of FFN research. IN-CAM is oriented towards networking and capacity building for CAM researchers and practitioners interested in NHP sub-sectors such as cultural/traditional medicines and homeopathy. Spanning the entire NHP spectrum, the NHPRS mandate is to provide the infrastructure needed to represent, coordinate and promote NHP research. Throughout this project, stakeholders continued to support, uphold, and in many cases strongly champion this role for the organization.

Proposal for Coordinating NHP Research in Canada: A Summary

From the time of the first NHPD research consultation in 1999 up to the present, stakeholders have consistently identified the priority need for an infrastructure to coordinate NHP research and communications, and to devise and implement strategies for advancing NHP research. The types of focused NHP research networks which could potentially be funded under the current, conventional scientific grant programs could contribute towards but could not fulfill many of the needs that have been identified in this report.

It was recognized that no one government, academic, or industry stakeholder group could satisfactorily address the above needs by working in isolation. All of these stakeholder groups have an important role to play in the development of a national strategic plan for NHP research and the coordination of NHP research in Canada. However, it will be important for one organization to take a lead role to facilitate collaboration and cooperation on a national level.

To undertake many of the recommendations identified in this report, a focused and dedicated approach will be required by a national coordinating body that has the capacity to build cohesion, coordinate strategic planning and promote NHP research. The mandate and activities of the national coordinating body should mirror as closely as possible with the needs for advancing NHP research. This alignment will help to maximize efficiencies and minimize potential duplication with other organizations. Key attributes of this organization will include the capability to undertake and manage the policy and communication initiatives recommended by stakeholders.

7.0 Summary of Recommendations and Next Steps

The extremely valuable role the NHPD has played in building cohesion amongst research stakeholders is widely recognized. While NHP research associations have the potential to fulfill some of the infrastructure needs, there are still many important areas in which the NHPD should actively participate. The NHPD is encouraged to:

Recommendation 1

Continue to work collaboratively with stakeholders to further clarify regulatory boundaries and the attendant levels of evidence required to support the safety and efficacy of products.

Recommendation 2

Strive to more actively engage with key FFN representatives and policy-makers to raise awareness regarding the unique challenges in NHP research, their definition, and the potential socio-economic benefits of NHP research.

Next Steps:

- Identify key FFN representatives and policy-makers across Canada.
- Develop briefing documents and presentations regarding NHP research, NHP definition, and research for the public good.
- Host virtual, in-person and/or consultative meetings with key FFN representatives.

Recommendation 3

Invite and encourage FFN industry associations and research institutes to more actively engage in the NHP research dialogue. A clearer picture of the objectives and parameters of their nutraceutical research programs at the existing FFN research institutes is needed in order to develop a comprehensive strategic plan. The FFN industry does not have a unified national voice and most associations do not have a formal policy position on research, yet they are well-situated to solicit and focus industry input. This dialogue should be encouraged and facilitated.

Next steps:

- Initiate a dialogue with FFN research institutes to explore their research objectives and the parameters of their nutraceutical research programs, and to identify points of commonality and divergence in relation to NHP research, potential research barriers and champions.
- Initiate a dialogue with FFN industry associations to explore their organizational objectives and the parameters of their activities, and their potential role in the development of the strategic plan for nutraceutical research.
- Host a strategic planning meeting with these stakeholders to obtain focused input and build consensus on the strategic plan for nutraceutical NHP research.

Recommendation 4

Up-date and expand the NHP research environmental scan (ES) to include nutraceutical researchers, research expertise sub-classifications and research capacity data. The ES template

should retain objective criteria for evaluating NHP expertise and the veracity of this information should be validated through peer-review.

Recommendation 5

Take a lead advocacy and coordination role in building support for an NHP literature database collaboratively funded by government and non-governmental organizations.

Recommendation 6

There are significant research gaps in the NHP sub-categories of animal-based bioactives, homeopathy, traditional/cultural medicines, and product quality. Industry, professional, and scientific associations can play lead roles in identifying current and potential researchers, strategic planning, and research capacity building. Capacity building strategies should focus on fostering the integration of these “orphans” into the larger research community and building cohesion.

Next steps:

- Identify and survey stakeholder organizations regarding their vision, objectives, and resources for research.
- Invite and encourage their participation in national dialogue on strategic planning for NHP research.
- Foster and promote interaction with the larger research community, especially interdisciplinary meetings, workshops, and conferences to disseminate research skills.

Recommendation 7

Establish a standard of evidence committee comprised of experts in the critical evaluation of scientific evidence and research methodology, to advise on the further delineation of more detailed standards of evidence, including:

- maximum and minimum levels of safety evidence for each risk category,
- maximum and minimum evidence requirements for each level of efficacy claims
- nature and degree of evidence required to establish proprietary claims,
- nature and degree of evidence required to establish generic product phytoequivalence,
- algorithms for equating different levels of evidence, and
- case examples.

Recommendation 8

Champion public funding and prioritize NHPRP support for generic NHP research and other potentially beneficial projects which lack direct IP value. The NHPD is encouraged to provide seed funding for a pilot study on the socio-economic benefits of exemplary NHPs (e.g. vitamin, amino acid, essential fatty acid, herb, etc.).

Recommendation 9

The NHPD is strongly encouraged to take an active role in promoting and facilitating product quality research as there is a clear consensus that this is a leading national priority. It is

recommended that the NHPD support the development of a quality network by facilitating the formation of an advisory committee and providing seed funding to establish the network.

Next Steps:

- Form an advisory committee consisting of representatives from the industry associations, individual lead companies, BCIT, NRC, NSERC, ODS, and the NHPRS with an initial mandate to create a business plan for quality research. The draft NRC/NSERC framework could be used as a starting place for these discussions.
- Contract a business consultant with experience in public funding should be hired to guide the development of the plan. Based upon the input from the committee members, the consultant should draft and circulate a plan outlining the most promising management and funding structures.
- Host an advisory committee meeting to develop a firm consensus on the business plan and timeline for its implementation.

Recommendation 10

Establish a “virtual” WHO Collaborating Centre for Traditional Medicine that builds upon existing nodes of expertise and fosters the development of new research clusters. The NHPD is encouraged to work collaboratively with traditional medicine researchers to realize this goal.

Next Steps:

- Form a scientific committee consisting of ethnopharmacology researchers to fully develop a national traditional medicine research plan, in consultation with their extended collaborative networks. This plan should build incrementally upon existing projects and expertise to create a cohesive program that encompasses both health and natural sciences. I.e. The initial focus should be on filling the most critical research and infrastructure gaps, followed by small steps of planned growth and development in priority areas.
- Identify the infrastructure required to implement this plan and develop a funding strategy to address these needs.
- Appoint a program administrator to carry out the funding strategy and coordinate the initial organization of the network.
- Appoint a scientific director and form a larger, standing advisory committee consisting of First Nations traditional medicine stakeholders and researchers to review and direct the research program. In forming this committee, explore the possibility of drawing upon existing institutional advisory committees to minimize duplication and facilitate coordination of efforts.
- Create a network planning and development sub-division to foster capacity building in other areas of traditional medicine research.

Recommendation 11

Develop a comprehensive communication plan for building cohesion amongst NHP research stakeholders, with customized strategies for each sector. Key elements of this integrated plan

include the following:

1. Identify and solicit input from scientific, professional, industry, and consumer groups interested in NHP research in regards to:

- NHP/nutraceutical researchers to be included in the database
- Their organizational goals, objectives, and needs in relation to NHP research
- Establishing effective two-way communication, and
- Development of a strategic plan for research in their sector.

2. Design and build consensus on the communication processes and timelines for developing sector strategic plans.

3. Organize and host national research conference and regional meetings to facilitate strategic planning, networking, and research capacity building.

Recommendation 12

Establish a NHP Research Policy Committee under the national coordinating body to develop customized strategies for building support for NHP research amongst consumers and other key national and international stakeholders. These strategies should effectively address the issues of IP, health claims, product quality and research for the public good, from the perspective of the target audience.

Recommendation 13

Establish a Peer-review Advisory Committee under the national coordinating body to facilitate appropriate peer-review and act as an industry liaison. This committee should be comprised of NHP research experts and provide proportional representation for all NHP sub-sectors.

Recommendation 14

Develop a policy communication plan for the national coordinating body, to coordinate internal and external strategic input on policy development and ensure consistent delivery of key messages and content aimed at raising awareness and building support for NHP research.

Recommendation 15

Establish an expert Product Quality Standards Committee to further develop more detailed product quality standards. The scientific committee should include experts from Canada and abroad, and conduct its work in close cooperation with parallel foreign initiatives.

Recommendation 16

Identify and support a lead organization that can provide national coordination for NHP research. This organization should have the capability to undertake and manage a number of activities including the following:

- Establishing and managing a NHP Research Policy Committee to develop strategies to build support for NHP research.

- Establishing and managing a NHP Research Communications Committee to develop a strategy and implementation plan for facilitating communication amongst NHP stakeholders and public relations to raise awareness and build support for NHP research.
- Establishing and managing a NHP Peer-review and Industry Liaison Committee.
- Establishing and managing a Standard of Evidence Expert Committee further develop a more detailed scientific framework for NHP research evidence.
- Establishing and managing a Quality Standards Expert Committee to further develop more detailed product quality standards.
- Hosting educational activities and events to raise awareness and support for NHP research among a diverse group of stakeholders.
- Act as a focal point to build a strong NHP research network, and facilitate collaboration and partnerships.

More specifically, organizational communication and policy tasks identified by various stakeholders under this coordinating body include the following:

- Identify and solicit input from scientific, professional, industry and consumer groups interested in NHPs.
- Up-date and expand the NHP research database.
- Organize and host national research conference and regional meetings to facilitate strategic planning, networking, and research capacity building.
- Facilitate and foster the development of successful focused research networks.
- Develop strong linkages and partnerships with other national and regional associations involved in the NHP sector as well as with other stakeholder groups that have an interest in the advancement of NHP research.

Appendix 1: Montreal Meeting Report

Introduction

Over the past five years, the Natural Health Product Directorate (NHPD, Health Canada) conducted an extensive series of consultations on Natural Health Product (NHP) research priorities. One of the major themes that emerged from these consultations was the need for an infrastructure to coordinate research, and facilitate stakeholder communication and knowledge transfer. The discussions surrounding this concept invariably involved the formation of some type of national research network to develop and carry-out a strategically planned research program. While there was a strong consensus amongst all stakeholders regarding the need for a network, there was a wide array of concepts as to the constitution, scope and objectives of such a network.

To build further consensus on the coordination of NHP research and the development of a national network, stakeholders were invited to attend a consultation meeting in Montreal February 22-23, 2004 following the landmark First NHP Research Conference. The meeting was organized and hosted by Mage Consulting and Dr. Allison McCutcheon served as meeting chair. The consultation included approximately 40 stakeholders from academia, industry and practitioner associations, government, funding agencies, and individual companies. In order to provide a starting point for the discussions, a consultation document sketching out a potential scientific framework for the network was developed and circulated to the participants prior to the meeting.

Following welcoming remarks and participant introductions, the floor was opened to a wide-ranging round-table discussion. Some of the key issues identified during these discussions included:

- Definite need for a national strategic plan on NHP research
- The plan must encompass all NHP stakeholders and should emphasize networking
- Major challenge to balance the research needs of the diverse NHP sectors
- Before we can develop a consensus strategic plan, we must build the infrastructure required to facilitate interaction, communication, and collaboration amongst the different groups
- How do we build the needed infrastructure?

Specific stakeholder group perspectives emerging from the roundtable discussions:

Funders

- require excellence in research
- have had difficulty with finding the appropriate “fit” for NHP research within their traditional funding streams
- optimum short-medium term strategy would be to have appropriate NHP experts participate on existing review committees
- funding agencies would appreciate assistance in identifying pool of appropriate peer-reviewers that existing committees could draw upon

Government (NHPD)

- General goal is building capacity in ALL areas of NHP research including nutrients (vitamins and minerals), NHP ingredients (animal products such as elk velvet, dairy based CLA, plant and marine bioactives such as EFAs, fibre, bioactive peptides, glucosamine etc.), botanicals, traditional cultural medicines, and homeopathics.
- More specifically, the top priority is research to facilitate the NHPD mandate of ensuring Canadians have access to safe, efficacious, and high quality NHPs; and their informed and appropriate use by consumers.
- Key research themes include: biomedical, product quality, clinical, health systems and health services, issues related to regulation, information and knowledge transfer, and societal, cultural, environmental influences on health and the health of populations

Health Practitioners

- Areas of greatest interest are the major disease and metabolic disorders, and their related health care costs
- Practitioners are apprehensive about consumer usage of NHPs due to the lack of scientific data, especially in regards to interactions with drugs.
- Research priorities are scientific evidence on the safety and efficacy of NHPs and data to enable most appropriate, efficacious use.
- Existing data not readily available and practitioners lack the expertise needed for rigorous critical review; effective knowledge transfer an even greater priority. Dedicated funding essential because granting agencies do not consider this type of work as research.

Homeopathy and other Traditional /Cultural Medicines

- Homeopathics differ from other NHPs, in that product quality is not a priority issue.
- Greatest research challenge is developing scientifically rigorous methodologies that accommodate the individualized treatment approach of these modalities.
- Clinical research has a significant way to go, as there is very little, if any work currently being conducted in Canada.
- There are several homeopathy and Traditional Chinese Medicine (TCM) organizations which provide some cohesion amongst practitioners and industry members but a unified national voice and research community linkages are lacking.
- Practitioners of modalities such as First Nations, Ayurveda, and other traditional medicines do not necessarily have representative organizations and are perhaps even more estranged from the research community.
- Practitioners interested in research but need support to develop capacity, perhaps starting with a conference or workshop.
- How do we link practitioners into the NHP research strategy? Suggestions included:
 - Identify and recruit high-profile champions.
 - Build linkages with international experts and activities such as conferences.
 - IN-CAM could provide a logical entry point into research for this sector.
 - Canadian Pediatric-CAM Network currently being formed could also potentially play a role in fostering development of the needed linkages.
 - Emphasis should be placed on integration into the research community, not segregation as “less-advanced” stakeholder groups

Industry

- Research priorities are scientific evidence to support health claims and product quality claims.
- Greater industry involvement is needed to ensure that research outcomes are relevant to industry – need a mechanism to actively involve industry in research prioritization.
- Linkages between industry and researchers generally very poor, industry members do not know who to contact, who has appropriate expertise to meet their needs, how to contact, etc.
- Urgent need for a searchable public database of reputable NHP researchers to enable industry to meet new regulatory requirements; NHPD should give priority to funding an expanded and up-dated version of the NHP environmental scan through a credible third party such as the NHP Research Society.
- Industry needs clearer guidelines regarding the regulatory requirements for scientific evidence to support claims and product safety; need to know up front what evidence will be deemed acceptable, what constitutes “enough” evidence to support a claim, etc.
- Intellectual property (IP) is a critical issue for industry; industry members reluctant to invest in research due to uncertainties surrounding the protection of proprietary processes and/or formulations.
- FFN stakeholders are essential partners who need to be drawn into the national dialogue.

Researchers

- Need secure, dedicated funding for NHP research, cannot successfully compete against conventional bio-medical researchers.
- Need more appropriate peer-review of research grant applications.
- Product quality is the top priority. Well characterized products are a fundamental prerequisite for reproducible, scientifically valid research.
- Significant amount of research needs to be done to develop methods and materials required for ensuring product quality.
- To ensure greatest relevance to the health of Canadians, commercial products should be used in the research.
- NHPs are promoted to consumers for regular, long term use, are more complex than drugs, and at present long term data is not available. There needs to be a much greater emphasis on efficacy and population health studies that extend beyond the usual 3-12 month clinical trial period.
- Need to recognize that aboriginal peoples are not just sources; there is a strong need to place a research emphasis on their most prominent health issues and the NHPs that may potentially provide efficacious treatments.

The Role of the NHPD in Research

- NHPD consultations have made very significant contributions towards building cohesion amongst research stakeholders.
- NHPD can play a key role in facilitating research capacity building in areas such as traditional cultural medicines and homeopathy. Eg. Hosting workshops and meetings that bring together stakeholders and members of the research community.
- Still a strong need for NHPD to champion other NHP research, especially generic products due to their lack of IP value.
- NHPD should partner with and provide support for lead stakeholders such as the NHP Research Society, as they have an integral role in advancing NHP research (Eg. Developing researcher database, appropriate peer-review, product standards, etc.)
- There is a sharp disconnect between FFN and NHP stakeholders. NHPD has a key role to play in defining the regulatory interface between FFNs and NHPs, fostering communication and building cohesion amongst these two sectors.
- NHPD monographs should be living documents that evolve as the science evolves, based upon the totality of evidence.

Proposal to have a Canadian WHO Collaborating Centre for Traditional Medicine

A proposal was put forward at the WHO meeting in December 2003 to establish a new Canadian and a Latin American Centre (WHO approached NHPD as a lead agency; Robin Marles designated NHPD representative). WHO has very little funding for the program and it is up to the host country to designate and fund the centre. This is at a very early stage and there has only been verbal discussion at this point. Initially it was suggested that it be housed in Ottawa; Calgary and Vancouver are also possible alternatives – but input is welcome.

Feedback from group: Given the diversity of the country, a more diffuse, virtual network may be more appropriate for Canada, rather than a “bricks and mortar” entity headquartered in Ottawa as suggested. Concept should be developed within the framework of the NHPRS. CIHR-IAPH and NCCAM (DCRC) suggested as potential funding sources.

Summary of Uniting Themes

Need for databases: research capacity/expertise and existing evidence

Need for national network: what is feasible versus what is needed

Product quality essential prerequisite

Disjunct between Functional Food and Nutraceutical (FFN) and NHP research stakeholders

Need to build more linkages with FFN stakeholders; First Nations, homeopathy, and other cultural/traditional medicine stakeholders; funding agencies

Networks and Networking

The participants had very diverse ideas regarding the actual formation of a national network and from the roundtable discussions, two very distinct approaches emerged. Some approached the problem from a very practical perspective governed by what funding was realistically available while others were more concerned with the conceptual development. Consequently, the participants separated into two break-out groups to build consensus on the larger conceptual framework for NHP research and a very practical, focused NSERC network proposal model.

1. Conceptual Framework for NHP Research

Building upon the consultation document, the group developed a consensus on the following model for NHP research. It was suggested that the NHP Research Society, working in concert with the NHPD and the IN-CAM network, should play a lead role in actualizing this framework.

Vision: Global recognition of Canada as the world leader in high quality natural health product research and innovation.

Mission: To promote collaborative, multi-disciplinary research to ensure high quality, safe and efficacious NHPs, and their informed and appropriate use.

Objectives:

- Protect and promote the health and well-being of Canadians and the global community
- Promote sustainable, social, cultural, economic and environmental development of NHPs
- Ensure high NHP quality in both consumer products and research materials
- Foster integrated, multidisciplinary research
- Foster partnerships amongst all stakeholders through
 - Dialogue
 - Communication
 - Engagement
 - Capacity building
 - Information dissemination
 - Knowledge transfer
 - Education
 - Capacity building
- Optimize integration of traditional healing and allopathic medicine
- Ensure appropriate funding of Canadian research priorities
- Promote research to develop innovative new products and services (value-added products; reference standards, bioassays and other new and emerging laboratory research methodologies)
- Facilitate training of highly-qualified personnel (HQPs)

Challenges:

- Lack of communication, linkages between NHP sectors and stakeholders
- Reluctance of the medical community to be involved in NHP research; lack of awareness of NHP research findings and/or sceptical of their scientific validity.
- Botanicals carry a stigma within many of the funding agencies, don't get the multimillion \$ investments. Much more support for FFN and relationship to health care.
- Very diverse range of products and limited amount of money available for the R & D.
- NHP research sectors are at different levels of sophistication and evolution. NHPD may need to re-examine shorter term and longer term foci for NHP research.
- Have not identified all of the associations and potential partners that can assist in moving NHP R & D agenda forward.

Opportunities

- Insurance coverage would increase product and industry confidence.
- Tie-in with other priority themes of the government such as the new Agriculture Policy Framework (quality, safety and traceability), Industry Canada (quality, safety and efficacy, marketability and innovation), Forestry (sustainable non-timber forest products or NTFPs), etc.
- Build linkages with major federal initiatives to create research network with nodes and to leverage funding.
- Strive to influence and build “Genome Canada” type of scenario, using business case for focus.

Natural Health Product Research Matrix

While a consensus was quickly reached on NHP sub-categories, there was considerable debate surrounding the description of the various research areas. It was recognized that “NHP research” spanned from NP production through the various levels of medical research to health outcomes, as illustrated below.

Production ←-----> Health

NHPs	Basic Discovery	Biomass Production	Product Innovation and Development	Product Quality	Pre Clinical Safety and Efficacy	Clinical	Population Health	Health Services	Knowledge Transfer
Botanicals									
Ethnomedicines									
Homeopathics									
Nutrients & bioactives									
Amino acids									
Animal-based									
EFAs									
Enzymes									
Minerals									
Probiotics									
Vitamins									
Other NHPs									

Potential strategies

Concrete practical steps are needed to bring all the groups together. Significant awareness building is required, as many stakeholders do not identify themselves with the NHP category (Eg. FFN industry).

- Need to identify and contact all associations/groups with a stake in NHP research
- Every effort needs to be made to publicize what is going on, be inclusive
- Email news list
- Delegates should inform their networks about NHPD and NHPRS activities, and vice versa to promote two way communication.

2. Developing a focused NSERC network proposal

In order to create a successful network, significant infrastructure and dedicated research funding is required. Formal research “network” funding opportunities are fairly limited in Canada at the present time. The NSERC Network Grant appears to be the largest and most secure funding program currently available, as no further National Centres of Excellence (NCE) Network competitions have been announced and it is not yet known whether CIHR will host future (Infrastructure Capacity Enhancement (ICE) or New Emerging Team (NET) competitions.

There was a consensus that the NSERC program offered the best potential opportunity for obtaining funding for a formal NHP network. In terms of scientific merit, an NSERC Network application should be headed up by recognized leaders in the field, have a clearly defined research focus with strong uniting or umbrella theme, and the research program should be discussed in the context of a comprehensive scientific framework for the network. The NSERC program places a strong emphasis on innovation, industry participation, and technology transfer, the applicants must provide a strong business case for the network. This should include a marketability and innovation matrix as this type of presentation provides a compelling rationalization for the involvement of both industry and government.

The short-comings of a previous unsuccessful NSERC network application were reiterated and discussed by the group. These points included:

- Network was too limited and insular in terms of both academic and industry participants; lacked interconnectivity
- Research program too broad (herbal medicine) and lacked focus
- Research program lacking in key elements such as toxicology
- Inadequate management plan
- Lack of convincing business case

Through these discussions, the group reached a consensus that in order to meet the NSERC criteria (unique, focused, industry participation) and successfully win support, the scope of the network research program should be very tightly focused in terms of the type of NHP studied and restricted to key health areas where there was a pre-existing critical mass of expertise (Eg. infection, immunity, diabetes). The group agrees that the network should focus on botanicals as the “lead” NHP category with the greatest critical mass. It was suggested that the strategy should

be to first concentrate on developing the optimal approach for botanicals, establish a strong research base and then use it to build broader support for work on other types of NHPs. The botanical model could then subsequently be adapted for other areas of NHP research.

While the scope of such a network may be fairly limited, especially in the initial stages, it was postulated that this formal network may provide a useful model for other NHP research foci. And although it would not be the primary organizational objective, this type of formal network could also help advance larger goals such as a broader power base for NHP research, legitimization, access to human and information resources, forging solidarity and alliances.

Criteria for research materials selection were identified as:

- Significant scientific interest
- Products highly relevant to Canadians from both agricultural, health and consumer perspectives
- Credible body of existing research already being sponsored or of significant interest to Canadian industry
- Significant innovation in the application.

Echinacea and ginseng were discussed as examples of candidate botanicals in this context.

Industry representatives noted that marketability must also be considered and that it was essential that the network develop a clear IP strategy.

The areas of current research expertise in botanicals were identified as:

- Cancer
- Traditional medicines (Ethnopharmacology)
- Pharmacognosy
- Toxicology & Pharmacology
- Metabolic and Degenerative Diseases
- Infection, Inflammation & Immunity
- Production and Processing (agriculture, forestry [NTFPs], and product formulation).

Network theme

As in the preceding plenary discussions, the issue of product quality arose repeatedly throughout the session. There was a clear consensus that quality should be the unifying theme of the network. It was suggested that the tag line “quality from the field to the clinician/consumer” could be used as a highly attractive “hook” for funding support and buy-in on the part of all stakeholders. In further support of this focus, it was pointed out that Canada has a distinct international market advantage in terms of product quality.

Scientific Framework

The network should develop reproducible research protocols from the ground up that include product production and processing, pre-clinical investigation and finally clinical research. To ensure optimum relevance, all experimental and clinical research should be based upon the use of thoroughly characterized, reproducible commercial products. These protocols would also

encompass the investigation of herb/herb interactions and herb/drug interactions in a standardized fashion. The latter issue was considered to be of significant importance as there are already research projects underway in Canada where herbals are being tested as adjuvant therapies along with conventional pharmaceuticals. The establishment of this rigorous methodological framework would allow the network to subsequently expand into the investigation of combination products and other types of NHPs.

Network Structure

The NSERC Network program provides funding over a five-year period, given satisfactory interim progress report. It was generally agreed that while the majority of the five-year budget should be reserved for research operating funds, the group also recognized the critical importance of developing a strong infrastructure, especially in the initial stages. This infrastructure would include a salaried executive director and support staff (administration and communications); project planning and liaison; development of a network communications system; executive, advisory committee, node, and annual network meetings; and travel to support the interdisciplinary training of highly qualified personnel. It was estimated that approximately 15% of the overall budget should be directed towards infrastructure, although this proportion would be somewhat higher in the first two years and would decrease over the following three years. It was projected that the balance of monies would support approximately 15-20 lead researchers by providing operating funds for adjuncts, post-docs, and graduate students.

It was proposed that the network should adopt an easily recognized name that would effectively impart its major functions to scientists, industry, government and consumers. It was thought that it should reflect the network's goals regarding quality, safety, and efficacy, and convey the principle of evidence-based research. The name "Canadian Evidence-Based Botanical Research Network" was suggested and was positively received.

Wrap-up plenary discussion

In the closing session of the day, synopsis of the consensuses developed in these two break-out groups were presented in plenary. The floor was then opened for general debate and discussion of the agenda for the following day. Within the context of a strategic plan for NHP research Canada, there was a general agreement that further work was needed to specifically flesh out the scientific framework for efficacy and safety research and product quality research, and to develop strategies for addressing the issues of NHP research policy, communication, and education.

Day Two: Opening Plenary

The chair recapped the discussions from the previous day and the four key areas which had been flagged for further exploration. The group then broke into two break-out sessions to focus on the development of the framework for efficacy and safety research, and product quality research.

3. Strategic Plan for NHP Safety and Efficacy Research

The initial discussion focused upon the existing nodes of NHP bio-medical research expertise within the context of the CIHR Institutes. These were identified as:

Aboriginal Traditional Medicine
Cancer
Diabetes/metabolism
Gender health
Health Services and Policy
Infection and Immunity
Mental health
Musculo-skeletal
Paediatrics

Action Plan:

1. Identify groups already active in these nodes and build on them
2. Identify leaders for those nodes with non-existent organization
3. Hold meetings for each node – identify champion, director, leader
4. Develop research funding strategy along nodes
5. Develop a national research/funding strategy INCLUDING all stakeholders particularly industry and traditional practitioners
6. Track high quality NHP research that is funded/presented

Over arching principles

- All research to be done with high quality, well-characterized NHPs
- Work WITH existing groups
- Multi-disciplinary research teams
- Training of highly qualified personnel (HQP)

Long Term:

International

Develop international reputation (Example Cochrane review)
International centres for medicinal plants (IRAC, CGIAR Network)
Canadian WHO Collaborative Center for Traditional Medicine

National

Peer review committees specifically for NHP research
Include NHP researchers in existing peer review committees of funding agencies
Ensure NHPs are part of educational “curricula” – secondary and post-secondary

4. NHP Quality Research

There was a strong consensus that ensuring product quality is an essential prerequisite for all NHP research. Recognizing that the term “quality” means different things to different people, the group defined product quality as well-characterized, reproducible material of consistent strength, free from contaminants and/or adulterants.

In order to ensure quality, research is needed to develop/establish:

- Reference materials/standards (biological, botanical, chemical)
- Validated methods
- Product quality standards and specifications
- Lab proficiency program
- Educational programs

The most **serious challenge** is that funders (peer-reviewers) do not perceive this type of work as “research” due to its applied nature. The NHPD has a mandate to ensure high quality products but doesn’t have the analytical capacity nor a sufficient research funding base to carry out the needed work.

Loss of consumer confidence in product quality and the subsequent market slump, together with the new NHP regulations, has provided significant motivation for industry to address the issue. Therefore, industry may be the key driver needed to move this agenda forward. The industry driven NHP Lab Proficiency Program at BCIT is evidence that NHP companies are willing to invest both time and money in quality.

The Program in Food Safety, Nutrition and Regulatory Affairs (PFSNRA), which was driven and funded by industry, provides a good model of how this could be accomplished. The Mission of the PFSNRA is to address the scientific basis of current issues of food, nutrition, health and regulatory activities through collaboration with scientists and health professionals from universities, the food industry, government and non-governmental organizations, to achieve the goal of a healthier Canadian population. Its objectives are:

- To enhance research and development partnerships in academic settings
- To identify and evaluate the scientific evidence required to address issues identified by the membership
- To serve as an information resource on food, nutrition and health.

Both the mission and the objectives of the PFSNRA appear to be similar to that envisioned for a national NHP Quality Network and a means to drive forward a “Quality Agenda” that would extensively involve industry.

Strategy for moving the “Quality Agenda” forward:

- Establish stakeholder advisory committee and program committee

- Develop funding, research and education protocols
- Establish/formalize working groups in each area

Role of the NHP Quality Program Advisory Committee (AC):

- Prioritize NHPs and projects
- Feedback on relevance and feasibility of projects
- Input on product standards
- Input on educational requirements
- Liaise between working groups and HC
- Research Program Funding Application (eg. NCE, NSERC Network)
- Project funding review

Membership: primarily industry reps, government and expert reps

Role of Working Groups (WG):

- Determine scientific feasibility of projects
- Coordinate research efforts
- WG Chair to liase with AC
- Technical review
- Application for project funding

Membership: industry and academic experts

Action Plan:

- Form NHP Quality Program Advisory Committee consisting of representatives from the industry associations, individual lead companies, BCIT, NRC, NSERC, ODS, and the NHPRS.
- Identify and hire a business consultant to guide the development of a business plan outlining management and funding structures. Circulate draft to the advisory committee members.
- Host advisory committee meeting to develop consensus on the proposed business plan for the quality program. Appoint WG Chairs for each program area; Chairs to be responsible for establishing their groups from pool of experts identified through the NHP Research Environmental Scan.

Other suggestions:

- The US NIH Office of Dietary Supplements (ODS) initiated the Dietary Supplement Methods and Reference Materials Program in recognition that product quality is essential for scientific study, market growth and consumer confidence. Although Canada must create their own program priorities, partnering with existing programs can be cost effective. Furthermore, maintaining awareness of international initiatives is important to ensure efforts are not duplicated. The NRC INMS has partnered with NIST and ODS; research to produce a CRM for Panax species is currently underway.
- Method validation project proposal currently being developed for submission to the

NSERC/NRC Industry Research Program and AFMNet. This could perhaps be expanded to “NHP Quality NSERC/NRC Network”. Same challenges exist: need to convince funders that this is research AND secure matching industry dollars. Could potentially include International partners, such as AOAC International who hold the ODS contract to establish Official Methods for selected dietary supplements, the AHP, and USP.

- Practical barriers for Lab proficiency/accreditation include lack of available and/or suitable reference materials and validated analytical methodology. Establish a laboratory proficiency program for NHP analysis modeled on the research initiatives undertaken at BCIT.

5. Policy and Communication

Up-dating and expanding the NHP research environmental scan (ES) again identified as a critical need. This resource should be shared with the funding agencies to ensure that they can identify appropriate experts for peer-review. Use this database to facilitate the appointment of an increased number of NHP research experts on various funding peer review committees. NHPRS’s role should be to host and maintain this database, and nominate NHP experts to granting agencies.

There was some discussion around whether the granting agencies should be lobbied to establish NHP peer-review committees to review these grant application. It was suggested that this was not the best route for CIHR, as the committee may not have enough expertise around the table when the grants are related to specific areas such as cancer or heart disease. The short term goal should be to have as many NHP experts on the various committees as possible. CIHR and NSERC would find value in having list of researchers with NHP expertise in various areas. The longer term goal would be to have NHP experts as internal reviewers (not category specific).

NHPRS should have a peer-review resource committee that partners with granting agencies and NHPD. Search out NHP champions in the funding arenas. NHPRS should start by targeting the CIHR institutes and NSERC committees that would be most open to NHPs and lobby for appointments on their advisory committees. Industry Liaison programs may be of an easier route to funding for both CIHR and NSERC.

The NHP ES database should be linked with the IN-CAM database. When people join IN-CAM, they provide their contact information and authorization to post this info. People become members to know who is doing what, basic information is already there and there is potential to add sections of information.

Raising Awareness and Building Support for NHP Research

In the final brainstorming session, a number of concrete suggestions for building support emerged.

1. Up-date and expand NHP research ES.
2. Establish peer-review committee.
3. Establish policy committee to develop customized strategies for raising awareness in government, and amongst industry, consumers, and stakeholder organizations.

- Develop strategies to get specific Ministries in the federal government involved or at least aware of NHP research. Eg. Industry Canada – Innovation Agenda. Identify potential champions in these agencies, especially those who interact with industry.
- Develop stronger linkages with industry, build cohesion and support for research strategy. Provide human interface with ES database.
- Consumers are a tremendous up-tapped source of support: need to develop a strategy and communication plan to link with them and mobilize support.
- Bring together/meet with other stakeholder organizations to coordinate policy initiatives.
- Lobby internally for NHP priority in the University system.
- Once strategies have been developed, create short summaries and professional position/policy paper (Eg. 2 page max; glossy, professional-looking documents) that incorporate buzz word and key issues to position/link NHP research within national and international initiatives such as Innovation Canada, Health Innovation, etc.
- Develop a communication plan. Ensure that you know your message and it is a good one. Must be well-organized, with only official representative speaking for the group. Make sure that other organizations are included and know what is going on (Eg. Provincial groups, etc.). Follow up with meetings.

6. Summary of Specific Themes Identified

1. Up-date and expand NHP research ES.
2. Significant disconnect between FFN and NHPs, especially re the regulatory, research perspectives, positioning with granting agencies, IP, and industry investment. Need concerted effort to identify and engage nutraceutical FFN stakeholders in the NHP research dialogue. Sub-theme: identify the players & their research capacity, build cohesion.
3. Current capacity and gaps requiring capacity building: animal bio-actives, cultural medicines, homeopathy, etc. Sub-theme: identify the players & their research capacity, build cohesion.
4. Research networks: need for both highly focused (NSERC) addressing specific priorities and a broader body to address policy development, long-term planning, and implementation (potential NHPRS/IN-CAM roles).

Appendix 2: Current Capacity in Canadian Institutions and Organizations

Each institution/agency that is included in this summary was assessed through literature and web site searches and through personal interviews. The key areas of research activities are listed.

1.1 Agriculture and Agri-Food Canada¹

Research Branch

The department runs a network of 19 research centres located across the country. Work at the centres is linked to four national science programs.

- The [Environmental Health](#) program aims to develop knowledge and technologies that minimize the impact of agricultural production on soils, air, water and biodiversity while maintaining the sustainability of the sector.
- The [Sustainable Production Systems](#) program targets the development of crop and livestock production systems that are economically and environmentally sustainable and improve the competitiveness of Canadian agri-food products in domestic and international markets.
- The [Bioproducts and Bioprocesses](#) program does research to discover and develop value-added biobased products and processes.
- The [Food Safety and Quality](#) program provides knowledge and technology to enhance the ability of the Canadian food industry and the government to keep the food system safe, and to produce quality food products to meet current and future consumer needs.

The [Bioproducts and Bioprocesses](#) and the [Food Safety and Quality](#) programs include research activities in the areas of FFN. There is very little research per say directed towards herbs and botanicals, vitamins or minerals but instead is focused on the development of FFN from pulses, oilseeds, forages and horticulture.

The total budget for the Research Branch in 2001/02 was \$252 M. Over 2400 staff were employed of which 620 were professionals including scientists. Of the 345 projects underway across all stations, approximately 20 are directly related to the FFN and NHP areas. The department also funds the Matching Investment Initiative (MII) which matches private sector investment in collaborative research. In 01/02, total funding of \$27M was available in the MII.

The expertise available at each of the Research Centres reflects the type of industry in the agro-ecological region where they are located. The key Centres² that conduct research in the FFN, and to a limited extent in bioactives that may be developed for the NHP market) area include:

¹ Agriculture and Agri-food Canada Research Branch. 2004. Internet: <http://res2.agr.gc.ca/research-recherche/>

² Agriculture and Agri-Food Canada. Research Centres. Internet: <http://res2.agr.gc.ca/>.

- Atlantic Food and Horticulture Research Centre – Kentville, Nova Scotia: develops and transfers technology to increase productivity, competitiveness and stability in the horticultural food system while maintaining food quality and safety and sustaining the environment.
- Pacific Agri-Food Research Centre – Summerland and Agassiz, British Columbia: Horticultural and field crop production and protection, processing of plant products and biology of plant pathogens. Programs include tree fruits, small fruits, greenhouse vegetables, special crops, and forages. The Food Science group at PARC brings added value to agricultural products through research on postharvest physiology, modified atmosphere packaging, sensory evaluation, and functional foods.
- Saskatoon Research Centre – Saskatoon, Saskatchewan: Has capability and facilities to conduct comprehensive investigations in natural product chemistry in support of value-added opportunities with plants and holds 98,000 accessions including the world-base collections of barley and oats in Plant Gene Resources of Canada.
- Southern Crop Protection & Food Research Centre – London, Guelph, Vineland and Delhi, Ontario: Alternative protection technologies for tree fruits, vegetables, field crops, and ornamentals. Programs include alternative crop development, soil and water quality, and chemical and microbial food quality.
- Food Research and Development Centre – St.-Hyacinthe, Quebec: Canada's largest research centre devoted to food processing, specializing in food quality, safety, preservation and processing.
- [Food Research Program](#) - Guelph, Ontario: Research and technology transfer in support of the agri-food sector. Programs include the development of functional foods and nutraceuticals, food preservation technologies, molecular and cellular biology, structure and function of foods and food components.
- Cereal Research Centre - Winnipeg, Manitoba: Wheat and oat development for the prairies. Programs include food development, grain storage technology and cereal disease screening.

Table 1: Research Overview – AAFC Research Centres

	Atlantic Food & Horticulture Research Centre	Food Research & Development Centre	Horticulture Research & Development Centre	Eastern Cereal & Oilseed Research Centre	Southern Crop Protection & Food Research Centre
LOCATION	Kentville, NS	Ste. Hyacinthe, QC	Ste. Jean-sur-Richelieu, QC	Ottawa, ONT	London, Vineland
FOCUS	Fruits, vegetables	Milk & meat products, fruits & vegetables	Fruits & vegetables	Cereals	Medicinal plants
Genomics, proteomics & bioinformatics			X	X	X
Production, primary processing	X		X	X	
Processing, formulation and food production	X		X		
Extraction, purification, characterization	X	X		X	X
Nutritional, toxicology, clinical studies		X			
Early stage processing		PILOT PLANT			
Consumer Acceptability					

Table 1: Research Overview – AAFC Research Centres (con't)

	Saskatoon Research Centre	Lacombe Research Centre	Lethbridge Research Centre	Pacific Agri-food Research Centre
LOCATION	Saskatoon SK	Lacombe AB	Lethbridge AB	Summerland BC
FOCUS	Field crops	Meat products	Meat products, cereals	Fruits, vegetables, medicinal plants
Genomics, proteomics & bioinformatics	X	X	X	X
Production, primary processing	X	X	X	X
Processing, formulation and food production				X
Extraction, purification, characterization	X	X	X	X
Nutritional, toxicology, clinical studies				
Early stage processing				PILOT PLANT
Consumer Acceptability				

1.2 The National Research Council of Canada (NRC)

The research capacity of the NRC is organized around biotechnology, information and communications technologies, measurement standards, molecular sciences, aerospace, manufacturing, construction, ocean engineering and others. With regard to FFN, research initiatives are included under the broad mandate of biotechnology of which five institutes deliver the NRC Biotechnology Program. For NHP and FFN, one important initiative is lead by the Plant Biotechnology Institute (PBI) in Saskatoon, an institute that is dedicated to plant and crop research. In addition, the Institute for National Measurement is involved in developing analytical assessment techniques for screening pre- and post market NHP products for quality. An NHP reference materials program has been initiated with infrastructure funding. The program will develop certified reference materials for industry, RD community, etc. These will include raw materials, extracts, calibration standards, and others. This is a collaborative project with US organizations including the ODS, FDA, AOAC and the USP. The project will produce 1 - 2 methods with reference materials per year.

In October, 2002 the National Research Council announced \$10 million of funding over a five year period for a research program at PBI aimed at developing crops for enhanced human health. The funding is part of NRC's national community technology cluster strategy designed to promote regional innovation and sustainable economic growth.

Table 2: Research Overview - National Research Council of Canada

	Institute for Marine Biosciences	Institute for National Measurement Standards	Institute for Chemical Process & Environment Technology	Plant Biotechnology Institute
LOCATION	Halifax NS	Ottawa ONT	Ottawa ONT	Saskatoon SK
FOCUS	Marine	Analytical development for NHP and FFN bioactives	Processing technologies	Regional crops, medicinal plants
Genomics, proteomics & bioinformatics	X	X		X
Production, primary processing	X			X
Processing, formulation and food production	x			
Extraction, purification, characterization	X	X	X	X
Nutritional, toxicology, clinical studies				
Early stage processing			Pilot plant	X
Consumer Acceptability				

1.3 University, College and other Public Research Facilities

The majority of Canadian universities are involved to various extents with NHP and FFN research and training. Other colleges and publicly funded organizations also work to varying degrees in this area, mostly in applied research. The following tables summarize the activities of the key institutions. Descriptions of individual institutions that are focusing significant funding and research infrastructure to FFN and NHP is also included.

Table 3: University, College and other Public Research Programs

	Food Technology Centre	Food Research Centre	Dalhousie University	NS Agricultural College	Marine Biotechnology Research Centre
LOCATION	Charlottetown PEI	U Moncton Moncton NB	Halifax NS	Truro NS	Rimouski QC
FOCUS	Food and marine	Marine, Milk, fruits vegetables	Medicinal Plants	Fruits & vegetables, animal products	Food and Marine
Genomics, proteomics & bioinformatics			X		
Production, primary processing				X	
Processing, formulation and food production	X	X		X	X
Extraction, purification, characterization	X	X	X		X
Nutritional, toxicology, clinical studies			X		
Early stage processing					
Consumer Acceptability					

Table 3: University, College and other Public Research Programs (con't)

	Université de Montréal	University of Ottawa	Centre for Human Nutrition U Western ONT	University of Centre for Functional Foods & CAFBN *
LOCATION	Montreal QC	Ottawa ONT	Guelph ONT	Guelph ONT
FOCUS	Medicinal Plants	Medicinal Plants Esp. Botanicals	Clinicals – Cancer, CVD, Diabetes	FFN
Genomics, proteomics & bioinformatics	X	X		X
Production, primary processing				X
Processing, formulation and food production				X
Extraction, purification, characterization	X	X		X
Nutritional, toxicology, clinical studies	X		X	X
Early stage processing				
Consumer Acceptability			LIMITED	

Table 3: University, College and other Public Research Programs (con't)

	Human Nutraceutical Research Unit	Guelph Technology Centre	Food	Departments of Nutritional Sciences, Pharmacy and Medicine U Toronto **
LOCATION	Guelph ONT	Guelph ONT		UT ONT
FOCUS	Clinical research for industry	Food Development		Clinical Studies – all areas of chronic disease Basic & Applied
Genomics, proteomics & bioinformatics				X
Production, primary processing		X		
Processing, formulation and food production		X		X
Extraction, purification, characterization				X
Nutritional, toxicology, clinical studies	X			X
Early stage processing		X		
Consumer Acceptability				

* **Canadian Advanced Foods and Biomaterials (CAFBN)**

Led by the University of Guelph

** **Canadian Interdisciplinary Network for Complementary and Alternative Medicine Research (IN-CAM)** (www.incamresearch.ca)

Table 3: University, College and other Public Research Programs (con't)

	Institute for FFN (INAF)	National Centre for Agri-food Research in Medicine	Richardson Centre for Functional Foods & Nutraceuticals	Food Development Centre
LOCATION	Quebec City QC	Winnipeg MB	Winnipeg MB	Portage La Prairie MB
FOCUS	Marine, milk products, fruits, vegetables, medicinal plants	Clinical Studies CVD & Diabetes Basic & Applied	Western Canadian Crops	FFN and Food
Genomics, proteomics bioinformatics	X		X	
Production, primary processing	X		X	X
Processing, formulation and food production	X		X	X
Extraction, purification, characterization	X		X	
Nutritional, toxicology, clinical studies	X			
Early stage processing	PILOT PLANT		PILOT PLANT	
Consumer Acceptability			LIMITED	

University of Laval “Institute for Functional Foods and Nutraceutical (INAF)

The focus at INAF is on dairy and horticultural based-products which complements well the activities and provide the strong research base needed in Canada. The research community at INAF focuses upon the effects of FFN in the prevention of chronic diseases, such as obesity, cardiovascular, immunity and various cancers. INAF consists of more than 65 researchers from French speaking Universities including Quebec, McGill, Montreal, Moncton and AAFC’s Quebec based research centres. The activities of INAF are very synergistic with that of the RCFFN.

National Centre for Agri-Food Research in Medicine

NCARM was established in 1999 as a research initiative funded by a multi million-dollar partnership of the federal and provincial governments through the Agri-Food Research & Development Initiative (ARDI). The four laboratories that comprise NCARM are located at the St. Boniface General Hospital Research Centre.

Construction of the I.H. Asper Clinical Research Institute, a \$ 25 million facility that will be physically linked to the St. Boniface General Hospital Research Centre, is nearing completion. To my knowledge, there are only two other research groups with similar capabilities in the world today.

NCARM's mandate is twofold:

- To perform research on the health-related effects of natural health products and NHP.
- To provide the scientific community and general public with reliable, scientific evidence-based information concerning natural health products, functional foods and nutraceuticals.

NCARM investigates natural health products and NHP in both non-human studies and clinical trials. Non-human studies (animal and in vitro models) are conducted to ascertain the safety, tolerance, active constituents and mechanism of action of natural health products, functional foods and nutraceuticals. Clinical trials are performed to investigate the efficacy and safety of natural health products, functional foods and nutraceuticals in humans.

The Richardson Centre for Functional Foods and Nutraceuticals (RCFFN)

The RCFFN will be a \$25 million centre of excellence where researchers from numerous disciplines, along with their industry partners, will work together to develop functional, health-enhancing foods and nutraceuticals, from agricultural products of importance to the prairie region, including oats, wheat, barley, buckwheat, canola, flax, hemp, pulses as well as animal derived products.

The Centre will enable research of international calibre and stature, will potentially lead to major health innovations, and will offer significant benefits to the researchers, the University, and regional and national commercial enterprises. In support of the research goals, the following research objectives have been declared:

- To identify, enhance and economically extract bio-active compounds
- To standardize potency as well as efficacy of bio-active compounds using tissue culture and small animal experiments
- To conduct experiments for assessing bio-safety of FFN
- To incorporate safe and efficacious bio-active ingredients into functional foods
- To conduct research to pilot production level ready for pre-commercialization
- To conduct research into the consumer acceptability of FFN
- To provide scientific evidence of the relationship between functional foods and nutraceuticals and population health outcomes

Table 3: University, College and other Public Research Programs (con't)

	POS Pilot Plant Corp.	University of SK	University of AB Dept Ag, Food and Nutritional Sciences	Food Processing Centre	OLDS Centre Innovation	College for
LOCATION	Saskatoon SK	Saskatoon SK	Edmonton AB	Leduc AB	Olds, AB	
FOCUS	FFN from crop and marine sources	NHP	Western Canadian crops, meat and milk products	Food	Western Canada crops and NHP	
Genomics, proteomics & bioinformatics			X			
Production, primary processing			X			X
Processing, formulation and food production	X		X	X		X
Extraction, purification, characterization	X	X	X	X		X
Nutritional, toxicology, clinical studies		X	X			
Early stage processing	PILOT PLANT					
Consumer Acceptability						

Table 3: University, College and other Public Research Programs (con't)

	Alberta Research Council	BC Institute of Technology Herb Analysis and Evaluation Laboratory (HEAL), Food Processing Resource Centre	University of BC Faculties of Pharmaceutical Sciences and Agriculture, Nutrition Research Program
LOCATION	Edmonton AB	Burnaby BC	Vancouver BC
FOCUS	NHP	NHP (HEAL), Food Processing and Development	Food, FFN, NHP Basic Science and Clinical
Genomics, proteomics & bioinformatics			X
Production, primary processing		X	X
Processing, formulation and food production		X	X
Extraction, purification, characterization	X	X	X
Nutritional, toxicology, clinical studies	Animal safety Testing	X	X
Early stage processing	Limited	PILOT PLANT	
Consumer Acceptability			

2. Networks

The following networks have been established with specific focus and emphasis on FFN, NHP and CAM. Other such networks do exist in Canada, but not on the national level.

2.1 Natural Health Product Research Society of Canada (NHPRS)

The NHP Research Society is a non-profit organization founded in 2003 by a collaboration of academic, industry and government researchers from across Canada. NHPRS membership is open to all NHP stakeholders and within a few months, it has already grown to encompass some 200 individual, association, affiliate and corporate members. The mission of the NHPRS is to support and promote scientifically rigorous research and education on natural health products, to enable the safe, informed and appropriate use of NHPs that are effective, non-toxic and of the highest quality. To help protect and promote the health of Canadians, the society's specific objectives are to facilitate and support Canadian natural health product education and research priorities to:

- ensure the safe and appropriate use of natural health products (NHPs);
- ensure the efficacy, safety, and high quality of NHPS;
- facilitate effective NHP knowledge transfer and translation;
- inform decision-making and evidence-based policy development;
- foster interdisciplinary NHP research collaborations and networking;

- build NHP research and education capacity;
- develop national product quality standards, reference materials and validated methods;
- advocate and uphold fair and ethical standards in NHP education and research;
- provide representation and a communication forum for the NHP research community
- promote the use of high quality, well-characterized and standardized NHPs in research.

To accomplish these objectives, the NHPRS is developing an array of programs and projects.

The first major initiative undertaken by the society was the organization of the First Natural Health Product Bridge Building Conference to showcase Canadian NHP research, and to foster networking and new collaborations amongst researchers, industry and government stakeholders. Held February 20-22, 2004 in Montreal, the sold-out conference was a resounding success with over 300 participants in attendance.

All members are encouraged to take an active role in shaping the future of NHP research by participating in NHPRS committees and their projects. The core NHPRS programs under development include:

Policy and Funding

- National NHP research policy papers and discussion documents.
- Sub-theme and regional policy
- Peer-review policy paper
- Peer-review expertise database and referrals

Networking

- Research networking directory
- Research infrastructure database
- Infrastructure support

Product Quality and Standards

- National product quality standards
- Reference materials and methods program
- Laboratory accreditation program

Communications and events

- Electronic newsletter
- Annual national conference
- Regional workshops and forums
- National NHP research policy papers and discussion documents
- NHPRS web site including:
 - National database on analytical capabilities & expertise of researchers
 - NHP research networking directory
 - Research forums for NHP special interest groups

Longer-term goals include the development of:

- NHPRS Product Quality Seal Program
- Academic and industry research recognition awards

- National check-off with Research Investment Seal Program
- Research fund-raising

Other suggested activities for the NHPRS, either independently or in conjunction with NHPD to specifically facilitate the development of a Framework for NHP Research

2.2 IN-CAM

The mission of IN-CAM is to create a sustainable, well-connected, highly trained Complementary and Alternative Medicine (CAM) research community in Canada that is internationally recognized and known for both its excellence in research and its contributions to understanding CAM and its use.

Objectives

IN-CAM will increase the capacity for high quality, inter-disciplinary, collaborative CAM research by:

- Building a sustainable network that facilitates and supports researchers studying CAM from a health services and policy perspective;
- Developing CAM research priorities and a research agenda;
- Building CAM research capacity;
- Promoting knowledge transfer among researchers, health care practitioners, policy makers, research funders, and the public about CAM; and
- Linking with other relevant networks, organizations, and educational institutions to develop partnerships that further our objectives.

The Network's major activities consist of building research capacity, developing research priorities and a research agenda, promoting knowledge transfer and linking with relevant networks, organizations, and educational institutions to develop partnerships that further the Network's objectives.

The Network will host annual funding competitions for project seed funding and graduate studentships. The ultimate goal is to develop a program that becomes a recognized career path for graduate students interested in social-policy and health care. An annual CAM Research Symposium will provide an opportunity for members in the CAM research community to network, to share results of recent research and to participate in educational workshops.

Membership in IN-CAM is free of charge and may be established by completing a brief questionnaire on the Member's portion of the IN-CAM web site.

A five-member Steering Committee (chaired by Boon and Verhoef) and a nine-member Advisory Committee have created a five-year strategic plan to guide the development of a sustainable Network that facilitates and supports high quality collaborative CAM research from a health services and policy perspective. Steering and Advisory Committee members represent all Canadian regions as well as multiple conventional and CAM disciplines to ensure the Network realizes its national focus and diverse objectives.

IN-CAM has a key role in providing an organizational structure for both complementary and conventional practitioners, as well as CAM researchers. While IN-CAM theoretically encompasses all NHP researchers, in practice it simply cannot address all the needs of all NHP research stakeholders.

2.3 Canadian Advanced Foods and Biomaterials (CAFBN) Led by the University of Guelph

CAFBN is Canada's new national initiative and has the stated goal to serve as Canada's pre-eminent organization in "advanced foods and bio-materials research by establishing an infrastructure that is able to develop commercially viable, socially acceptable value-added products and processes that benefit all Canadians."

The approach is multidisciplinary and includes over seventy scientists from across Canada. The research themes are (I) Structure-Function of Food and Biomaterials which includes (a) Bioproducts; and (b) Biosurfaces and Biostructures; (II) Functional Foods and Nutraceuticals that includes (a) Mechanism, Extraction and Identification; and (b) Mechanism and Efficacy and; (III) Genetics, Ethics, Economics, Environment, Law and Society which includes (a) Consumer & Citizen Acceptance; (b) Regulation and Policy; and (c) Risk Assessment and Management Tools.

In early 2004, CAFBN was awarded approximately \$22 million in funding over a five year period from the National Network Centres of Excellence program. It has been estimated that the amount of funding that individual researchers will receive will be \$50,000 per year, and that the primary funding emphasis will be on the training of highly qualified personnel.

2.4 Other National Organizations (with some activities in the NHP area)

- Canadian Health Food Association
- National Coalition for Herbs and Spices
- Ayurvedic Medical Association of Canada
- Nutraceutical Alliance (Natural Health Products for animals)
- Canadian Coalition for Homeopathic Medicine
- [Canadian Homeopathic Pharmaceutical Association - Association Pharmaceutique du Canada](#)
- [Homeopathic Medicine Council of Canada](#)
National United Professional Association of Trained Homeopaths (Canada)
- Canadian Coalition of Herbal Associations
- The Canadian Association of Herbal Practitioners
- The Canadian Botanical Association L'Association Botanique du Canada
- The Canadian Naturopathic Association (CNA)
- Chinese Medicine and Acupuncture Association of Canada (CMAAC)
- Canadian Herbalist Association of BC
- Canadian Association of Natural Products
- Natural Health Products Manufacturers of Canada/Association Canadienne des Fabricants de Produits Naturels

- [Nonprescription Drug Manufacturers Association of Canada](#) (NDMAC)

Regional Networks (with some activities in the NHP area)

- BC FFN
- Health and Nutrition Division, Ag West Bio
- Sask Herb and Spice Association
- Ontario Herbalists Association
- Ontario Association of Naturopathic Doctors
- BCNA: BC Naturopathic Association
- Ontario Association of Acupuncture and Traditional Chinese Medicine (OAATCM)
- Ontario Chinese Medicine and Acupuncture Cooperative (OCMAC)
- Traditional Chinese Medicine Association of British Columbia

3. Funding

The principal direct funding sources for the FFN (and to a more limited extent, the NHP) research community and the industry include:

1. Agriculture and Agri-Food Canada (www.agr.gc.ca)
 - Matching Investment Initiative (<http://res2.agr.gc.ca/research-recherche/industry/mii/match.html>)
 - Research Partnership Program (<http://res2.agr.gc.ca/research-recherche/partnership.html>)
 - Canadian Adaptation and Rural Development (CARD) (http://www.agr.gc.ca/progser/card_e.phtml)
2. Industry Canada (<http://strategis.ic.gc.ca>)
3. National Research Council of Canada (<http://www.nrc.ca>)
 - Industry Partnership Funding
 - Industrial Research Assistance Program (IRAP) (<http://www.nrc.ca/irap/home.html>)
 - An innovation assistance program for small and medium-sized Canadian enterprises (SMEs).
4. Natural Sciences and Engineering Research Council of Canada
 - Industry Partnership grants (<http://www.nserc.ca>)
 - An initiative to facilitate the joint participation of Canadian industry and university researchers in international projects.
5. Western Economic Diversification (<http://www.wd.gc.ca/>)
 - The Innovation Program: supports the Innovation Strategy by supporting the growth knowledge based companies.

- The Entrepreneurship Program: supports the growth of SMEs.
 - The Sustainable Communities Program: Supports the development & diversification of the western Canadian economy.
6. Canadian Institutes of Health Research (<http://www.cihr.ca>): Disease and health related research focused upon academic projects
 7. Health Canada (<http://www.hc-sc.gc.ca>)
 - NHP Directorate Research Program (seed funding)
 - HPRP (policy)
 8. Non-Governmental Organizations (NGOs/DOGs) – fund individual RD projects
 - Hospital for Sick Children Foundation
 - Heart & Stroke Foundation
 - Breast Cancer Society
 - Canadian Cancer Society
 - Canadian Diabetes Association
 9. Industry and Professional Associations – have access to NSERC/Industry/University matching funds in which industry investment is matched one on one by NSREC (in cash) and University (usually in-kind)
 - British Columbia FFN Network (BCFN)
 - Alberta New Crops Network
 - Health Division of Ag West Bio (formerly the SK Nutraceutical Network)
 - Saskatchewan Herb and Spice Association
 - National Coalition for Herbs and Spices
 - Canadian Institute for Food Science and Technology
 - Canadian Health Food Association
 - [Retail Council of Canada \(RCC\)](#)
 - [Canadian Federation of Independent Grocers \(CFIG\)](#)
 - [Food and Consumer Products Manufacturers Association \(FCPMC\)](#)
 - [Le Conseil Québécois du Commerce de Détail](#)
 - [British Columbia Naturopathic Association](#)
 - [Canadian College of Naturopathic Medicine](#)

Appendix 3: International SWOT Analysis (Strengths, Weaknesses, Opportunities and Threats)

The following analysis is meant to provide a general overview of FFN and NHP research activities in selected global regions. The assessment is not meant as an exhaustive review which is out of the scope of this project. Instead, the information presented has been gathered over a period of approximately seven years by the authors and updated for this report. The SWOT analysis is based upon industry and research surveys as well as personal observations and communications.

United States

Strengths

- Strong science and technology base
- Strong government and industry commitment to product quality research, with dedicated government funding (ODS)
- Strong industry based research in FFN development
- Strong biotech industry to support development of innovative FFN and NHPs
- Agriculture and health care industry advocacy efforts to government are very effective in changing policy
- Several regional initiatives are underway in the US which are funding research activities.
- Several industry and research associations with various levels of funding for industry directed research are focused in the areas of FFN and NHP.
- Headquarters for a number of multinationals involved in FF&N and NHP are located in the USA

Weaknesses

- The industry tends to use push versus pull marketing approaches (less consideration of consumer wants and needs are taken into account than in other countries)
- In the dietary supplement (DS) industry, there are a large number of small players that have been the cause of recent negative media focus due to low standards, lack of quality control and science to back efficacy
- DS claims don't have to be backed by scientific evidence, little incentive for DS industry to invest in research
- "Scientifically-proven" claims often based upon weak in vitro and/or animal data only
- Poor knowledge transfer
- Health professionals and consumer lack expertise to evaluate scientific claims
- Few formal training programs

United States Background

1. Key Research Programs

1.1 National Centre for Complementary and Alternative Medicine (NCCAM)

Under the National Institute of Health (NIH), the National Centre for Complementary and Alternative Medicine (NCCAM) was established in '98 (preceded by the Office of Alternative Medicine (established in '93)³. NCCAM was charged to “conduct basic and applied research, research training, and disseminate health information with respect to identifying, investigating and validating CAM treatments, diagnostic and prevention modalities, disciplines and systems.”

The priority that NIH has placed in this area is reflected in their funding levels. Total NIH investments into NCCAM have increased steadily since the first office was established in 1992 which started with a total budget of \$3.18M. By 1999, funding had reached \$50 M. In 2003, funding will be at the level of \$117.7 M and \$121.1 M is estimated for 2005.

NCCAM is currently developing a new 5-year strategic plan. The current plan outlined four areas of priority as follows:

a) ***Clinical research***: is the highest priority and centerpiece of research portfolio (vs. discovery of new knowledge through basic research). Large Phase III clinical trials will be supported that appear to be most promising and important from evidence-based reviews as well as Phase I and Phase II clinical trials.

Areas of emphasis: pressing public health concerns that are closely aligned with NIH-designated areas of emphasis: biology of brain disorders, new preventative strategies against disease, new avenues for the development of therapeutics

b) ***Training***: promotes the training and professional development of researchers through use of awards and promotion of collaborations between CAM and conventional practitioners and researchers

c) ***Information Dissemination***: use of various mechanisms to distribute credible information to public

d) ***Integration***: provide scientific evidence and inform policy makers to ensure integration of CAM with traditional practices.

1.1 Office of Dietary Supplements (ODS)

As an office in the Office of the Director at NIH⁴, the ODS does not have the authority to directly fund investigator-initiated research grant applications. Instead the ODS supports research either by funding awards to support grant applications to scientific investigators in cooperation with the Institutes and Centers at NIH or through contracts.

³ National Centre for Alternative and Complementary Medicine. 2004. Internet: <http://nccam.nih.gov>.

⁴ Office of Dietary Supplements. 2004. Internet: <http://ods.od.nih.gov/>.

As an NIH office, the ODS follows the overall mission of NIH which is "...to uncover new knowledge that will lead to better health for everyone ... by ... conducting and supporting research, helping to train research investigators; and fostering communication of biomedical information."

The goal of NIH research is "...to acquire new knowledge to help prevent, detect, diagnose, and treat disease and disability, from the rarest genetic disorder to the common cold."

1.2 Regional Initiatives and Clusters

A number of individual States have established and supported their own programs in the area of FF & N as part of their larger research programs. Some of the large programs include:

The Nutraceuticals Institute⁵

The Nutraceuticals Institute is a joint partnership of Rutgers, The State University of New Jersey, and St. Joseph's University, Philadelphia. Its mission is "to perform the scientific research, develop safe and efficacious products, standardize quality assurance measures, transfer the technologies developed from research to industry, inform policy decisions, link with the health care industry and develop markets".

Functional Foods for Health⁶

The Functional Foods for Health (FFH) is a joint program between U of Illinois, Chicago and U of Illinois, Urbana-Champaign. It is dedicated to the improvement of human health through multi-disciplinary research, education, and communication which focuses on the identification of safe and efficacious foods and other physiological active natural products which may reduce chronic disease risk or promote optimal health.

Research Goals for the FFH include:

- Identify and quantitate promising bioreactive food compounds
- Assess human health-promoting properties through metabolic, clinical, and population studies
- Develop methods to enhance levels of selected phytochemicals and other bioreactive compounds in raw and processed foods
- Define technical issues that impact FDA regulations and health claim evaluations

⁵ The Nutraceuticals Institute. 2004. Internet: www.foodsci.rutgers.edu/nci

⁶ Functional Food for Health Program. University of Illinois. 2004. Internet: <http://www.ag.uiuc.edu/~ffh/>.

The Institute of Nutraceutical Research (INR)⁷

The INR involves a consortium of institutions in South Carolina including Clemson University; the [South Carolina Research Authority](#), the [University of South Carolina](#), and the [Medical University of SC](#). One focus of this partnership is on industry-wide problems and economic development in rural South Carolina.

European Union

Strengths

- Historical use of foods and herbs for health, greater acceptance by health professionals
- Home of multinational food and pharmaceutical companies involved in FFN and NHP development
- Numerous well-established research centres with strong cadre of experienced NHP researchers and training programs, especially in Germany
- Large market size which has demonstrated growth in market share over the past few years
- The EU has developed a strategic focus for research that is supported with regional and EU Commission funding
- Established, harmonized process for regulatory approval of NHP claims
- Individual governments in number of countries have begun to focus on and develop clear priorities with financial allocations in the area of product development aimed at health care cost reductions
- Strong science focus especially in the area of FF
- Not-for-profit organizations more effective at providing information to consumers (organizations tend to be larger with substantially higher budgets to allocate to communications due to support from multinationals)

Weaknesses

- The EU is the furthest behind in developing an accepted definition or cohesive regulatory approach in FFN and NHP
- The EU has imposed the most complex approval system when compared against other countries
- Consumers are generally more skeptical about novel foods and the role of government due to recent food safety issues (BSE, GMOs, hormones)

European Union Background

2. Key Research Programs

2.1 Sixth Framework Program⁸

⁷ Institute of Nutraceutical Research. South Carolina. 2004. Internet: <http://www.clemson.edu/INR/>.

⁸ European Commission Sixth Framework. 2004. Internet: <http://europa.eu.int/comm/research/fp6/>

The European Commission's 6th framework program sets out the priorities for research, technological development and demonstration activities for the period 2002 - 06 which are meant to address the major concerns of increasing industrial competitiveness and the quality of life for European citizens.

The European Commission proposed three key research topics under the Framework linked to food:

- **Quality:** the development of new materials, methods and processes to improve food quality. In particular: the development of functional foods and the use of "naturally soft" technologies such as biopackaging
- **Safety:** processes for eliminating infectious, toxic and allergenic agents and new tests for their rapid detection
- **Health:** research on the role and impact of food on the physiological functions of the human body, the physical and mental performance of individuals and the nutritional needs of certain population groups

As an example of one initiative, in February 2002, the PROEUHEALTH program was established as a Food, GI-tract Functionality and Human Health Cluster of 16 EU countries and 64 research partners. The 5 year program is focused upon the development of new diagnostic tools for gut health as well as new functional foods and therapies. The cluster aims to achieve a clearer understanding of the relationships between food, intestinal bacteria and human health and disease.

This work will be subsidized by the European Commission's 6th Framework, Quality of Life and Management of Living Resources Programme. Approximately \$750 M (of a total ca. \$6B budget) was dedicated to the broad category of research under Food, Nutrition and Health.

2.2 Regional Initiatives and Clusters

2.2.1 Finland

Tekes is the National Technology Agency for R&D in Finland which provides funding and expert services for R&D projects. It also promotes national and international networking. Foreign companies conducting R&D activities in Finland are also welcome to work within the Tekes programs. Two separate programs funded by Tekes are outlined below.

Tekes: Innovation in Foods Programme

Finland established an Innovation in Foods programme for the 2001-2004 period. This joint program, with a total budget of \$70.13M, is coordinated by Tekes (the National Technology Agency of Finland). Both the Finnish Food and Drink Industries Federation and Sitra (the Finnish National Fund for R&D) are partners in this program. Four priority areas have been identified as follows:

- Gut health
- Plant-based substances promoting health

- Separation and encapsulation techniques
- Commercialization process management

The overriding goal of this program is to promote consumer-oriented product development and commercial applications of new food technologies for the US, Japan and Europe as target markets.

VTT Biotechnology

A number of dedicated research programs for functional foods also exist such as VTT Biotechnology, one of Finland's 9 VTT Institutes. VTT Biotechnology coordinates a Future Foods Programme with a focus on bioprocessing, packaging and consumer acceptability.

Turku, a port city in western Finland, is one of the birthplaces of functional foods, located in the main agricultural and food-processing. A host of food companies cluster around the city, such as Raisio, the creators of Benecol, which actively collaborates with researchers both at Helsinki and Turku. In 2001, the Functional Foods Forum was established at Turku University, representing a total investment of €20 million.

The Forum's purpose is to provide an R&D function for companies so that they can outsource costly R& D activities. It is to provide an new product development resource and support companies at all stages of the commercialisation process. In the Finnish cluster, University-corporate co-operation is intense, with universities successfully collaborating with even the smallest companies. One reason for this may be that academic staff are free to a large extent to profit commercially from their own research and this provides a powerful incentive.

2.2.2 Sweden⁹

Although FFN activities take place all over Sweden and many universities are involved in the area the focus is on Lund University, Scandinavia's largest higher education establishment with over 40,000 students. The city is home to a business school and to Sweden's Veterinary & Agricultural University and the Swedish University of Agricultural Science is also located close by. In addition, research activities involved with functional foods is significant as 45% of the entire Swedish food industry is located in the area around Lund.

Examples of some of the significant participants in this unique cluster include:

Functional Food Science Centre Lund: which has the goal of strengthening the competitiveness of the Swedish food sector through promoting technology transfer.

Ideon Agro Food: a network foundation that establishes and develops contacts between companies and universities and improves in industry's ability to use research in product development.

The Swedish Nutrition Foundation: which aims to support scientific research in nutrition. It also operates the Swedish food industry's health claims scheme.

⁹ 2004. Internet: <http://www.ffsc.lu.se/>; <http://www.foodoresund.com>; <http://www.agrofood.ideon.se/>

As in Finland, academics are able to profit from their own research and this has contributed to dynamism of the cluster with university researchers holding shares in companies that are commercialising their science.

2.2.3 Denmark

Functional foods network of European FFN industries¹⁰

In the fall of 2003, a new functional foods network will be established based out Denmark and involving about 40-50 non-competing food companies, ingredients companies and a number of experts and scientists to assist the industry in FFN new product development and marketing. The overall objective of the Network is to strengthen FFN innovation, specifically based on the new scientific results generated within the EC 4th, 5th, and 6th Framework Programmes. Funding for Network activities, including research and product development, is envisioned to consist of both private, industrial and government sources.

Japan

Strengths

- Has the least restrictive regulatory system and is furthest ahead in the development of a FFN industry
- Has approved the highest number of products with claims (over 400)
- Funding programs that support both science as well as industry development are structured and highly focused

Weaknesses

- Since few independent sources exist for information, communications tend to be well coordinated but only through government sources

Japan Background¹¹

Ministry of Education, Culture, Sports, Science and Technology (MEXT)

MEXT provides scientific research grants (*kaken-hi*) directly to researchers at universities and their affiliated institutions in support of research into food-related science.

From 1984 to 1994, three very large programmes were initiated for a total of \$21M. These programmes were oriented to developing new products in the area of functional foods (although the results of which products or how many are unavailable).

¹⁰ Flair-Flow Europe. 2004. Internet: www.flair-flow.com

¹¹ 2004. Internet: <http://www.japanscan.com>; <http://www.mext.go.jp/english>; <http://www.mhlw.go.jp/english/>

Ministry of Agriculture, Forestry and Fisheries (MAFF)

MAFF plays a major role in the support of the development of functional food technology for Universities and industry. This Ministry has contributed over \$28 M Canadian since 1990 and has played a significant role in helping to develop the functional foods industry. It provides financial assistance to private companies who work in consortia (known as “*Gijutsu Kumiai*”) to conduct joint research.

The types of projects tend to be those that help to develop, support and advance the Japanese functional foods industry. One such example is a project working on “New Food Creation” currently involving 12 companies. The project is managed by the Japanese Research and Development Association for New Functional Foods. A budget of \$3.7M was allocated for 1999 – 2003.

The newest project, approved in 2001, is looking at the use of biotechnology to help create new businesses and/or revive the food industry through the creation of new products. This project includes the use of feasibility studies and applied research for a total budget of \$3.8M.

Ministry of Health, Labour & Welfare (MHLW)

MHLW oversees the safety and labelling of daily-consumed food products and establishes standards concerning foods in support of maintaining the lives and good health of the population. Like MEXT, MHLW provides funding for scientific research which is considered useful for the promotion of the health and safety of the human living environment. Under this system “Health Sciences Research Grants” (*kosei kagaku kenkyu-hi hojokin*) four research programmes with budgets of 2.5 billion yen per year are available as follows:

- Policy Planning- and Evaluation-Related,
- Comprehensive Research (cancer/long-life/AIDS),
- Medical Frontier Research, and
- Environmental Health-Related.

Research projects selected under these programmes normally continue for 3 years. Researchers who belong to private and public institutions (including universities) are eligible to receive funding. Research relating to “functional foods” is carried out under the flagship of the Environmental Health-Related Program.

¹Health Canada. Standards of Evidence for Evaluating Foods with Health Claims – Fact Sheet. November 2000. Internet : http://www.hc-sc.gc.ca/food-aliment/ns-sc/ne-en/health_claims-allegations_sante/e_soe_fact_sheet.htm.

²Health Canada. Regulations Amending the Food and Drug Regulations (Nutrition Labeling, Nutrition Claims and Health Claims). Canada Gazette Part II. January 2003. Internet: <http://canadagazette.gc.ca/partII/2003/20030101/pdf/g2-13701.pdf>. (accessed 4 January 2003).

³Health Canada. Product-Specific Authorization of Health Claims for Foods: A Proposed Regulatory Framework. October 2001. Internet : http://www.hc-sc.gc.ca/food-aliment/ns-sc/ne-en/health_claims-allegations_sante/e_finalproposal01.html. (accessed 11 November 2003).

⁴Health Canada. Interim Guidance Document: Preparing a Submission for Foods with Health Claims Incorporating Standards of Evidence for Evaluating Foods with Health Claims. Updated. Internet : http://www.hc-sc.gc.ca/food-aliment/ns-sc/ne-en/health_claims_allegations_sante/pdf/e_guidance_doc_interim.pdf. (accessed 9 November 2003).

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- ⁵ Food and Drugs Act. Natural Health Product Regulations. http://www.hc-sc.gc.ca/hpfb-dgpsa/nhpdpsn/regs_cg2.pdf
- ⁶ Natural Health Products Directorate. http://www.hc-sc.gc.ca/hpfb-dgpsa/nhpd-dpsn/faq_general_e.html
- ⁷ Evidence for the Safety and Efficacy of Finished Natural Health Products. http://www.hc-sc.gc.ca/hpfb-dgpsa/nhpd-dpsn/evidence_for_safety_efficacy_finished_nhp_e.html. Evidence for Quality of Finished Natural Health Products. http://www.hc-sc.gc.ca/hpfb-dgpsa/nhpd-dpsn/evidence_for_quality_nhp_e.html
- ⁸ Natural Health Products Research Priority-Setting Conference in Halifax, Nova Scotia, November 6-8, 1999. http://www.hc-sc.gc.ca/hpfb-dgpsa/nhpd-dpsn/priority_setting_intro_e.html
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- ²² Institutions identified as fulfilling these criteria included CINE (McGill), IAH (UBC), Royal Roads University, University of Brandon, University of Ottawa, and University of Victoria.
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