Natural Health Products: State of the Industry & NRC’s NHP Program Overview

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Bob Chapman
Program Leader
NHP Program
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GLOBAL INDUSTRY OVERVIEW
SIGNIFICANT OPPORTUNITY FOR CANADIAN INDUSTRY GROWTH

- Industry evolving from nascent to growth stage
- Competition expected to fuel innovation and R&D investment
- Plethora of products driving regulators to act

Global Sales in $B and CAGR for 2010

<table>
<thead>
<tr>
<th>Category</th>
<th>2010 Sales ($B)</th>
<th>CAGR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functional Foods</td>
<td>$102</td>
<td>4.8%</td>
</tr>
<tr>
<td>Natural &amp; Organic Personal Care</td>
<td>$31</td>
<td>8.7%</td>
</tr>
<tr>
<td>Natural &amp; Organic Foods</td>
<td>$84</td>
<td>7.2%</td>
</tr>
<tr>
<td>Supplements</td>
<td>$85</td>
<td>5.4%</td>
</tr>
</tbody>
</table>

CANADIAN INDUSTRY OVERVIEW
SIGNIFICANT OPPORTUNITY FOR CANADIAN INDUSTRY GROWTH

- Canadian SMEs need to add capacity to overcome regulatory-related testing requirements
- Canadian firms need science-based evidence to support claims to both maintain and build market share

750 functional foods & natural health products (FFNHP) establishments.
Total R&D expenditures for FFNHP establishments $240M.
181 have trade secrets, 175 have trademarks, & 94 hold patents.
16,400 individuals were employed by FFNHP establishments.
32,300 FFNHP product lines on the market 85% were NHPs.

Source: Stats Can Report, 2011
<table>
<thead>
<tr>
<th><strong>USE</strong></th>
<th><strong>FOOD</strong></th>
<th><strong>NHP &amp; FF</strong>*</th>
<th><strong>Rx DRUGS</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy and satiety</td>
<td>Enhance energy; wellness</td>
<td>Treatment of disease, symptom or condition</td>
<td></td>
</tr>
<tr>
<td>Basic Nutrition</td>
<td>Beyond basic nutrition</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Reduce risk of diseases</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>OBTAINED BY</strong></td>
<td>Consumer selects</td>
<td>Consumer selects or recommended by naturopathic doctor</td>
<td>Prescribed by health care provider</td>
</tr>
<tr>
<td>Consumer selects</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>DISTRIBUTION</strong></td>
<td>Supermarkets, farmers markets</td>
<td>Supermarkets, drug stores, online, specialty retailers; direct to consumer marketers</td>
<td>Hospitals, pharmacies</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>REGULATIONS</strong></td>
<td>Historically low; focus on safety</td>
<td>Moderate and increasing; focus on safety and efficacy</td>
<td>High; focus on safety and efficacy</td>
</tr>
<tr>
<td>As desired; guided by Canada’s Food Guide</td>
<td>As desired; guided by product dosage recommendations</td>
<td></td>
<td>As prescribed</td>
</tr>
<tr>
<td><strong>CONSUMPTION</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>FORM</strong></td>
<td>Natural and processed foods</td>
<td>NHPs complex mixtures sold as pills, powders, creams &amp; liquids</td>
<td>generally single active substance sold as pills &amp; liquids</td>
</tr>
</tbody>
</table>

*Functional Ingredients are used to make Functional Foods (FFs) and NHPs.

Source: Adapted from PriceWaterhouseCoopers
Addresses key national & global challenges

- Demographic shifts: population growth, aging
- Nutrition & health: rise of lifestyle-related diseases

Competitive pressures and regulatory hurdles are growing

- Demand driven by engaged consumers seeking safer, healthier NHPs
- Health claims carry weight in the marketplace
- Regulation oversight becoming more stringent and growing globally
- Canadian regulators ahead of competitor nations

Consultations with Canadian industry participants confirms need for R&D support

- Industry seeking product & process innovations to fuel growth and marketplace differentiation
- Companies require product development support to validate safety and efficacy of products
NRC’S UNIQUE VALUE PROPOSITION

- Specializing in state of the art technology
- Drawing expertise and know-how from across NRC for multidisciplinary solutions-tailored to the needs of our clients
- Combining NRC strategic R&D, tech capabilities with innovation support and specialized infrastructure to provide a powerful mix of research & technology operations for Canada

Solving innovation and competitive technology problems. Developing, adapting and deploying technology.
NRC’S UNIQUE VALUE PROPOSITION

• Helping industry manage risk to develop innovative ideas, reduce start-up costs, and shorten time to market

• Offering access to unique research infrastructure as well as the experts to optimize its use
To make Canada a world leader in the sustainable transformation of bio-based resources into economic value
Programs

• Bio-Based Specialty Chemicals
• Natural Health Products
• Canadian Wheat Improvement (flagship)
• Algal Carbon Conversion (flagship)
Helping companies involved in Canada's Natural Health Product (NHP) and Functional Ingredient (FI) industries develop, differentiate and create value for their existing or in-development products.

**OBJECTIVES**

• Co-developing new high-value NHPs
• Differentiating NHPs through science-supported NHPs and FIs
• Developing FIs from Canadian bioresources and waste streams
• Increase Canada’s Global Reputation for Quality and Safety
NHP program operates and benefits from resources at 5 sites in 5 provinces.
• Accelerating & enhancing the product development cycle for NHPs and Functional Ingredients (FIs) by addressing the evidence-based, preclinical science gap identified by industry.

The NHP Program will:
• help shorten the product development cycle by 10-20%.
• work directly with 30–40 companies
• create 20 new enabling technologies
• develop 8 innovative and differentiated functional ingredients
# NHP PROGRAM

**CAPABILITIES ALIGNED WITH NRC INVESTMENTS**

<table>
<thead>
<tr>
<th></th>
<th>Analytical Services</th>
<th>Natural Products Chemistry</th>
<th>Preclinical Biological Services</th>
<th>Bio-Oils</th>
<th>Bio-conversion &amp; Bio-processing</th>
<th>Specialized Facilities &amp; Models</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lipid &amp; Oils</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
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<tr>
<td>Protein</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
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<tr>
<td>Skin Health</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
<td>●</td>
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<tr>
<td>Metabolic Health</td>
<td>●</td>
<td>●</td>
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<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Quality &amp; Safety</td>
<td>●</td>
<td>●</td>
<td>●</td>
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<td>●</td>
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<tr>
<td>Extraction &amp; Formulation</td>
<td>●</td>
<td>●</td>
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</tbody>
</table>
ANALYTICAL SERVICES

• Qualitative and quantitative analysis of raw materials, extracts, or formulated products
• Ingredient characterization (isolation and structure elucidation)
• QA/QC method development and validation for ingredient specifications, active ingredients, and known & unknown contaminates
• Quality assurance and quality control (ingredients, finished products, and adulteration/contamination)
• Reference material development and standardization (NRC Measurement Science and Standards Portfolio)
ANALYTICAL SERVICES
QUALITY ASSURANCE AND VERIFICATION
NATURAL PRODUCTS CHEMISTRY

- Chemical profiling and quantitative analysis
  - Carotenoids from plants and algae
  - Polyphenolics from berries and seaweeds
- Compound isolation, purification & chemical identification
- Bioassay guided fractionating support
- All of the ‘omics (metabolomics, proteomics, genomics…)
- Synthetic chemistry: labeled compounds & standards
- Enzyme-assisted extraction
- Lab scale process development
PRECLINICAL BIOSERVICES

- Validated and Custom Assay Development
- In vitro Bioassay Capabilities
- Cell-based assays for evaluating skin health applications
- Model skin systems
- High Content Imaging and Screening
- HCS Oris™ cell migration assay
- Pharmacological and Toxicological Characterization of NHP Ingredients and Product Formulations
- Metabolic Health
PRECLINICAL BIOSERVICES
IN VITRO BIOASSAY CAPABILITIES

GENERAL COMPETENCIES

- Immunology
- Metabolism & Lipids
- Neurological disorders
- Pharmacology and Toxicology
- Biochemistry
- Cancer Biology
- Antimicrobials
- Molecular & Cell Biology

APPLICATIONS

- Compound/ingredient discovery
- Lead identification and optimization
- Proof of concept
- Demonstration of efficacy
- Mechanism(s) of action
- Claim validation
- Product line extension
- Value-added product development
- QC & Standards

preclinical studies that deliver efficacy and mechanistic data
Accelerated breeding programs through advanced genomics.

- Trait characterization.
- Development and application of Molecular Markers for Marker Assisted Breeding.
- Doubled Haploid (DH) production for trait stabilization and rapid variety development.
- Extensive expertise in oilseed crops and herbs.
• Biosynthesis (fermentation) and processing of industrial and nutraceutical lipids
• Bioconversion of biomass molecules into value added products such as protein and fiber
• Enzyme technologies
• Technologies for agricultural waste stream utilization, including isolation, characterization and modification
SPECIALIZED FACILITIES AND MODELS

- In vitro bioassay capabilities supported by a state-of-the-art, automated imaging technology: MD Image Xpress XLS
- *In vivo* models such as zebrafish
- Expanded Bed Adsorption Chromatography
- Supercritical CO$_2$ extraction (high pressure 1000 Bar)
- Micro and macro algae marine research station
- Plant growth: phytotron, greenhouse, sunrooms
NHP PROGRAM CLIENTS AND COLLABORATORS

- Ascenta
- POS Bio-Sciences
- Neurodyn
- SEVITA INTERNATIONAL
- Jamieson
- Acadian Seaplants
- Delivra
- Bioriginal
- Honibe
- Origin BioMed
- TCI
- Prairie Plant Systems Inc.
NHP PROGRAM
CONTACTS

Bob Chapman
NHP Program Leader
bob.chapman@nrc-cnrc.gc.ca
902-566-7405

Jason Steele
Client Relationship Leader
jason.steele@nrc-cnrc.gc.ca
902-402-1714