Natural Health Products: State of the Industry and the Importance of Product Quality

Bob Chapman and Jeffrey Chisholm
April 2015
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 by $B and CAGR % for 2012

- Functional Foods: 5.5% CAGR, $112B
- Natural & Organic Personal Care: 10.3% CAGR, $37B
- Natural & Organic Foods: 10.3% CAGR, $101B
- Supplements: 7.0% CAGR, $97B

Source: Nutrition Business Journal (NBJ) 2014
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
Canadian Industry Overview
A National Canadian Industry

- 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: NBJ, George Morris Centre, Team analysis

Source: Stats Can Report, 2011
About NRC

• Canada’s Research and Technology Organization (RTO)
• $774M budget (2013)
• 4,000 employees
• Serving 1000s of clients annually – industry and government
NRC Organizational Structure

DIVISIONS

Emerging Technologies

PORTFOLIOS

Information and Communications Technologies
Measurement Science and Standards
National Science Infrastructure
Security and Disruptive Technologies

Engineering

Aerospace
Automotive and Surface Transportation
Construction
Energy, Mining and Environment
Ocean, Coastal and River Engineering

Life Sciences

Aquatic and Crop Resource Development
Human Health Therapeutics
Medical Devices

Industrial Research Assistance Program

Pacific Region
West Region
Ontario Region
Quebec Region
Atlantic & Nunavut
National Office

Common Services to support portfolios and IRAP
Aquatic and Crop Resource Development (ACRD)

To make Canada a world leader in the sustainable transformation of bio-based resources into economic value
Aquatic and Crop Resource Development Strategic Areas

- **Natural Health Products**
  - Validating efficacy and commercializing high-quality natural products

- **Biobased Specialty Chemicals**
  - Producing alternatives to traditional chemical feedstocks

- **Algal Carbon Conversion**
  - Developing algal biomass solutions that divert CO$_2$ emissions

- **Canadian Wheat Improvement**
  - Improving Canadian wheat’s yield, sustainability, and profitability
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

**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; Bi-processing</th>
<th>Specialized Facilities &amp; Models</th>
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</table>
NRC’S Role in the NHP Value Chain
Quality: Controlling the Entire Value Chain: Value Added Products from Canadian Resources

- Bioriginal
  - Innovative EFA Solutions®
  - Borage Oil

- Rhoziva
  - Nanton Nutraceuticals

- North American Ginseng

- Mazza Innovation

- AppleActiv

- TCI

- Island Abbey Foods

- Peazazz™
  - Field Peas

- Burcon Pea protein

- AppleActiv

- AhiFlower Oil

Natural Health Products Program
• **Plant Sterols** and Blood Cholesterol Lowering (2010)
• **Neptune Krill Oil** (lowers LDL and triglycerides and increases HDL) (2010)
• BioK **Probiotic** (reduce the risk of diarrhea due to *Clostridium difficile* in hospitalized patients) (2013)
• **Fruit d’Or** (2014) – Cran Naturelle for UTI
• **Soy Protein** and Blood Cholesterol Lowering (2015)
• List of **Health Canada** approved claims -
  • Flaxseed, Psyllium products, Barley products, Oat products (Cholesterol lowering), and others
What Messages are Reaching Consumers
Omega 3 Industry Findings

Source: GOED analysis of Factiva data
Negatively and Neutral Studies Have also Played a Role

- **Rizos Study**: No CVD benefit for omega-3s
- **Macchia Study**: Omega-3s do not prevent recurring AF
- **Risk & Prevention**: Omega-3s do not reduce MI risk in at-risk patients
- **Strand Study**: High intakes of omega-3s increase risk of fatal MI
- **AREDS2**: Omega-3s do not reverse AMD
- **OPERA Study**: Omega-3s do not prevent post-operative AF
- **Gould Study**: n-3s don’t improve cognitive or visual development
- **Brasky Study**: Omega-3s increase prostate cancer risk
- **Fenton Review**: High doses of omega-3s may be dangerous
- **NICE Guidelines**: No CVD benefit for omega-3s
- **Turkish MOH**: Expresses concern about prostate cancer
How Do Consumers Respond
Omega 3 Industry Findings

Source: GOED analysis of Factiva data
Quality and Safety
Ripped from the headlines

February 2, 2015

Michael G. Archbold, CEO
GNC Holdings, Inc.
300 Sixth Avenue
Pittsburgh, Pennsylvania 15222

Re: CEASE & DESIST NOTIFICATION
Herbal Plus—GNC Distributed Herbal Dietary Supplements

Dear Mr. Archbold:

This letter constitutes a demand to cease and desist engaging in the sale of adulterated and/or mislabeled herbal dietary supplements, and in particular to immediately stop the sale of five “Herbal Plus” dietary supplements as identified by lot number in the exhibit annexed hereto.

What is echinacea? This much we can say with some certainty: it is a pretty, pink-flowered member of the daisy family—a native of the American prairie. It is also, according to a small body of (mostly German) scientific research, an immunostimulant. Its proponents contend that, consumed in tea, tincture, or capsule form, it can treat AIDS, boils, and the common cold and purge the liver of toxins. These claims have not been evaluated by the U.S. Food and Drug Administration, which declines to regulate the herb as a medicine, consigning it instead to the fluffier category of dietary supplement. Echinacea...
Why should we be starting the conversation about NHP and ingredient quality?

- Negative press
- Consumer confidence
- Industry reputation
- Product differentiation
- GMP and Health Canada regulations when properly implemented and followed are minimum thresholds to ensure product safety
- Reduce risk of further regulation
- Reduce legal risk
Why NRC?

- We are Canada’s Research Technology Organization (RTO) and through the NHP Program we work with the NHP and Functional Ingredient Industries to develop, differentiate and create value for their existing or in-development products.

- Helping industry partners develop new or modified methods to improve NHP quality and safety is a key area the NHP Program participates by applying our expertise and technology.
Authenticity, Quality, Safety and Adulteration

- **Authenticity** - the ingredient is what it is supposed to be and free of adulteration or substitution.

- **Quality** - The quality of the ingredient meets predetermined specifications - This occurs through appropriate controls and an overall assurance program.

- **Safety** - the ingredient is safe for the intended purpose, authentic, of acceptable quality, free of adulterants and uncharacterized contaminants and meets specifications for known potential contaminants, pesticides, heavy metals, solvent residues, fungi and microbiologials etc...

- **Adulteration** - To make impure by adding extraneous, improper, or inferior ingredients.
### Known, reported harmful situations

<table>
<thead>
<tr>
<th>Facilities where supplements were contaminated with rodent feces and urine</th>
<th>Adverse reactions</th>
<th>GMP, Chain of Custody, QA/QC</th>
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</thead>
<tbody>
<tr>
<td>Products are sometimes mislabeled, accidentally or intentionally</td>
<td>Adverse reactions</td>
<td>GMP, Fraud, Knowledge, QA/QC</td>
</tr>
<tr>
<td>“Ayurvedic” remedies found to contain potentially harmful levels of lead, mercury or arsenic (2003)</td>
<td>Poisoning</td>
<td>Heavy Metal Testing</td>
</tr>
<tr>
<td>Products found to contain 200+ times more selenium than labels stated (2008)</td>
<td>Hair loss, muscle cramps, diarrhea, joint pain, fatigue, blisters</td>
<td>GMP, QA/QC</td>
</tr>
<tr>
<td>Vitamins and minerals made by Purity First Health Products were found to contain two powerful anabolic steroids</td>
<td>Masculinizing symptoms in women</td>
<td>Fraud, Ingredient Authentication, QA/QC testing</td>
</tr>
<tr>
<td>Herbal products (i.e. St. John’s Wort and ginkgo biloba) containing completely different, and sometimes dangerous, herbs or contaminants</td>
<td>Adverse reactions</td>
<td>Fraud, Ingredient authentication, GMP.</td>
</tr>
<tr>
<td>Approximately 50,000 adverse reactions to dietary supplements every year</td>
<td>Adverse reactions</td>
<td>QA/QC, Authentication, Safety and Drug-Drug Interaction testing, Clinical safety studies.</td>
</tr>
</tbody>
</table>
Types of Adulterants

- Pesticides, toxic elements, filth, microbial organisms
  - Some ayurvedic and traditional chinese medicines intentionally contain toxic elements
  - During 2000-2003 12 cases of lead poisoning among adults were associated ayurvedic medicines.

- Hazardous natural products (e.g., aristolochic acid, ephedrine alkaloids, pyrrolizadine alkaloids, etc.)

- ED drugs, steriods, stimulants, lovastatin (red rice yeast extract), etc.

- Substituted ingredients/misidentification:
  - e.g., star anise, hoodia, bilberry, aloe
Adulteration in The Marketplace

- **Digitalis lanata** instead of **Plantago lanceolata** - Slifman et al. *NEJM* (1998) **339**:806

- **Pesticides in ginseng** - Durgnat et al 2005 *Food Addit Contam* **22**:1224


Why should the industry invest in ensuring quality and authenticity?

It’s all about risk reduction

• Improve consumer confidence by demonstrating the quality of your ingredients and products through thorough “fit for purpose” testing.

• Reduce bad press and improve confidence in the NHP industry.

• Demonstrate your dedication to quality and differentiate your company from the competition.

• Reduce the risk of more regulation.

• Reduce potential legal liabilities.
Food for thought- NYAG Impact on GNC stock

GNC Holdings Inc. (GNC) ⭐ Watchlist
46.90 -0.97 (-2.03%) NYSE - As of 4:02PM EDT
GMP in NHP Manufacturing

GMP- Good Manufacturing Practices; cGMP- Current Good Manufacturing Practices

Health Canada- GMPs are ongoing measures designed to ensure an effective overall approach to product quality control and risk management. They do so by setting appropriate standards and practices for product testing, manufacturing, storage, handling and distribution.

- Places (premises and equipment), People (personnel and quality assurance); Processes (sanitation program and operations); and Products (specifications, stability, samples, records, recall reporting and sterile products).

FDA- The rule establishes cGMPs for the dietary supplements industry-wide use that are necessary to require that are manufactured consistently as to identity, purity, strength, and composition.

... testing final product or incoming and inprocess materials ...
# NHP Manufacturing and Supply Chain

<table>
<thead>
<tr>
<th>Ingredient Supplier</th>
<th>Ingredient Source</th>
<th>Harvest</th>
<th>Storage and Transport</th>
<th>Processing</th>
<th>Transport</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

**Authenticity**  
**Chain of Custody** - **Stability of Ingredient**  
**QA/QC**

**Validation**  
**In Process Testing**  
**QA/QC**  
**QA**

**Loading Dock**  
**Manufacturing**  
**Finished Product**  
**Shelf Stability**

**Traceability** - Lot and batch sample retention
Role of Functional Ingredients

Functional ingredients are the ingredients in NHP’s that have evidence of health benefit

• Individual natural compounds from plants, microorganisms, marine organisms and sometimes the lab.
• Extracts of plants, microorganisms and marine organisms- Final form can be liquid or powder.
• Powders or extracts of powders can be from whole plants, or other organisms or parts of plants or organisms. I.e. stems or leaves
The Fourteen Myths of Traditional Medicine

1. This traditional medicine has been used for thousands of years (ergo it is safe and effective)
2. Using the “correct” plant is adequate
3. The biological effects are the same from different plant parts
4. The biological effects are the same irrespective of the origin of the plant
5. The biological effects are the same irrespective of the plant preparation
6. Older plant material is less effective (or more toxic)
7. “Wild”-collected plants are more active than cultivated plants
8. All of the materials in a complex prescription are necessary for effectiveness
9. Complex mixtures of plants cannot be standardized
10. This medicinal plant product is already well-regulated
11. Medicinal plants are safer than synthetic drugs
12. The medicinal plant will always be available
13. The traditional knowledge will always be there
14. “traditional medicines are not effective, and are therefore not worth considering as a part of a contemporary health care system”

Variables potentially impacting functional ingredient authenticity, quality and efficacy

- Plant or organism strain
- Growing or harvest location
- Time of harvest - Seasonal and climate variation
- Whole plants or select plant parts
- Soil and water
- Fertilizers, pesticides and herbicides
- Storage
- Moisture
- Ingredient contamination from weeds and by-catch
- Adulteration - intentional and unintentional
NHP Manufacturing and Supply Chain

**Ingredient Supplier**

- **Authenticity**
- **Chain of Custody - Stability of Ingredient**
- **QA/QC**

- **Ingredient Source**
- **Harvest**
- **Storage and Transport**
- **Processing**
- **Transport**

**GMP Manufacturer**

- **Validation**
- **In Process Testing**
- **QA/QC**
- **QA**

- **Loading Dock**
- **Manufacturing**
- **Finished Product**
- **Shelf Stability**

Traceability - Lot and batch sample retention
Finished product

- Finished product testing is essential to ensure safety and comply with GMP and product monographs, but some types of tests are complicated by mixtures and ingredient processing.
- Cost is also an issue for manufacturers of small lots and batches.

Ingredient Quality and Authentication

- There is an opportunity to improve ingredient sourcing and raise expectations for the quality of ingredients going into NHP’s
- An emerging concept is **Ultrasourcing**
How can we move towards ultrasourcing of functional ingredients?

The manufacturing company sets the standard, but much of the burden is on the Ingredient Suppliers.

Manufacturer

- Understand the ingredient - especially risks to authenticity and stability.
- Qualification of suppliers - Due diligence, review authentication procedures and methods, chain of custody, storage and transport, supply chain reputation, sample retention, understand the variables in supply (source, climate, time, plant part etc.).
- Confirmation of CoA's at the loading dock using “fit for purpose” methods.
- Know what you are importing; CFIA puts the burden on the importer.
- Verification of your supply chain and process controls through third party testing or certification.
How can we move towards ultrasourcing of functional ingredients?

Functional Ingredient Supplier

- Authentication of source material by appropriate “fit for purpose” methods
- Chain of custody
- Validated storage and transport procedures
- Final ingredient authentication and quality control - again “fit for purpose” methods appropriate for ingredient authentication, contamination or adulteration detection
- Batch and lot sample retention
- Documentation
- QA/QC procedures
Targeted

- Genetic identity - Bar coding, sequencing or related approaches
- Validated analytical fingerprints - HPLC, LC/GC-MS, Spectroscopy
- Bioactive ingredient(s) - Quantitation and sometimes bioactivity
- Known adulterants - pharmaceuticals, known substitutions

Standard Assays

- Known toxins
- Heavy metals
- Pesticides
- Solvent residue
- Microbiology
- Etc.
Methods for assessing ingredient quality and authenticity

- Traditional Herbology or Botany - Microscopic and morphological characterization.
- DNA barcoding and related genetic methods.
- Near IR - lacks resolution for conclusive authentication.
- Phytochemical fingerprinting and Metabolite profiling
  - HPTLC, HPLC, GC, GC/LC MS, NMR
- Regardless of approach methods must be “fit for the required purpose”, appropriately validated, reproducible, reliable and standardized, ideally to high quality or certified reference materials.
- In some cases reference materials may need to be developed.
DNA and DNA Barcoding

DNA Double Helix that encodes genetic information

Barcodes use a short unique DNA sequence from a uniform locality on the genome to identify an individual species.

**DNA barcoding** is a method that uses a short genetic marker in an organism's DNA to identify it as belonging to a particular species.

Complicated to apply to plants at the species level without optimization and validation using appropriate bar codes and reference materials. Not highly quantitative. Usefulness may decrease by processing.

[Harbaugh, Mishler, Neal-Kabaick and Brown, 2015, Authentechnologies white paper](#)
Example of why “Fit for Purpose” is so important
DNA Barcoding Plants - Considerations (validation and “fit for purpose”)

Key areas that must be addressed in order to perform accurate species identification using any DNA method, including DNA barcoding:

1. Perform Method Validation Specific to the Intended Application
2. Identify the Most Appropriate Genes
3. Run Positive and Negative Control
4. Follow Strict Quality Control Procedures: Avoid contamination
5. **Use Authentic Reference Sequences**
6. Understand Acceptable Variation: Plant species are highly variable, especially in species that have a broad geographic distribution
7. Identification Algorithms

Harbaugh, Mishler, Neal-Kabaick and Brown, 2015, Authentechologies white paper
Authentication: Chemical Analysis

**Approach**

- Identify unique, species-specific chemical marker
- Isolate and identify purified reference standards
- Develop ‘user-friendly’, accessible techniques
- Identify markers for likely botanical adulterants and contaminants

**Issues**

- Requires extraction and sample preparation
- Levels of phytochemicals may vary substantially due to environmental and genetic factors as well as storage and handling procedures
- Chemical markers may not be related to biological effects
Case Study: Star Anise (Illicium sp.)

Genus: *Illicium verum* L.
Family: Illiciaceae or Magnoliaceae
Parts used: Fruits

- Common adulterants: *Illicium religiosum* Sieb. & Zucc. *Illicium anisatum* L. (Japanese anise) used as ornamental potpourri and used in fish poisoning.

- FDA Advisory 2003: food poisoning incidents caused by Star Anise tea; patients showed neurological symptoms like seizure, vomit, jitteriness and rapid eye moving, which are typical for those caused by Japanese Star Anise ingestion.

Kahn and Calvey- June 16-18, 2010, 11th Annual Fera/JIFSAN Symposium
Comparison between fruits of *Illicium verum* Hook f. and *Illicium anisatum* L.

**Fruits**

**Fruits with pedicel**

**Ground Fruits**

*I. verum*  
*I. anisatum*
GC phytochemical fingerprint of solvent extracts

I. verum fruit

I. anisatum fruit

10% I. anisatum Fruit

Joshi et al. (2005) J AOAC Intl, 88, 703
Detection of adulterant *I. anisatum* in *I. verum* (PCR Method)

1/500 or < 0.2% of *I. anisatum* can be detected.

Kahn and Calvey- June 16-18, 2010, 11th Annual Fera/JIFSAN Symposium
# Bilberry products quality and method dependence

<table>
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<tr>
<th>No</th>
<th>Batch</th>
<th>Anthocyanins (HPLC) (%)</th>
<th>Anthocyanins (UV/Visible) (%)</th>
<th>Label</th>
<th>Compliance to label</th>
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</table>

Table 2: Summary of bilberry analysis and compliance to label: variability in bilberry extract analysis and the differences among available commercial extracts. Compliance with the declared content is not always observed.

Artaria et al (2007), Nutrafoods 6, 13
Case Study: Aloe species

Aloe Vera

Aloe arborescens

Aloe ferox

Photos from Van Wyk and Smith, 2003
Aloe NMR Metabolomics

Aloe Species

- A. arborescens
- A. ferox
- A. vera

Aloe Products

- Aloe gel product with preservatives
- Aloe gel product adulterated with maltodextrine
- Aloe vera gel product

Kahn and Calvey- June 16-18, 2010, 11th Annual Fera/JIFSAN Symposium
HPTLC phytochemical fingerprint of Hoodia gordonii

Authentic Standards

Hg Extract
Std Mixture

Want to Improve ingredient and product authentication?

- Understand your ingredients and the potential issues
- Review “fit for purpose” of existing methods
- Where possible validate methods using “Certified Reference Materials”
- Consult with experts on the ingredient, authentication and quality control and methods.
- Numerous organizations are available in Canada and elsewhere to advise and help you develop or validate methods and your testing paradigm, including NRC.
- We welcome feedback to better understand your perspective, challenges and needs.
What else can you do to improve quality, safety, and efficacy and potentially differentiate your product?

- Third party industry certifications, non-GMO, NSF etc…
- Advance the science supporting your product
  - Efficacy testing of your product and formulation
  - Better formulations- Less ingredient more efficacy
- Bioavailability- Less ingredient more efficacy
- Check for potential NHP-Drug interactions
- Clinical testing
Bob Chapman- NHP Program Leader (bob.chapman@nrc-cnrc.gc.ca; phone: 902-566-7405)

Jeffrey Chisholm- NHP Technical Team Leader, Project Development (jeff.chisholm@nrc-cnrc.gc.ca; phone: 902-314-6566)

Jason Steele- Client Relationship Leader (jason.steele@nrc-cnrc.gc.ca; phone: 902-402-1714)
Extra Slides
Authentication Challenges

- Techniques need to be “fit for purpose” suitable for the material being tested and able to identify known quality issues and ideally identify known and unknown adulterants.

- Requires one or more distinguishing characteristics of the desired species are known. CRM’s (Certified reference materials) if available can help.

- Methods or combinations of methods must be reliable, accurate and economical.