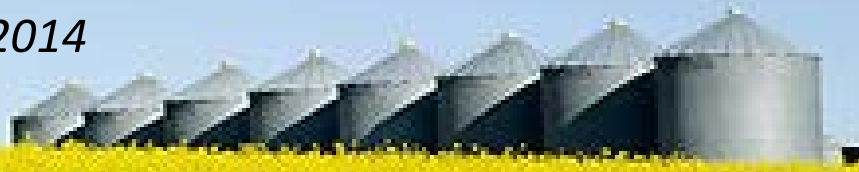
Developing Botanical ingredients for Natural Health products

From Concept to Commercialization

Natural Health Products & Functional Foods Workshop
Agri-Food Discovery Place
Edmonton, Alberta
November 6, 2014



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Topics

1. Botanical Ingredients
2. Traceability and Sustainability
3. From Concept to Commercialization
4. Bio-Industrial Opportunities Branch
5. Summary

Natural Health Product

“Natural health products (NHPs) are naturally occurring substances that are used to restore or maintain good health. They are often made from plants, but can also be made from animals, microorganisms and marine sources. They come in a wide variety of forms like tablets, capsules, tinctures, solutions, creams, ointments and drops.”

Natural health products, often called "complementary" or "alternative" medicines, include:

- vitamins and minerals
- herbal remedies
- homeopathic medicines
- traditional medicines like traditional Chinese and Ayurvedic (East Indian) medicines probiotics
- other products like amino acids and essential fatty acids

Many everyday consumer products, like certain toothpastes, antiperspirants, shampoos, facial products and mouthwashes are also classified as natural health products in Canada.

Source: http://www.hc-sc.gc.ca/dhp-mps/prodnatur/about-apropos/cons-eng.php

The World of Botanicals

Food

Fuel

Cosmetics

Clothing

Medicine

Botanical Extracts

Definition:

A botanical extract is typically the result of using a solvent to extract out the actives components from one or more parts of a plant.

Types:

- Essential oils
- Fluidextracts
- Tinctures and hydrosols

Botanical ingredients

- Are a complex mixture of hundreds of unique compounds.
- Many of these compounds haven’t been characterized.
- The biological activity can vary between species and varieties/cultivars.
- A plant species can be grown in the same location under similar conditions and will always have a different balance of compounds.

Single Actives vs. Botanical Extracts

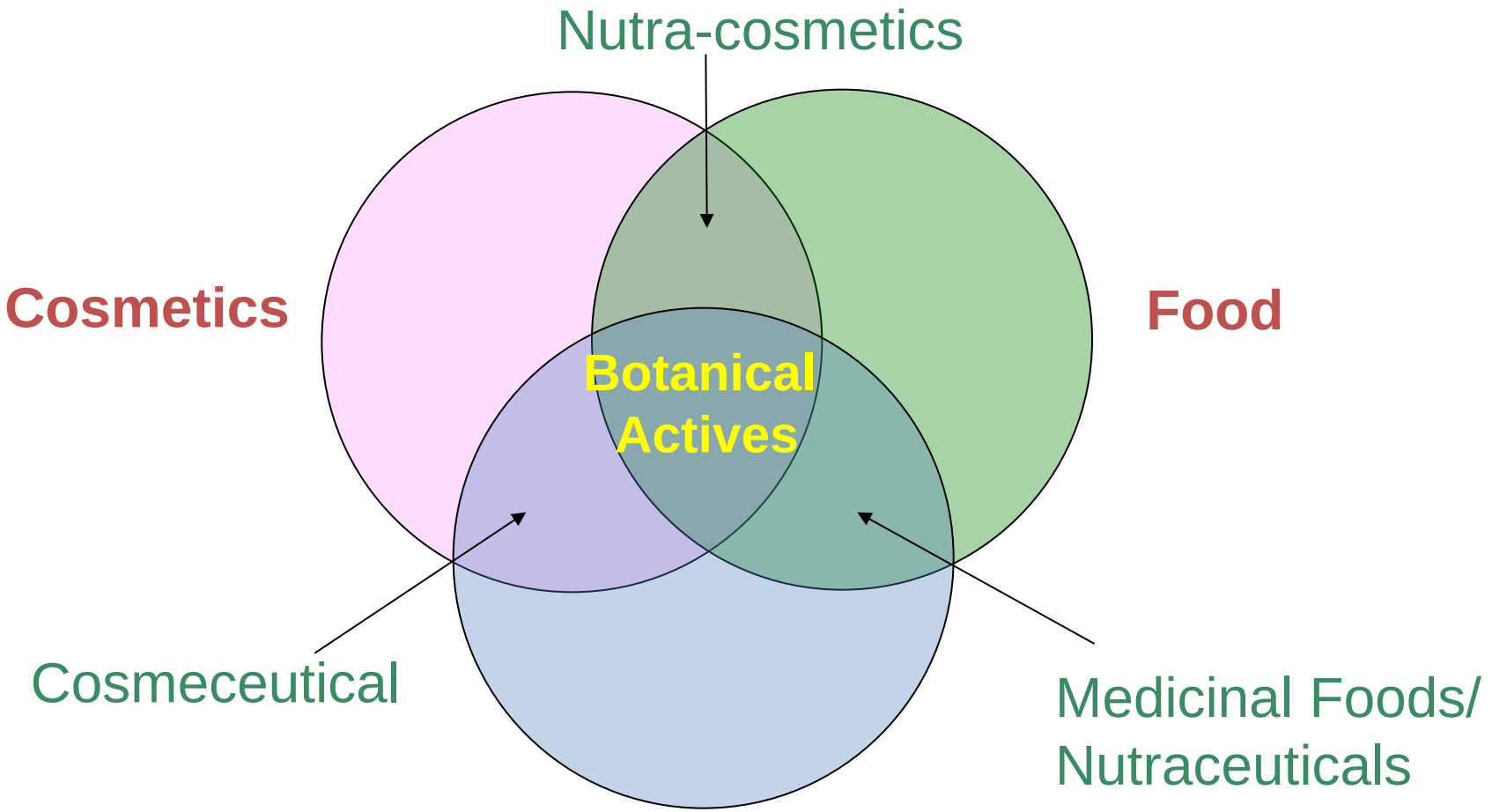
- Benefit of using an isolated active
  - Defined chemistry and site/mode of action
  - Standardized extract or purified active.
  - Better safety data
  - Moderate to high concentrations possible
  - ‘Cosmeceutical’ claims

- Benefit of using a full spectrum botanical active.
  - Many say there work better in harmony with the body.
  - Could miss out on synergistic action of the different compounds or classes of compounds.
  - Some components won’t have been identified.

Compounds present in a botanical?

- Protein
- Lipids
- Carbohydrates
- Polyphenols
- Saponins
- Alkaloids
- Carotenoids
- Lactones
- Phytosterols
- Terpenoids

Market Convergence of Botanicals



The Grey Zone

Nutraceutical

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

Cosmeceutical

Cosmeceuticals are cosmetic products with biologically active ingredients purporting to have medical or drug-like benefits.

Nutricosmetic

When ingested, nutricosmetics support the function and the structure of the skin, nails, and hair, having a preventive or reactive effect.

Botanical ingredients chain

Grower

Processor

Manufacturer

Distributor

Customer

BIO - INDUSTRIAL OPPORTUNITIES

Sustainability & Traceability

- Three Pillars of Sustainability
  - Environmental
  - Economic
  - Social
- Threatened Species (CITES)
- Where does it come from?
- Does it have a yearly crop?
- Is there more than one source?
- Is it fair trade; sustainable?

Good Agricultural & Collection Practices

- Identification
- Quality Assurance
- Cleanliness
- Environmental Stewardship
- Legal Conformity
- Optimal Harvest Conditions

Source: AHPA-AHP Good Agricultural and Collection Practice for Herbal Raw Materials, (2006)

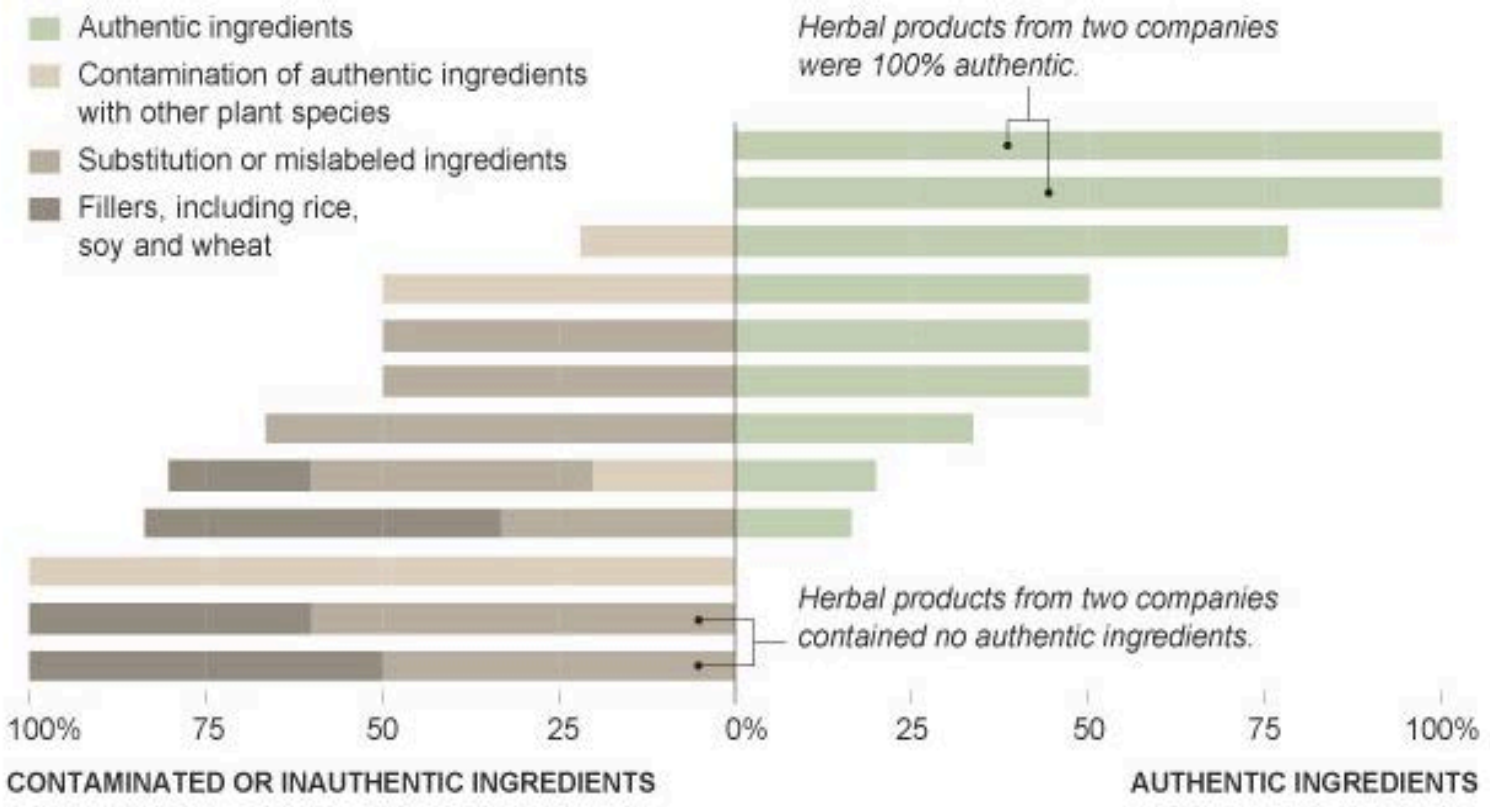
Adulteration of Botanicals

- Reliability & Authenticity an issue
- Mixing of different genus
- Incorrect species.

- Substitution (e.g. marigold for saffron)
- Addition of synthetic components, dilution, etc.
- Miss-labeling

44 Natural Products sold in Canada

(produced by 12 different companies)



[Source: **DNA barcoding detects contamination and substitution in North American herbal products**; (2013); *BMC Medicine*, 11:222

Developing a commercial Botanical Ingredient

From Concept to Commercialization

- **Four integrated components**
- **Each company will have varied degrees of experience in each of these areas.**

Business Development

- Competitive Landscape
- Market Research
- Branding
- Product cost analysis
- Routes to Market
- Funding

The cost of a botanical ingredient

- Plant material
- Processing, Cleaning, Extraction & Purification
- Laboratory testing
- Overhead (Building, Equipment, Utilities)
- Packaging
- Labour
- Shipping and Transportation costs

Growing Forward 2

GF2 provides programs and services to achieve a profitable, sustainable, competitive and innovative agriculture, agri-food and agri-products industry that is market-responsive, and that anticipates and adapts to changing circumstances and is a major contributor to the well-being of Canadians.

Programs:

- Agri-Processing Automation & Efficiency
- Product & Market Development
- Business Opportunity
- Traceability training

Website: http://www.growingforward.alberta.ca

Website: http://www.agr.gc.ca/eng/?id=1396016168338

Science

- Understanding the agronomics of your crop.
- Developing a product/process with commercial intention.
- Learn as much about the bio-actives in your crop as possible.
- Strong claim substantiation is important.
- Intellectual property

Physaria tenella

Quality Actives from Plants

Choice of Variety

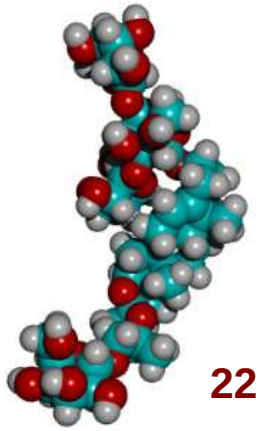
- *Genetics*
- *Breeding programs*
- *Agronomics and Environmental Conditions*

Processing, Extraction, & Purification

- *Location of Active component*
- *Maximizes recovery of active component*
- *Environmentally friendly processes*

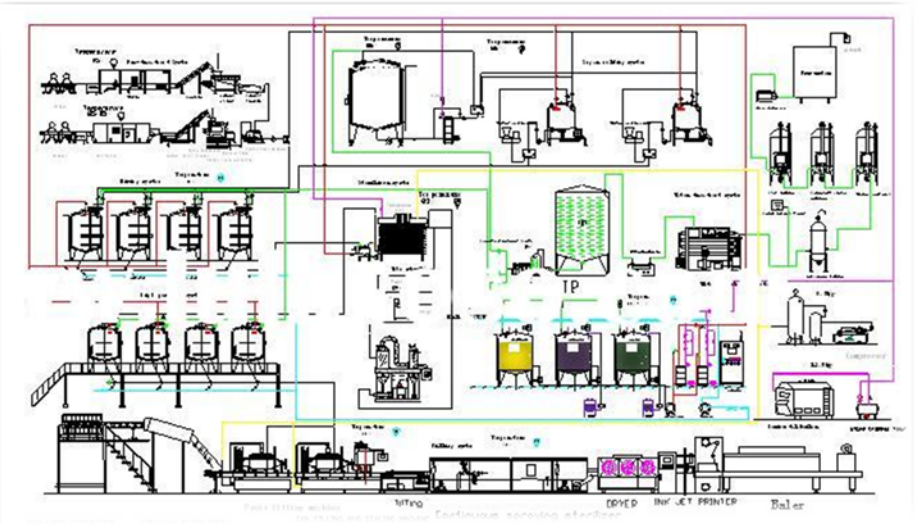
Standardization

- *Identification of the active molecules*
- *Use of reproducible analytical methods for the active component(s).*
- *Dose Response and Clinical Efficacy*



Engineering & Process Scale-up

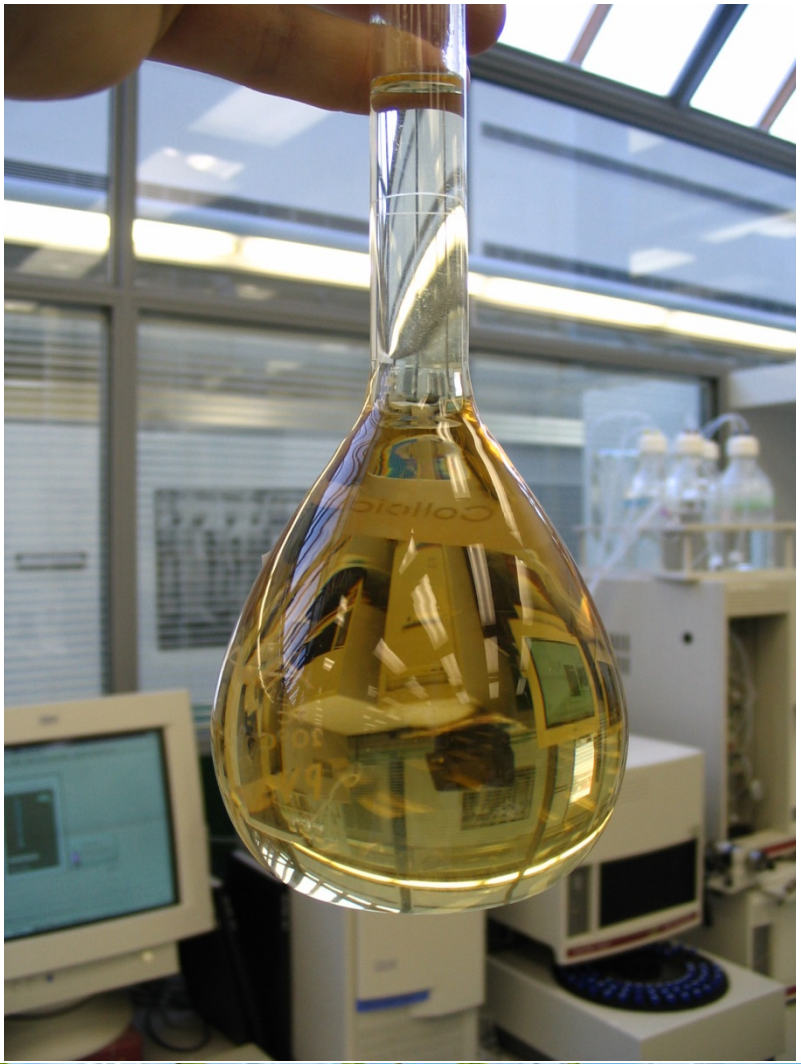
- Process optimization
- Pilot scale testing
- Equipment evaluation
- New or add-on to existing facility
- Production Cost Analysis



Commercial production of Botanical ingredients

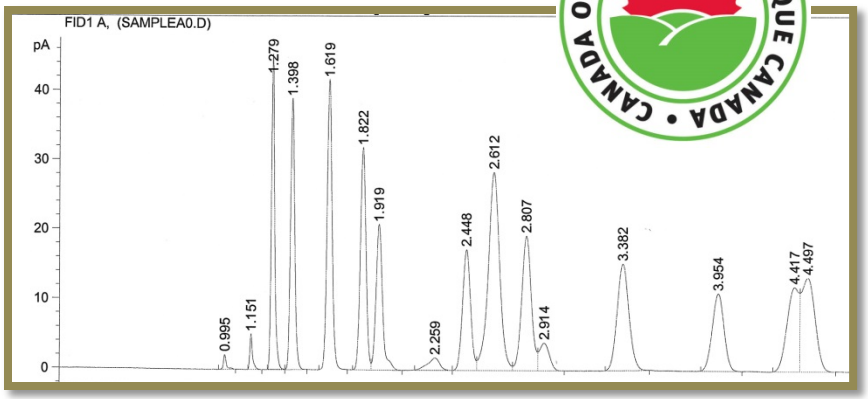
- Harvest
- Cleaning
- Milling
- Extraction
- Purification
- Preserving
- Finishing
- Packaging

Not all similar extracts are alike….



Quality

- Good Agriculture & Collection Practices (GACP)
- Good Manufacturing Practices (GMP)
- Standardization of active
- Safety
- Regulatory compliance
- Certification



Quality Control – Why?

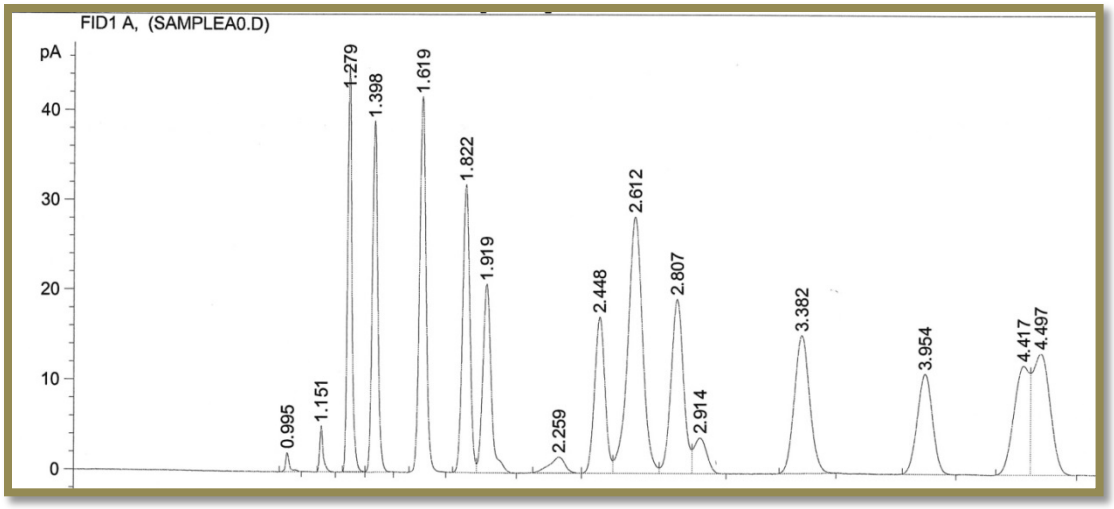
- The concentration of the actives is directly related to the activity of the product.
- To confirm that the correct plant species is used to make the product.
- To confirm that there has been no adulteration to the product.
- To ensure there are no other fillers or synthetic chemical used.

Quality Control – How?

Natural Products must be standardized in order to control the concentration of actives or chemical markers in ***every*** batch.

Chromatography is a analytical method to separate the active components in a product and measure their concentration.

Measuring the Botanical actives



- The chromatograph is like a finger-print and provides unique information.
- Each peak in the chromatograph represents one unique molecule.
- The area under the peak is proportional to the amount in the extract.
- Pure Standards are used to calculate the concentration of that component in the extract.
- The more peaks in the chromatograph, the more complex the mixture.

Government of Alberta Programs

- www.agriculture.alberta.ca/biobasedchemicals

Bio-Industrial Opportunities Branch

- Industrial Processing experience.
- Strong engineering, scientific & technical expertise.
- Business Development Assistance

- Dry Processing
- Wet Processing
- Product development laboratory
- Explosion-proof extraction area
- Pilot scale processing
- Analytical capabilities

New Extraction & Fractionation Program

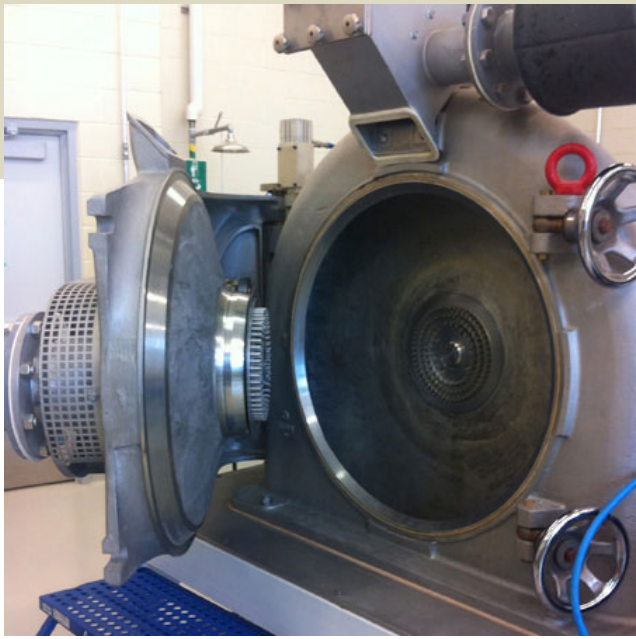
Business Development Assistance

Laboratory to Pilot Scale process/product Development

Analytical Services support

Primary Processing

- Bio-mass cleaning
- Sorting
- Drying
- Tempering
- Milling
- Grinding
- Extrusion



Secondary Processing

- **Extraction**
  - Cold Press
  - Traditional solvent-based methods
  - Super and Sub-critical extraction
  - Cryo-extraction, Zeodration
  - Ultrasonic , Microwave technology
- **Isolation**
  - Centrifugation,Filtration
- **Concentration**
  - Precipitation, Distillation, UF/RO
- **Drying** (e.g. Catalytic FIR, spray, drum)

Fractionation - Tertiary Processing

- Precipitation/Flocculation
- Membrane Filtration
  - MF, UF, NF, RO
- Chromatography
  - Conventional
  - Radial
  - Simulated Moving Bed
  - Expanded Bed

Opportunities in Alberta

- Strong Agricultural sectors
- Wide range of specialty crops grown in Alberta
- Innovative and entrepreneurial spirit.
- Canadian products are traditionally identified with quality.
- Commitment by both federal and provincial governments to support applied research and new product development and Lean Manufacturing.

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