

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

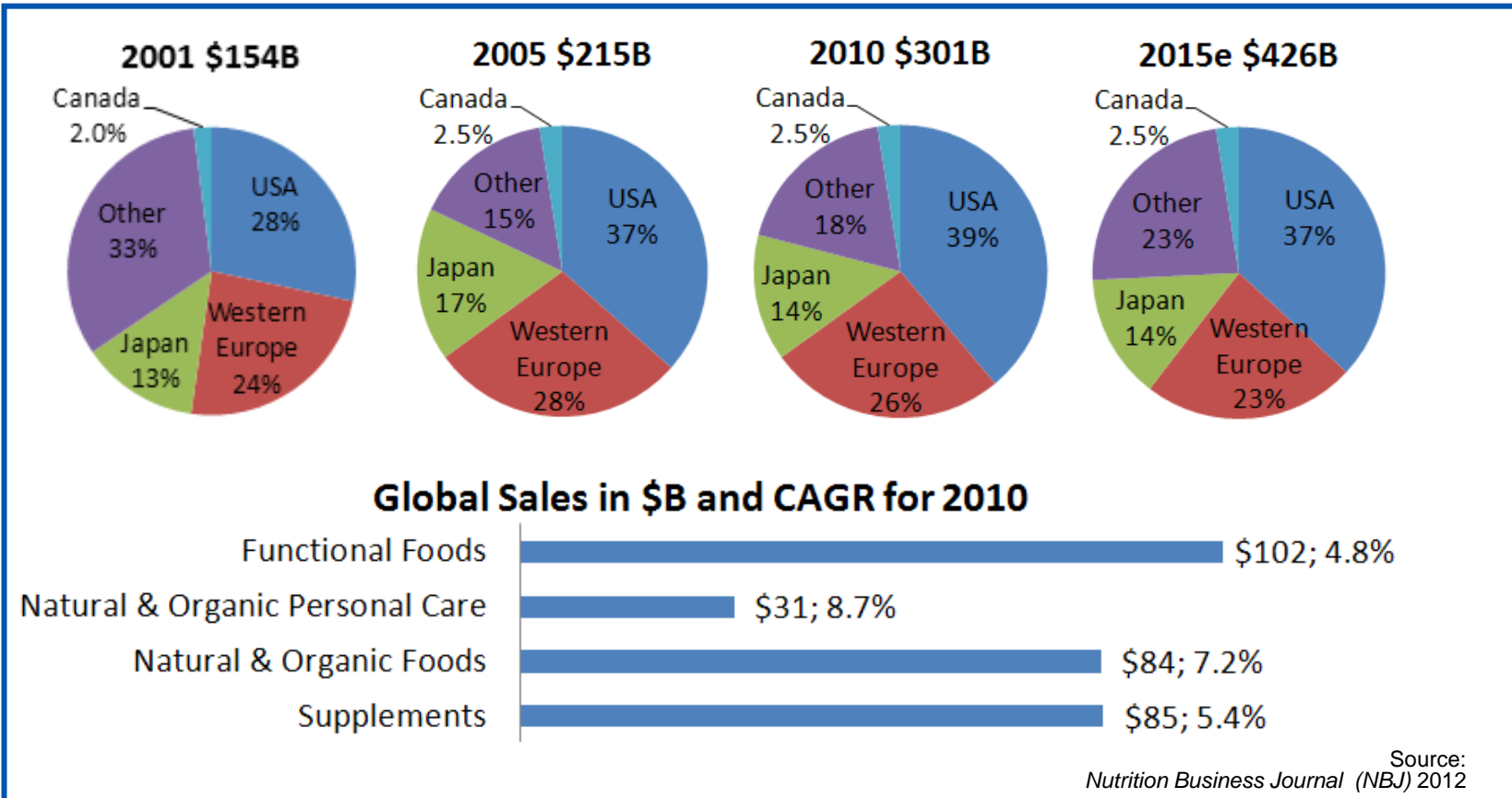
NHP Workshop, Edmonton, Alberta

Bob Chapman
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NHP Program
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GLOBAL INDUSTRY OVERVIEW

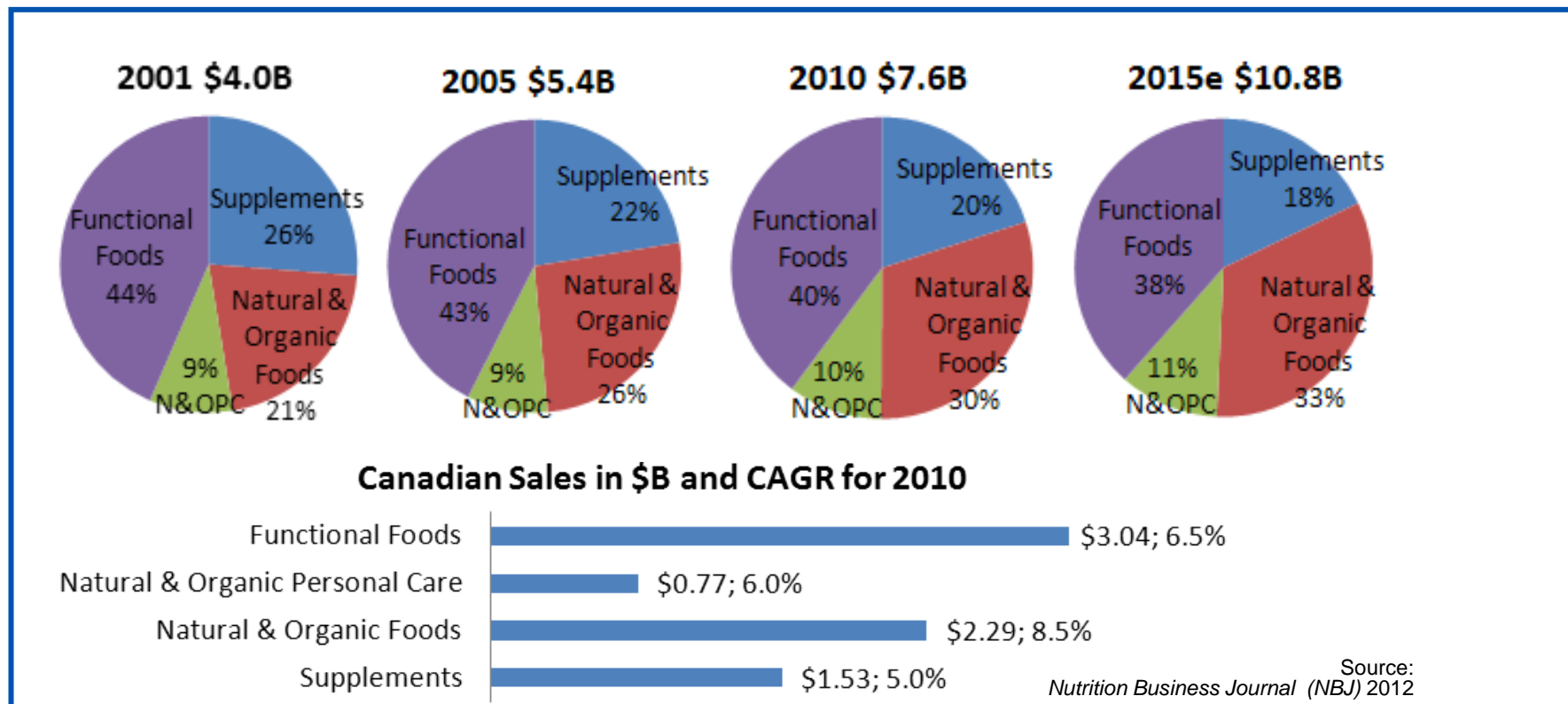
SIGNIFICANT OPPORTUNITY FOR CANADIAN INDUSTRY GROWTH



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

CANADIAN INDUSTRY OVERVIEW

SIGNIFICANT OPPORTUNITY FOR CANADIAN INDUSTRY GROWTH



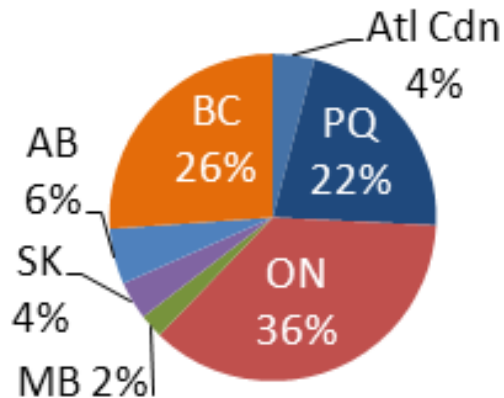
- Canadian SMEs need to add capacity to overcome regulatory-related testing requirements
- Canadian firms need science-based evidence to support claims to both maintain and build market share

CANADIAN INDUSTRY OVERVIEW

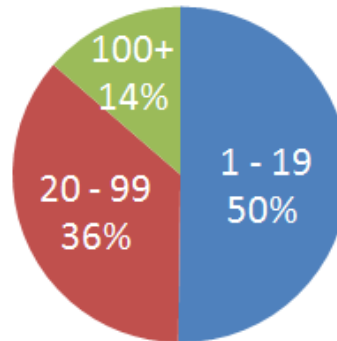
A NATIONAL CANADIAN INDUSTRY

Distribution of Canadian

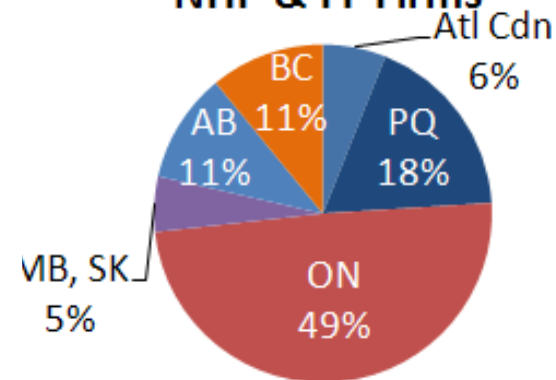
NHP & FF Firms



Canadian NP&FF firms by # of employees



Sales of Canadian NHP & FF Firms



Source: NBJ, George Morris Centre, Team analysis

- 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

FOOD PHARMA CONTINUUM

PROGRAM FOCUS

FOOD

NHP & FF*

R_x DRUGS

USE	<ul style="list-style-type: none"> Energy and satiety Basic Nutrition 	<ul style="list-style-type: none"> Enhance energy; wellness Beyond basic nutrition Reduce risk of diseases 	<ul style="list-style-type: none"> Treatment of disease, symptom or condition
OBTAINED BY	<ul style="list-style-type: none"> Consumer selects 	<ul style="list-style-type: none"> Consumer selects or recommended by naturopathic doctor) 	<ul style="list-style-type: none"> Prescribed by health care provider
DISTRIBUTION	<ul style="list-style-type: none"> Supermarkets, farmers markets 	<ul style="list-style-type: none"> Supermarkets, drug stores, online, specialty retailers; direct to consumer marketers 	<ul style="list-style-type: none"> Hospitals, pharmacies
REGULATIONS	<ul style="list-style-type: none"> Historically low; focus on safety 	<ul style="list-style-type: none"> Moderate and increasing; focus on safety and efficacy 	<ul style="list-style-type: none"> High; focus on safety and efficacy
CONSUMPTION	<ul style="list-style-type: none"> As desired; guided by Canada's Food Guide 	<ul style="list-style-type: none"> As desired; guided by product dosage recommendations 	<ul style="list-style-type: none"> As prescribed
FORM	<ul style="list-style-type: none"> Natural and processed foods 	<ul style="list-style-type: none"> NHPs complex mixtures sold as pills, powders, creams & liquids FFs resemble foods 	<ul style="list-style-type: none"> generally single active substance sold as pills & liquids

*Functional Ingredients are used to make Functional Foods (FFs) and NHPs
 Source: Adapted from PriceWaterhouseCoopers

NHP INDUSTRY OPPORTUNITIES & DRIVERS

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



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

Programs

- Bio-Based Specialty Chemicals
- Natural Health Products
- Canadian Wheat Improvement (flagship)
- Algal Carbon Conversion (flagship)



NHP PROGRAM CLIENTS AND COLLABORATORS

Ascenta 



 **Neurodyn**



 **Acadian
Seaplants**

 **delivra**TM



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NATURAL HEALTH PRODUCTS (NHP) PROGRAM

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



NRC'S NATURAL HEALTH PRODUCTS PROGRAM



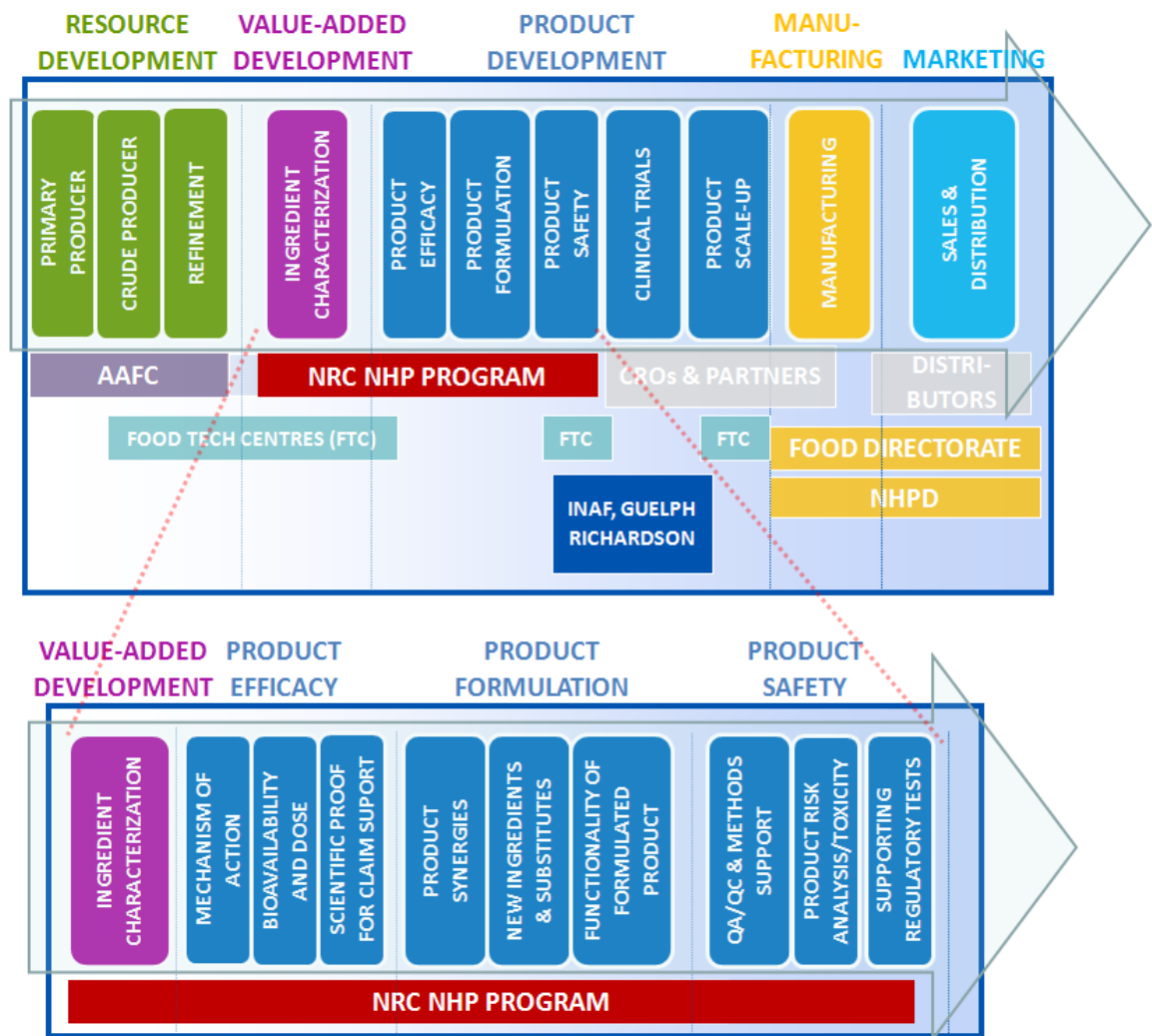
NHP PROGRAM VALUE PROPOSITION

- *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

NRC'S ROLE IN THE NHP VALUE CHAIN



NHP PROGRAM

CAPABILITIES ALIGNED WITH NRC INVESTMENTS

	Analytical Services	Natural Products Chemistry	Preclinical Biological Services	Bio-Oils	Bio-conversion & Bio-processing	Specialized Facilities & Models
Lipid & Oils	•	•		•		•
Protein	•				•	•
Skin Health	•		•			•
Metabolic Health	•		•			•
Quality & Safety	•	•	•			•
Extraction & Formulation	•	•		•		•

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 contaminants
- 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

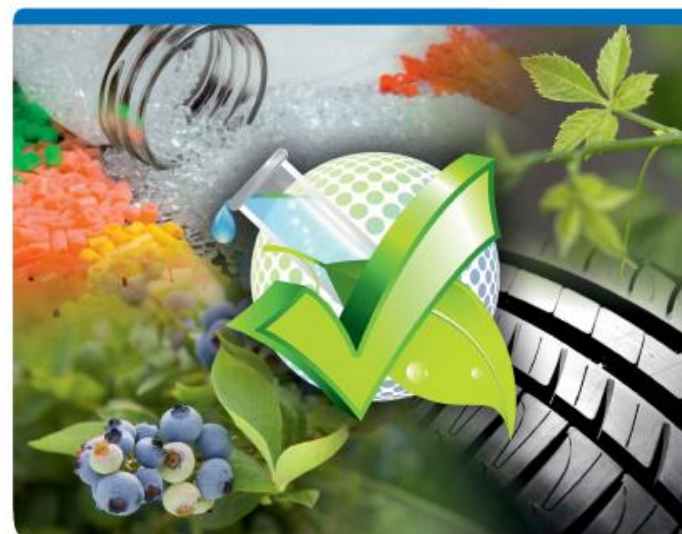


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Assure Raw Material Screening

• Easy, Customizable, Automated NMR

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

preclinical studies that
deliver efficacy and
mechanistic data

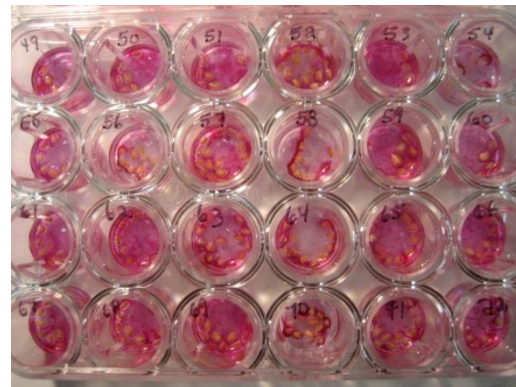


APPLICATIONS

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

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.



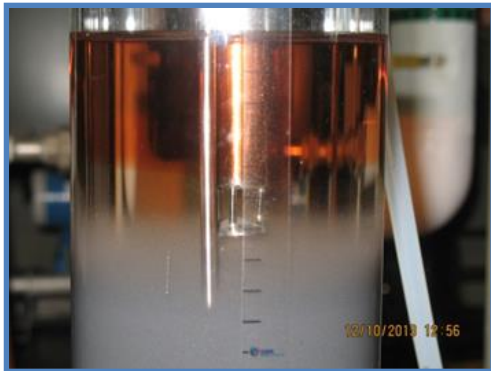
BIOCONVERSION AND BIOPROCESSING

- 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 CO₂ extraction (high pressure 1000 Bar)
- Micro and macro algae marine research station
- Plant growth: phytotron, greenhouse, sunrooms



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