

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

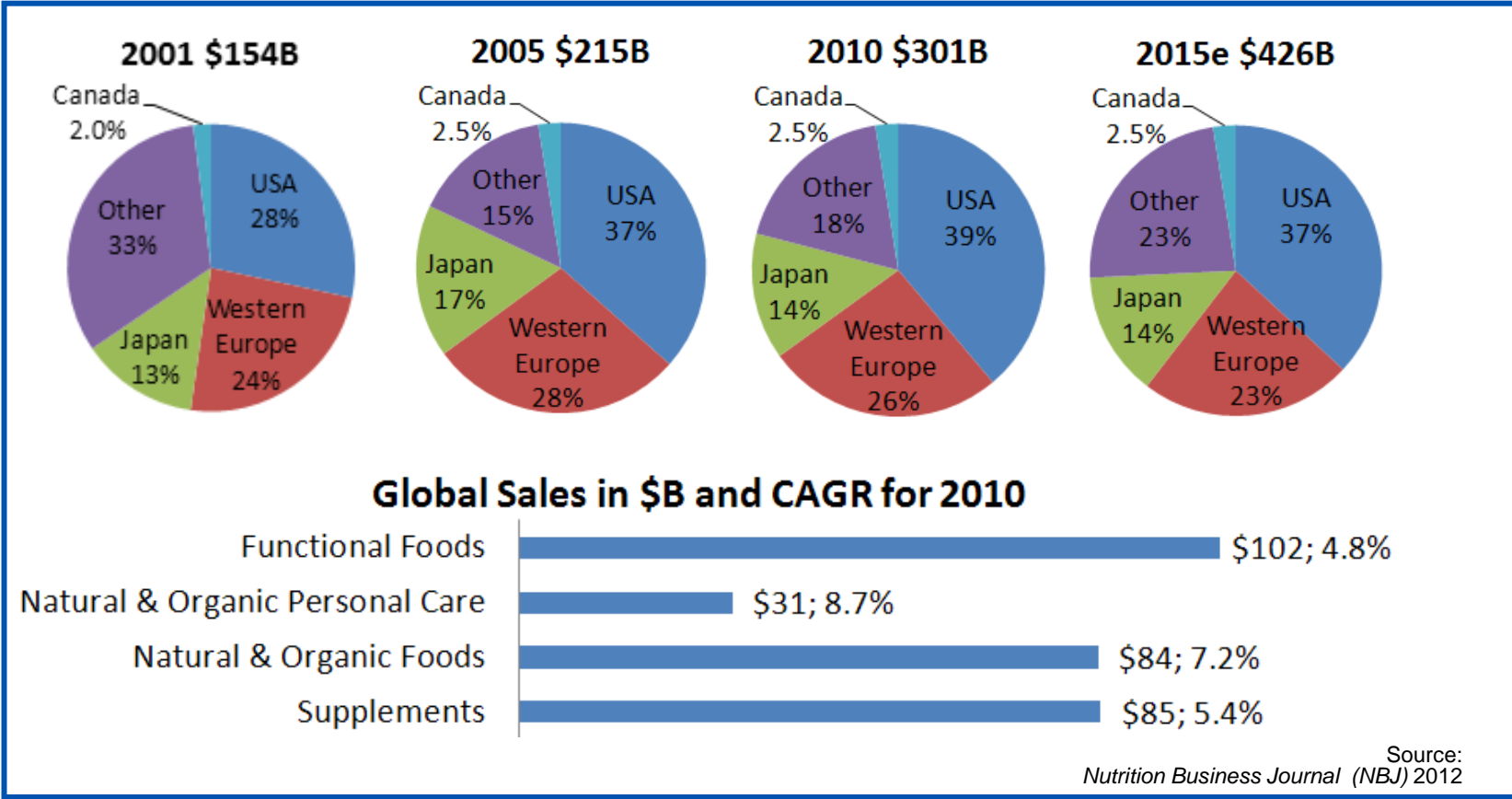
NHP Workshop, Edmonton, Alberta

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NHP Program
November 6, 2014



GLOBAL INDUSTRY OVERVIEW

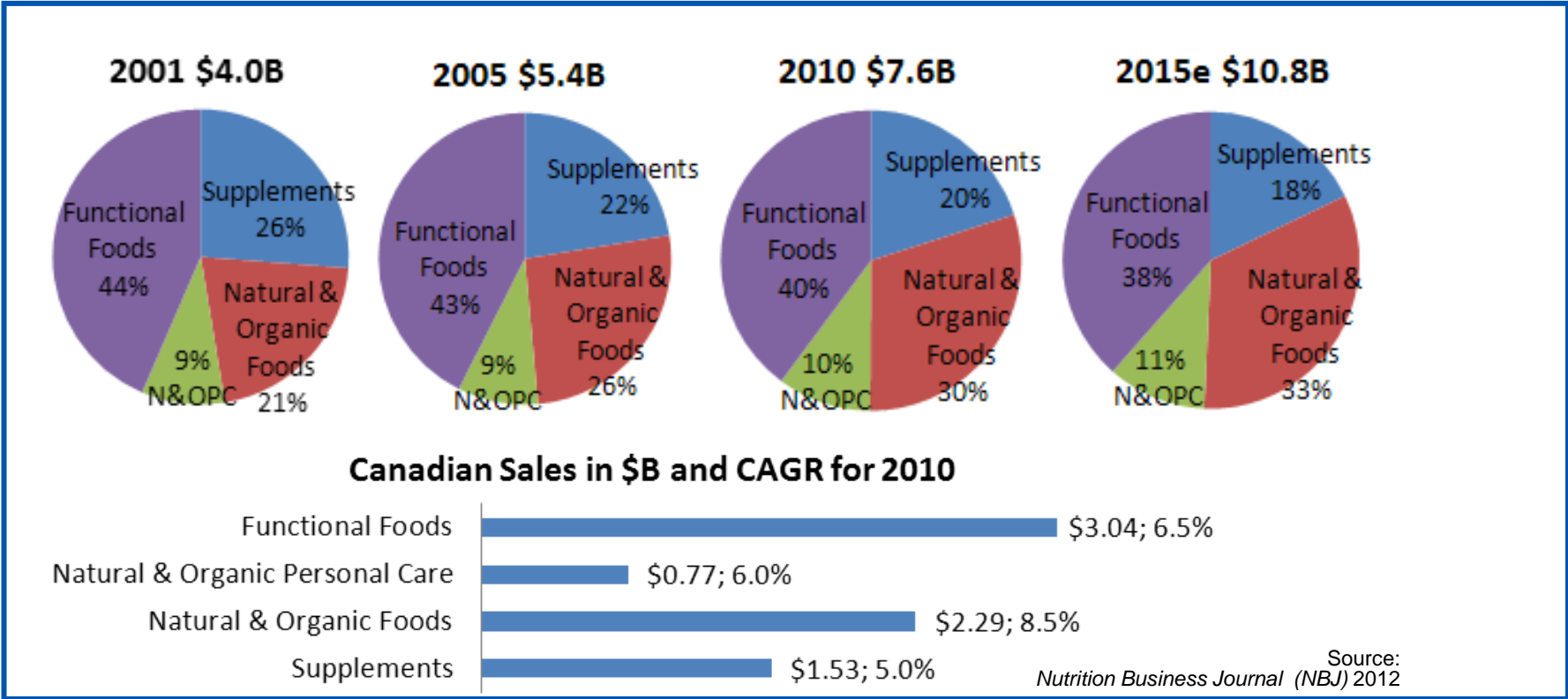
SIGNIFICANT OPPORTUNITY FOR CANADIAN INDUSTRY GROWTH



- 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



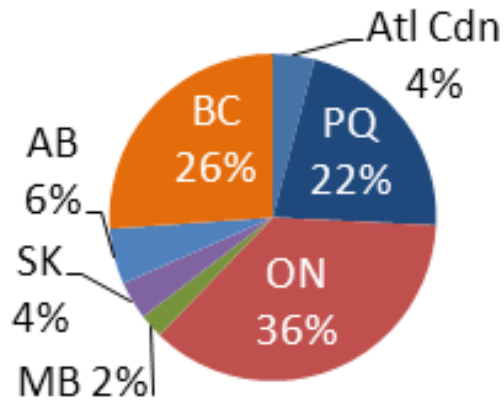
- Canadian SMEs need to add capacity to overcome regulatory-related testing requirements
- Canadian firms need science-based evidence to support claims to both maintain and build market share

CANADIAN INDUSTRY OVERVIEW

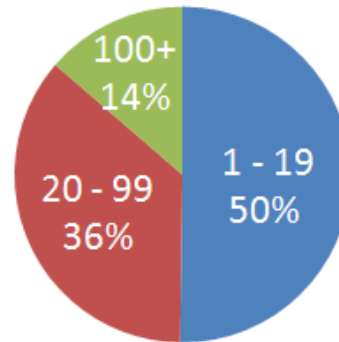
A NATIONAL CANADIAN INDUSTRY

Distribution of Canadian

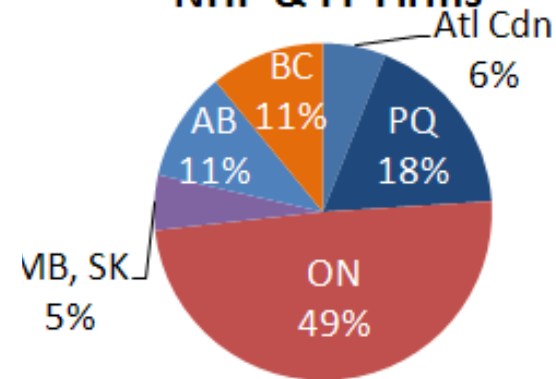
NHP & FF Firms



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

	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**



Bioriginal
Innovative EFA Solutions



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 operates and benefits from resources at 5 sites in 5 provinces

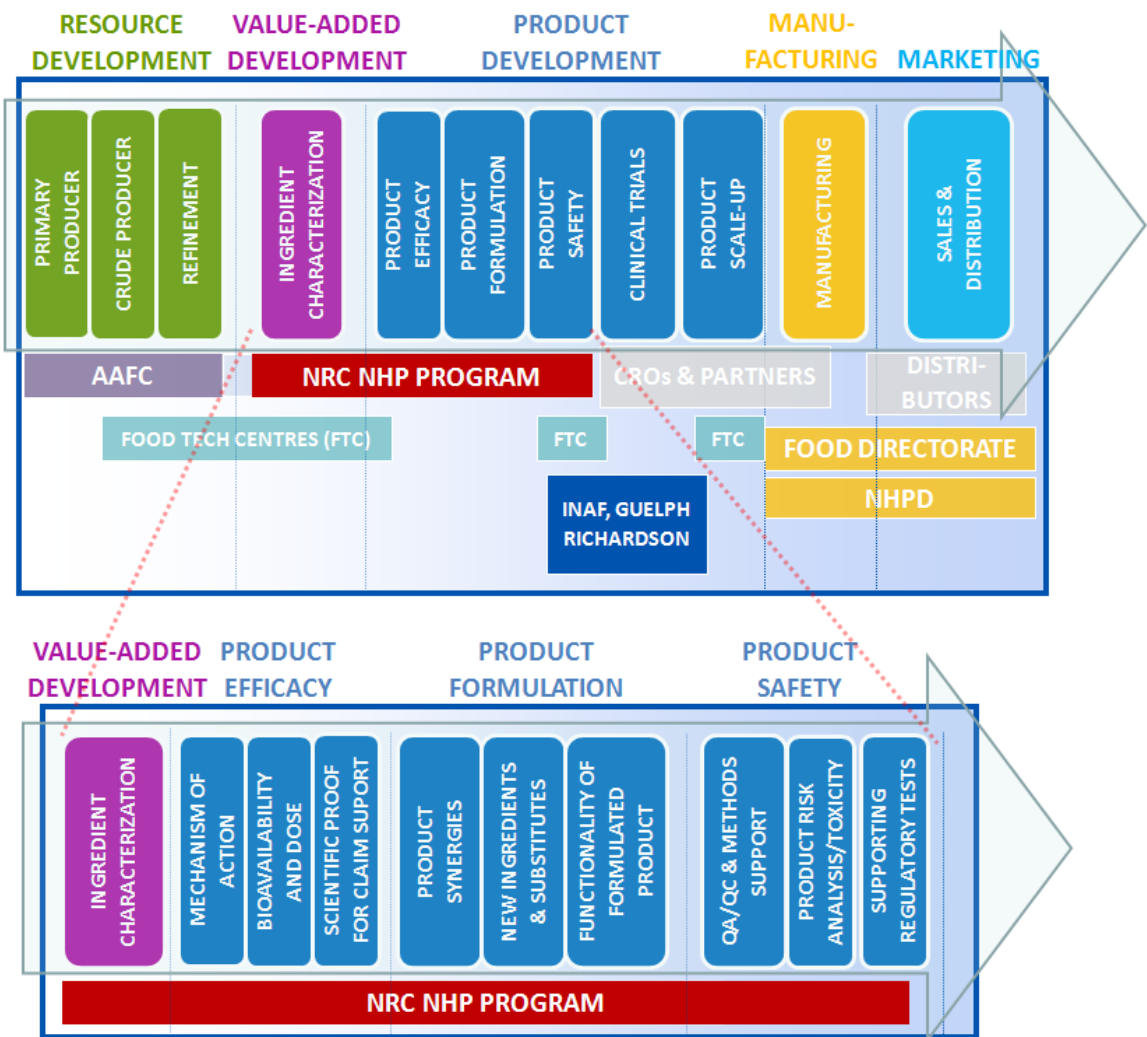
NHP PROGRAM VALUE PROPOSITION

- *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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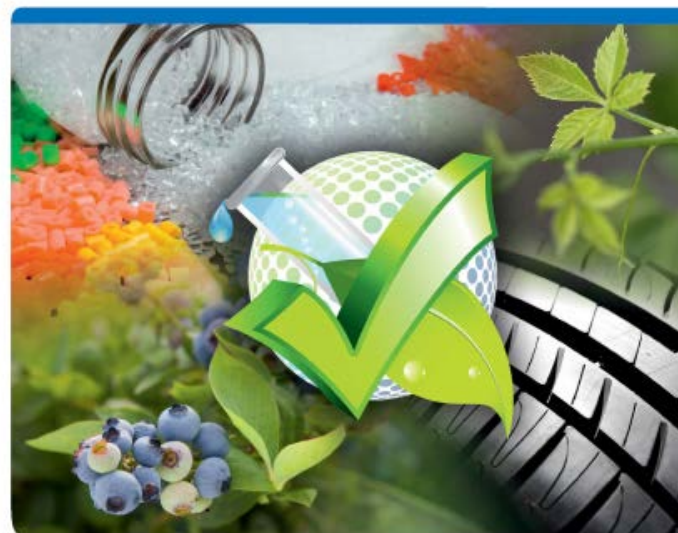
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ChemBioPrint™



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

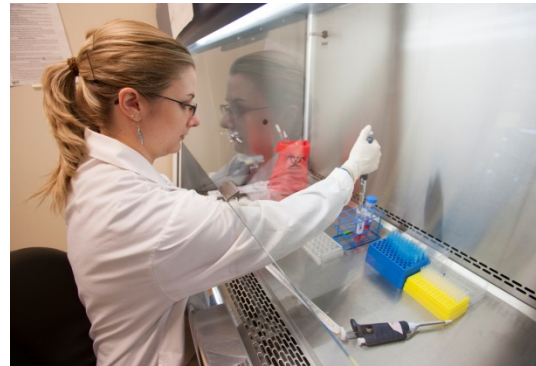


PRECLINICAL BIOSERVICES

- 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

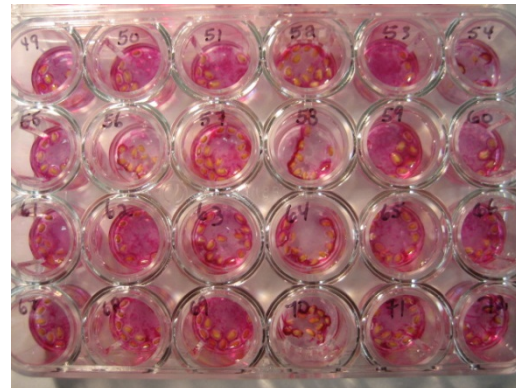


APPLICATIONS

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.



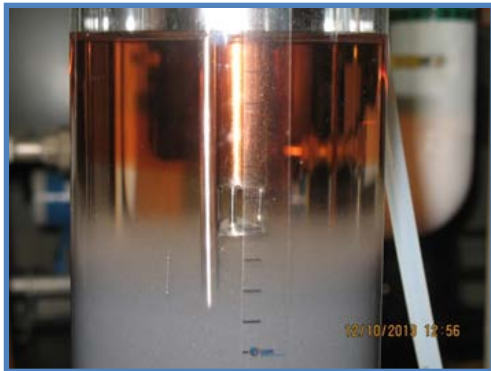
BIOCONVERSION AND BIOPROCESSING

- 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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