



Agriculture and
Agri-Food Canada

Agriculture et
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Partnerships for delivering AAFC's food and health research priorities: *past, present and future*

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Canada 

Outline

Delivering AAFC's food and health research priorities:

➤ **Past:**

- The Story of Oats and Food Grade Soybeans

➤ **Recent Past and Present:**

- Agriculture Regulatory Action Plan
- Partnering for Health Claim Substantiation

➤ **Present & Future:**

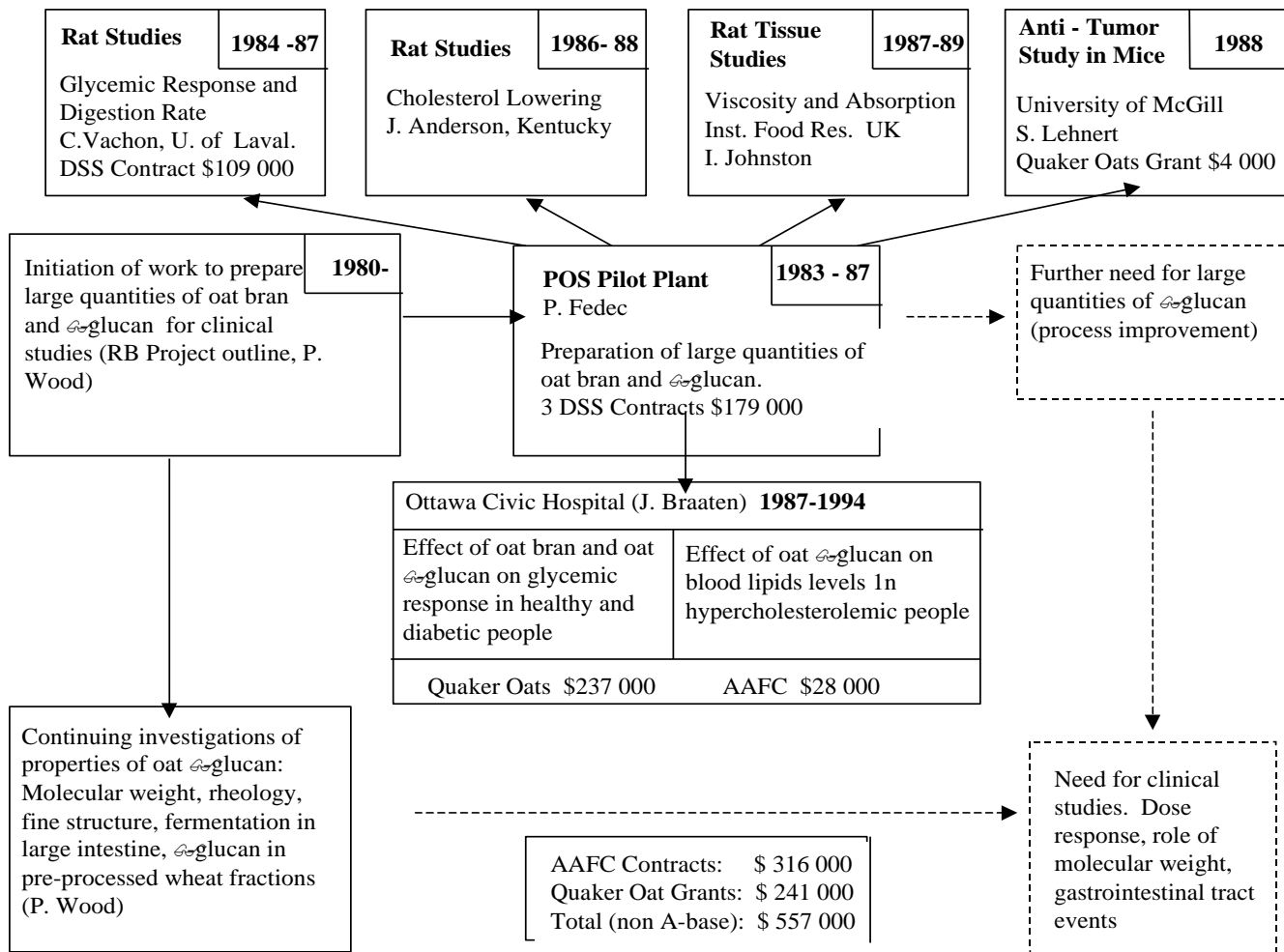
- Strategic Direction – 3 Pillars
- Sector Strategies
- Food and health research at AAFC-STB
- Mandate to engage in and fund human clinical trials



PAST Collaborations: The Story of Oats

AAFC RESEARCH TO DEVELOP OATS AS A FUNCTIONAL FOOD FOR HEALTH, AND RELATED ACTIVITIES

Studies done by P. Wood and collaborators 1980 - present.



PAST Collaborations: Food Grade Soy Beans

- Contributed to the science to develop soybean demanded by the market
 - Maple Leaf collaborated with plant breeders at Harrow Research Centre (*var* Harovinton - late 1980's)
 - The Ottawa Program focused on Natto soybeans and released varieties (12) to capture this market in Japan
 - Under the Matching Investment Initiative: >29 collaborative projects on food grade soybeans worth \$2.5 million



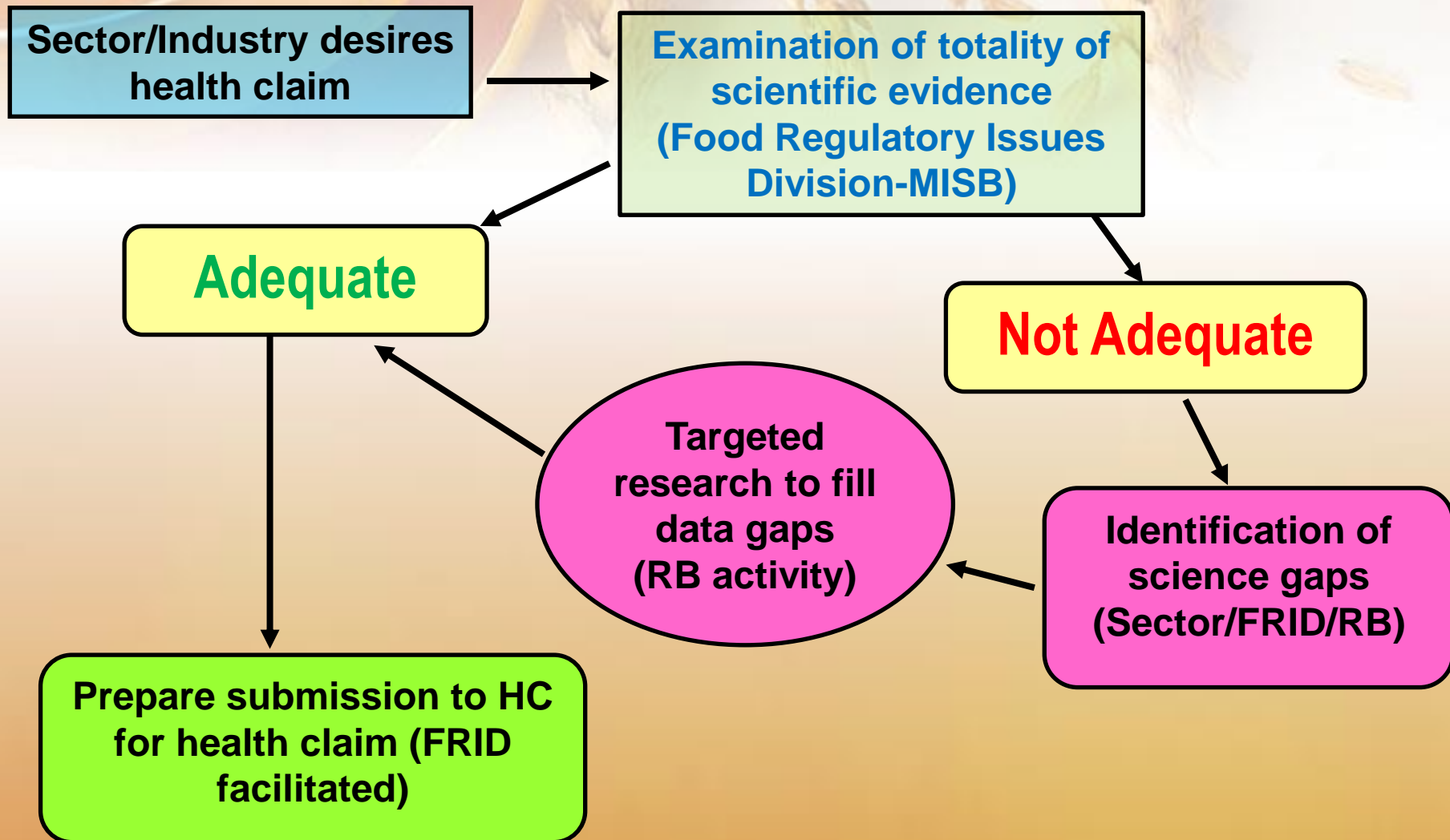
AAFC Science and Innovation Strategy (2006): Strategic research priorities

AAFC Research Priorities

1. Enhancing human health and wellness through food and nutrition, and innovative products
2. Enhancing the quality of food and the safety of the food system
3. Enhancing security and protection of the food supply
4. Enhancing economic benefits for all stakeholders
5. Enhancing environmental performance of the agricultural system
6. Understanding and conserving Canadian bioresources
7. Developing new opportunities for agriculture from bioresources



Agricultural Regulatory Action Plan (ARAP) Health Claims, Novel Foods and Ingredients



Growing Forward 1: Substantiation of Health Claims, Novel Foods and Ingredients

Science Substantiation

Initial objectives

- Establish domestic and international science partnerships
- Conduct research to address gaps in the knowledge needed to establish the validity of health claims and the safety of novel ingredients

Results:

- Projects and initiatives funded through peer review (2009-2013)
 - *Oat/barley beta-glucans and serum cholesterol lowering*
 - *Oat avenanthramides and anti-inflammatory effects*
 - *Pre-biotic fructans and gastro-intestinal status*
 - *Flaxseed and reduced risk of chronic disease*
 - *Lentils and improved serum cholesterol, insulin sensitivity and vascular responsiveness*
- New projects implemented in four priority areas (April 1st, 2011 for 2 years)
 - *Milled flaxseed and reduced risk of heart disease*
 - *Whole soy as a food ingredient and reduced risk of heart disease*
 - *Probiotics and gut health*
 - *Plant-Fruit bio-actives and antioxidant status*

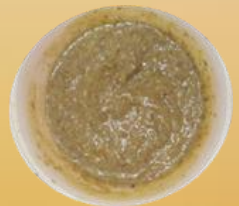


Lentil as a functional food to improve glycemic control in persons with insulin resistance



- **Goal:** To determine whether consumption of one serving of lentil on 5 days per week for 12 weeks will result in attenuation of 2h post OGTT blood glucose
- **Partners:** AAFC-GFRC; Pulse Canada; Univ of Manitoba; Univ of Toronto; AAFC-CCARM;

5 food items being used in human trial with average GI difference of 30 between test and placebo food



(Ramdath et al 2012)



Gut Health Promoting Potential of Flaxseed



Goal: To determine the role of flaxseed and flaxseed supplemented products (i.e. bread and pasta) on biomarkers of colon health and disease

Partners: AAFC-GFRC, SRC, FRDC, CLRC;
Univ of Guelph



- Experimental diets supplemented with ground flaxseed, purified bioactives, and food products (bread/pasta) to determine effects on:
 - Gut barrier integrity and function
 - Microbiota activity and community structure
 - Chronic disease (Inflammatory bowel disease and colon cancer)



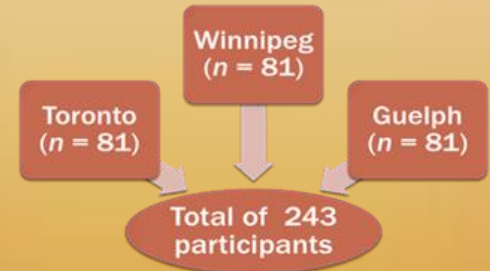
Cholesterol lowering effect of whole soy flour



Goal: To determine the efficacy of whole soy flour, standardized at 12.5 and 25g protein, in lowering LDL-C

Partners: AAFC-GFRC; Univ of Guelph - HHNS & Food Sciences; Soy 20/20; AAFC-CCARM; Univ of Toronto;

- Koushik Seetharaman + graduate students: formulated, produced and shipped 28,000 muffins (Soy flour from Soy 20/20)
- Alison Duncan (Guelph); Tom Wolever (Toronto); Heather Blewett (AAFC-CCARM)
- Rong Cao is tracking isoflavone
- Emily Padhi - PhD student



AAFC-STB revised its Strategic Direction in 2013

Clinical research Trials
Sector Food Program
Export Resiliency priorities
Economic Regulatory
Knowledge Substantiation
engagement markets
Growing prosperity Forward
Strategies Productivity Agri-Innovation Claim
Industry Science Partnerships transfer
Pillars Human enhancement
Strategic
Direction

Health



AAFC-STB: PRESENT & FUTURE 2013-2018

THREE roles defined for AAFC-STB:

1. Informing regulatory and policy decisions
2. Producing far-from-adoption applied science with broad stakeholder application
3. Supporting innovation to improve economic prosperity

STB Objectives

1. Increase agricultural productivity
2. Enhance environmental performance
3. Improve attributes for food and non-food uses
4. Address threats to the value chain



Strategic Objective: Increase agricultural productivity

Agri-food focus areas

1. Support sector in developing:
 - a. Cost-effective agri-food processes
 - b. New agri-food products and/or ingredients with novel health and/or functional attributes to enhance competitiveness**
 - c. Secure new markets and address food insecurity in target sub-populations and markets
2. Enhance by-product utilisation in the development of agri-food products to boost the agricultural system and the bio-economy at large



Strategic Objective: Improve attributes for food and non-food uses

Agri-food focus areas

- Generate new knowledge to support the differentiation of Canadian agri-food products and ingredients
- Identify Canadian crops, livestock and agri-food products with bioactive and/or functional properties of economic interest
 - determine nutritional and physicochemical properties and/or bio-functional benefits



Growing Forward 2 Funding Program

- Growing Forward 2 Agri-Innovation Program (AIP), implemented in April 2013 to March 2018
- Continuously providing funding through the Crop, Livestock and Food initiative
- Grants and contributions through Industry Clusters and Agri-Science projects involving industry leadership
 - Industry led with 25-35% contribution
 - Critical mass of science and technology to support innovation in food for economic growth and safety.
- A complete list of AAFC programs and services at:
<http://www.agr.gc.ca/eng/programs-and-services/list-of-programs-and-services/?id=1362151577626>



Human Clinical Trials: background issues

- May 2013, Office of Audit and Evaluation completed assessment of GF Agriculture Regulatory Action Plan (ARAP) including the “Health Claims, Novel Foods and Ingredients” initiative
- STB was Lead for one component: “Scientific Substantiation”:
 - *“to assist industry in addressing the knowledge gaps related to the scientific information required to obtain regulatory approval for health claims by Health Canada”*



Recommendations - Office of Audit and Evaluation

1. Review research alignment of human clinical trials with AAFC's mandate, priorities and capacity

Task Force to provide a recommendation on whether AAFC should continue in this area.

Unclear whether AAFC's role in undertaking human clinical trials as part of the initiative was appropriate due to capacity limitations

2. Review AAFC research project selection process to ensure that it adequately considers all AAFC research priorities

Ensure that future AAFC research addresses the research gaps and meets the standards of evidence required to support future health claims



Product Pipeline Stages from Foundational to Clinical Research

INNOVATION STREAMS

“Inherently Functional Foods”
(e.g. oats, barley fruits & vegetables)

(“Functional Foods”)
Supplemented, Fortified Foods
(Transitional terms)

AAFC does research only on NHP’s sold and consumed as foods
(e.g. probiotics) not “pills, capsules, etc”

FOOD/HEALTH LINKAGES MAP

THROUGH THE AGRI-FOOD SECTOR STRATEGY (2014-2019)

FOOD INNOVATION FOR GROWTH

Improve attribute for food and non-food uses

PRODUCT PIPELINE Evaluation Progression

| Foundational | | Pre-clinical | | Clinical |
|-------------------------------|---------------------------------------|----------------------------------|--------------------------|-------------------------|
| Stage 1 Bioactive Research | Stage 2 <i>In vitro</i> Evaluation | Stage 3 Cell & Tissue Evaluation | Stage 4 Animal Models | Stage 5 Human Trials |

At the discretion of the Minister, AAFC-STB **MAY** participate in human trials **but only through Collaborative R&D Agreements** with LICENSED, MEDICAL/CLINICAL CAPACITY AND EXPERTISE



Broader AAFC Role in Human Clinical Research

For Stage 5 (Human Clinical Trials Research)

Primarily 3 types of funding agreements to promote this type of research, each with different liabilities:

1. **Contribution Agreements (CAs)**: Vote 10 funds provided to trial sponsor (e.g. Flax, Soy, Pulse, etc.)
2. **Collaborative Research and Development Agreements (CRADAs)**: AAFC provides research support funded through Vote 1 in the form of AAFC scientists' work and other resources, to a clinical trial sponsor (eg. as above.)
3. **Service Agreement**: AAFC procures the services of a research service provider using monies obtained from a Vote 1 appropriation



Funding Human Trials: decision criteria

Funding approval requires a case-by-case, fact-based “risk/benefit” evaluation by qualified personnel using 3 different criteria frameworks

1. LIABILITY FRAMEWORK (*doing things safely*)
 - Legal relationship with recipient
 - Crown personnel or property involvement
 - Project evaluation decision by qualified personnel
2. ARCHITECTURAL FRAMEWORK (*doing things right*)
 - Experimental Protocol in accordance with Health Canada’s “Best Practices” guidelines on Human Clinical Trials and Tri-Council Policy Statement 2010 (TCPS2)
 - Research carried out according to the REB oversight
3. ECONOMIC FRAMEWORK (*doing the right things*)
 - Targeted agri-food product or sector importance demonstrated and potential increase of its competitiveness for Canada
 - Timely translational plan for disseminating the results regardless of the outcomes



ROADMAP FOR CRADA PROJECT PROPOSALS DECISION STREAM

For projects with clinical trials to support health claims, PI submits proposal to AAFCSENIOR MANAGEMENT for screening based on “risk / benefit” analysis. IF SUPPORTED/AMENDED:

PI should engage Health Canada as a consultation step for any aspects of best practices and evaluation criteria for clinical trial data in Canada, and with the sponsor, secure appropriate preliminary support of funding by sponsor and AAFC

IF SUPPORTED/AMENDED:
PI submits proposal to AAFC Human Research Ethics Committee (HREC, TCPS2 compliancy)

IF SUPPORTED/AMENDED:
PI submits proposal to collaborating/partnering institution or university Research Ethics Board

IF SUPPORTED/AMENDED:
PI submits proposal to partnering hospital or clinical Research Review Board (RRB)

IF SUPPORTED/AMENDED:
Assigns CI (QI) (MD or DD)
Chief Medical Officer signs off on proposal

IF SUPPORTED/AMENDED:
PI submits final proposal to AAFC STB

IF SUPPORTED/AMENDED:
PI registers Clinical Trial

Human Research Ethics Policy Framework

<http://intranet.agr.gc.ca/agrisource/AgriDoc.do?id=4481338&lang=eng>

As an example: At the **University of Manitoba Health Research Ethics Board**

<http://umanitoba.ca/faculties/medicine/ethics/2688.html>

As an example: **St. Boniface Hospital RRB**

<http://www.sbrc.ca/home/facilities-and-support/office-of-clinical-research/research-review-committee/>

As an example: **St. Boniface Hospital Executive Director Clinical Programs & Chief Medical Officer**

www.sbgh.mb.ca/aboutUs/admin.html

In this example: **AAFC STB**

<https://collab.agr.gc.ca/apps/stbpss-sspdgst/sitepages/home.aspx>

Registration/Notification of Clinical Trial
(e.g. registry at www.clinicaltrials.gov)



Thank you

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