



REPORT:

Evaluation of the Agricultural Regulatory Action Plan under Growing Forward – Health Claims, Novel Foods and Ingredients; Food Fortification; and Veterinary Drugs

The AAFC Evaluation Committee recommended this evaluation report for approval by the Deputy Minister on May 28, 2013.

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EXECUTIVE SUMMARY

This evaluation examines the relevance and performance of three initiatives of Agriculture and Agri-food Canada's (AAFC's) Agricultural Regulatory Action Plan under Growing Forward: Health Claims, Novel Foods and Ingredients; Food Fortification; and Veterinary Drugs. The Agricultural Regulatory Action Plan was designed to address regulatory pressures facing the agriculture and agri-food sector in order to support the achievement of the Growing Forward strategic outcome of a competitive and innovative sector.

The evaluation was conducted by AAFC's Office of Audit and Evaluation in accordance with the Treasury Board Policy, Directives and Standards on Evaluation (2009). The evaluation was undertaken to inform program and policy development for Growing Forward 2, the next agricultural policy framework.

The evaluation also examined the fourth initiative of the Regulatory Action Plan, the Minor Use Pesticides Program (MUPP). As the MUPP addressed unique regulatory pressures related to pest management, evaluation results for that initiative are presented in a separate evaluation report.

Background and Profile

The Agricultural Regulatory Action Plan included initiatives designed to address major regulatory issues identified during consultations for Growing Forward:

- Improving regulatory responsiveness in the areas of **health claims, novel foods and ingredients** through dedicated resources in AAFC's Market Information and Services Branch (MISB) and Science and Technology Branch (formerly Research Branch), as well as in Health Canada's Food Directorate;
- Improving management of discretionary **food fortification** at the Food Directorate of Health Canada; and
- Improving access to **veterinary drugs** for Canadian livestock producers through support for Health Canada's Veterinary Drugs Directorate.

AAFC's Food Regulatory Issues Division (FRID) within MISB played an overall coordination role for the Agricultural Regulatory Action Plan, organizing semi-annual Joint Management Committee meetings between AAFC and Health Canada, and preparing annual reports to the Deputy Minister.

AAFC expenditures for 2008-2009 to 2011-2012, and transfers to Health Canada for 2008-2009 to 2012-2013, totaled \$29.9 million for the Health Claim, Novel Foods and Ingredients initiative, \$4.3 million for Food Fortification and \$5.0 million for Veterinary Drugs. Funding for the components delivered by Health Canada was transferred from AAFC as per two Memoranda of Understanding (MOUs), which defined the funding

agreement, roles and responsibilities, performance indicators, and reporting structures for the initiatives.

As part of AAFC's Program Activity Architecture, the Health Claims, Novel Foods and Ingredients initiative comprised Sub-activity 2.4.2 under the Program Activity of Regulatory Efficiency Facilitation (2.4). The initiative was designed to support AAFC's strategic outcome of "a competitive agriculture, agri-food and agri-based products sector that proactively manages risk."

Evaluation Scope and Methodology

The evaluation examined the relevance and performance of the Agricultural Regulatory Action Plan for the period of 2008-2009 to 2011-2012. Consistent with the provisions of the MOUs, the evaluation focused primarily on the components delivered by AAFC, which included the Industry Engagement and Knowledge Transfer and Science Substantiation components of the Health Claims, Novel Foods and Ingredients initiative. The evaluation also examined, in lesser detail, the relevance and performance of the components delivered by Health Canada, based on performance reporting and contextual interviews with Health Canada and AAFC officials.

Quantitative and qualitative data were collected through the following lines of evidence: a document review; program performance and financial data; key informant interviews (n=30); an online survey of Health Claims, Novel Foods and Ingredients stakeholders (n=186); and case studies of two health claims related to barley and soy.

Key Findings – Health Claims, Novel Foods and Ingredients

The evaluation found that the program theory of the Health Claims, Novel Foods and Ingredients initiative was sound. The initiative was well-targeted to address key regulatory impediments identified prior to Growing Forward, including a limited industry capacity and knowledge related to health claim regulations and submissions, a complex regulatory and approval process, and limited Health Canada resources for reviewing health claim submissions.

The Health Claims, Novel Foods and Ingredients initiative was aligned with federal priorities related to innovation and reducing regulatory barriers to competitiveness, and with the departmental strategic outcomes of competitiveness and innovation. AAFC's role in helping industry to build its own regulatory navigation capacity was appropriate during Growing Forward.

Through the Industry Engagement and Knowledge Transfer component, MISB provided industry with effective guidance and information related to health claims by mentoring industry and developing online resources, among other activities. This improved the number and quality of regulatory submissions to Health Canada. The Science Substantiation component funded nine projects to address knowledge gaps related to

food-health linkages. The component also established a series of networks, many of which were specifically used to deliver on the funded projects. While it is too early to assess the extent to which the funded research will support future health claims, a case study demonstrated that research by AAFC's Science and Technology Branch had a positive impact on past health claim submissions.

The Regulatory Enhancement component at Health Canada resulted in improvements to regulatory processes related to health claims. This included increased capacity at Health Canada during Growing Forward for reviewing health claims submissions, and improved processes and guidance materials. In addition, Growing Forward was one of the factors that contributed to the streamlining of the regulatory process, which included increasing the authorities of the Health Canada Minister to include making regulatory amendments.

Improvements to the regulatory framework and industry capacity helped to facilitate a significant increase in health claims. Five health claims were approved between 2010 and 2012, compared with none between 2004 and 2010. Additional health claim submissions were also being reviewed by Health Canada at the time of the evaluation. Over 60 product launches related to four of these new health claims were noted by FRID, as of September 2012.

Notwithstanding the positive results from the initiative, the evaluation identified two areas requiring attention:

- It is unclear whether AAFC's role in undertaking human clinical trials as part of the initiative was appropriate. The department lacked the physical infrastructure and had limited expertise in this area, requiring the development of partnerships with other research organizations. This type of research also involves more complex ethical and liability issues than the foundational research that the Science and Technology Branch has traditionally conducted on food-health linkages.
- The Science Substantiation component highlighted limitations in the research project selection process for Science and Technology Branch research.

Key Findings – Food Fortification and Veterinary Drugs

For the Food Fortification initiative, the evaluation found there was a need for support for temporary regulatory measures when changes to regulations governing food fortification did not proceed in 2009. The initiative helped Health Canada begin to lay the groundwork for interim authorization of innovative fortified foods.

Access to veterinary drugs is important for the competitiveness of the livestock sector. The Veterinary Drugs initiative of the Agricultural Regulatory Action Plan reduced approval times for veterinary drugs at Health Canada, and increased the availability of veterinary drugs for food producing animals in the Canadian market.

Recommendations

The evaluation identifies the following two recommendations related to the Health Claims, Novel Foods and Ingredients initiative:

Recommendation #1:

Science and Technology Branch should:

- Review the alignment of research involving human clinical trials with AAFC's mandate, priorities and capacity, and report back to AAFC senior management with a recommendation on whether the department should continue in this area.

Recommendation #2:

Science and Technology Branch should:

- Ensure that multiple partners across AAFC branches are involved in the process for identifying AAFC research priorities and gaps in order to align AAFC research activities with areas of greatest priority for the department.

LIST OF ACRONYMS

AAFC	Agriculture and Agri-Food Canada
ADM	Associated Deputy Minister
CDSR	Cabinet Directive on Streamlining Regulation
CFIA	Canadian Food Inspection Agency
CIHR	Canadian Institutes of Health Research
FDA	Food and Drug Administration
FDR	Food and Drugs Regulations
FRID	Food Regulatory Issues Division
FTE	Full Time Equivalent
JMC	Joint Management Committee
MISB	Market and Industry Services Branch
MOU	Memorandum of Understanding
MRL	Maximum Residue Limit
MUMS	Minor Use / Minor Species
MUPP	Minor Use Pesticides Program
NDS	New Drug Submissions
OAE	Office of Audit and Evaluation
S&T	Science and Technology
TMA	Temporary Market Authorization
TMAL	Temporary Marketing Authorization Letter
US	United States

1.0 INTRODUCTION

The Office of Audit and Evaluation (OAE) of Agriculture and Agri-Food Canada (AAFC) conducted an evaluation of the Agricultural Regulatory Action Plan under Growing Forward (the Regulatory Action Plan). The initiatives of the Regulatory Action Plan support AAFC's strategic outcome of "a competitive agriculture, agri-food and agri-based products sector that proactively manages risk". With the Growing Forward policy framework expiring at the end of 2012-2013, the evaluation was undertaken to inform program and policy development for Growing Forward 2, the next agricultural policy framework.

This report presents the evaluation results for three initiatives under the Regulatory Action Plan: Health Claims, Novel Foods and Ingredients; Food Fortification; and Veterinary Drugs. Evaluation results related to the fourth initiative, the Minor Use Pesticides Program, which addressed unique regulatory issues related to pest management, are presented in a separate report.

1.1 EVALUATION SCOPE

The evaluation examines the three initiatives of the Agricultural Regulatory Action Plan for the period from 2008-2009 to 2011-2012. Consistent with the responsibilities outlined in the Memoranda of Understanding (MOUs) between AAFC and Health Canada, evaluation activities are being undertaken by both AAFC and Health Canada for the components that each department delivers.¹ Thus, the evaluation focuses primarily on the Industry Engagement and Knowledge Transfer and Science Substantiation components on the Health Claims, Novel Foods and Ingredients initiative. The evaluation findings presented in this report related to the components delivered by Health Canada are based on Health Canada's performance reporting to AAFC and a small number of contextual interviews.

As per the Treasury Board Directive on the Evaluation Function, the evaluation examined the evaluation issues of relevance and performance. Limited information was available to address the issue of efficiency/economy. The evaluation also examined the effectiveness of the Regulatory Action Plan's governance structure in facilitating accountability and achievement of results.

¹ Health Canada is undertaking an evaluation of its Food Safety and Nutritional Quality program, which includes activities funded under the Regulatory Enhancement component of the Health Claims, Novel Foods and Ingredients initiative, as well as the Food Fortification initiative. It is also evaluating its Veterinary Drugs Directorate, which received funding under the Regulatory Action Plan's Veterinary Drugs program.
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1.2 EVALUATION APPROACH AND METHODOLOGY

The evaluation used a non-experimental design, incorporating both qualitative and quantitative data to address the evaluation issues and questions. The evaluation included multiple lines of evidence:

1. Document and Data Review

The document and data review provided information on program design and delivery and helped to assess the alignment of the Health Claims, Novel Foods and Ingredients initiative with departmental strategic outcomes and federal priorities. The document review also provided information on the achievement of results. The review was comprised of program documentation, including MOUs, performance reports and project reports, Joint Management Committee (JMC) documents, literature reviews conducted for the initiative, departmental reporting, project reports, key sources of background literature and other documentation. The review also examined draft Health Canada evaluation reports related to the components it delivered. An analysis of program financial data was undertaken to examine program costs.

2. Key Informant Interviews

Interviews with key stakeholders from government, industry and academia provided information related to all evaluation issues. A total of 30 interviews were completed, including 12 interviews with AAFC staff and managers, six interviews with Health Canada officials, and 12 interviews with external stakeholders (including seven industry representatives, as well as representatives from academia, the United States (US) Department of Agriculture, a commercialization centre and a consultant).

Interviewees were selected by OAE to represent a wide cross-section of perspectives on the Health Claims, Novel Foods and Ingredients initiative. External stakeholders were also selected to include experts who were not currently program beneficiaries or involved in program delivery, in order to obtain more neutral perspectives. In addition, to provide context to performance reporting, a small number of interviews were conducted with government officials knowledgeable about the Veterinary Drugs initiative (four interviews) and Food Fortification initiative (three interviews).

3. Survey

OAE conducted an online survey of the Food Regulatory Issues Division's (FRID's) listserv subscribers in May and June 2012. The survey included questions on stakeholders' awareness of, and satisfaction with, FRID

services; their views on the regulatory system; perceived program impacts; and suggestions for improvements to the program and the regulatory system in general. The survey was emailed to 1,253 listserv members, who were encouraged to email the survey link to other relevant stakeholders with whom they were in contact. Survey respondents included food manufacturers and processors, representatives of industry/producer associations, federal and provincial government officials, academics, members of non-profit organizations and consultants. The survey yielded a total of 186 responses.²

4. Case Studies

To examine in more detail the performance of the Health Claims, Novel Foods and Ingredients initiative, OAE conducted two case studies of claims related to cardiovascular health: barley and soy. The case studies were selected as they were information-rich and represented two significant investments of staff time and resources by AAFC's FRID and Science and Technology (S&T) Branch. Each case study included interviews with AAFC, Health Canada and industry stakeholders knowledgeable about the health claims, as well as a review of relevant documentation.

1.3 METHODOLOGICAL CONSIDERATIONS

There are three limitations to note when reading the evaluation. Table 1 below details the limitations, OAE's mitigation strategy for each, and impacts on the evaluation.

² As listserv members could forward the link to others, the response rate could not be calculated.
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_AND_VETERINARY_DRUGS_(E.DOC

Table 1: Methodological Limitations of the Evaluation		
Limitation	Mitigation Strategy	Impact on Evaluation
The initiatives had relatively limited time to achieve results given that the evaluation was undertaken during the fourth year of new initiatives, and complex scientific and regulatory initiatives require significant time to see impacts.	The case studies provide some data on the extent to which longer-term outcomes can reasonably be expected to be achieved in the future.	Comprehensive information on the extent to which some program activities will result in expected outcomes is not available.
There was no ability to assess cost-effectiveness, as the nature of the Health Claims, Novel Foods and Ingredients initiative did not lend itself to an assessment of cost per output or outcome, and there were no benchmarks identified.	Evaluation examined extent to which funding for the AAFC components was spent as originally planned.	There are limited data on cost-effectiveness in the evaluation.
No ability to determine the representativeness of survey data.	Survey data were supplemented in the evaluation by other lines of evidence, including interviews and case studies.	Survey data may not be representative of stakeholders generally, and should not be interpreted as conclusive.

2.0 PROFILE OF THE PROGRAMS

2.1 BACKGROUND

Consultations with stakeholders in May 2008 during the development of Growing Forward highlighted the need for regulatory reform in the agriculture and agri-food sector. Stakeholders felt that Canada had fallen behind other countries in regulatory approval for health claims, novel foods and ingredients, discretionary food fortification, veterinary drugs, and minor use pesticides. The consultations suggested that Canada's regulatory environment was impeding sector investment, innovation and competitiveness.

In March 2009, Treasury Board approved AAFC funding for the Regulatory Action Plan under Growing Forward. Through the Regulatory Action Plan, AAFC committed to addressing the immediate regulatory pressures facing the sector.

The Regulatory Action Plan included three initiatives (as well as the Minor Use Pesticides Program, which is discussed in a separate evaluation report), which corresponded to the specific regulatory areas that were identified by stakeholders as most in need of improvement:

- Improving regulatory responsiveness in the areas of **health claims, novel foods and ingredients**;
- Improving regulatory management of discretionary **food fortification**; and
- Improving access to **veterinary drugs** for Canadian livestock producers.

As Health Canada regulates these three areas, the Regulatory Action Plan aimed to bolster, in a targeted manner, the department's capacity to address impediments to sector competitiveness and profitability. Thus, two Regulatory Action Plan initiatives are delivered by Health Canada: the Food Fortification and Veterinary Drugs initiatives. The Health Claims, Novel Foods and Ingredients initiative is delivered jointly by AAFC and Health Canada.

As part of AAFC's Program Activity Architecture, the Health Claims, Novel Foods and Ingredients initiative comprises the Sub-Activity of Health Claims, Novel Foods and Ingredients (2.4.2) under the Program Activity of Regulatory Efficiency Facilitation (2.4). This Sub-Activity is comprised of two Sub-Sub-Activities representing the two distinct components delivered by AAFC: Industry Engagement (2.4.2.1) and Science Substantiation (2.4.2.2).

All AAFC components of the Regulatory Action Plan were designed to contribute to AAFC’s strategic outcome of “A competitive agriculture and agri-based products sector that proactively manages risk”.

2.2 DESIGN AND DELIVERY

AAFC and Health Canada jointly implement the Regulatory Action Plan through two MOUs. The MOUs define the lead department for each component, as well as the working relationships, funding agreements, performance indicators, and reporting structures. One MOU covered the Health Claims, Novel Foods and Ingredients and Veterinary Drugs initiatives (in addition to the Minor Use Pesticides Program), while the Food Fortification initiative was covered by a second MOU.³ Table 2 outlines the lead departments for the three components covered in this evaluation.

Table 2: Initiatives of the Agricultural Regulatory Action Plan*	
	Lead
1) Health Claims, Novel Foods and Ingredients	
i) Industry Engagement and Knowledge Transfer	AAFC – Market & Industry Services Branch
ii) Science Substantiation	AAFC – Science & Technology Branch**
iii) Regulatory Enhancement	Health Canada – Food Directorate
2) Food Fortification	Health Canada – Food Directorate
3) Veterinary Drugs	Health Canada – Veterinary Drugs Directorate

* Not including the Minor Use Pesticides Program

** Known as Research Branch until 2012

The following sections provide more detail on the design and delivery of each of the three initiatives.

³ A second MOU was developed due to changes in policy at Health Canada that required Food Fortification initiative to be refocused to support activities at Health Canada rather than the Canadian Food Inspection Agency.
 AAFC AAC-#3886489-V11-2012-13_OAE-EV_-_Report_-_EVALUATION_OF_HEALTH_CLAIMS_NOVEL_FOODS_AND_INGREDIENTS_FOOD_FORTIFICATION_AND_VETERINARY_DRUGS_(E.DOC

Health Claims, Novel Foods and Ingredients

The goal of the Health Claims, Novel Foods and Ingredients initiative is to accelerate the market entry of new food products and to advance innovation in the expanding category of "foods with added health benefits". It includes work in three areas:

1. AAFC's FRID, within the Market and Industry Services Branch, led the Industry Engagement and Knowledge Transfer component, which comprised the following types of activities:
 - facilitating the collection, review, interpretation and documentation of information on market opportunities, sector capacity, product/claim approvals in other jurisdictions, and the state of science;
 - assisting value chains and sector groups in understanding regulatory processes and in developing regulatory submissions;
 - working with industry, the research community, and other stakeholders on outreach to build their understanding of regulatory processes/requirements and to facilitate information dissemination; and
 - providing government and industry with timely, analysis-based advice and information on food regulatory issues that have an impact on food industry investment, innovation and competitiveness.
2. AAFC's S&T Branch (previously called the Research Branch until 2012) led the Science Substantiation component, which included:
 - determining research priorities and providing advice for study designs through the establishment of expert task forces on the status of scientific information and gaps in priority areas;
 - working with industry and research partners to assess the technical feasibility of generating products containing bio-actives, making sure that they keep their bioactivity, and catalyzing research efforts in order to properly document related health claims;
 - providing advice to universities, industry, and research centres involved in human clinical trials to ensure studies are performed according to accepted practices, with scientific rigor and address scientific gaps related to health claims.
3. Health Canada's Food Directorate led the Regulatory Enhancement component, which involved:
 - improving regulatory processes to help make pre-market approval and review processes more predictable, transparent and timely, while retaining health and safety standards;

- developing enhanced policy frameworks, standards and regulations that will continue to protect and promote health but are better able to respond to advances in food technology and innovations in product development.

Table 3 presents the budget and expenditures for the AAFC-delivered components of the Health Claims, Novel Foods and Ingredients initiative, for the fiscal years of 2008-2009 to 2012-2013. As shown, a total of \$12.5 million was expended by AAFC for 2008-2009 to 2011-2012. In addition, \$17.4 million was transferred to Health Canada for the Regulatory Enhancement component of the initiative for 2008-2009 to 2012-2013. A total of \$29.9 million was expended by AAFC or transferred to Health Canada.

Table 3: AAFC-Delivered Components of Health Claims, Novel Foods and Ingredients – Budget, Expenditures, 2008-2009 to 2012-2013 (\$ millions)						
	2008-2009	2009-2010	2010-2011	2011-2012	2012-2013*	Total
Industry Engagement & Knowledge Transfer (AAFC – Market & Industry Services Branch)						
Budget	1.2	2.0	2.0	2.0	2.0	9.2
Expenditures	1.1	1.6	1.9	1.9	TBD*	TBD*
Science Substantiation (AAFC – S&T Branch)						
Budget	0.9	2.0	2.0	2.0	2.0	8.9
Expenditures	0.0	1.9	2.0	2.1	TBD*	TBD*

Source: AAFC

* Actual expenditures for 2012-2013 not yet available

The staff complement for the Industry Engagement and Knowledge Transfer component included, rounded to the nearest Full Time Equivalent (FTE), seven FTEs in 2008-2009, 10 FTEs in 2009-2010, 13 FTEs in 2010-2011, 13 FTEs in 2011-2012, and 10 FTEs in 2012-2013.

The Science Substantiation component funded five realigned FTEs per year for the entire five-year period.

Food Fortification

Foods sold in Canada are regulated under the *Food and Drugs Act* and the associated *Food and Drug Regulations* (FDR). Normally, to permit the sale of a food that does not currently meet the FDR requires a regulatory amendment. However, Health Canada can also, in specific cases, allow for a non-compliant food to be sold before a regulatory amendment is made

through the use of a Temporary Market Authorization (TMA). Industry can obtain Temporary Marketing Authorization Letters (TMALs) for food fortified on a discretionary basis with vitamin and mineral nutrients not currently permitted.

The process of issuing TMALs requires dedicated Health Canada staff to manage the review and assessment of the safety of fortified foods. In addition, further analysis and consultations were required by Health Canada in order to determine a long-term path forward with regard to regulation of fortified foods.

Under the Food Fortification initiative, Health Canada's Food Directorate was responsible for the following activities:

- organizing multi-stakeholder consultations;
- supporting dedicated staff to manage the issuance of TMALs for fortified foods; and
- developing a knowledge base supporting the development of regulations to manage fortified foods on a long-term basis.

Under the Regulatory Action Plan, Treasury Board allocated a budget of \$8.0 million over four years for the Food Fortification initiative. Funding was originally earmarked to be transferred to the Canadian Food Inspection Agency (CFIA) for enforcing new food fortification regulatory amendments. When the regulatory amendments did not proceed as planned, funding was instead allocated to Health Canada for further work in this area. Funding transferred to Health Canada totalled \$4.3 million over the period from 2009-2010 to 2012-2013.

According to Health Canada, the initiative's funding covered the costs of four FTEs for Food Fortification during Growing Forward.

Veterinary Drugs

The Veterinary Drugs initiative was delivered by Health Canada's Veterinary Drugs Directorate. It aimed to increase the availability of newer and more effective veterinary drugs to Canadian livestock producers by improving the regulatory environment for veterinary drugs, including closer harmonization of technical requirements with those in the US and a timelier, more transparent approvals process that would encourage companies to make submissions. Activities included:

- developing an action plan for closer harmonization of Canadian and US Maximum Residue Limit processes;
- reducing veterinary drug submission review-time standards against international standards;

- improving regulatory approval processes for new and generic veterinary drugs to help make the review process predictable, transparent and timely through consultation with stakeholders and the implementation of veterinary generic drug guidelines; and
- Reviewing new, generic and Minor Use Minor Species veterinary drug submissions; and developing a Minor Use Minor Species policy framework to facilitate the regulatory process and increase the availability of veterinary drugs for food-producing animals.

Under the Regulatory Action Plan, Treasury Board allocated a budget of \$5.0 million over five years for the Veterinary Drugs initiative. Actual transfer of funding from AAFC totalled \$5.0 million from 2008-2009 to 2012-2013.

According to Health Canada, funding under this initiative covered the costs of six FTEs in the Veterinary Drugs Directorate during the Growing Forward period.

2.3 GOVERNANCE

The MOUs between AAFC and Health Canada outlined the governance structure for the Regulatory Action Plan, including roles and responsibilities, reporting structure, and a performance measurement strategy for each initiative.

The initiatives were each governed by Interdepartmental Working Groups. The Working Groups reported semi-annually to Director General Joint Management Committees which, in turn, reported semi-annually to Assistant Deputy Ministers (ADMs) in both departments. The ADMs reported each February to their respective Deputy Ministers to allow time for the transfer of resources from AAFC to Health Canada for the following fiscal year.

FRID played an overall coordination role for these three initiatives of the Regulatory Action Plan within the department and prepared the annual reports for the Deputy Minister. The division was responsible for organizing the Joint Management Committee meetings.

3.0 HEALTH CLAIMS, NOVEL FOODS AND INGREDIENTS – EVALUATION FINDINGS

3.1 RELEVANCE

3.1.1 The program theory of the Health Claims, Novel Foods and Ingredients initiative was sound as there was a need to reduce regulatory impediments and help build industry capacity in navigating and meeting the requirements of the regulatory system.

The following section discusses how health claims can foster innovation and increase competitiveness, and the importance of reducing regulatory impediments to health claims in Canada.

Health Claims Linked to Increased Economic Activity and Innovation

Consumers are increasingly seeking out foods that are differentiated by health and nutrition attributes.⁴ Between 2005 and 2008, global sales of foods with enhanced health benefits grew at more than twice the rate of packaged foods.⁵ Health claims present opportunities for farmers to diversify their crops and shift demand to more value-added crops, and for food companies to increase their sales of high value products.

Case study research undertaken prior to Growing Forward found that health claims have been associated with economic benefits and new product introductions.⁶ For example, in the 11 years following the introduction in the US of a health claim linking soy with a reduced risk of heart disease, American retail sales for soy foods grew by 19%. The study also found a five-fold increase in the number of new soy products following the introduction of the health claim. Overall, the study concluded that there “is a business case for health claims when considering the economic impacts through the agri-food supply chain”.⁷

Interviewed stakeholders also linked health claims with economic benefits for the agri-food industry. According to industry representatives, having Health Canada-approved health claims facilitates domestic and international marketing. As authoritative statements supported by peer reviewed science, health claims can have a direct effect on purchase behaviour. Health claims

⁴ Leatherhead Food International. 2006. The International Market for Functional Foods: Moving into the Mainstream.

⁵ Euromonitor International, The World Market for Functional Foods & Beverages, January 2004.

⁶ Groenewegen, John, Culhane, Carol and Thompson, Shelley. 2008. The Nature and Magnitude of Economic, Business and Market Value Activity Generated by Health Claims along the Agriculture and Agri-Food Value Chain.

⁷ Groenewegen, J., *et al.* 2008. p.6.

can also enhance food manufacturers' ability to differentiate their product lines, which can increase domestic and export sales.

In addition to economic benefits for the industry, health claims can have benefits related to health and wellness. According to stakeholders, health claims can improve consumer ability to make healthy food choices by increasing both the availability of information about, and the number of, healthy food products.

Need to Reduce Regulatory Impediments to the Introduction of Foods with Health Benefits

Despite the importance of health claims, Canada's regulatory framework prior to Growing Forward was seen as a drag on innovation. There was broad agreement across all lines of evidence that there was a need to reduce regulatory impediments to the introduction of foods with health benefits. For example, a 2008 review concluded that Canada's regulatory system was not competitive with those of other developed countries.⁸ The associated costs in lost economic opportunities to the Canadian economy were significant; foregone output, wages/salaries, and taxes were estimated at over \$400 million for the case studies examined in the review.⁹ The review found regulatory impediments were hampering the approval of new health claims in Canada: prior to Growing Forward, 16 health claims had been approved in the US (between 1993 and 2008) whereas only five were approved in Canada.^{10 11}

Stakeholder consultations during the development of Growing Forward highlighted the regulatory impediments faced by the agriculture and agri-food sector.¹² These impediments were subsequently raised by agri-food stakeholders in Value Chain Roundtables facilitated by AAFC.¹³ All stakeholders interviewed for this evaluation confirmed that the regulatory framework prior to Growing Forward was problematic.

Impediments were identified across all major aspects of the regulatory framework. First, the regulatory system and approval processes for health claims, novel foods and ingredients were considered complex and burdensome. The need for regulatory amendments to the *Food and Drugs Act* for any new health claim, and the associated process for amendments,

⁸ George Morris Centre. 2008. Food Regulatory Systems: Canada's Performance in the Global Marketplace.

⁹ George Morris Centre. 2008. p.3.

¹⁰ George Morris Centre. 2008. p.15.

¹¹ Qualified health claims are permissible in the United States.

¹² Agriculture and Agri-Food Canada. 2008. Growing Forward – What We Heard: Report from the May 27-28, 2008 Consultation, p.6.

¹³ Value Chain Roundtables. 2010. Growing the Canadian Food Processing Sector – An Industry Government Action Plan. Retrieved January 8, 2013 at: <http://www.ats-sea.agr.gc.ca/rt-tr/5708-eng.htm>
AAFCAAC-#3886489-V11-2012-13_OAE-EV_-_Report_-_EVALUATION_OF_HEALTH_CLAIMS__NOVEL_FOODS_AND_INGREDIENTS__FOOD_FORTIFICATION__AND_VETERINARY_DRUGS_(E.DOC

was considered onerous, particularly compared to the process in the US, where full regulatory amendments are not required for new health claims. The process at Health Canada for reviewing regulatory submissions was also seen by industry as slow.

There was also limited industry capacity and knowledge related to health claims. Industry stakeholders, and some consultants, lacked experience and awareness of the regulatory framework and health claim submission process as well as the type of scientific proof required to substantiate health claims. In addition, single companies have been reluctant to absorb the significant costs associated with generating the scientific evidence required for health claim submissions, as the economic benefits are spread across the entire commodity sector.

The Health Claims, Novel Foods and Ingredients initiative was designed to address these regulatory impediments. The initiative's three components each focused on separate, but interrelated, aspects of the regulatory framework. AAFC's FRID was created to address the need for industry support and guidance related to the regulatory system for health/nutrient claims. Health Canada could not provide extensive guidance to industry on health claim submissions. The Scientific Substantiation component was designed to assist industry in addressing the knowledge gaps related to the scientific information required to obtain regulatory approval for health claims by Health Canada. Funding for Health Canada was designed to help the department develop its capacity and processes to increase the speed of approvals. The evaluation found these components were well-designed to address the identified needs related to health claims, novel foods and ingredients.

In conclusion, the program theory of the Health Claims, Novel Foods and Ingredients initiative addressed the need to reduce regulatory impediments and help build industry capacity.

3.1.2 Since Growing Forward began, some regulatory impediments have been reduced, and industry stakeholders have built capacity in navigating the regulatory system, particularly among larger organizations.

Growing Forward facilitated regulatory enhancements at Health Canada. For example, Bill C38, in June 2012, gave greater authority to the Minister of Health and streamlined the regulatory process for health claims.

Process changes have also made the regulatory and approval process more transparent and accessible, with Health Canada now posting on-line guidance documents related to seeking approval of claims. There is also an increased focus at Health Canada on facilitating a timely approval process for health claim submissions. Interviews suggested that Health Canada is hoping to continue with the capacity it built up during Growing Forward for reviewing submissions, although it is not known whether this will be sustainable in the future. It is expected that the positive relationship between Health Canada and AAFC established as a result of Growing Forward will continue into the future.

The significant work undertaken during Growing Forward has helped to build industry capacity in navigating the regulatory system, according to stakeholders. In addition, resources and guidance documents have been developed by both AAFC and Health Canada to assist industry to understand and navigate the system. However, according to the interviews and survey responses, there remain gaps in industry knowledge and capacity, especially among smaller organizations.

In conclusion, some regulatory impediments to health claims have been reduced during Growing Forward. In addition, industry has built capacity in navigating the regulatory system.

3.1.3 The Health Claims, Novel Foods and Ingredients initiative was aligned with federal priorities related to reducing regulatory barriers to competitiveness, and with departmental strategic outcomes of competitiveness and innovation.

The evaluation assessed the alignment of the Health Claims, Novel Foods and Ingredients initiative with federal priorities and with AAFC strategic outcomes.

Alignment with Federal Priorities and Departmental Strategic Outcomes

The Health Claims, Novel Foods and Ingredients initiative was aligned with federal priorities related to regulatory improvement and modernization. The 2007 Cabinet Directive on Streamlining Regulation, and its successor, the Cabinet Directive on Regulatory Management, committed the federal government to developing a more effective, efficient, transparent and accountable regulatory system. The initiative also aligned with the recent Red Tape Reduction Commission (2011), which was designed to reduce regulatory irritants stemming from federal regulations. The initiative also aligned with agri-food sector initiatives related to regulatory modernization,

including the 2006 Blueprint for Renewal II: Modernizing Canada's Regulatory System for Health Products and Foods and the 2007 Regulatory Modernization Strategy for Food and Nutrition. Furthermore, as the initiative was designed to support new product development, it was aligned with the overall federal government priority of innovation.¹⁴

The initiative was aligned with the AAFC departmental strategic outcomes of competitiveness and innovation. The initiative was designed to help address impediments to industry competitiveness and innovation identified in consultations with industry prior to Growing Forward. The overall goal of the Health Claims, Novel Foods and Ingredients initiative is to support industry to foster the development of innovative new agri-food products.

In conclusion, the Health Claims, Novel Foods and Ingredients initiative was aligned with federal priorities related to reducing regulatory barriers to competitiveness, and with departmental strategic outcomes of competitiveness and innovation.

3.1.4 AAFC's role during Growing Forward in helping industry to build its own regulatory navigation capacity was appropriate. Science and Technology Branch has conducted foundational research on health benefits of foods in the past, but has limited capacity to deal with the complex issues related to conducting human clinical trials.

Appropriate Departmental Role

AAFC was well-placed to assist industry during Growing Forward in strengthening sector capacity and knowledge through the Industry Engagement and Knowledge Transfer component. AAFC had the expertise, industry relationships and understanding of industry needs. It built a strong relationship with the Food Directorate at Health Canada, and a clear understanding of the federal regulatory environment that it could share with stakeholders. AAFC's support to agri-food businesses in this area aligns with the federal role of supporting industry competitiveness by fostering sector knowledge and capacity. Industry Canada plays a similar role in supporting the competitiveness of businesses in other sectors. Furthermore, interviews indicated that most provinces had limited or no capacity to provide support to agri-food businesses in this area.

¹⁴ Government of Canada. 2011. The Next Phase of Canada's Economic Action Plan – A Low-Tax Plan for Jobs and Growth.

Undertaking foundational research through the Science Substantiation Component aligns with AAFC's mandate for innovation and the 2006 Science and Innovation Strategy, including its focus on innovation, enhancing human health, and increasing collaboration with other research organizations.

Interviews suggest that there is limited industry and provincial funding specifically for foundational research on food-health linkages, although some university research is carried out in the area. Multinational agri-food companies do not typically have research and development capacity in Canada. Small- and medium-sized companies are unable to fund these studies. Within universities, some research in this area is conducted through the Richardson Centre for Functional Foods and Nutraceuticals at the University of Manitoba and the Institute of Nutraceuticals and Functional Foods at Laval University (both of which partnered with AAFC to assist in research for this component). St. Boniface Hospital, affiliated with the University of Manitoba, also conducts related research. Other universities have also undertaken work in support of health claims, including the University of Toronto on the oat health claim submission.

Outside of AAFC, there is limited federal support for research in this area. The Canadian Institutes of Health Research (CIHR) funds some university research on food and health. CIHR has a Nutrition, Metabolism and Diabetes Institute, which is managing a CIHR Programmatic Grants in Food and Health funding opportunity, and a first call for proposals was issued in 2012 for research on food and health. As emphasized in interviews, Health Canada, as regulator, cannot generate scientific data in support of health claims due to the associated conflict of interest.

The appropriateness of AAFC conducting human clinical trials as part of its in-house research is less clear.¹⁵ Several projects carried out through the Science Substantiation component involved human clinical trials to examine the human health effects of specific foods. These included human clinical trials examining the relationship between soy and barley consumption and blood cholesterol levels, among others.

Prior to Growing Forward, AAFC had limited capacity in this area and research involving human clinical trials was undertaken by contracted researchers outside the department. According to interviews, there were concerns with the quality of past research undertaken outside of AAFC related to food health benefits. There was a perceived need for AAFC to have direct involvement in research studies for this initiative, to ensure the rigour and utility of the research results. Since the department did not have

¹⁵ While the term "human clinical trial" is generally used in reference to drug and medical research, throughout this report the term is used in reference to research on humans related to nutrition and foods.

the physical infrastructure to run human clinical trials, it developed partnerships and official agreements with organizations that did. This included the renewal of the AAFC-Canadian Centre for Agri-food Research in Health and Medicine at St. Boniface Hospital partnership, and the establishment of an agreement with the Richardson Centre for Functional Foods and Nutraceuticals, where AAFC scientists were co-located to conduct this research. In addition, several collaborative research and development agreements were established with the University of Guelph and the University of Toronto to perform human studies, as well as an agreement with USDA-Tufts University. The role of AAFC scientists was to work to prove the efficacy of bioactives and develop the knowledge necessary to address bioactive stability, accessibility and availability in the agri-food context.

In addition, S&T Branch worked with MISB in an advisory capacity to document best practices for conducting food health claim clinical trials and to leverage existing Canadian expertise in this area. The findings were expected to be presented to the research community via a MISB webcast in February 2013 and the best practices document made available on the FRID website.

Research involving human clinical trials presents more complex ethical and liability issues (with associated risks) than the department's traditional research related to agricultural production. Given these challenges, it is not clear whether it is an appropriate role for AAFC staff to undertake human clinical trials.

AAFC's role during Growing Forward in helping industry to build its own regulatory capacity was appropriate. S&T Branch had an appropriate role in undertaking foundational research on health benefits. However, due to the complexity of issues related to human clinical trials, it is unclear whether the departmental role in undertaking this type of research was appropriate.

Recommendation #1:

S&T Branch should:

- Review the alignment of research involving human clinical trials with AAFC's mandate, priorities and capacity, and report back to AAFC senior management with a recommendation on whether the department should continue in this area.

3.2 PERFORMANCE – EFFECTIVENESS

The following section presents the findings related to the effectiveness of the three components of the Health Claims, Novel Foods and Ingredients initiative: Industry Engagement and Knowledge Transfer, Science Substantiation, and Regulatory Enhancement.

Industry Engagement and Knowledge Transfer

3.2.1 AAFC provided industry with effective guidance and information on health claims, which improved the number and quality of submissions to Health Canada.

FRID undertook a range of activities to support its role in the Health Claims, Novel Foods and Ingredients Initiative. As shown in Table 4, FRID had exceeded all of its output targets for the initiative in the third year of Growing Forward.

Table 4: FRID Expected Outputs, Targets and Results		
Expected Output	Targets	Results (2009-2010 to 2011-2012)
Regulatory issues/impact documents	15 by end of March 2013	103 issue memos, reports and briefing notes
Plans/priorities	3 sets by end of March 2013	17 plans and priority documents
Literature reviews, research gap lists	6 literature reviews, expert panels, symposia by end of March 2013	27 documents/reports and expert meetings have generated information for sector submissions 8 key research gaps identified
Meetings, commentary workshops, websites	30 meetings, workshops and/or informational resources by end of March 2013	152 meetings, workshops, information sessions, educational resources

Key guidance resources and information tools developed by FRID included a regular Food Regulatory Issues e-bulletin, a “Canadian Food Health Claim Roadmap”, a “Canadian Regulatory System for Foods with Health Benefits – An Overview for Industry” guidance document, and “An Example of a Systematic Literature Review”, all of which were accessible to stakeholders through the FRID website. Nine educational webcasts reached over 2,600 sector and research community stakeholders. The survey of stakeholders

conducted for the evaluation found that FRID guidance and information resource materials were viewed positively by those who had accessed them. Surveyed stakeholders were especially satisfied with FRID's electronic newsletter and the Canadian Food Health Claim Roadmap, with 83% and 81% of surveyed stakeholders indicating they were satisfied or very satisfied with these resources, respectively.

The evaluation found that FRID acted as an effective liaison with industry. The case studies, and interviews with industry representatives, Health Canada, AAFC staff and external experts all confirmed that FRID had fulfilled its liaison role with industry. For example, FRID mentored 44 food industry clients, 15 commodity associations, and five other stakeholders. According to industry stakeholders, FRID helped industry to better understand what was required in a health claim submission by providing advice and reviewing industry health claim submissions. By being available to provide information to industry in an accessible way, FRID's assistance was said to have reduced the burden on Health Canada's regulatory staff of responding to industry inquiries.

There has also been improved industry-regulator communication as a result of FRID's engagement with Health Canada. Regular meetings between AAFC and Health Canada allowed for the development of trust and sharing of information. Health Canada used FRID's expertise to assist it in communicating to industry.

According to Health Canada staff, AAFC's assistance improved the quality of health claim submissions and, thus, reduced the time needed to review and make decisions on those submissions. Six of eight health claim submissions and both of the two food additive claim submissions facilitated by FRID were deemed by Health Canada to meet the scientific requirements for submissions. Industry stakeholders said that at least two of the health claim submissions would not have moved ahead without FRID's assistance. Overall, the Industry Engagement and Knowledge Transfer component resulted in complete and substantiated sector regulatory submissions, an expected intermediate outcome of the initiative.

Furthermore, 47% of stakeholders who responded to the evaluation survey indicated that their ability to navigate the regulatory system had increased during Growing Forward. While other factors may have contributed to this increased stakeholder capacity, it appears, based on interviews and case studies, that FRID has contributed to an enhanced sector ability to navigate the regulatory system, an expected long-term outcome of the initiative.

Sector guidance and outreach was affected by the time required for staffing a new initiative; approximately 18 months was required for FRID to reach full

staffing capacity. In addition, some industry stakeholders noted that FRID made significant use of web-based communication such as webcasts, though a few indicated a preference for more face-to-face interaction.

In conclusion, AAFC successfully worked with industry to improve the number and quality of health claim submissions to Health Canada.

Science Substantiation

3.2.2 The Science Substantiation component developed domestic and international networks to address research gaps related to food-health linkages. While it is too early to assess the extent to which the research will support future health claims, a case study demonstrated how S&T Branch research has contributed to successful health claims in the past.

Domestic and international science networks were developed by S&T Branch to study food-health linkages. These included linkages with researchers in the United Kingdom, Europe, Australia and New Zealand, with an emphasis on gut health, which is pertinent to prebiotics and probiotics. National networks within Canada were developed to deliver on research projects funded through this initiative. Other networks were also developed to look at strategic research issues related to food-health linkages, and included the CIHR, National Research Council (Institute of Nutrisciences and Health), and others. A total of 18 domestic and international research networks were developed by S&T Branch to further the study of food-health linkages over the four-year period. As emphasized in AAFC interviews, networks were designed to help build synergies, reduce the costs and time required to achieve research results, and perform multi-centre trials.

S&T Branch conducted research to address gaps in the knowledge needed to establish the validity of health claims and the safety of novel ingredients. Projects were designed to address research gaps identified through seven systematic scientific literature reviews spearheaded by FRID and S&T Branch. These included examining dose response components of ingredients, which is critical for obtaining a health claim approval from Health Canada. As listed in Table 5, below, there are nine ongoing projects being conducted by S&T Branch for the initiative.

Table 5: Science Substantiation Projects
Projects launched in 2009-2010
Oat/barley beta-glucans and serum cholesterol lowering
Oat avenanthramides and anti-inflammatory effects
Pre-biotic fructans and gastro-intestinal status
Flaxseed in cereal-based products and reduced risk of chronic disease
Lentils and improved serum cholesterol, insulin sensitivity and vascular responsiveness
Projects launched in 2011-2012
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

As projects were ongoing at the time of the evaluation, the evaluation could not examine their impact on health claims. The barley case study conducted as part of this evaluation did demonstrate, however, how foundational research conducted by AAFC can contribute to health claim submissions. S&T Branch research beginning in the 1980s led to collaboration between AAFC and industry on a submission on the cholesterol lowering effects of barley. The collaboration resulted in a health claim that was approved by Health Canada in 2012. In addition, S&T Branch indicated that the body of scientific evidence that supported the health claim on the cholesterol-lowering effects of oats approved in 2010 was generated over a period of approximately 30 years.

The dedicated funding through the Science Substantiation component helped AAFC address limitations in the departmental research project selection process. The component was designed to address research gaps on food-health linkages not targeted through past AAFC scientific research or by external researchers, and to conduct research according to the standards required by Health Canada to effectively support health claim submissions. The dedicated funding helped AAFC target its research efforts to specific research gaps identified early in the initiative. AAFC's S&T Branch collaborated with FRID in developing research areas for the internal call for research project proposals, and through a Steering Committee for evaluating project proposals. Expert working groups were also established to provide methodological advice and information on research protocols to address scientific gaps in claim validity. S&T Branch's collaboration with FRID and

Health Canada also helped to facilitate a knowledge transfer strategy for the research.

Going forward, consideration should be given to ensuring that the department's research project selection process addresses research gaps related to food-health linkages through research that meets the requirements for scientific evidence in health claims.

The use of Vote 1 operational funding to support the research projects under this component resulted in some project delays due to the time needed to put contracts in place with external research partners. Vote 1 funding was requested for the component, as AAFC wanted to retain control of the research to ensure it was sufficiently rigorous and targeted to support future health claims. However, Vote 10 grants and contributions funding may have facilitated timelier project implementation.

In conclusion, the Science Substantiation component developed domestic and international networks to address research gaps related to food-health linkages and undertook nine research projects. While it is too early to assess the extent to which that research will support future health claims, a case study demonstrated how S&T Branch research has supported the approval of a health claim for barley. The Science Substantiation component was implemented to address gaps in research for health claims that were not being filled through past AAFC research.

Recommendation #2:

Science and Technology Branch should:

- Ensure that multiple partners across AAFC branches are involved in the process for identifying AAFC research priorities and gaps in order to align AAFC research activities with areas of greatest priority for the department.

Regulatory Enhancement

3.2.3 The Regulatory Enhancement component improved regulatory processes during Growing Forward.

Overall, the Health Claims, Novel Foods and Ingredients initiative helped to advance the improvement of policy and regulatory approaches and pre-market processes and make them more efficient, an expected intermediate outcome of the initiative. The Regulatory Enhancement component—within

an overall federal context prioritizing innovation and the reduction of regulatory burden—resulted in regulatory improvements in three areas at Health Canada.

First, capacity improvements during Growing Forward were noted in Health Canada's Food Directorate as a result of AAFC funding. Twenty-two FTEs were hired in Health Canada's Food Directorate, which boosted the department's capacity to review submissions and address backlog. It also provided resources during Growing Forward to increase the department's capacity to undertake policy and process improvements related to the regulatory framework. It is not known to what extent this increased capacity will be sustainable in the future.

Second, this component resulted in a number of improved processes related to health claim submissions. For example, Health Canada developed for industry a "Guidance Document for Preparing a Submission for Food Health Claims"¹⁶, as well Standard Operating Procedures with timelines. The department also made progress toward streamlining the review process for low-risk submissions.

Third, Growing Forward provided the impetus and increased staff capacity for strategic thinking on the regulatory framework at Health Canada. This was said to have contributed to regulatory changes in Bill C38. This bill gave the Minister of Health new authorities to approve regulatory amendments, which formerly had required Cabinet approval. Bill C38 also allowed Incorporation by Reference under the *Food and Drugs Act*.¹⁷ These changes will allow decisions related to food health claims (as well as food standards, food fortification, and food contaminants) to be implemented more quickly. In addition, Health Canada now allows companies to make a health claim as soon as the science is approved, even before the amendments are made to the regulations. This can reduce the wait by one to two years, according to interviews.

The government staffing process was a challenge to the achievement of results at Health Canada. It took more than two years for Health Canada to hire the 22 specialized scientific evaluators funded under the MOU with AAFC. Staffing was hindered by departmental collective staffing processes and the scarcity of candidates with the necessary specialized expertise. According to interviews, Health Canada was also concerned about hiring indeterminate staff when funding was for a specific period of time only. This same concern was raised at AAFC related to the Industry Engagement and

¹⁶ Available at: http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/health-claims_guidance-orientation_allegations-sante-eng.php

¹⁷ For more information, see Health Canada's website at: <http://www.hc-sc.gc.ca/fn-an/legislation/acts-lois/c-38-eng.php>
AAFCAAC-#3886489-V11-2012-13_OAE-EV_-_Report_-_
_EVALUATION_OF_HEALTH_CLAIMS__NOVEL_FOODS_AND_INGREDIENTS__FOOD_FORTIFICATION
_AND_VETERINARY_DRUGS_(E.DOC

Knowledge Transfer component, and speaks to the difficulty across the federal government in hiring staff for time-limited programs.

New Health Claims and Products

3.2.4 The Health Claims, Novel Foods and Ingredients initiative supported a significant increase in new health/nutrient claims and related new products during Growing Forward.

There was a significant increase in the number of approved health benefit claims during Growing Forward. New, innovative and safe food products and claims, focusing on health benefits, were an expected long-term outcome of the Health Claims, Novel Foods and Ingredients initiative. Five health claims were approved in 2010-2012, compared to no claims approved from 2004 to 2010. Health claims were approved for barley, vegetable oil, psyllium, oats and plant sterols. Other health claim submissions (e.g., soy and flax) have been submitted to Health Canada, and reviews of these submissions are ongoing.

According to interviews, Canada significantly narrowed the gap with the US in the number of approved health claims, particularly related to cardiovascular health. It was also noted that the language allowed on labels related to health claims in Canada is clearer and more consumer-friendly than that allowed in the US.

According to tracking and monitoring activities undertaken by FRID, as of September 2012, there were 63 product launches related to health claims approved during Growing Forward.¹⁸

3.3 PERFORMANCE – EFFICIENCY AND ECONOMY

The efficiency/economy of the Health Claims, Novel Foods and Ingredients initiative was assessed through examination of the extent to which project funds were spent as planned.

3.3.1 AAFC funding was lapsed, particularly in the early years of the Health Claims, Novel Foods and Ingredients initiative.

As shown in Table 6, the Science Substantiation component lapsed its first year of funding for 2008-2009. According to program officials, this was a result of the program funding being approved late in that fiscal year.

¹⁸ This does not include store brands (e.g. President's Choice), for which data are not available
AAFCAAC-#3886489-V11-2012-13_OAE-EV_-_Report_-_EVALUATION_OF_HEALTH_CLAIMS_NOVEL_FOODS_AND_INGREDIENTS_FOOD_FORTIFICATION_AND_VETERINARY_DRUGS_(E.DOC

In addition, the Industry Engagement and Knowledge Transfer component underspent by nine percent of its total budget for the period from 2008-2009 to 2011-2012, primarily as a result of the time required in the first years of the initiative to reach full staffing capacity.

Table 6: Industry Engagement and Knowledge Transfer and Science Substantiation Budget, Expenditures and Variances, 2008-2009 to 2011-2012			
Fiscal Year	Budget	Actual Expenditures	Variance (% of Budget)
\$ millions			
Industry Engagement and Knowledge Transfer			
2008-2009	1.2	1.1	0.1 (9%)
2009-2010	2.0	1.6	0.4 (20%)
2010-2011	2.0	1.9	0.1(3%)
2011-2012	2.0	1.9	0.1 (4%)
Total	7.2	6.5	0.7 (9%)
Science Substantiation			
2008-2009	0.9	0.0	0.9 (100%)
2009-2010	2.0	1.9	0.1 (3%)
2010-2011	2.0	2.0	0.0 (2%)
2011-2012	2.0	2.1	(0.1) (+5%)
Total	6.9	6.0	0.9 (13%)

In conclusion, funding was lapsed for both components of the initiative, particularly during the early years of the initiative.

4.0 FOOD FORTIFICATION – EVALUATION FINDINGS

4.1 RELEVANCE

4.1.1 There was a need for temporary regulatory measures when changes to regulations governing food fortification did not proceed.

Funding under Growing Forward was needed to address the issue of regulating discretionary food fortification. Consultations with industry prior to Growing Forward highlighted concerns that delays in permitting food fortification were hindering competitiveness. The agri-food industry was not able to market in Canada new and innovative products fortified with vitamins and minerals and harness the associated market opportunities.

Under Growing Forward, funding was originally earmarked for CFIA to contribute to the cost of enforcing proposed Health Canada regulatory amendments to permit discretionary food fortification. The funding was originally earmarked for hiring and training new CFIA inspectors, and building the processes and scientific capacity to test fortified foods for compliance with proposed regulations. However, as a result of concerns expressed by health and consumer stakeholders, in 2009 Health Canada decided not to proceed with the regulatory amendments for discretionary food fortification and, instead, to undertake further consultation on the issue. However, Health Canada offers industry the opportunity to obtain temporary authorization for fortified foods. As a result, Growing Forward funding was needed for Health Canada, rather than CFIA, in order to implement this interim approach to regulating food fortification.

A Temporary Market Authorization (TMA) allows for a food to be marketed and sold in Canada prior to a regulatory amendment.¹⁹ The purpose of a TMA is to generate “in-market” data to inform regulatory amendment. The food must meet specific conditions, and the manufacturer or distributor must sign a Letter of Agreement setting out, among other requirements, the data to be provided to Health Canada during the period of authorization.

In addition to facilitating the regulation of new foods, the use of TMAs provided a temporary solution for products that had been regulated under the *Natural Health Products Regulations* but would no longer be categorized as Natural Health Products in 2013. Hundreds of products were reclassified as foods as a result of regulatory changes, and many, including energy drinks and energy bars, required food fortification-related Temporary Market Authorization Letters (TMALs) in order to remain on the market.

¹⁹ For more information, see Health Canada’s General Guidance Document for Temporary Market Authorization of Foods at <http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/food-market-author-marche-aliment-eng.php#a12>
AAFCAAC-#3886489-V11-2012-13_OAE-EV_-_Report_-_EVALUATION_OF_HEALTH_CLAIMS_NOVEL_FOODS_AND_INGREDIENTS_FOOD_FORTIFICATION_AND_VETERINARY_DRUGS_(E.DOC

To support the use of TMALs, Health Canada required additional funding for the provision of staff to review TMAL applications and provide guidance to industry. Health Canada also required funding to obtain the health and consumer behaviour data required to examine the potential impact of food fortification on consumers. These data allowed Health Canada to examine the potential health impact of food fortification based on food characteristics and the food choices of Canadian consumers. Funding was also intended to support Health Canada in determining the best approach for regulating fortified foods in the long term.

In conclusion, funding from Growing Forward was needed to assist Health Canada to implement temporary authorization of discretionary food fortification. Permitting food fortification was a priority for food processors and supported industry competitiveness.

4.2 PERFORMANCE

4.2.1 The Food Fortification component helped Health Canada begin to lay the groundwork for interim authorization of innovative fortified foods.

Growing Forward funding was used to build the capacity and information base at Health Canada to authorize fortified foods on an interim basis. Four FTEs were trained and dedicated to the issuance of food fortification TMALs and a Standard Operating Procedures Manual was developed. Further, the program developed and circulated guidance documents on TMAL requirements for foods and caffeinated energy drinks. Significant resources have also been dedicated to purchasing, compiling and analysing data related to food nutrients, food consumption patterns and nutrient status of Canadians. These data included information from the Canadian Nutrient File and the Canadian Health Measures Survey.

During 2011-2012, 14 submission packages were received from industry, for a total of 86 individual products. TMALs were issued for two submission packages (four products), and others were drafted or in process.

In winter 2012, Health Canada noted that approximately 400 new submissions had been received and were being processed by the department. This large spike in industry submissions was due to the regulatory transition of products from NHPs to foods. According to interviews with Health Canada, all of the groundwork that had been done in previous years of the program allowed them to prepare for this surge of submissions.

Finally, at the time of the evaluation, work at Health Canada related to developing the long-term path forward for food fortification policy was ongoing. Internal and external consultations were continuing, and policy options were being developed.

In conclusion, funding for food fortification supported the issuance of TMALs for new fortified foods during Growing Forward and the ongoing transition of fortified products from the regulatory framework of Natural Health Products to that of foods.

5.0 VETERINARY DRUGS – EVALUATION FINDINGS

5.1 RELEVANCE

5.1.1 Access to veterinary drugs is important for the competitiveness of the livestock sector. There was a need to improve the regulatory framework for veterinary drugs, which had been identified as a barrier to competitiveness prior to Growing Forward.

Producer access to a range of veterinary drugs is important to maintaining the health of livestock and the financial viability of livestock operations. Prior to Growing Forward, the livestock industry voiced concerns with the lengthy approval times for veterinary drugs in Canada, and with the availability and cost of veterinary drugs in Canada compared to those in the US. Stakeholders believed these issues were negatively affecting the competitiveness of the Canadian livestock sector.

Issues with the regulatory framework had resulted in backlogs of veterinary drug submissions at Health Canada: at the start of 2008-2009, there were 133 submissions awaiting review at the department. While the backlog was cleared by the end of that fiscal year, action was needed to avoid future backlogs developing during Growing Forward. Furthermore, Health Canada was slow in reviewing veterinary drug submissions. Review times prior to Growing Forward had exceeded 1,000 days for new and generic drug submissions. Improved regulatory processes were needed to make the review process predictable, transparent and timely.

Activities were also targeted to improving the regulatory framework for generic and Minor Use Minor Species (MUMS) veterinary drugs. Prior to Growing Forward, Health Canada had not received significant numbers of submissions for generic and MUMS drugs. Generic drugs are important to industry because they are cheaper for producers. MUMS veterinary drugs target types of livestock (such as sheep and goats) or health issues for which there is not a range of veterinary drugs as it is not financially viable for drug sponsors to obtain the necessary regulatory approvals. Funding to Health Canada was designed to attract a larger number of generic and MUMS drug submissions through improvements to the regulatory policy and guidelines.

Finally, the Veterinary Drugs Program supported activities related to harmonizing Canadian standards and regulatory requirements with international bodies. Harmonization activities were important to ensuring Canadian regulatory requirements were not a barrier to competitiveness, trade and investment.

Health Canada needed funding through Growing Forward to undertake activities that, while not critical to its primary mandate of ensuring human health, were part of its role as regulator of veterinary drugs and were AAFC priorities. As noted in interviews, the types of drug submissions received, and the review times of submissions, are of secondary concern to Health Canada as long as human health is not at risk. AAFC funding through Growing Forward was designed to assist Health Canada to implement changes to ensure the regulatory framework was not a hindrance to the competitiveness of the agricultural sector. Specifically, Growing Forward provided the Veterinary Drugs Directorate with funding to temporarily support additional capacity for submission reviews and policy development.

In conclusion, Growing Forward funding was needed to support the competitiveness of the livestock industry by contributing to improvements related to review times, the availability of veterinary drugs including MUMS and generic drugs, and international harmonization of regulatory standards.

5.2 PERFORMANCE

5.2.1 The Veterinary Drugs component has reduced review times for veterinary drugs, and increased the availability of veterinary drugs for food producing animals in the Canadian market.

Reduction in Review Times

Review times for veterinary drug submissions improved during Growing Forward. Review times for New Drug Submissions (NDSs) (i.e., for submissions that are not for generic drugs) were reduced from 1,115 days in 2009-2010, to 434 days in 2010-2011 and 657 days in 2011-2012. The increase in review times in 2011-2012 was said to have occurred as a result of a surge of submissions from industry during the previous year. The program has targeted a 600-day review time by March 2013.

Review times for generic drug submissions were similarly reduced from 1,119 days in 2008-2009 to 389 days in 2011-2012. The target is a 360-day review time by March 2013.

A 2011 survey conducted for the International Federation for Animal Health—an international organization representing companies producing

veterinary drugs—confirmed that between 2006 and 2011 the management of submissions improved at Health Canada, and review times declined.²⁰

Health Canada reported that no backlog in submissions accumulated throughout Growing Forward, despite a considerable jump in new submissions during 2010-2011.

Increased Availability of Veterinary Drugs

During Growing Forward there was a considerable increase in the number of veterinary drugs for food producing animals in Canada. Thirteen generic veterinary drug submissions were received from April 2009 to September 2012, which exceeded the program's target of five generic submissions by the end of March 2013. In addition, Health Canada indicated that it approved 30 NDSs between April 2008 and November 2012.

However, the program did not appear likely to reach its target of five new MUMS drug submissions by March 31, 2013. At the time of the evaluation, only one MUMS submission had been received. This submission had been reviewed and a Notice of Compliance issued.

Health Canada indicated that it had done what it could within its mandate to encourage MUMS submissions. For example, the Veterinary Drugs Directorate undertook free pre-submission consultations with industry, and informed stakeholders of the reduced fee status based on anticipated sales volumes of veterinary drugs. Health Canada indicated that a MUMS support program similar to the Minor Use Pesticides Program of AAFC and Health Canada may be a potential future solution to the limited MUMS veterinary drugs approved in Canada. A similar program targeted to veterinary drugs is in place in the USA, funded by the US Department of Agriculture.

Other policy and framework enhancements were undertaken at Health Canada to support increased veterinary drug submissions in the future, including:

- Generic Drug Guidelines were finalized and implemented in April 2010.
- An interim Horse as a Food Producing Animal Policy was drafted.
- A Labelling Policy was drafted.

²⁰ Biobridge Ltd., 2012. International Federation of Animal Health Global Benchmarking Survey 2011 – Canada. <http://www.cahi-icsa.ca/uploads/UserFiles/files/IFAH%20Benchmarking%20Survey%20-%20Final%20Report%202011.pdf>
AAFCAAC-#3886489-V11-2012-13_OAE-EV_-_Report_-_EVALUATION_OF_HEALTH_CLAIMS__NOVEL_FOODS_AND_INGREDIENTS__FOOD_FORTIFICATION__AND_VETERINARY_DRUGS_(E.DOC)

International Harmonization and Collaboration

The Veterinary Drugs program resulted in closer harmonization with the US of the technical requirements of veterinary drug approvals. Data standards have now been sufficiently harmonized to facilitate the implementation of a new pilot project through the Regulatory Cooperation Council Veterinary Drug Parallel Review initiative. The pilot project is undertaking a parallel (Health Canada and the US Food and Drug Administration (FDA) Center for Veterinary Medicine) review of a veterinary drug for a food producing animal and examining issues related to harmonizing Maximum Residue Limits (MRLs) between the two countries.²¹ The Veterinary Drugs program also established Canadian MRLs for 25 drug entities that have US MRLs, exceeding the target of three per year.

Furthermore, Health Canada is sharing information on pre- and post-market surveillance with international counterparts in the US, European Union, Australia, and New Zealand, and is working on optimizing the use of international regulatory information (such as review reports) to support its reviews of submissions.

In conclusion, the Veterinary Drugs Program reduced review times during Growing Forward and increased the availability of veterinary drugs in Canada, although the program has not seen the targeted number of MUMS submissions to date. Health Canada and the US FDA through the RCC are developing mechanisms to promote simultaneous applications with the ultimate goal of simultaneous market access.

²¹ The pilot project also featured Health Canada using, for the first time, a “rolling submission” process as is used in the US, whereby residue and efficacy test results are submitted as they become available, rather than all at once.
AAFC AAC-#3886489-V11-2012-13_OAE-EV_-_Report_-_EVALUATION_OF_HEALTH_CLAIMS_NOVEL_FOODS_AND_INGREDIENTS_FOOD_FORTIFICATION_AND_VETERINARY_DRUGS_(E.DOC

6.0 GOVERNANCE AND PERFORMANCE MEASUREMENT – EVALUATION FINDINGS

6.1 The governance structure, including the Joint Management Committee and MOU, was effective in ensuring accountability and achievement of results.

Across all three initiatives, the governance structure—including the Joint Management Committee and the MOUs—was felt to have been a highly effective aspect of the Regulatory Action Plan.

With respect to the Joint Management Committee, the level of participation, the continuity of membership, and FRID’s overall secretariat role were all identified as key strengths. Those interviewed agreed that having the Joint Management Committee function at the Director General-level, with regular reporting to ADMs, was appropriate, and participants were able to use the meetings for effective information sharing and problem-solving. This ability to problem-solve was evidenced in the change of approach developed for the Food Fortification program when expected regulatory amendments did not proceed at Health Canada. Furthermore, the membership of the Joint Management Committee did not change during Growing Forward, which facilitated the development of trust and strong working relationships between members. It was also noted that FRID had effectively organized Joint Management Committee meetings and interdepartmental reporting. All these elements fostered a structured and positive relationship between AAFC and Health Canada.

The transfer of funds via the MOUs was regarded as an effective means of ensuring that funding to Health Canada was dedicated to Growing Forward priorities. Each department was accountable under the MOU for specific activities and results, and inter-departmental reporting was undertaken on a semi-annual basis in advance of Joint Management Committee meetings. A year-end report was submitted to ADMs and DMs, including a recommendation on the transfer of annual funding from AAFC to Health Canada.

It was noted in interviews that the governance structure and funding mechanism could serve as effective models for future inter-departmental initiatives.

6.2 Performance measurement and reporting would have benefited from a stronger focus on outcomes.

While a performance measurement strategy had been developed for all three initiatives, actual ongoing performance measurement and reporting would have benefited from a stronger focus on outcomes. Formal reports to the JMC focused largely on detailing activities undertaken by the initiatives, and did not comprehensively report on results achieved based on the outputs and outcomes defined in the performance measurement strategies. It was noted that Joint Management Committee meetings did, however, provide opportunities for discussion on progress towards outcomes.

In addition to the formal reporting to the Joint Management Committee and through this evaluation, AAFC senior management have indicated interest in developing a final performance report to document all achievements of the Regulatory Action Plan following the end of Growing Forward.

In conclusion, the MOU and funding mechanism were felt to have been effective in ensuring accountability and achievement of results, and could serve as future models for similar inter-departmental initiatives. Performance measurement strategies were developed for all initiatives, but reporting to the Joint Management Committee was largely activity-based rather than outcome-based.

7.0 CONCLUSIONS AND RECOMMENDATIONS

7.1 CONCLUSIONS

Health Claims, Novel Foods and Ingredients

The program theory of Health Claims, Novel Foods and Ingredients was sound as the evaluation found there was a need to reduce regulatory impediments and help build industry capacity in navigating and meeting the requirements of the regulatory system. Health claims have been proven to foster industry competitiveness, but there was broad agreement across all lines of evidence that there were regulatory impediments to the introduction of foods with health benefits. The initiative was targeted at major areas that could be addressed by AAFC and Health Canada.

Since Growing Forward began, some regulatory impediments have been reduced, and industry stakeholders have built capacity in navigating the regulatory system, particularly among larger organizations.

The Health Claims, Novel Foods and Ingredients initiative was aligned with federal priorities related to reducing regulatory barriers to competitiveness, and with departmental strategic outcomes of competitiveness and innovation.

AAFC's role during Growing Forward in helping industry to build its own regulatory navigation capacity was appropriate. Science and Technology Branch has conducted foundational research on health benefits of foods in the past, but has limited capacity to deal with the complex requirements and issues involved in conducting human clinical trials. AAFC was well-placed to assist industry in strengthening its own capacity in regulatory navigation during Growing Forward. While AAFC's S&T Branch has undertaken foundational research on food-health linkages, it is not as well-placed to conduct human clinical trials.

AAFC provided industry with effective guidance and information on health claims, which improved the number and quality of submissions. The stakeholder survey, interviews, and case studies all support the conclusion that FRID has effectively assisted industry in improving its navigation of the regulatory system and the quality of its submissions.

The Science Substantiation component developed domestic and international networks to address research gaps related to food-health linkages. While it is too early to assess the extent to which the research

will support future health claims, a case study demonstrated how S&T Branch research has supported health claim submissions in the past. Nine ongoing research projects examining food-health linkages are currently underway. The Science Substantiation component addressed limitations in the AAFC research project selection process.

The Regulatory Enhancement component improved regulatory processes during Growing Forward. Regulatory enhancement at Health Canada was noted in three areas: increased capacity during Growing Forward, improved processes for health claim submissions, and an improved legislative framework, including allowing the Health Canada Minister authority to approve regulatory amendments. The extent to which the increased capacity can be sustained beyond Growing Forward is not known.

The Health Claims, Novel Foods and Ingredients initiative has supported a significant increase in new health/nutrient claims and related new products. Five health claims were approved during 2010-2012, and there were over 60 product launches related to health claims.

AAFC funding was lapsed for the initiative, especially in the early years of Growing Forward.

Food Fortification

There was a need for temporary regulatory measures when changes to regulations governing food fortification did not proceed. Health Canada required funding to support the issuance of TMALs for interim measures to allow foods fortified with vitamins and minerals on the market until longer-term regulatory approach is developed. Funding was needed for staff and to build policies and data to support TMAs, as well as to continue food fortification-related consultations and analysis.

The Food Fortification component helped Health Canada begin to lay the groundwork for interim authorization of innovative fortified foods. Submission packages for TMAs were being reviewed, and the need to transition foods that had been formerly categorized as Natural Health Products to food regulations had sparked hundreds of new submissions in 2012-2013. A long-term path forward for food fortification policy and regulation is still being developed.

Veterinary Drugs

Access to veterinary drugs is important for the competitiveness of the livestock sector. There was a need to improve the regulatory framework for veterinary drugs, which had been identified as a barrier to competitiveness prior to Growing Forward. Prior to Growing Forward, lengthy review times and significant backlogs were common at Health Canada for veterinary drug submissions.

The Veterinary Drugs component reduced review times for veterinary drugs during Growing Forward, and increased the availability of veterinary drugs for food producing animals in the Canadian market. The program has exceeded its targets for submissions for new drugs, generics, although it has received only one MUMS submission to-date. Health Canada has also undertaken significant activities related to harmonization of submission reviews and MRL calculations with its American counterparts in the US Food and Drug Administration Center for Veterinary Medicine.

Regulatory Action Plan Governance and Performance Measurement

The governance structure, including the Joint Management Committee and MOU, was effective in ensuring accountability and achievement of results. Performance measurement would have benefited from a stronger focus on outcomes. It was noted that the governance structure and funding mechanism could serve as effective models for future inter-departmental initiatives.

7.2 RECOMMENDATIONS

The evaluation identifies the following two recommendations:

Recommendation #1:

Science and Technology Branch should:

- Review the alignment of research involving human clinical trials with AAFC's mandate, priorities and capacity, and report back to senior management at S&T Branch with a recommendation on whether the department should continue in this area.

Recommendation #2:

Science and Technology Branch should:

- Ensure that multiple partners across AAFC branches are involved in the process for identifying AAFC research priorities and gaps in order to align AAFC research activities with areas of greatest priority for the department.

APPENDIX A: MANAGEMENT RESPONSE AND ACTION PLAN

RECOMMENDATION	MANAGEMENT RESPONSE AND ACTION PLAN (MRAP)	TARGET DATE	RESPONSIBLE POSITION(S)
<p>1. Science and Technology Branch should review the alignment of research involving human clinical trials with AAFC's mandate, priorities and capacity, and report back to AAFC senior management with a recommendation on whether the department should continue in this area.</p>	<p>Agree. Science and Technology Branch (STB) will review the alignment of its research involving human clinical trials and report back to senior management on the future role of the branch with respect to those trials.</p>	<p>April 1, 2014</p>	<p>DG, Cross-Sectoral, S&T Branch</p>
<p>2. Science and Technology Branch should ensure that multiple partners across AAFC branches are involved in the process for identifying AAFC research priorities and gaps in order to align AAFC research activities with areas of greatest priority for the department.</p>	<p>Agree. STB is developing a long-term direction for science and technology and developing Portfolio Strategies to govern sector-specific and cross-cutting science direction. It is engaging SPB, MISB and Programs Branch to ensure perspectives from these branches are considered in the development of the strategic direction and sector specific objectives and to identify gaps.</p>	<p>April 1, 2014</p>	<p>DG, Cross-Sectoral, S&T Branch</p>