MEMORANDUM OF UNDERSTANDING

between

Agriculture and Agri-Food Canada (AAFC)
(represented by the Deputy Minister of Agriculture)

and

Health Canada (HC)
(represented by the Deputy Minister of Health)

Pertaining to:

Initiatives being developed in accordance with *Growing Forward*, the next generation of agricultural policy. These initiatives will address regulatory impediments that impact various sectors' capacity to innovate and remain competitive in the marketplace.

1.0 OBJECTIVES

1.1 The objective of this Memorandum of Understanding (MOU) is to set out working relationships, performance indicators, funding agreements, and reporting structures between Health Canada (HC) and Agriculture and Agri-Food Canada (AAFC) on the following projects:

(a) Improving access to minor-use and reduced risk pesticides;
(b) Improving regulatory responsiveness in the area of health claims, novel foods, and ingredients; and
(c) Improving access to veterinary drugs for Canadian livestock producers.

1.2 The objectives of this MOU are supportive of the "Competitiveness and Innovation" theme of *Growing Forward*, and in particular, support the goals of collaborating with partners to find ways of minimizing the regulatory burden on producers, processors, and other stakeholders by taking targeted action to address specific priorities, while at the same time maintaining a strong regulatory system.

2.0 BACKGROUND

2.1 The Federal Government has recognized the important role that the regulatory environment plays in protecting public safety, promoting health and sustaining economic well-being. Accordingly, the 2007 *Cabinet Directive on Streamlining Regulation* (CDSR) commits the Government to developing a more effective,

efficient, transparent, and accountable regulatory system that protects and advances the public interest while promoting a fair and competitive market economy that encourages entrepreneurship, investment, and innovation.

2.2 Consultations with industry on the next generation of agricultural policy suggest that Canada's regulatory environment is impeding sector investment, innovation and competitiveness. Stakeholders feel that Canada has fallen behind other countries in approving pesticides, veterinary drugs, novel foods, food ingredients, and health claims. Canadian producers and processors are thus not able to compete on the same playing field as their major competitor countries.

2.3 Stakeholders cite problems with unclear and inconsistent regulatory requirements, slow and non-transparent decision-making, insufficient alignment between international and domestic regulatory/standards/policies, and an outdated system that is not responsive to change and rapidly evolving technology. In addition, the sector itself has limited understanding of the regulatory submissions process and requirements, and lacks a coordinated approach to developing priorities. The level of cost, coordination and expertise associated with scientifically substantiating a regulatory submission can also be an impediment. These factors have underscored the need to build industry, scientific and government regulatory system capacity, and to modernize the current Canadian regulatory environment.

2.4 Regarding pesticides, AAFC renewed its commitment through *Growing Forward* to continue supporting improved grower access to minor use pesticides through the Pest Management Centre. During the *Growing Forward* consultation process, stakeholders gave positive feedback on the activities of the Pest Management Programs of the Agricultural Policy Framework. The programs were established in 2003 in response to a number of concerns over pesticide use and regulation in Canada. Some of these concerns include: the availability of information related to pesticide regulation and use, long-term impacts and safety of pesticides, and availability and access to minor use and reduced-risk pest management tools. The Pesticide Risk Reduction Program has on-going, A-base funding under the "Building Public Confidence in Pesticide Regulation" (BPC) Memorandum to Cabinet and is not included in the body of this MOU. However, due to the highly complementary and integrated nature of the two pest management programs, the details pertaining to the Pesticide Risk Reduction Program are included in Annex D of this MOU.

2.5 In terms of health claims, novel foods, and ingredients, there is evidence that the Canadian agriculture and food industry needs practical support and services for innovation and competitiveness within a science-based regulatory system. Industry engagement and knowledge transfer are needed to: facilitate, in collaboration with the sector, the collection, interpretation and documentation of

information for determining plans/priorities and developing submissions; put together high quality and complete submissions for priority ingredients and claims; and build ongoing regulatory-navigation ability and leadership for the future. Science substantiation is needed to fill critical gaps in evidence required for novel ingredient safety and health claim validity; and, a strategic approach is needed to leverage AAFC's in-house scientific expertise and collaborative public-private research and international partnerships. Furthermore, aspects of the regulatory system itself need enhancement to improve processes and address existing bottlenecks, and facilitate the development of policy frameworks, standards and regulations that respond to technological advancements and innovative products while maintaining the health and safety of Canadians. The *Growing Forward* initiative will address these challenges through a suite of industry engagement and knowledge transfer, science substantiation, and regulatory enhancement activities.

2.6 Regarding veterinary drugs, expert consultations with stakeholders have identified areas in which the regulatory framework needs improvement to support innovation for the industry, as well as the competitiveness of the livestock sector. Consultations revealed industry's concerns that lengthy approval times for new veterinary drugs mean that drugs that are readily available in the U.S. are not available for use to Canadian producers. According to the International Federation of Animal Health report, regulatory risk assessment and management on a group of four archetype pharmaceutical products takes 2 years in Europe, whereas the average is 5.0-8.5 years in Canada. In response, *Growing Forward* will address these concerns through plans for closer harmonization of technical requirements for veterinary drug approvals and a timelier and more transparent process to improve the sector's competitiveness by increasing the availability of newer and more effective drugs to Canadian livestock producers.

3.0 PURPOSE

3.1 This MOU sets out the general terms, roles and responsibilities for AAFC and HC respecting the management of the joint initiatives to:

3.1.1 Improve access to new minor uses of pesticide products for the agriculture and agri-food sector;

3.1.2 Develop and implement an integrated suite of industry engagement and knowledge transfer, science substantiation, and regulatory system enhancement activities to address regulatory barriers to food innovation by the agriculture and agri-food sector, commencing with a focus primarily on health claims, novel foods, and ingredients;

3.1.3 Increase the availability of veterinary drugs for food producing animals in the Canadian market by providing a regulatory environment that encourages drug companies to submit for approval, new and generic veterinary drug submissions for food producing animals.

3.2 The three initiatives jointly aim at collaborating with partners to enhance the regulatory environment to more rapidly respond to advances in food technology and food product innovation, access to veterinary drugs, and minor use pesticides, and increasing public and stakeholder confidence through transparent and timely regulatory decision-making.

3.3 The initiatives are part of the Federal Government's commitments as outlined on the Treasury Board Submission "*Improving Innovation and Competitiveness in the Agricultural Sector through Regulatory Process Enhancements*". This MOU provides further detail regarding the commitments made by AAFC and HC in the Treasury Board Submission.

4.0 RESULTS/OUTCOMES

4.1 The initiatives fall under three activity areas and will benefit the public and stakeholders by achieving the results and outcomes as shown Tables 1-3 herein. The activities that fall under each area are detailed in Section 7 (Program Delivery) of this MOU.

Table 1. Outputs and Outcomes by Activity Area: Pest Management Programs (Minor Use Pesticide Program)

Activities	Outputs	Intermediate Outcomes	End Outcome
Identifying and prioritizing pest management needs	List of pest management priority projects selected Regulatory data packages and decisions for new minor uses of pesticides	Improved pesticide resistance management Improved crop protection practices	Improved competitive parity of agriculture and agri-food sector with regard to pest management
Literature searches, data generation, regulatory and outreach activities			
Compiling data, drafting final reports and assembling regulatory submissions			
Reviewing minor use regulatory submissions			

Table 2. Outputs and Outcomes by Activity Area: Health Claims, Novel Foods, and Ingredients Initiative

Activity Area	Outputs	Intermediate Outcomes	End Outcomes
Working with industry, research and regulatory communities to facilitate information collection, analysis and exchange	Regulatory-issue/impact documents Plans/priorities for claims and ingredients Literature reviews, research-gap lists Meetings, commentary Workshops, web sites	Complete and substantiated sector regulatory submissions Modernized and efficient policy and regulatory approaches and pre-market processes	Enhanced sector ability to navigate the regulatory system New, innovative and safe food products and claims, focusing on health benefits
Undertaking and coordinating collaborative scientific research	Domestic and international science networks Data and evidence to address priority knowledge gaps		
Developing and implementing targeted food policies, regulations and pre-market processes	Policies, regulations and pre-market processes Manuals, consultations, work-sharing agreements, reports		

Table 3. Outputs and Outcomes by Activity Area: Veterinary Drugs Initiative

Activity Area	Outputs	Intermediate Outcome	End Outcome
Regulatory harmonization initiatives with international regulatory agencies	Prioritized list of approved drug entities with US MRLs requiring Canadian MRLs Information and guidance for industry Enhanced policies, guidelines and regulatory frameworks	Increased availability of generic and MUMS veterinary drugs for food producing animals in the Canadian market --	Reduction in the end-to-end review time of veterinary drug submissions Increased availability of veterinary drugs for food producing animals in the Canadian market
Improving the generic veterinary drug regulatory process			
Improving the veterinary new drug regulatory process			
Developing Minor Uses and Minor Species (MUMS) policy to facilitate the regulatory process			
MUMS pilot program			

4.2 The results (outputs) of the initiatives and how they are expected to lead to the achievement of the expected outcomes are illustrated in the three logic models in Annex B. These logic models will form the basis for the selection of performance indicators and the foundation for ongoing performance measurement, evaluation and accountability.

4.3 Performance in achieving the results and outcomes will be measured using the indicators identified in Annex C. Approval of any significant changes to the performance measures will be sought from HC and AAFC's Deputy Ministers as stated in section 8.1.1, of this MOU. As well, the whole program will be systematically evaluated at the end of Year 3 and Year 5, and reported on, as described in Sections 9 and 14 of this MOU.

4.4 For detailed performance indicators, please refer to Annex C.

5.0 FUNDING

5.1 The total amount of funding of $104.3 M is provided under the *Growing Forward* Policy Framework for the three initiatives described in the subsection 7.0 of this MOU, over the period of five years starting April 1, 2008. The funding amount includes the following:

5.1.1 $38.3 M for the initiatives to be implemented by Health Canada over the period of five years starting April 1st, 2008, with $16.0 Million for the activities stipulated in the subsection 7.1 and specified in the Annex A to this MOU, $17.3 Million for the activities stipulated in the subsection 7.2 and specified in the Annex A to this MOU, and $5.0 Million for the activities stipulated in the subsection 7.3 and specified in the Annex A to this MOU.

5.1.2 $18.1 M for the activities in the area of Health Claims, Novel Foods, and Ingredients to be implemented by AAFC, as stipulated in the subsection 7.2 and specified in the Annex A to this MOU; and

5.1.3 $39.8 M for the activities in the area of Minor Use Pesticides to be implemented by AAFC, as stipulated in the subsection 7.2 and specified in the Annex A to this MOU.

5.2 Annual allocations of funding per department per initiative per year are specified in Annex A to this MOU. Each of the two participants to this MOU will prepare expenditure reports, as stipulated in section 8.4, and ensure financial controls for the initiatives of this program. Each Department will be responsible and

accountable for the decisions made about their respective funding. Any lapsed funds would need to be identified in writing to AAFC by September 1st.

5.3 Funding allocated to Health Canada under *Growing Forward* and stipulated in subsection 8.1 of this MOU will be transferred to Health Canada in the Supplementary Estimates process, following the AAFC/HC Deputy Ministers' Committee decision based upon the recommendations of the AAFC/HC Assistant Deputy Ministers' Committee based upon the AAFC/HC Joint Management Committee, as stipulated in subsections 8.1, 8.2 and 8.3. Funding decisions will be made before the start of each fiscal year.

6.0 PRINCIPLES

6.1 AAFC's mandate to build a competitive and profitable sector on a foundation of innovation will be respected as well as its mandate to provide information, research and technology, and policies and programs to achieve security of the food system, health of the environment and innovation for growth will be respected.

6.2 HC's mandate to help Canadians maintain and improve their health while respecting individual choices and circumstances will be respected.

6.3 The mandate of Health Canada's Pest Management Regulatory Agency as defined in the *Pest Control Products Act* (PCPA), will be respected. It consists of a primary objective to prevent unacceptable risks to people and the environment from the use of pest control products.

6.4 The commitments made in the Treasury Board submission (2002) entitled Building Public Confidence in Pesticide Regulation and Improving Access to Pest Management Products and associated Results-based Management and Accountability Framework (RMAF) will be respected.

6.5 The commitments made in the Government Response to the Report of the House of Commons Standing Committee on Agriculture and Agri-Food, Registration of Pesticides and the Competitiveness of Canadian Farmers (2002) will be respected.

6.6 The commitments made in the Government Response to the Report of the House of Commons Standing Committee on the Environment and Sustainable Development, Pesticides: Making the Right Choice for the Protection of Health and the Environment (2001) will be respected.

6.7 HC's commitments under the 2006 Blueprint for Renewal II: Modernizing Canada's Regulatory System for Health Products and Foods will be respected.

6.8 The commitments made by Government in the Cabinet Directive on the Environmental Assessment of Policy, Plan and Program Proposals (2004), will be respected.

6.9 The commitments made in the Cabinet Directive on Streamlining Regulation (2007), will be respected.

6.10 The principles, goals and objectives of *Growing Forward* will be respected.

6.11 As far as is possible under applicable law, HC and AAFC commit to sharing information arising from activities covered by this MOU, particularly so as to enhance the development of policy frameworks, standards and regulations; and to make pre-market approval and review processes more predictable, transparent and timely, and to these ends:

(a) HC will collect, and share with AAFC, information from third parties by securing the consent of such third parties for such sharing;

(b) AAFC and HC each undertake to fully maintain, respect, and protect the confidentiality of the information received under this MOU. Therefore, each participant ensures that:

(i) any disclosed information will only be used to achieve the objectives stated in section 1.0 or for a purpose authorized by applicable access to information and privacy statutes, and in accordance with applicable privacy, security and retention guidelines and policies. Should either participant desire to use the information disclosed under this agreement for other purposes, a written request must be forwarded to the other participant. If deemed acceptable by both participants, the MOU will be amended.

(ii) access to any disclosed information will be limited to only those employees who require access for the purposes listed in (i).

(c) The information disclosed under this MOU shall be administered, maintained, destroyed, or disposed of in accordance all applicable federal statutes and guidelines including the Privacy Act, National Archives of Canada Act, and the Privacy and Data Protection Policy, the Management of Government Information Policy and the Government Security Policy.

(d) The information management arrangements of each participant must be sufficient to ensure the confidentiality and integrity of information covered under

this MOU, and to safeguard the information against accidental or unauthorized access, disclosure, use, modification and deletion. Each participant will use a system that is effective in identifying who is accessing the personal information in its custody, in order to establish a chain of responsibility.

6.12 Funding for the new initiatives described in this MOU will be for activities to achieve the specified results/outcomes. Both participants are responsible for adhering to this principle and for providing an annual confirmation to this effect.

6.13 Due to the timing of the coming into force of this MOU and with respect to the fiscal year 2008-2009, the participants acknowledge that lack of timely reporting on the 2008-09 results should not preclude the ordinary release of the 2009-2010 funds relating to the health claims, novel foods and ingredients initiative. For greater clarity, the participants agree that 2009-2010 funds will not be prevented from flowing solely due to lack of adequate reporting under section 8 "Governance" for the health claims, novel foods and ingredients initiative.

7.0 ROLES, RESPONSIBILITIES AND PROGRAM DELIVERY

AAFC and HC will undertake the following three initiatives. The funding allotted to each initiative is shown in Annex A.

7.1 Pest Management Programs

AAFC-PMC (Pest Management Centre) and HC-PMRA (Pest Management Regulatory Agency) will continue working together fostering strong working relationships that will enhance the delivery of the Minor Use Pesticide Program and the Pesticide Risk Reduction Program (refer to Annex D for details on the Pesticide Risk Reduction Program), and informing each other on national and international activities and other initiatives in which either organization is participating that may affect the joint program or the programs and mandate of the other.

Minor Use Pesticide Program

A. Both AAFC-PMC and HC-PMRA recognize that stakeholder input is critical in identifying the needs for minor uses of pesticide products in Canada, and in determining the priorities for the minor-use initiatives. AAFC-PMC and HC-PMRA commit to improve access to new minor uses of pesticide products by undertaking the following activities.

B. AAFC-PMC and HC-PMRA will work with stakeholders to build awareness/interest in the regulatory system and participation therein, and broker relationships that facilitate communications/information dissemination.

C. Both AAFC-PMC and HC-PMRA will share and discuss their respective work plans. These work plans will consider both internally and externally selected work that will have influence on the Minor Use Pesticide Program and the work of each other.

D. AAFC-PMC will ensure it provides quality and complete submission data packages for the registration of new minor uses of pesticide products to HC-PMRA, in accordance with the work plans that are agreed upon between AAFC-PMC and HC-PMRA. This will involve the following:

(i) Annually, through the prioritization process, AAFC-PMC will determine national priorities, liaising with HC-PMRA, international bodies such as the U.S. Inter-Regional Project 4 (IR-4) and the Environmental Protection Agency (EPA) and stakeholders. Priority setting will make use of a list of priorities determined by stakeholders.

- compile national list (annually) of pest management needs from provincially generated lists established through consultation with growers and grower groups
- make the national pest management needs list available to stakeholders
- hold an annual priority setting workshop with stakeholders (growers, registrants, HC-PMRA, U.S. IR-4) to prioritize national projects to be undertaken by AAFC-PMC
- support specific research projects including screening trials for pest problems without solutions, as determined at the annual priority setting workshop.

(ii) Annually, AAFC-PMC will participate in the U.S. priority setting process, liaising with HC-PMRA and Canadian stakeholders, in order to determine projects for joint Canada-U.S. work.

(iii) In accordance with the agreed upon work plans, AAFC-PMC and HC-PMRA will cooperatively establish a schedule for submission and review of data packages.

(iv) Conduct research, data generation, regulatory and outreach activities in order to improve access to new minor uses of pesticide products. Pesticide residue data generated for submissions will be Good Laboratory Practices (GLP) compliant. There are several phases which contribute to the conduct of data generation and regulatory review. As each project can take several years to complete, sub-activity phases can overlap during a given year.

Research Planning

Through a cooperative process AAFC-PMC will conduct searches of the scientific literature and other existing data on pesticide efficacy, tolerance of crops to pesticides and magnitude of residues on/in crops and HC-PMRA will establish data requirements to support the registration of new minor uses of pesticide products.

- prepare and share with the HC-PMRA annual work plans encompassing all activities that will have influence on the Minor Use Pesticide Program and the work of HC-PMRA;
- assign priority projects by discipline (entomology, pathology, weed science) to project coordinators and study directors;
- consult with registrants, growers, and provincial officials to obtain project support, identify contacts, and establish product use pattern;
- conduct literature searches and stakeholder consultation to gather existing data in support of priority projects;
- pull together data from literature searches and consultations and prepare preliminary data packages for review and advice by HC-PMRA (pre-submission consultation)
- prepare research authorization applications (where required) for review by HC-PMRA; and
- develop study protocols to determine pesticide efficacy, crop tolerance to pesticides, and magnitude of pesticide residues on/in crops.

Trial Assignment

AAFC-PMC has nine regional sites which provide support and conduct efficacy, crop tolerance and magnitude of residue field and greenhouse trials. These sites have capacity for approximately 2/3 of the annual trials required to generate data in support of minor use projects. The remaining trials are assigned through a

competitive process to established field trial contractors throughout Canada and the United States.

- hold an annual research planning meeting with AAFC-PMC regional research staff to assign pest management field and greenhouse trials as determined by the HC-PMRA;
- develop terms of reference seeking bids to conduct field and greenhouse trials through a competitive process for trials that cannot be conducted at AAFC-PMC research sites.

Study Conduct – Field Phase

Field and greenhouse trials to support efficacy, crop tolerance and magnitude of residue studies are conducted annually to generate data in support of regulatory submissions.

- oversee conduct of field and greenhouse trials at AAFC-PMC regional sites and contractor locations to determine efficacy, crop tolerance and magnitude of residues;
- oversee conduct of field and greenhouse residue trials at Canadian (AAFC and contractor) locations and U.S. (IR-4) locations for Canadian-led joint projects;
- conduct Quality Assurance (QA) audits (AAFC staff and contractor) to ensure Good Laboratory Practices (GLP) compliance of residue studies;
- prepare and submit pesticide efficacy, crop tolerance to pesticides, and magnitude of residue trial reports for review and approval of project coordinator and study directors;
- review and approve trial reports submitted by contractors and AAFC-PMC regional staff.

Study Conduct – Analytical Phase

Determination of the magnitude of residue trials requires laboratory analysis by a GLP certified laboratory. AAFC-PMC does not have in-house capacity for analytical studies and all work is assigned to qualified laboratories through a competitive contracting process.

- determine terms of reference seeking bids to conduct laboratory analysis to determine the magnitude of residues in/on crops for GLP residue studies;
- oversee conduct of lab analysis by contractor labs; and

- contractor labs will submit a Final Analytical Report for review and approval by study directors.

Reporting Phase

Final reports summarizing field and greenhouse trial data and laboratory data to support efficacy, crop tolerance and magnitude of residue studies will be prepared for regulatory submissions to HC-PMRA.

- pull together all efficacy, crop tolerance and magnitude of residue field and laboratory phase trial reports into final reports for each project; and
- compile all data, reports and supporting documentation and prepare regulatory packages for submission to HC-PMRA.

Quality Assurance (QA)

Pesticide regulations require that every phase and all reports generated by trials conducted to determine the magnitude of pesticide residue on/in crop samples must be audited by a qualified auditor to ensure compliance to GLP guidelines. AAFC-PMC QA staff provides QA services to all reports generated in house and conducts inspection at research sites. QA findings must be addressed and signed by management.

E. HC-PMRA will provide regulatory advice and review submissions to register new minor uses of pesticide products. This will involve:

(i) Providing pre-submission consultation to applicants seeking registration of new minor uses of pesticide products.

(ii) Screening submissions for completeness, organization and formatting to ensure that these satisfy the submission criteria.

(iii) Reviewing submissions for new minor uses of pesticide products, in accordance with the work plans that are agreed upon between AAFC-PMC and HC-PMRA. -

(iv) Coordinating with the U.S. EPA for the submission and review of joint minor use reviews.

(v) Making regulatory decisions and if the health risks, environmental risks, and value are acceptable and there is registrant support for the new minor use, registering the use.

F. To support the introduction of new minor uses of pesticide products, AAFC-PMC will continue to fund specific research projects including screening trials for pest problems without solutions.

7.2 Health Claims, Novel Foods, and Ingredients

A suite of industry engagement and knowledge transfer, science substantiation, and regulatory enhancement activities will be developed and implemented to address regulatory barriers to food innovation by the agriculture and agri-food sector, commencing with a focus primarily on health claims, novel foods, and ingredients.

Approaches will be developed to allow the work with respect to health claims, novel foods, and ingredients to be undertaken effectively in an integrated fashion, building on existing sectoral information and recent pilot projects.

Industry engagement and knowledge transfer will build regulatory awareness, understanding and capacity within the stakeholder community and, in turn, contribute to the priority-setting of science substantiation activities. This experience will then be applied to regulatory enhancement.

Ultimately this will create a regulatory environment conducive to timely market entry of new, safe innovative food products.

Industry Engagement and Knowledge Transfer

The Canadian agri-food value chain requires technical and regulatory support for innovation in the growth-opportunity category of foods with added health benefits within a science-based regulatory system.

Work in this area will be led by AAFC with involvement from HC.

Activity areas will include:

A. Providing government (especially HC) and industry with timely, analysis-based advice and information on cross-sectoral domestic food regulatory issues (particularly in the category of foods with added health benefits), to enable the development of policies and strategies that take into account international best practices and foster innovation

and competitiveness along the value chain, recognizing that consumer health and safety are paramount.

Specific activities in this area will include analyses of and reporting on potential industry impacts of regulatory issues, monitoring the status of food regulatory issues in other jurisdictions, and AAFC participation on HC committees, working groups and task forces associated with regulatory issues of importance to food-for-health innovation by industry.

HC and AAFC will establish a proactive, cooperative, bilateral working relationship respecting and building on independent complementary mandates in the identification of, and approaches to, regulatory issues and activities relevant to food innovation.

B. Facilitating, in collaboration with the agriculture and agri-food sector, the collection, interpretation, and documentation of information (on market opportunities, sector capacity, product/claim approvals in other jurisdictions, and state of science) for determining plans/priorities, identifying gaps, and developing regulatory submissions Specific activities in this area will include:

   i. Facilitating information-sharing with stakeholders on: a) market opportunities and sector capacity, through linkages with ongoing market research, analysis and bench-marking efforts by government and industry, b) scientific promise of health claims and novel ingredient classes, through linkages with the domestic and international science communities, and c) approvals in other jurisdictions for products and claims;

   ii. Reviewing the aforementioned information with stakeholders and determining plans and priorities accordingly, through organized meetings/workshops and ongoing liaison with established groups including the AAFC-facilitated Value Chain Roundtables, industry associations and functional food networks.

   HC will attend and, on occasion, give presentations at meetings and events to inform and update stakeholders on the status of current HC initiatives; and

   iii. Encouraging/facilitating systematic scientific literature reviews and summaries, domestic and international science symposia

and proceedings preparation, and the convening of expert panels, to facilitate stakeholders' gathering, understanding and documenting of existing scientific data, as well as the identification of scientific evidence gaps in safety and/or claim validity.

HC will provide input and advice on conducting literature reviews, determining the topics and agendas for science symposia, and the composition of expert panels.

C. As a transition measure, working with value chains and industry groups (including producers) to assist in putting together high quality and complete regulatory submissions for priority ingredients and claims, and in so-doing assist in equipping them with an understanding of the process and requirements.

Specific activities in this area will include working with HC to improve the usefulness and enhance the availability of guidance documents and submissions templates, and mentorship and advice to industry on HC's standards-of-evidence requirements and the submissions process.

HC officials will support AAFC as appropriate with expertise, training, information, ongoing guidance and advice in order to provide interdepartmental consistency in related industry outreach areas.

D. Working with industry, the research community and other stakeholders to build awareness in the regulatory system and ongoing capacity/leadership to participate therein in the future, and to broker relationships that facilitate communication/information dissemination

Specific activities in this area will include the sharing of success stories to encourage additional food-for-health submissions, work with industry to show-case best practices that have led to successful product approval, and work with research networks and industry associations to undertake activities in these regards. These efforts will also help cast Canada's regulatory environment in a positive light domestically and internationally.

Science Substantiation

Scientific research has documented the promise of a large number of food ingredients as potential contributors to improved human health. However, there is

a critical knowledge gap in terms of the kind of scientific information required to obtain the approval of these products by regulatory agencies.

The Federal Government is in a unique position of being able to leverage existing science and technology at AAFC in collaboration with Canadian and international science research networks that will be established for this initiative and that the food industry does not have access to.

The Federal Government also has a role to play where the benefits to human health are strong but where the economic benefits would be spread across the entire industry so that a single company may not have to absorb all of the cost of developing the scientific evidence. Generating knowledge platforms that can be used by multiple industry players to advance their products through Canada's regulatory system is very cost effective.

The targeted outcome from the Science Substantiation function is provision of internationally recognized science expertise, solid scientific evidence as well as advice to the other two functions. Research will be performed in-house or in collaboration with established science networks (nationally and internationally) to address regulatory knowledge gaps and to establish clear linkages between food/ingredients and human health, critical for regulatory decision-makers, industry and consumers.

The overarching activity is the coordination of prioritized scientific research projects which provide necessary evidence to fill critical gaps in understanding the safety of novel ingredient and validity of health claims by leveraging in-house, national collaboration and international research.

More specifically the following activity areas will be led by AAFC with HC involvement as appropriate:

A. Facilitating the determination and coordination of research priorities and providing advice for study designs through the establishment of targeted expert task forces, such as assembling various experts from various institutions to discuss the status of scientific information and gaps in priority areas. AAFC's Research Branch will be responsible for establishing these expert working groups. These will include suggestions of methodologies and research protocols to address scientific gaps in claim validity. This will be done through the organization of several targeted workshops.

   Through the evaluation of regulatory requirements, the strength of available scientific evidence and market and business intelligence/analysis, research priorities will be determined and coordinated to guide efforts of the Research

Branch (RB) focused on providing necessary evidence to fill critical regulatory gaps in claim validity in order to facilitate the market entry of food products with enhanced health attributes. This includes: 1) the establishment of science-based criteria for the determination of research priorities; 2) the creation of science/regulatory advisory groups based on bioactives and/or food vectors and/or health claims potential; and 3) the organization of targeted meetings of these groups to address science issues pertaining to health claims (including: the state of science, data gaps, experimental design, human clinical trials, results).

Selection of a few "functional products" obtained from the potential successful coupling of: 1) bioactives from Canadian agricultural sources with demonstrated or proven benefits to health; and 2) food vectors and matrices available to incorporate promising bioactives into real-life, nutritious and appealing products.

B. Working with targeted industries and/or other research partners to assess the technical feasibility of generating large quantities of real-life nutritious, appealing and stable products containing bioactives making sure that they keep their bioactivity until consumption in a reproducible and controlled manner through the choice of appropriate technologies. AAFC's Research Branch has some scientific capacity to perform research in areas that are identified by AAFC's MISB Industry Engagement and Knowledge Transfer function

The technical feasibility of generating large quantities of real-life, nutritious and appealing products containing bioactives that will ensure stability and bioactivity in a reproducible and controlled manner through the choice and combination of appropriate technologies will be assessed.

Through experimental work, answers to the three following questions will be provided: 1) Does the bioactive remain stable during processing in real food matrices? 2) Does the bioactive need to be protected during its incorporation? If so, identify, select and work on appropriate technologies (for example, encapsulation); 3) Does the microstructure of the food matrix protect the bioactive until the delivery? If so, identify the effect of the microstructure in protecting the bioactive. Appropriate technologies will be chosen to produce samples in sufficient quantities (pilot plant level) utilizing in-house capacity and resources with AAFC's. These samples would be further used for human clinical trials to assess: feasibility, limits, product quality, safety and efficacy (activity E).

C. Catalyzing research efforts aimed at understanding the behaviour of targeted bioactives within the context of complex food matrices in human subjects; especially the gastrointestinal delivery in order to properly document health claims in collaboration with HC, and other Canadian networks and international partners. AAFC Research Branch will be responsible for ensuring that a complete scientific data package is assembled by gathering it and/or coordinating with universities, hospitals, Health Canada and industry. For example, in the first year, there will be a call for proposals for targeted areas of research, projects will be selected, and the research will be undertaken in the subsequent 3-4 years. International workshops will be organized to create science networks (two);

   Through experimental work, answers to the three following questions will be provided: 1) How available is the bioactive in the human gastrointestinal tract and how much is being absorbed by the human body?; 2) What are the biomarkers for diet-related diseases providing evidence of the beneficial effects of food and food ingredients with functional attributes on human health?; and 3) What is the mode of action of the bioactive, including site and mechanism of action?

D. Providing advice to universities, industry, and research centres involved in human clinical trials in order to ensure that these studies are performed according to well accepted practices and scientific rigor, and that they address the question to be answered in scientific gaps related to health claims. In addition, AAFC's Research Branch will coordinate these studies. Two to three meetings a year will be held in order to ensure that they are on track.

E. Funds will be given to third parties to perform human clinical trials. Specific activities will include establishing various contacts able to perform required human clinical trials, writing up contracts and terms of reference for the work to be done, distributing funding and following up on projects. There will be discussion and/or even suggestions of protocols to be used to provide evidence for health claims. Health Canada will encourage the increased use of pre-submission meetings with applicants as necessary to clarify data requirements and help ensure completeness and quality of submissions.

Enhancing the Regulatory Environment

Modernized regulatory frameworks and approaches are needed that will continue to protect and promote health, but are better able to respond to consumer and industry interest in safe value-added products, some with claims of added health benefit. In order to respond to growing market opportunities and emerging innovation, industry needs appropriate tools and processes so as to have a clear

understanding of what is required of them, as well as greater predictability, transparency and timely regulatory decisions around food innovation.

Work in this area will be led by HC with involvement and support from AAFC.

Activities focus on two key areas:

A. Improving Regulatory Processes to help make pre-market approval and review process more predictable, transparent and timely, while retaining health and safety standards.

   This work will be done by HC, with support of AAFC in outreach and industry training.

   Specific sub activities will include:

   a) improved management of the submission process moving towards a single window for all food submissions and addressing key bottlenecks in the submission process;

   b) improved coordination of reviews through establishment of a central office for submission receipt;

   c) developing and meeting service standards and performance targets for 90% of submissions (considering best international practices);

   d) development of an integrated submission tracking system;

   e) improved guidance to industry through documents and workshops;

   f) increased use of pre-submission consultations in order to provide guidance to industry on submission requirements;

   g) addressing backlog through increased capacity and expertise; and

   h) increase international engagement and third party work sharing, including encouraging simultaneous submissions by industry to Canada and other regulatory authorities as appropriate.

B. Development of 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.

Specific activities initially include a focus on modernizing the regulatory framework for management of health claims for foods in Canada. This will include activities to support policy development related to: disease risk reduction claims, managing function and other types of claims, and claims for novel and innovative products at the food and natural health product interface. Additionally, policy and framework development and modernization will be undertaken related to novel foods and technological advances (including where appropriate, the innovative use of food additives and packaging approaches). A key activity will be increased international engagement with recognized standard setting bodies to help develop comparable and compatible approaches, identify opportunities for work sharing, and conduct science/technology/industry foresight analysis.

This work will be done by HC with AAFC support in the context of issues related to food-for-health innovation by industry, including (as appropriate): participating on relevant working groups, consultations task forces, undertaking joint research, and collaborating on identifying and filling science gaps (including building on recent pilot projects to improve quality of scientific reviews). AAFC will provide input on agriculture and food-sector implications. HC and AAFC will develop confidentiality agreements as needed to facilitate the sharing of information.

7.3 Veterinary Drugs

Increase the availability of veterinary drugs for food producing animals in the Canadian market by providing a regulatory environment that encourages drug companies to submit for approval, new and generic veterinary drug submissions for food producing animals.

In order to help respond to livestock producers concerns with the Canadian veterinary drug market (lack of availability of drugs and higher prices in comparison to the US), the veterinary drug industry and livestock producers need appropriate tools and processes so as to have a clear understanding of what is required of them, as well as greater predictability, transparency and timely regulatory decisions regarding veterinary drug approvals.

Both HC and AAFC recognize that stakeholder input is critical in identifying the needs for new and generic veterinary drugs in Canada, and in determining the priorities for the Minor-Use Minor-Species (MUMS) initiatives.

Work in this area will be led by HC with involvement and support from AAFC.

Activities focus on three key areas:

A. Regulatory harmonization initiatives to align Canadian standards and regulatory requirements with international bodies

Funding will be used by HC to conduct a review to identify the differences in regulatory frameworks that may be having a detrimental impact on competitiveness, trade and investment.

The objective of such a review will be to achieve closer harmonization of technical requirements for veterinary drug approvals with international regulatory agencies such as the US FDA Center of Veterinary Medicine, without compromising the protection of the environment and the health and safety of Canadians.

As part of the review, specific sub-activities will include:

a) Scrutinizing non-harmonized data requirements with the U.S., EU and Australia;

b) Completing a Maximum Residue Limit (MRL) and Acceptable Daily Intake (ADI) comparison study for approved drugs in Canada, with the US, EU and Australia;

These sub-activities will be combined with ongoing HC harmonization efforts, including:

- Working with international partners in the sharing of information on approval and post-market surveillance;
- Participating in international committees (VICH and CODEX) to move forward on international harmonization issues;
- Working towards increasing MOUs and acceptance of international review standards.

Collectively, these new and on-going activities will result in revised standards and better alignment of Canadian standards and regulatory requirements with those of international bodies.

B. Improved regulatory approval processes for new and generic veterinary drugs to help make the review process predictable, transparent and timely

Additional resources are required by HC to increase its capacity to scrutinize new and generic drug submissions. This initiative to improve regulatory approval processes will target drug approval times to address the backlog of submissions and increase the efficiency and maintain the timely review of submissions. This

process would be transparent as HC will undertake consultations with stakeholders during this process.

This work will be completed by HC, with support of AAFC in outreach and industry engagement.

Specific sub-activities will include:

a) Streamlining and enhancing efficiency in submission review to improve management of the submission process by developing new review and training tools,

b) Developing process and guidance documents to help in filing complete and high quality submissions by industry;

c) Streamlining priority reviews and addressing backlog through increased scientific capacity and expertise;

d) Reviewing and revising submission review standards against international (US, EU, Australia) standards;

e) Establishing guidelines and inspection requirements specific to veterinary drugs, such as generic drug guidelines;

f) Developing and implementing Good Review Practices:

   i. Reviewer training programs
   ii. Scientific expert contracting database
   iii. Establish training processes for new staff and contractors
   iv. Health Canada joint Therapeutic Products Directorate and Veterinary Drugs Directorate intranet site for training and good practices tools

g) Identifying priority reviews based on industry input;

h) Conducting regulatory foresight using annual environmental scans to identify upcoming trends;

i) Developing a strategy to streamline the approval of generic veterinary drugs, develop generic drug guidelines, and participate in VICH harmonization efforts on generic drugs.

Collectively, these new activities will result in improved regulatory approval processes for new and generic veterinary drugs that in turn will help make the review process predictable, transparent and timely.

C. Address Minor Use Minor Species (MUMS) and the availability of veterinary drugs for food producing animals such as sheep and goats.

Minor Use drugs are for use in major species (cattle, swine, chickens, turkeys) that are needed for diseases that have a limited geographic range or affect a small number of animals. Minor Species are all animals other than the major species, which include fish, sheep, goats, horses, and honeybees.

Veterinary drugs for MUMS are largely unapproved and unavailable in Canada, given the relatively small market. HC requires additional resources to increase its capacity to conduct technical reviews of drugs for MUMS as well as its capacity to develop policies to facilitate regulatory process. This initiative will help increase the availability and streamline the approval of drugs for MUMS, thus making it more cost effective for drug companies to file submissions in Canada.

To that end, HC will develop a framework to increase the availability and to streamline the approval of drugs for MUMS.

Specific sub-activities will include:

a) Reviewing international approaches to increase drug availability for MUMS;
b) Developing policy to facilitate regulatory process for MUMS with consideration of U.S., EU and Australian frameworks;
c) Identifying priority reviews based on industry input;
d) Conducting a pilot project with small ruminants sector;
e) Streamlining MUMS submission review;
f) Producing MUMS policy and guidance documents;
g) Establishing Maximum Residue Limits (MRLs) for MUMS drugs.

8.0 GOVERNANCE

8.1 AAFC/HC Deputy Ministers

8.1.1 The Deputy Minister of Agriculture and Agri-Food Canada and the Deputy Minister of Health Canada will be updated annually, in the month of February, to:

A. assess progress, through a written report provided at least two weeks in advance of the update, against work plan milestones and performance indicators;

B. meet if required to address disputes the Assistant Deputy Ministers' (ADM) Committee is unable to resolve, including progress to date versus work plan and recommendations concerning funding;

C. approve changes to annual performance measures;

D. approve annual work plans for the next fiscal year; and

E. approve funding amounts (e.g., a percentage of the total budget, the entire budgeted amount or no funding at all) for the subsequent fiscal year based on satisfactory progress of program delivery and recommendations from the ADMs' Committee.

8.2 AAFC/HC Assistant Deputy Ministers Committee

8.2.1 An Assistant Deputy Ministers (ADMs) Committee will be established to oversee the management of this MOU. The Committee will be comprised of ADMs from HC and AAFC. The ADMs Committee will be updated and meet semi-annually, as needed, and will report to the Deputy Ministers annually to:

A. discuss overall performance, based on a written report, of the initiatives undertaken under this MOU;

B. address disputes a Joint Management Committee is unable to resolve;

C. review performance to date, measure achievement of key milestones and overall progress of outcome target versus targets set out in annual work plans and provide an assessment of the variances linked to expenditures and approved annual work plans;

D. recommend re-allocation of funds between fiscal years, using existing mechanisms, as recommended by a Joint Management Committee;

E. recommend Deputy Ministers' approval of changes, where objectives of this MOU change materially or if annual performance measures need adjustments; and

F. recommend Deputy Ministers' approval of work plans and funding amounts for the subsequent fiscal year.

8.3 AAFC/HC Joint Management Committees

8.3.1 AAFC and HC will establish three Joint Management Committees (JMCs) to manage the implementation of this MOU. Membership on these Committees will be at the Director General level with representation from the three respective programs. The Committees will be updated quarterly by the working groups and will meet regularly (2-4 times annually). The three JMCs will report to the ADM Committee on a semi-annual basis.

8.3.2 Each AAFC/HC JMC will:

A. develop terms of reference to outline its governance structure;

B. concur on business cases that outline the key commitments to be achieved over the years of funding;

C. concur on annual costed work plans, with milestones, indicators and targets, to deliver on implementation;

D. review quarterly progress against work plan reports to assess progress on milestone and target performance outcomes to provide direction for program implementation and delivery;

E. assess options to manage fund transfers within and between years to support work commitments under work plans and via this MOU;

F. report semi-annually on results/achievements to the ADMs' Committee;

G. agree on incremental changes to the work plan objectives, as applicable, where objectives have been achieved and funding remains;

H. recommend changes to the work plan objectives of this MOU for the ADMs' Committee review, where objectives of the MOU change significantly;

I. recommend for ADM Committee approval the annual amount of funding to be reallocated between fiscal years, if required, using existing mechanisms; and

J. review requests for dispute resolution and, if required, forward them to ADMs' Committee as per Section 11.

8.4 AAFC/HC Working Groups

8.4.1 AAFC and HC will establish three working groups at the Director/Officer-level level to manage the implementation of each of the three initiatives described in section 7 of this MOU. The Working Groups will meet frequently as required, and will report to their respective JMCs on a semi-annual basis.

A. improve access to new minor uses of pesticide products for the agriculture and agri-food sector;

B. develop and implement an integrated suite of industry engagement and knowledge transfer, science substantiation, and regulatory enhancement activities to address regulatory barriers to safe food innovation by the agriculture and agri-food sector, commencing with a focus primarily on health claims, novel foods, and ingredients; and,

C. increase the availability of veterinary drugs for food producing animals in the Canadian market by providing a regulatory environment that encourages drug companies to submit for approval, new and generic veterinary drug submissions for food producing animals.

8.4.2 Each working group will provide their respective AAFC/ HC JMC with:

A. business cases (i.e., Annex A of this MOU) that outline the key commitments to be achieved over the years of funding;

B. annual costed work plans, with milestones, performance indicators and targets, for each fiscal year;

C. quarterly performance to assess progress on work plan objectives and performance targets; and

D. semi-annual budget and expenditures reports linked to progress reports, and if necessary, adjusted work plans.

8.4.3 The working groups will also assume any additional responsibilities as assigned by the AAFC/HC JMC, as needed.

8.4.4 The working groups will also communicate progress with stakeholders, such as the Value Chain Round Tables and program specific advisory and technical committees.

8.4.5 The working groups will seek the advice of the AAFC/HC JMC on the management of their respective initiative, as needed, and resolve any disputes as per Section 11.

8.4.6 Working Groups will ensure that reliable data and baseline information is generated and managed in a fashion that supports performance measurement, audit and evaluation as required by the Treasury Board Secretariat.

9.0 PERFORMANCE REPORTING

9.1 AAFC and HC will each report on the performance of the joint initiatives through the Parliamentary reporting process, using the Report on Plans and Priorities (RPP) and the Departmental Performance Report (DPR). The content of the RPP and the DPR will be drawn from the ongoing reports of results achieved as well as evaluation reports. The performance of the initiatives forms part of the plans and results achieved for:

9.1.1 A competitive agriculture, agri-food and agri-based products sector that proactively manages risk, strategic outcome under AAFC's program activity architecture; and

9.1.2 Access to safe and effective health products and food and information for healthy choices strategic outcome for health claims, novel foods, and ingredients and for veterinary drugs; and, reduced health and environmental risks from products and substances and healthy sustainable living and working environments strategic outcome for minor use pesticides, under HC's program activity architecture.

9.2 In addition, HC will report to Parliament annually, as required under the *PCPA*. This annual report will include, among other things, a status report on the registration of pest control products that pose lower risks, re-evaluations and special reviews under the *PCPA*.

9.3 AAFC may use the information from any performance reports as input for the preparation of any public reports prepared under Growing, in consultation with

the AAFC/HC Joint Management Committee. Prior to issuing any such reports, there will be an exchange of information between AAFC and HC.

9.4 Performance reporting based on the initiatives will use a common template based on Annex C.

9.5 AAFC and HC will ensure that reliable data and baseline information is generated and managed in a fashion that supports performance measurement, audit and evaluation as required by Treasury Board.

9.6 The preliminary environmental scan of the Growing Forward Strategic Environmental Assessment (SEA) indicated that because of the uncertainty associated with implementing these initiatives, a follow-up report would be required during the 2011-12 fiscal years. AAFC and HC will therefore also be responsible for providing a follow-up SEA report as part of their annual performance reporting in 2011-12.

10.0 COMMUNICATIONS

10.1 With respect to all communication activities, projects and products in connection with the three initiatives HC and AAFC will:

(a) consult with each other on the planning and development of such activities, and
(b) where applicable, refer to *Growing Forward* and its objectives, and shall fully and fairly reflect the contribution of each Party.

10.2 The above will not prevent either of the two organisations from engaging in communication activities to meet their respective mandates/obligations.

10.3 Both organizations will have websites that provide information regarding the initiatives, but will avoid, as much as possible, duplication of information by linking the two sites.

11.0 DISPUTE RESOLUTION

11.1 Dispute resolution involves early recognition of conflict, promotion of cooperation and building stronger relationships through effectively and fairly managed conflict. The participants agree to strive to resolve any dispute arising from implementation of this MOU through informal negotiations and development of mutually satisfactory options.

11.2 Where informal negotiations by HC and AAFC fail to resolve the matter to the mutual satisfaction, the participants agree to refer the matter to the JMC pursuant to Section 8.3.2.

11.3 Where informal negotiations by the JMC have failed to resolve the matter to the mutual satisfaction, the participants agree to refer the matter to the Assistant Deputy Ministers' Committee.

11.4 In case the dispute still remains unresolved, Deputy Ministers will be invited to intervene to resolve the dispute.

12.0 DURATION OF MOU

This MOU will be in effect as of the date the last signature is affixed and will remain in effect until March 31, 2013, at which time it may be reviewed, renewed or renegotiated by the participants.

13.0 AMENDMENT

This MOU can be amended, with the written consent of the signatories, based upon mutual agreement, at any party's request. The operation of this MOU will be reviewed annually by either party's request.

14.0 AUDITS AND EVALUATIONS

14.1 The evaluation strategy will draw on the performance data as one of the lines of evidence from an in-depth study of outcomes achieved that would include testing of the causality described in Section 4 of this MOU and examining unintended outcomes within the program and on other programs. The cost of these evaluations will be shared between the participants. Funds to implement the evaluations will come from the program funding.

14.2 For Health Canada, there are a number of scheduled evaluations and/or audits that will be used as baseline for the relevant programs. For the Minor Use Pesticide Initiative, the 'Summative Evaluation of the Building Public Confidence (BPC) in Pesticide Regulation and Improving Access to Pest Management Products Horizontal Initiative' evaluation will be used as baseline in 2009-2010. A five-year cycle of evaluations will then be implemented, with the next one scheduled for 2014-2015, as per the HC Five Year Evaluation Plan. For the Health Claims, Novel Foods, and Ingredients initiative, the audit of the "Food Safety and Nutrition Quality" completed in 2008, as well as an evaluation of the "Food Safety and Nutrition Quality" scheduled for 2008-2009, will be used as baseline with the next evaluation scheduled for 2012-2013 and every five years thereafter. For the Veterinary Drugs initiative, an evaluation of "Veterinary Drugs" will be used as baseline in 2010-2011, with the next one scheduled for 2015-2016 and every five years thereafter.

14.3 Should an audit related specifically to the initiatives described in this MOU be performed by one of the participants, a copy of the audited financial statements and audit report will be forwarded to both participants by no later than six (6) months following the year covered by the audit. All audits will be conducted in accordance with Generally Accepted Auditing Standards and with any applicable Risk-based Audit Framework (RBAF) that may come in the future. The purpose and scope of the audit will be approved and shared by both participants.

14.4 When evaluations related specifically to the initiatives described in this MOU are performed by one of the participants, a copy of the evaluation report will be forwarded to both participants by no later than six (6) months following the year covered by the evaluations. All evaluations will be conducted in accordance with Treasury Board Evaluation Policy and the *Federal Accountability Act*. The

purpose and scope of the evaluation will be approved and shared by both participants.

15.0 SIGNATORIES

This is to certify that the terms contained in this Memorandum of Understanding are acceptable to both participants.

In witness whereof, the participants have signed this Memorandum of Understanding,

Deputy Minister, HC

MAY 16 2009

Date

Deputy Minister, AAFC

Date

purpose and scope of the evaluation will be approved and shared by both participants.

15.0 SIGNATORIES

This is to certify that the terms contained in this Memorandum of Understanding are acceptable to both participants.

In witness whereof, the participants have signed this Memorandum of Understanding,

Deputy Minister, HC	Date
	APR 2 8 2009
Deputy Minister, AAFC	Date

List of Annexes:

Annex A – Funding table

Annex B – Logic models

Annex C – Performance Indicators

Annex D – PMC/PMRA Risk Reduction Program

Annex A – Funding Table

Summary Table by Initiative (dollars)						
Organization Name: Agriculture and Agri-food Canada						
	Fiscal Year					
Regulatory Action Plan	*2008–2009*	*2009–2010*	*2010–2011*	*2011–2012*	*2012–2013*	Total
Health Claims, Novel Foods, and Ingredients						
Industry Engagement (AAFC)	1,208,970	1,994,790	1,994,790	1,994,789	1,994,789	9,188,128
Science Substantiation (AAFC)	895,695	1,994,980	1,994,980	1,994,980	1,994,980	8,875,615
Regulatory Enhancement (MOU – HC)	2,200,000	4,538,000	3,541,000	3,541,000	3,541,000	17,361,000
Total	**4,304,665**	**8,527,770**	**7,530,770**	**7,530,769**	**7,530,769**	**35,424,743**
Minor Use Pesticides						
Implement PMC (AAFC)		9,974,448	9,971,942	9,972,269	9,972,693	39,891,352
Implement Agency (MOU – HC)		3,990,000	3,989,000	3,989,000	3,989,000	15,957,000
Total		**13,964,448**	**13,960,942**	**13,961,269**	**13,961,693**	**55,848,352**
Veterinary Drugs (MOU – HC)	**400,000**	**1,150,000**	**1,150,000**	**1,150,000**	**1,150,000**	**5,000,000**

Annex B – Performance Indicators

Health Claims, Novel Foods, and Ingredients

Program Area	Program Name	Responsibility	Type Selection	Expected Result (Output)	Key Performance Indicator	Data Source	Frequency of Data Collection	Target	Date to Achieve Target
Regulatory Action Plan	Health Claims, Novel Foods, and Ingredients	AAFC MISB	Output	• Regulatory-issue/impact documents • Plans/priorities for claims and ingredients • Literature reviews, research-gap lists • Meetings, commentary • Workshops, web sites	• Number of issue impact memos, briefings, reports • Documents identifying plans and priorities regarding claims & ingredients worthy of sector pursuit • Number of literature reviews, expert panels and science symposia which have generated information for sector submissions • Lists of identified research gaps for priority health claims, novel-food classes and ingredients • Number of meetings, workshops and educational/informational resources	• Reports • Consultations	Annually	• 5 issue memos, briefings, reports • 1 set of plans/priorities, reviewed annually • 2 literature reviews, expert panels and/or science symposia per year • Key research gaps • 10 meetings, workshops and/or informational resources	March 31 annually
Regulatory Action Plan	Health Claims, Novel Foods, and Ingredients	AAFC RB	Output	• Domestic and international science networks • Data and evidence to address priority knowledge gaps	• Number of domestic and international collaborative/networking research partnerships • Number of priority knowledge gaps filled (including new or improved methodologies and processes to characterize functional ingredients and bio-actives for the purposes of providing information needed to set or meet regulatory frameworks, definitions, standards and protocols) for health claims, novel foods and ingredients	RB FSQ scientist productivity templates	Annually	• 3 networks per year • 5 knowledge gaps per year	March 31 annually

Health Claims, Novel Foods, and Ingredients

Program Area	Program Name	Responsibility	Type Selection	Expected Result (Output)	Key Performance Indicator	Data Source	Frequency of Data Collection	Target	Date to Achieve Target
Regulatory Action Plan	Health Claims, Novel Foods, and Ingredients	HC FD	Output	• Policies, regulations and pre-market processes • Manuals, consultations, work-sharing agreements, reports	• Number of new/revised regulations developed (e.g., for health claims) • Number of policies developed/reviewed • Number of pre-market submission processes developed • Number of manuals, guidance documents, workshops, information for stakeholders • Number of consultations • Number of reports • Number of work-sharing and international cooperation initiatives	• FD records • Consultations • HC web site	Annually	• 2-4 new regulations (e.g., health claims) • 3 policy proposals • 1 suite of submission review processes • 6 manuals/ guidance documents, workshops, information for stakeholders • 2 consultations • 3 reports • 2 work-sharing agreements/ MOUs	March 31, 2013
Regulatory Action Plan	Health Claims, Novel Foods, and Ingredients	AAFC MISB	Outcome (Immediate)	Sector guidance and communication	• Number of national and regional partners identified for disseminating guidance tools and communications for the sector • Number of sector client groups to whom guidance is provided	• Partnership agreements • MISB FVCB records • Client lists	Annually	• 5 partnerships • 5 sector client groups	• March 31 annually
Regulatory Action Plan	Health Claims, Novel Foods, and Ingredients	HC FD	Outcome (Immediate)	Enhanced policy/regulatory/process engagement with industry, consumers and international standard-setting partners	• Percent of policy/regulatory reviews that undertake stakeholder, international expert engagement • Number new/revised guidance documents and meetings for/with industry • Incorporation of international work-sharing and collaborations	• FD records • Consultations • HC web site	Annually	• 90% policy development/ regulatory reviews • 6 guidance documents, workshops • 2 international work-sharing pilots incorporated in decision-making	March 31, 2013

Health Claims, Novel Foods, and Ingredients

Program Area	Program Name	Responsibility	Type Selection	Expected Result (Output)	Key Performance Indicator	Data Source	Frequency of Data Collection	Target	Date to Achieve Target
Regulatory Action Plan	Health Claims, Novel Foods, and Ingredients	• AAFC MISB • AAFC RB	Outcome (Intermediate)	Complete and substantiated sector regulatory submissions (through improved sector understanding of regulatory processes & requirements, and defensible science being used to fill evidence gaps)	• Percentage of sector submissions (facilitated by the Initiative) that are acceptable with respect to completeness and substantiation (in keeping with regulatory processes and requirements, including scientific)	AAFC engagement with industry and HC	Annually	70% of submissions	March 31 annually
Regulatory Action Plan	Health Claims, Novel Foods, and Ingredients	HC FD	Outcome (Intermediate)	Modernized and efficient policy and regulatory approaches and pre-market processes	• Percentage of submission review and decision performance targets and standards being achieved • Percentage of submission backlogs reduced • International best practices, industry and consumer needs reflected in decision-making documents, processes	FD, RIAS and policy documents	Annually	• 90% of health claim reviews meet target • Backlogs reduced by 50% • 90% RIAS & policy documents consider international approaches, consumer, industry input	March 31, 2013
Regulatory Action Plan	Health Claims, Novel Foods, and Ingredients	AAFC OAE	Outcome (End)	Enhanced sector ability to navigate the food regulatory system	Percentage of sector respondents who indicate that their ability to navigate the regulatory system has increased	Qualitative and/or quantitative surveys	Once	75% of respondents	March 31, 2013
Regulatory Action Plan	Health Claims, Novel Foods, and Ingredients	AAFC OAE	Outcome (End)	New, innovative and safe food products and claims, focusing on health benefits	Number and breadth of new products and claims introduced by Canadian firms in the Canadian marketplace	Qualitative surveys and/or ACNielsen data	Once	10 products and 3 claims	March 31, 2013

Minor Use Pesticides

Program Area	Program Name	Responsibility	Type Selection	Expected Result (Output)	Key Performance Indicator	Data Source	Frequency of Data Collection	Target	Date to Achieve Target
Regulatory Action Plan	Minor use pesticides	AAFC PMC	Output	List of pest management priority projects selected	Annual national minor use pesticide priority projects selected by grower consensus.	AAFC program lead and provinces	Annual	36 projects	March 31 annually
					Annual joint Canada-US priority projects selected		Annual	10 projects	March 31 annually
Regulatory Action Plan	Minor use pesticides	• AAFC PMC • HC PMRA	Output	Regulatory data packages and decisions for new minor uses of pesticides	Number of projects completed and submitted by AAFC (pre-submission and submission)	Internal databases and program leads	Annual	• 64 projects (2009-10)	March 31 annually
					Number of pre-submission packages reviewed by PMRA (from all sources)		Annual	80 pre-submission packages	March 31 annually
					Number of joint minor use pesticide reviews with EPA completed		Annual	3 reviews	March 31 annually
					Number of minor use pesticide submissions evaluated by PMRA (from all sources)		Annual	75 evaluations	March 31 annually
Regulatory Action Plan	Minor use pesticides	• AAFC PMC • HC PMRA	Immediate Outcome	New minor uses of pesticides available to growers through a dedicated minor use review process by PMRA	Number of new minor uses of pesticides registered	Internal databases and program leads	Annual	170 registrations	March 31 annually
Regulatory Action Plan	Minor use pesticides	• AAFC PMC • HC PMRA	Intermediate Outcome	Improved Pesticide resistance management	Percentage of new minor uses of pesticides which provides resistance management	Internal government databases and stakeholders information	Annual	25% of registered new minor uses	March 31 annually

Minor Use Pesticides

Program Area	Program Name	Responsibility	Type Selection	Expected Result (Output)	Key Performance Indicator	Data Source	Frequency of Data Collection	Target	Date to Achieve Target
Regulatory Action Plan	Minor use pesticides	• AAFC PMC • HC PMRA	Intermediate Outcome	Improved crop protection practices	Percentage of new minor use pesticides available for incorporation into best management practices	Internal government databases and stakeholders information	Annual	25% of registered new minor uses	March 31 annually (starting in 2011)
Regulatory Action Plan	Minor use pesticides	• AAFC PMC • HC PMRA	End outcome	Improved competitive parity of agriculture and agri-food sector with regard to pest management	Number of new minor uses of pesticides harmonized with trade partners	Internal databases and program leads	Annual	25 uses harmonized	March 31 annually (starting in 2011)
64 = 18 AAFC pre-submission, 6 joint IR-4 pre-submission, 40 submission									
86 = 36 AAFC pre-submission, 10 joint IR-4 pre-submission, 40 submission									

Veterinary Drugs

Program Area	Program Name	Responsibility	Type Selection	Expected Result (Output)	Key Performance Indicator	Data Source	Frequency of Data Collection	Target	Date to Achieve Target
Regulatory Action Plan	Veterinary Drugs	HC VDD	End Outcome	Increased availability of veterinary drugs for food producing animals in the Canadian market	Number of submissions for generic drugs, and number of submissions for MUMS pilot program	VDD submissions records	Annual	10 new submissions in total (~~6~~ submissions each for generic drugs and MUMS pilot)	March, 2013
Regulatory Action Plan	Veterinary Drugs	HC VDD	End Outcome	Reduction in the end to end review time of new drug submissions	Number of days required to review new drug submissions	VDD Drug Submission Tracking System (DSTS)	Annual	Reduce from 733 days to 600 days	March, 2013
					Number of days required to review generic drug submissions (first review stage & second review stage)	VDD Drug Submission Tracking System (DSTS)	Annual	• 1st review stage - reduce from 300 days to 240 days • 2nd review stage - reduce from 150 days to 120 days	March, 2013
Regulatory Action Plan	Veterinary Drugs	HC VDD	Intermediate Outcome	Increased availability of Generic and MUMS veterinary drugs for food producing animals in the Canadian market	Combined number of submissions for generic veterinary drugs and MUMS veterinary drugs	VDD Drug Submission Tracking System (DSTS)	Annual	5 new submissions in total (combined generic drugs and MUMS veterinary drugs).	March, 2011
Regulatory Action Plan	Veterinary Drugs	HC VDD	Immediate Outcome	Closer harmonization of technical requirements for veterinary drug approvals with the US FDA Center for Veterinary Medicine	• Development of report and action plan following the review of Canadian and US MRL processes • Number of drug entities for which MRLs are established from prioritized list	Manual count	Annual	• 1 report developed (Non-harmonized data requirements Report and Action plan following the review of Canadian and US MRL processes) • Establishment of MRLs for 3 drug entities from the prioritized list per year	• Report and action plan March 2010 • MRLs for 3 drug entities • Annually, starting March 2010

Veterinary Drugs

Program Area	Program Name	Responsibility	Type Selection	Expected Result (Output)	Key Performance Indicator	Data Source	Frequency of Data Collection	Target	Date to Achieve Target
Regulatory Action Plan	Veterinary Drugs	HC VDD	Output	Enhanced policies, guidelines and regulatory frameworks	Timely review and revision of policies, guidelines and regulatory frameworks	Manual count	Annual	• Generic Drug Guidelines Implemented by March 2011 • MUMS policy and Guidelines by March 2012 • Canadian approach to horse as a food-producing animal policy by March 2011 • Review and revise a subset of submission review time standards against international by March 2012	See Targets
Regulatory Action Plan	Veterinary Drugs	HC VDD	Output	Information and guidance for industry	Timely completion of information and guidance for industry	Manual count	Annual	• Draft Generic drug guidelines March by 2009 • Labelling guidelines March by 2009 • MRL and Acceptable daily intake comparison study for approved drugs in Canada, with US by March 2010 • Annual environmental scan Starting by March 2010	See Targets
Regulatory Action Plan	Veterinary Drugs	HC VDD	Output	Prioritized list of approved drug entities with US MRLs requiring Canadian MRLs	Percentage of approved drug entities prioritized	Manual count	Annual	100% of approved drug entities with US MRLs requiring Canadian MRLs prioritized	Prioritized list March 2009

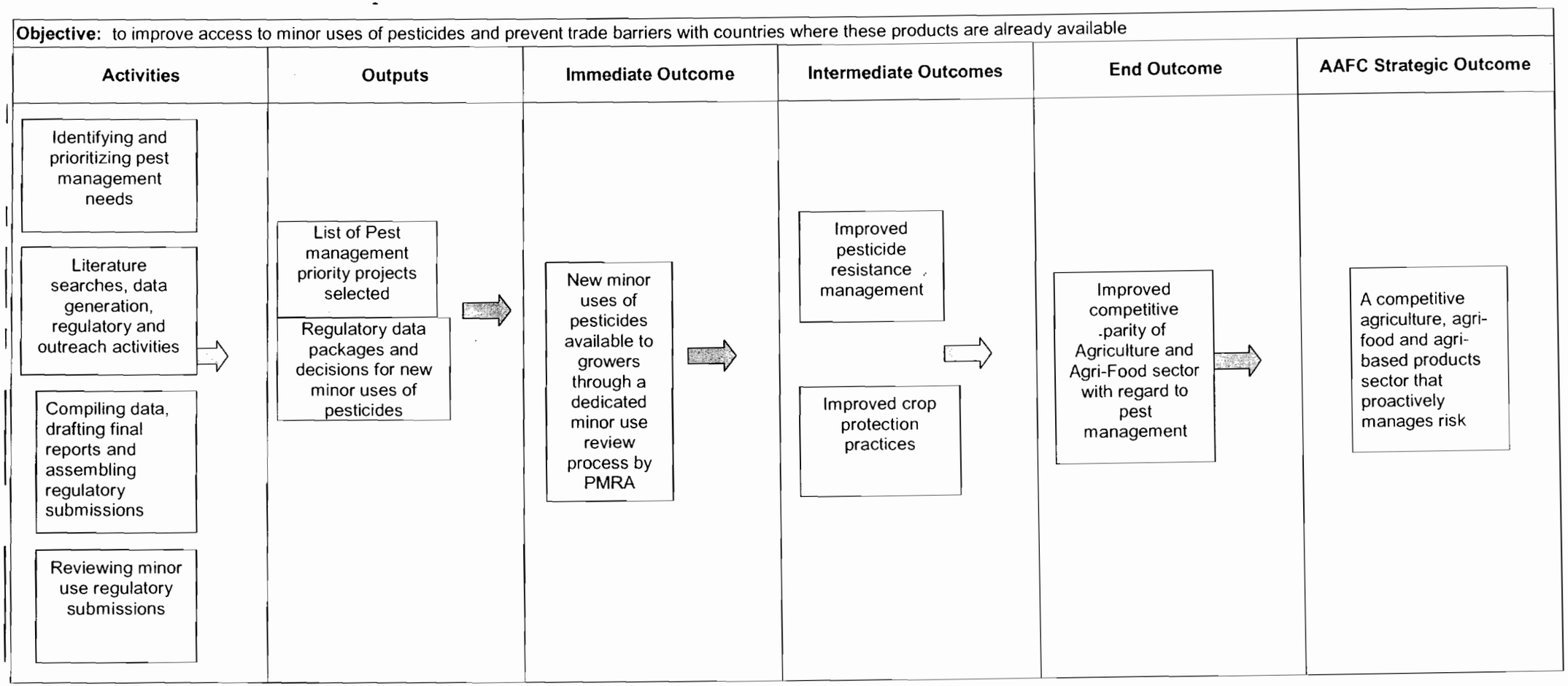
Annex C - Logic Models

The following logic model visually describes the linkages between the ***Health Claims, Novel Foods, and Ingredients Regulatory Initiative*** activities, outputs, immediate outcomes, and intermediate outcomes and end outcomes. Also included is the AAFC Strategic Outcome supported by the program.

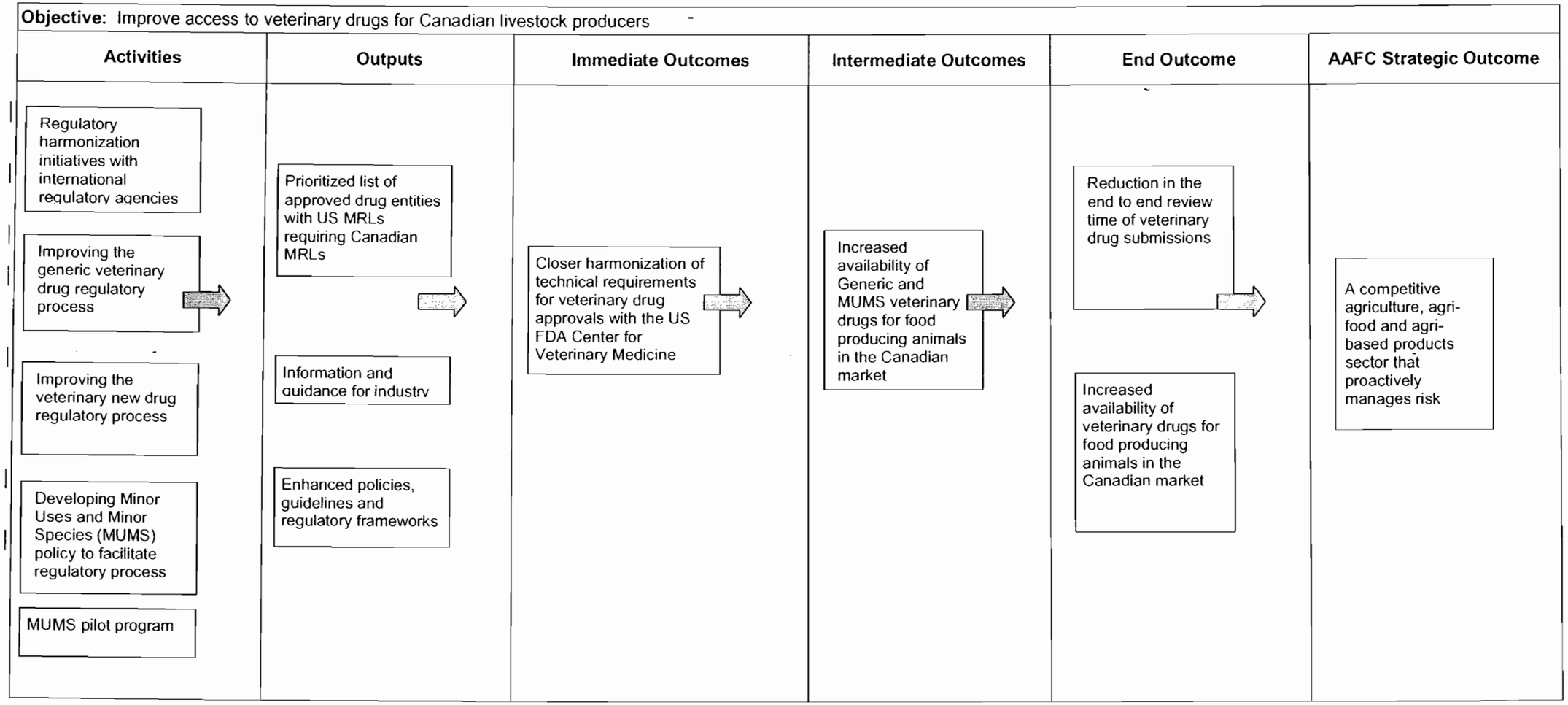
Objective: To help industry navigate the food regulatory system to facilitate the accelerated market entry of new products, and thus advance agriculture and agri-food sector innovation in the category of foods for health.

Activities	Outputs	Immediate Outcomes	Intermediate Outcomes	End Outcomes	AAFC Strategic Outcome
Working with industry, research and regulatory communities to facilitate information collection, analysis and exchange	- Regulatory-issue/impact documents - Plans/priorities for claims & ingredients - Literature reviews, research-gap lists - Meetings, commentary - Workshops, web sites	Targeted sector guidance and communication	Complete and substantiated sector regulatory submissions	Enhanced sector ability to navigate the regulatory system	A competitive agriculture, agri-food and agri-based products sector that proactively manages risk
Undertaking and coordinating collaborative scientific research	- Domestic & international science networks - Data and evidence to address priority knowledge gaps	Enhanced policy/regulatory/process engagement with industry, consumers and international standard-setting partners	Modernized and efficient policy and regulatory approaches and pre-market processes	New, innovative and safe food products and claims, focusing on health benefits	
Developing and implementing targeted food policies, regulations and pre-market processes	- Policies, regulations and pre-market processes - Manuals, consultations, work-sharing agreements, reports				

The following logic model visually describes the linkages between the ***Minor Use Pesticide*** Program activities, outputs, immediate outcomes, and intermediate outcomes and end outcomes. Also included is the AAFC Strategic Outcome supported by the program.



The following logic model visually describes the linkages between the ***Veterinary Drugs Program*** activities, outputs, immediate outcomes, and intermediate outcomes and end outcomes. Also included is the AAFC Strategic Outcome supported by the program.



Annex D – PMC/PMRA Risk Reduction Program

BACKGROUND

While the joint AAFC/HC Pesticide Risk Reduction Program has on-going, A-base funding under the "Building Public Confidence in Pesticide Regulation" (BPC) Memorandum to Cabinet, the program is being included as an Annex to this MOU because of the complementary nature of the Pesticide Risk Reduction Program to the Minor Use Pesticide Program and they share the same governance structure. In addition, the two programs provide outputs which support the shared objectives for the sector of: 1) adoption of safer pest management practices and products; 2) improved pesticide resistance management; and 3) improved crop protection practices and competitiveness.

Both programs were established together under the Agricultural Policy Framework (APF) as part of the multi-departmental Building Public Confidence of Pesticides initiative to address issues raised by witnesses appearing before the federal Standing Committee on Agriculture and Agri-Food. Two major issues were revealed in these consultations: (a) public concern with the long-term impact of pesticide use, and the need for more information in this area; and (b) limited access by growers to reduced-risk and minor use pesticides, which impaired their ability to compete on the international market and improve environmental sustainability in their production systems.

The on-going program provides a framework for collaboration with stakeholders for prioritizing issues and developing strategic action plans to address priority pesticide risk reduction issues. Program outcomes include improved access to and adoption of safer pest management tools and practices by Canadian producers and enhanced stakeholder engagement.

1.0 OBJECTIVES

To establish performance indicators and reporting structures between AAFC-PMC and HC-PMRA with respect to the on-going program, aiming to develop and implement pesticide risk reduction strategies and transition strategies, and to improve access to reduced-risk pesticides for agricultural use.

2.0 RESULTS/OUTCOMES

2.1. The activities under the Risk Reduction Programs have been designed to benefit the public and stakeholders. Target results and outcomes are indicated in Table 1. Details of the activities to develop and implement pesticide risk reduction strategies are provided in Section 4 below.

Table 1. Results and Outcomes by Activity Area: Develop and Implement Pesticide Risk Reduction Strategies

Activity Area	Result (Output)	Intermediate Outcome	Final Outcome
Develop and Implement Pesticide Risk Reduction Strategies Improve access to reduced-risk pesticides for agricultural use	Pesticide Risk Reduction Priorities & Strategies Regulatory data packages and decisions for reduced risk and biological pesticides Reduced-risk pest management tools, practices, products and publications	Increased awareness of and access to safer pest management products and practices	Adoption of safer pest management practices and products

2.2. The logic model for the Pesticide Risk Reduction Program can be found in Table 2. The results and outcomes will be measured using the performance indicators indicated in Table 3.

3.0 GOVERNANCE

3.1 AAFC-PMC/HC-PMRA Joint Management Committee (JMC)

The Pesticide Risk Reduction Program will report to the JMC which is established for the governance of the Minor Use Pesticides Program. With respect to the Pesticide Risk Reduction Program, this JMC will be responsible to:

A. Develop terms of reference to outline its governance structure.

B. Concur on annual work plans, with milestones, performance indicators, and targets, to deliver on planned activities.

C. Review semi-annually reports to assess progress on outputs and outcomes achievement and to provide direction for successful delivery.

D. Report annually on results achievements to ADMs.

E. Agree on incremental changes to the objectives, as applicable.

F. Recommend changes to the objectives of this program for ADMs' Committee review, where objectives of the program change significantly.

G. Review requests for dispute resolution and, if required, forward them to DMs as per Section 6.1.1 of this MoU.

3.2 PMC/PMRA Working Group

3.2.1 PMC and PMRA will continue to collaborate via the Risk Reduction Strategies working group.

3.2.2 The working group will continue to share annual work plans with milestones, indicators and targets to deliver on planned activities. Through the working group, PMC and PMRA will inform each other of their participation in national and international activities or initiatives relevant to the mandate of the other.

3.2.3 The working group will assume additional responsibilities as assigned by the AAFC-PMC/HC-PMRA JMC, as needed.

3.2.4 The working group will seek the advice of the AAFC-PMC/HC-PMRA JMC on the management of their respective programs, as needed, and resolve any disputes as per Section 11 of this MoU.

4.0 PROGRAM DELIVERY

Develop and implement pesticide risk reduction strategies and transition strategies for the agriculture and agri-food sector.

A. PMC and PMRA will continue to work jointly to develop and implement risk reduction strategies and transition strategies using science-based risk management to help reduce the risks associated with pesticide use in agriculture. Strategies will be implemented by increasing the availability and adoption of reduced risk tools and practices to control pests in agriculture. PMC will contribute its knowledge of agriculture, agricultural programming, and integrated pest management tools and practices. PMRA will contribute its knowledge of the pesticide regulatory system, pest management tools, and of the comparative risk and value associated with pest control products.

B. PMC and PMRA will promote the continued development of collaborative mechanisms for joint priority setting for risk reduction strategies.

C. PMC will continue to lead, with PMRA participation, in work with stakeholders to develop and maintain crop profiles on a national basis. Crop profiles describe how commodities are produced, with emphasis on pest management practices, including the role of integrated pest management in commodity production, and provide information on the

critical pest management issues to underpin the development of a pesticide risk reduction strategy. PMRA may use the pesticide-use information contained in these crop profiles when assessing the risks of new pest control products and those under re-evaluation. PMC will continue to publish profiles via its website.

D. PMC and PMRA will continue to work with interested stakeholders including growers, the pesticide industry, consumer and environmental groups and provincial representatives to facilitate the development of risk reduction strategies and transition strategies. These strategies will focus on pesticide risk issues for sustainable pest and crop management. PMC and PMRA will cooperate in measuring the impact of these strategies.

E. PMRA will continue to undertake activities to support the development and implementation of risk reduction strategies and transition strategies focused on solutions which include reduced-risk pest control products and biopesticides. These activities may encompass assessment of risks associated with priority issues, promoting and facilitating the registration of biopesticides, and providing regulatory support (facilitating presubmission consultations, advice regarding scientific data waiver rationales) to applicants, registrants and consultants, and other stakeholders. In particular, regulatory support will be provided for products that address identified needs in risk reduction and transition strategies, and steps will be taken to report on the success of these strategies, with results and outcomes made available to stakeholders.

F. PMC will continue to undertake activities to support the development and implementation of risk reduction strategies focused on solutions which are based on alternative management approaches including cultural practices, decision support tools, and biopesticides. Support will be provided to projects which address needs identified in these alternative management strategies, and steps will be taken to measure and report on the success of projects and strategies, with results and outcomes made available to stakeholders.

G. PMC and PMRA will work jointly to support companies wishing to register biopesticide products in Canada which support the implementation of pesticide risk reduction strategies and transition strategies. This activity may include development, regulatory and market building support.

H. PMC and PMRA will continue to collaborate to obtain and assess data (may include pest management data collected through expert polls, pesticide use and IPM adoption data, etc.) to support program activities and to measure and report on the results and success of the program. PMRA may use this data when making regulatory decisions.

I. PMC and PMRA will work to strengthen communication efforts on the program to apprise stakeholders of ongoing work and successes, including publication of the developed risk reduction and transition strategy documents on PMC and PMRA websites. PMC and PMRA will continue to use available communication tools (list serv, news releases and events, published articles, stakeholder meeting presentations, website, etc.), and will identify the joint nature of the program in all communications, including presentations to stakeholders. PMC will maintain its Technical Working Group as an element of strong communication with provincial integrated pest management specialists. PMRA will initiate communication with a similar Technical Working Group.

G. HC-PMRA will consider the information gained through stakeholder consultations and through the strategies when making pesticide registration and re-registration decisions.

Table 2: Logic Model – Pesticide Risk Reduction Program

The following logic model visually describes the linkages between the Pesticide Risk Reduction Program activities, outputs, immediate outcomes, and intermediate outcomes and end outcomes. Also included are the AAFC Strategic Outcomes supported by the program.

Objective: to improve access to and adoption of reduced risk pest management tools, products and practices

Activities	Outputs	Immediate Outcomes	Intermediate Outcomes	End Outcome	Strategic Outcomes
Identifying and prioritizing pesticide risk reduction issues Developing and implementing pesticide risk reduction strategies Improving access to reduced-risk pesticides for agricultural use	Pesticide risk reduction priority lists developed Pesticide risk reduction strategies developed Reduced-risk pest management tools, practices, products and publications Regulatory data packages and decisions for reduced-risk and biological pesticides	Increased awareness of and access to safer pest management products and practices.	Adoption of safer pest management practices and products Improved pesticide resistance management Improved crop protection, practices and competitiveness	Improved sustainability and competitive parity of Agriculture and Agri-food sectors with respect to pest management	**AAFC Strategic Outcomes:** A competitive and innovative agricultural sector; A sector that responds to society's priorities **Health Canada Strategic Outcomes:** Reduced health and environmental risks from products and substances, and safer living and working environments

Table 3. Performance Indicators – Pesticide Risk Reduction Program

Program Area	Program Name	Respon-sibility	Type Selection	Expected result / Output	Performance Indicator	Data Source	Frequency of data collection	Target	Date to Achieve Target
Pest Management Programs	Pesticide Risk Reduction	HC (PMRA); AAFC (PMC)	Output	Pesticide risk reduction priorities established	Number of stakeholder consultation groups established	AAFC program lead and provinces	Annual	1-2	March 31 annually
					Number of pesticide risk reduction priorities identified		Annual	3-6	March 31 annually
Pest Management Programs	Pesticide Risk Reduction	AAFC (PMC); HC (PMRA)	Output	Pesticide risk reduction and transition strategies developed	Number of strategy documents developed	Internal databases and program leads	Annual	1-2	March 31 annually
Pest Management Programs	Pesticide Risk Reduction	AAFC (PMC)	Output	Reduced-risk pest management tools, practices, products and publications	Number of reduced-risk pest management tools, practices, products and publications developed/available	Internal databases and program leads	Annual	2-5	March 31 annually
Pest Management Programs	Pesticide Risk Reduction	HC (PMRA)	Output	Regulatory decisions on reduced risk products	Number of regulatory decisions for RR products made	Internal government databases	Annual	2-3	March 31 annually

Program Area	Program Name	Respon-sibility	Type Selection	Expected result / Output	Performance Indicator	Data Source	Frequency of data collection	Target	Date to Achieve Target
Pest Management Programs	Pesticide Risk Reduction	AAFC (PMC); HC (PMRA)	Immediate Outcome	Increased awareness of and access to safer pest management products and practices.	Number of strategies in implementation phase (projects or other activities outlined in strategies underway)	Internal databases and program leads	Annual	2	March 31 annually
					Number of outreach activities undertaken; and number of information products disseminated to growers	Internal databases and program leads	Annual	2 outreach activities; 2 information products disseminated	March 31 annually
Pest Management Programs	Pesticide Risk Reduction	AAFC (PMC); HC (PMRA)	Intermediate Outcome	Adoption of safer pest management practices and products Improved pesticide resistance management Improved crop protection, practices and competitiveness	Percentage of reduced risk pesticides sold vs conventional pesticides; Number of new reduced-risk pesticide uses available for growers; # Workshops held with stakeholders Number of pest management beneficial management practices (BMPs) available for adoption by growers	Internal government databases and stakeholders information	Annual	5-10 new reduced risk pesticide uses registered annually; 3-5 new BMPs available annually	March 31 annually (starting in 2011)

Program Area	Program Name	Respon-sibility	Type Selection	Expected result / Output	Performance Indicator	Data Source	Frequency of data collection	Target	Date to Achieve Target
Pest Management Programs	Pesticide Risk Reduction	AAFC (PMC); HC (PMRA)	End outcome	Improved sustainability and competitive parity of Agriculture and Agri-food sectors with respect to pest management	Percentage of reduced risk pesticides sold vs conventional pesticides; percentage increase in growers compensated for pest management BMPs under EFP	Internal databases and program leads	Annual	2% increase annually of RR vs conventional pesticides sold; 2% increase annually in growers compensated under EFP	March 31 annually (starting in 2011)