



Health Santé
Canada Canada

**BUILDING PUBLIC CONFIDENCE IN PESTICIDE
REGULATION AND IMPROVING ACCESS TO PEST
MANAGEMENT PRODUCTS - HORIZONTAL INITIATIVE**

SUMMATIVE EVALUATION

Final Report

Approved by

Executive Committee

Finance, Evaluation and Accountability (EC-FEA)

February 8, 2011

Canada 

TABLE OF CONTENTS

- **Management Action Plan for the Building Public Confidence in Pesticide Regulation and Improving Access To Pest Management Products — Horizontal Initiative — Summative Evaluation**
- **Building Public Confidence in Pesticide Regulation and Improving Access To Pest Management Products — Horizontal Initiative — Summative Evaluation Report**

Building Public Confidence in Pesticide Regulation and Improving Access To Pest Management Products
Horizontal Initiative - Summative Evaluation
Management Response and Action Plan

Recommendations	Management Response and Actions	Responsible Manager	Proposed Timing
Activity Area 1: Research and Monitoring on the Presence and effects of Pesticides in the Environment (EnvCan, DFO, NRCan CFIA and AAFC)			
The 6NR partners, under the leadership of the HC-PMRA to:			
1.1. Develop a joint strategy to maintain and strengthen the focus of their pesticide-related research and monitoring work in support of HC-PMRA priority needs, and determine the associated funding requirements.	Agreed: Recognizing that the demand for research and monitoring work exceeds what can be done with the BPC funding allocations, the 6NR Research and Monitoring DG Committee will develop a strategy to strengthen the focus of pesticide-related research and monitoring work.	Director General, Environmental Assessment Directorate (EAD), Pest Management Regulatory Agency (PMRA), Health Canada (HC) in collaboration with 6NR partners	March 2012
1.2 Investigate the feasibility of sharing the findings from the 6NR research and monitoring work, and a summary of planned future work under the integrated 6NR work plans, with interested external stakeholders. This information sharing should be used to increase awareness of the environmental effects of pesticide use among external stakeholders.	Agreed: The 6NR Research and Monitoring DG Committee will develop a strategy for more broadly sharing, with interested external stakeholders, information on planned research and monitoring projects and the findings from current and past work. The plan will include provisions to ensure that 6NR research may still be published in peer reviewed journals.	Director General, EAD, PMRA, HC in collaboration with 6NR partners	March 2012
Activity Area 2: Strengthened Pesticide Regulation: Re-Evaluation (HC-PMRA)			
With regard to the re-evaluation of older active ingredients, HC-PMRA should:			
2.1 Prepare a work plan forecasting the anticipated timing of proposed re-evaluation decisions for the active ingredients first registered prior to 1995 and the initial group of active ingredients subject to 15-year re-evaluation, and associated workload and resource requirements, for use in the planning and management of the re-evaluation program.	Agreed: HC-PMRA has already drafted a work plan to ensure timely re-evaluation decisions for the remaining Phase 1 active ingredients. In addition, an annual summary of re-evaluation progress has been made available to interested stakeholders.	Director General, Re-evaluation Management Directorate (REMD), PMRA, HC	April 2011

Recommendations	Management Response and Actions	Responsible Manager	Proposed Timing
2.2 Publish an annual summary identifying the active ingredients that HC-PMRA will be re-evaluating in the coming year, the anticipated timing of proposed decisions for the active ingredients, and the progress made in the prior year.	Agreed: On an annual basis HC-PMRA will develop a workplan for each active ingredient under the 15 year statutory re-evaluation cycle, including a proposed time frame for proposed decisions. The summary of re-evaluation progress will continue to be updated annually and made available to interested stakeholders.	Director General, REMD, PMRA, HC	April 2011
Activity Area 2: Strengthened Pesticide Regulation: Incident Reporting, Regulation of Formulants, and Provision of Material Safety Data Sheets in workplaces (HC-PMRA)			
Formulants: With regard to the application and maintenance of the formulants policy, HC-PMRA to:			
2.3 Publish an up-to-date breakdown of the formulants in each of the five risk-based categories of such products on a regular basis, either annually or biennially.	Agreed: HC-PMRA will post its list of formulants to the website. Since updates to this list will be made automatically, this process will go beyond the recommendation to republish the list of formulants on an annual or biennial basis.	Chief Registrar, Registration Directorate (RD), PMRA, HC	March 2011
2.4 Develop and publish a strategy and time frame for gathering and reviewing information on the potentially adverse effects of the remaining potentially toxic formulants on List 2 and List 3 products for which HC-PMRA does not have information to determine which of the other four lists these formulants should be categorized to.	Agreed: When the USEPA begins its formulant reassessment program, HC-PMRA will work with its US counterparts, where appropriate. Details regarding the structure and implementation of this program will be posted to the HC website.	Chief Registrar, RD, PMRA, HC	March 2012
Incident Reporting:			
2.5 HC-PMRA's pesticide incident reporting system, accessed through the Public Registry should include supporting contextual information explaining the differences between possible associations and causal relationships between pesticide use and health or environmental effects.	Agreed: HC-PMRA will prepare plain language material for interested stakeholders to clearly explain the limitations of incident reporting data, and the way in which causal relationships between pesticide use and health or environmental effects are assessed.	Director General, Health Evaluation Directorate (HED), PMRA, HC	March 2011

Recommendations	Management Response and Actions	Responsible Manager	Proposed Timing
<p>Material Safety Data Sheets:</p> <p>2.6 HC-PMRA to finalize and implement regulations under the PCP Act as a matter of priority to ensure that consistent Material Safety Data Sheets are available for all pest control products available for use in Canada.</p>	<p>Partially Agreed:</p> <p>HC-PMRA encourages the availability of Material Safety Data Sheets for all pest control products used in Canadian workplaces. As indicated in the report, HC-PMRA surveyed pesticide manufacturers in 2008. An estimated 73% of Canadian pesticides already have Material Safety Data Sheets.</p> <p>In light of HC's anticipated publication of proposed revisions to the Hazardous Products Act and the Controlled Products Regulations which could affect workplace chemicals, HC-PMRA will closely monitor this work for opportunities to further ensure that consistent Material Safety Data Sheets are available for all pest control products in Canada.</p>	Director General, Policy, Communications and Regulatory Affairs Directorate (PCRADP), PMRA, HC,	December 2012
Activity Area 3: Pest Management Strategies: Risk Reduction Program (HC-PMRA, AAFC and NRCan)			
AAFC, HC-PMRA and NRCan to:			
<p>3.1 Periodically measure and report on the level of awareness and rate of application of risk reduction strategies, practices and tools developed by the PMC, NRCan and HC-PMRA among intended users. Provincial/territorial pest coordinators and grower groups should be involved in the development and application of the data collection methods.</p>	<p>Agreed:</p> <p>AAFC and HC-PMRA will jointly explore possible methods to collect data to gain better knowledge of trends in agricultural grower awareness and use of reduced risk tools and practices and techniques made available to them as a result of the program. AAFC and HC-PMRA are participating on the Planning Committee for a 2011 OECD Integrated Pest Management workshop which will focus on the implementation and adoption of Integrated Pest Management and the resulting risk reduction benefits.</p> <p>Following this workshop, AAFC, and HC-PMRA will jointly develop a performance measurement strategy, in cooperation with appropriate provincial/territorial ministries and grower groups, to measure the awareness and uptake rate of risk reduction practices and tools developed by the PMC and HC-PMRA. Information related to the workshop and the performance measurement strategy will be shared with NRCan.</p> <p>NRCan will explore possible methods to collect data to assess and report on the forestry sector trends in the use of reduced risk tools, practices and techniques developed by NRCan as a result of the risk reduction program.</p>	<p>Director General, Pest Management Centre (PMC), Agriculture and Agri-Food Canada (AAFC) and Director General, Value and Sustainability Assessment Directorate (VASD), PMRA, HC</p> <p>Director General, Canadian Forest Service (CFS), Natural Resources Canada (NRCan)</p>	<p>March 2014</p> <p>March 2014</p>

Recommendations	Management Response and Actions	Responsible Manager	Proposed Timing
3.2 Identify the cost and revenue parameters of risk reduction tools and practices developed by the Pesticide Risk Reduction Program to enable growers to estimate impacts from applying these tools and practices. This information should be made available to growers and other interested stakeholders as part of the promotion and demonstration of these tools and practices.	<p>Agreed: AAFC will continue to make efforts to include economic parameters associated with risk reduction tools and practices developed through the Pesticide Risk Reduction Program, thereby better enabling growers to estimate the impacts from adoption.</p> <p>AAFC and HC-PMRA will also continue to work together on communications materials and approaches to inform growers and users about the use and utility of reduced risk tools, practices and techniques developed through their collaboration.</p> <p>Together these activities should lead to adoption of safer pest management practices and products, and improved crop protection practices and competitiveness.</p>	Director General, PMC, AAFC and Director General, VSAD, PMRA, HC	December 2012
	<p>Where appropriate, NRCAN will provide economic information related to risk reduction tools and practices developed through the Pesticide Risk Reduction Program, thereby better enabling user groups to estimate returns from adoption.</p>	Director General, CFS, NRCAN	December 2012

Recommendations	Management Response and Actions	Responsible Manager	Proposed Timing
Activity Area 3: Pest Management Strategies: Minor Use Program (HC-PMRA, AAFC)			
HC-PMRA and AAFC to:			
<p>3.3 Assess the current size and structure of the minor use technology gap facing Canadian growers, and periodically update this analysis and report on the extent to which the gap is being addressed.</p>	<p>Agreed: HC PMRA in collaboration with AAFC is committed to reducing the technology gap for Minor Uses and preventing future expansion of the technology gap through minor use label expansions under the Minor Use program. Other separate programs that address these commitments include a streamlined process for the evaluation of grower identified priority active ingredients (i.e., Program 914) and Global Joint Reviews of new pesticides.</p> <p>The US/Canada Grower Priority Database will be used as the primary measure of the trends in the technology gap for minor and other uses of pesticides. Based on input from Canadian growers, the database, which was initiated by the NAFTA Technical Working Group on Pesticides, will gauge our success in increasing the access to pest control products for the agricultural sector.</p> <p>HC PMRA will assess the minor use technology gap and report broadly, on an annual basis on trends and initiatives to reduce or prevent future expansion of the technology gap.</p>	<p>Director General, VSAD, PMRA, HC</p>	<p>December 2011</p>
<p>3.4 Develop an integrated approach to the measurement and reporting of the numbers of potential new minor use registrations involved in the PMC's projects, and the associated numbers of minor use registration submissions reviewed by HC PMRA and new minor uses registered.</p>	<p>Agreed: HC PMRA and AAFC are working together to develop clear, harmonized reporting that will illustrate how PMC projects contribute to minor use registration submissions reviewed by HC PMRA and new minor uses registered. This new reporting structure will provide more useful information to senior management/decision makers and will improve performance measurement.</p>	<p>Director General, PMC, AAFC and Director General, VSAD, PMRA, HC</p>	<p>March 2012</p>

Recommendations	Management Response and Actions	Responsible Manager	Proposed Timing
Activity Area 4: Enhanced Stakeholder and Public Transparency and Engagement (HC-PMRA)			
HC-PMRA to:			
<p>4.1 Continue to enhance its web presence to provide better access to information on all aspects of the pesticide regulatory system, including the findings from the research and monitoring work of the HC PMRA's partners in the BPC Initiative.</p>	<p>Agreed: Since the initiation of this evaluation, HC PMRA has completed the enhancement of its web presence based on stakeholder feedback on the changeover to the Government of Canada's Common Look and Feel standard.</p> <p>As indicated in the Management Response to Recommendation 1.2, the 6NR Research and Monitoring DG Committee will develop a strategy for the sharing more broadly with interested external stakeholders of information on planned research and monitoring projects and the findings from current and past work.</p>	<p>Director General, EAD, PMRA, HC in collaboration with 6NR partners</p>	<p>March 2012</p>
<p>4.2 Conduct an assessment of the effectiveness of current methods used to strengthen awareness and understanding of the pesticide regulatory system, the health and environmental effects of pesticides, and status of proposed decisions and other regulatory initiatives, and implement changes and refinements to address any identified gaps.</p>	<p>Agreed: HC PMRA recognizes the importance of better informing Canadians about how pesticides are regulated and how these products should be used, and has made public confidence a strategic outcome in its 2008-2013 Strategic Plan. Work is already underway to enhance the effectiveness and transparency of current communications methods. HC PMRA is working jointly with HC Public Affairs, Consultations and Communications Branch on a Consumer Information Strategy which includes various initiatives aimed at measuring, improving and evaluating communication activities for the Canadian public. As a result, HC PMRA has updated its suite of Pest Notes (25) and public fact sheets (5) and made changes to its web presence to increase its visibility and improve search hit results. HC PMRA has also implemented an exhibit plan to promote responsible pesticide use and protection of health and the environment to interested stakeholders and the Canadian public. In the future, HC PMRA will continue to develop effective communications strategies and products for targeted Canadian audiences.</p>	<p>Director General, PCRAD, PMRA, HC</p>	<p>September 2010</p>

**BUILDING PUBLIC CONFIDENCE IN PESTICIDE
REGULATION AND IMPROVING ACCESS TO PEST
MANAGEMENT PRODUCTS – HORIZONTAL INITIATIVE**

Summative Evaluation

Final Report

November 2010

Canada 

Prepared by:

KPMG LLP
160 Elgin Street, Suite 2000
Ottawa, ON K2P 2P8

Table of Contents

Executive Summary.....	iii
A. Objectives and structure of the initiative.....	iii
B. Objectives of the evaluation.....	iv
C. Evaluation methodology.....	v
D. Effectiveness of the research and monitoring stream (HC-PMRA, EnvCan, DFO, NRCan, CFIA).....	v
E. Effectiveness of the strengthened pesticide regulation stream (HC-PMRA).....	viii
F. Effectiveness of the pest management strategies stream (HC-PMRA, AAFC, NRCan).....	xii
G. Effectiveness of the enhanced transparency and engagement stream (HC-PMRA).....	xv
H. Overall relevance and performance of the BPC Initiative.....	xvii
I. Progress toward the achievement of intended final outcomes.....	xx
I. Introduction.....	1
II. Evaluation Objectives.....	2
A. Objectives of the evaluation.....	2
B. Context for the evaluation.....	3
C. Evaluation issues.....	3
D. Data collection methodology.....	5
E. Limitations.....	7
III. Overview of the BPC Initiative.....	8
A. Context for pesticide regulation in Canada.....	8
B. Objectives, structure and governance of the BPC Initiative.....	9
C. BPC logic model.....	11
D. Funding allocated to the BPC Initiative.....	13
E. Organization and presentation of the evaluation findings.....	14
IV. Research and Monitoring in Support of Pesticide Regulation.....	15
A. Purpose of the BPC research and monitoring activities.....	15
B. Research and monitoring activities.....	16
C. Findings from internal interviews and documents.....	19
D. Findings from external sources.....	25
E. Conclusions and recommendations.....	29
V. Strengthened Pesticide Regulation.....	33
A. Program description.....	33
B. Re-evaluation of older pesticides.....	34
C. Pesticide incident reporting system.....	46
D. Implementation of a policy on formulants.....	52
E. Provision of Material Safety Data Sheets (MSDS) data to workplaces.....	56
F. Overall conclusions and recommendations.....	58
VI. Pest Management Strategies.....	60
A. Purpose of the BPC pest management strategies stream.....	60
B. Pesticide Risk Reduction Program.....	61
C. Minor Use Pesticides Program.....	70
D. Conclusions and recommendations.....	80
VII. Enhanced Transparency and Engagement.....	85
A. Purpose of the enhanced transparency stream.....	85
B. Enhanced transparency and engagement activities.....	86
C. Achievement of intended outcomes.....	89
D. Conclusions and recommendations.....	98
VIII. Overall relevance and performance of the BPC Initiative.....	100
A. Relevance and performance of the BPC Initiative.....	100
B. Progress towards intended final outcomes.....	110
C. Implementation of formative evaluation recommendations.....	116

EXECUTIVE SUMMARY

A. Objectives and structure of the initiative

Formal responsibility for the regulation of pesticides is shared between the federal and provincial/territorial levels of government. The federal government has the authority to regulate the import, manufacture, sale and use of pesticides, which is exercised under the *Pest Control Products Act* (PCP Act) and regulations with the objective of preventing unacceptable risks to people and the environment from the use of pest control products.

The *Building Public Confidence in Pesticide Regulation and Improving Access To Pest Management Products Initiative* (BPC Initiative) was created in 2002/03 to enable key new provisions of the new PCP Act¹ to be implemented, improve access to reduced risk pest control products and methods, and strengthen public and stakeholder confidence in pesticide regulation in Canada. In doing so, the BPC Initiative is expected to contribute to the achievement of three final outcomes:

1. Improved protection of health and the environment.
2. Improved competitive parity of agricultural and forestry sectors.
3. Increased public and stakeholder confidence in the pesticide regulatory system.

Four streams of activity are involved:

- Research and monitoring activities to provide Health Canada's Pest Management Regulatory Agency (HC-PMRA) with information on the environmental effects of pesticides and presence of residues on foods consumed by children, and to enable CFIA to verify fertilizer-pesticide guarantees and monitor fertilizer products for pesticide contamination.
- Implementation of actions to strengthen pesticide regulation required by the new PCP Act – re-evaluation of pesticides registered prior to 1995, reporting of incidents due to the unintended presence and effects of pesticides, strengthened regulation of formulants used in pesticides, and the provision of Material Safety Data Sheets (MSDS) to workplaces where pesticides are manufactured, handled or used.
- Development and implementation of commodity based risk reduction strategies for the agriculture and forestry sectors, and actions to facilitate registration and access to reduced risk and minor use pesticides.
- Implementation of mechanisms to increase public and stakeholder consultation and engagement regarding proposed HC-PMRA decisions, and policies, and provide for the conduct of special reviews if there are reasonable grounds to believe a pesticide poses unacceptable health or environmental risk.

¹ The new PCP Act intended received Royal Assent in December 2002 and came into force in June 2006.

Delivery of the BPC Initiative is via thirteen component programs distributed amongst six departments and agencies: HC-PMRA, Agriculture and Agri-Food Canada (AAFC), Environment Canada (EnvCan), Fisheries and Oceans Canada (DFO), Natural Resources Canada (NRCan), and the Canadian Food Inspection Agency (CFIA). Total funding allocated for the initial six-year period of the BPC Initiative, from 2002/03 to 2007/08, is shown in the table below. Funding for the research and monitoring, strengthened pesticide regulation and enhanced transparency streams of the BPC Initiative continued at 2007/08 levels thereafter as part of the A-base for each of the participating departments and agencies.

Composition of BPC Initiative funding by participating departments and agencies, 2002/03 to 2007/08	
Research and monitoring	(\$ millions)
HC-PMRA – linking regulation and research	\$3.4
EnvCan – Monitoring and research of presence and effects of pesticides in the environment	\$8.0
DFO – monitoring and research of presence and effects of pesticides in marine and freshwater ecosystems	\$6.9
NRCan – monitoring and research of presence and effects of pesticides in the forest environment	\$3.0
CFIA – enhanced monitoring and enforcement of pesticide residue limits in foods and feed ²	\$2.7
CFIA – enhanced monitoring and enforcement of pesticide residues in fertilizers and pesticide guarantees in fertilizer-pesticide combinations	\$1.9
Sub-total:	\$25.9
Strengthened pesticide regulation	
Accelerated and priority re-evaluation of older pesticides (HC-PMRA)	\$13.8
Tracking adverse effects of pesticides (HC-PMRA)	\$6.0
Updating processes to regulate pesticide formulants (HC-PMRA)	\$9.0
Meeting Workplace Hazardous Material Information System (WHMIS) objectives for pesticides (HC-PMRA)	\$4.5
Sub-total:	\$33.3
Pest management strategies:	
Developing and implementing commodity specific risk reduction strategies	
- AAFC	\$58.5
- HC-PMRA	\$46.0
Developing and facilitating use of reduced risk pesticides and biological pesticides for forestry (NRCan)	\$3.6
Sub-total:	\$108.1
Enhanced transparency and engagement:	
Consultation on and reconsideration of registration decisions, access to regulatory information, sharing confidential information (HC-PMRA)	\$18.4
Total – BPC Initiative:	\$185.7

B. Objectives of the evaluation

The objectives of the summative evaluation of the BPC Initiative were to:

- Assess key areas of relevance and performance (effectiveness, efficiency and economy);
- Highlight achievements and lessons learned, as well as any challenges that were experienced;
- Determine the degree to which the management action plan commitments in response to the formative evaluation recommendations were met;

²

Under the BPC Initiative, the CFIA monitors the incidence of pesticide residues in foods consumed by children and infants. This activity supplements work by the CFIA monitoring the presence of chemical residues in the food supply under the National Chemical Residue Monitoring Program (NCRMP).

- Address accountability requirements of the commitments made in the original submission to Treasury Board; and
- Address broad performance measurement needs of senior management in support of management decision making with respect to the future of the programs.

In addressing these objectives, the evaluation was expected to answer a series of evaluation issues and questions relating to the Initiative's rationale and relevance, achievement of short and medium term intended outcomes, extent to which the long-term outcomes are likely to be achieved. The key findings from the evaluation summarized below are organized under these evaluation issues, many of which are directly linked to the achievement of the intended short and medium-term outcomes of the BPC Initiative.

C. Evaluation methodology

The methodology for the evaluation involved the following lines of enquiry:

- **Literature review.** A literature review was used to investigate peer reviewed and other published information on best practices in promoting public confidence in a wide range of science-based regulatory initiatives with direct implications for pesticides regulation.
- **Review of BPC documents.** BPC-related documentation was reviewed to identify and assess the rationale for the BPC, its execution, and outputs and outcomes.
- **Key informant interviews.** Two separate programs of key informant interviews were used to obtain information and insights into the achievement of intended outcomes from the BPC Initiative. The first group were program managers and leads at each of the participating departments and agencies. The second group was composed of a sample of representatives of selected external key stakeholders, spanning growers, registrants, provincial governments, public interest advocacy groups, and federal and academic researchers.
- **Online survey of external stakeholders.** An online survey of stakeholders was used to complement and extend the investigation of the effectiveness of the BPC Initiative among external stakeholders who indicated they were aware of one or more of the thematic groupings of the major streams of work covered by the BPC Initiative. The survey sample was composed of stakeholders who had requested that they be kept informed of pesticide regulation or minor use and risk reduction matters by HC-PMRA and AAFC. A total of 282 individuals completed the survey giving a response rate of 20% on the starting sample of 1,425 individuals, which is considered to be in the normal range of response rates for a survey of this kind.

D. Effectiveness of the research and monitoring stream (HC-PMRA, EnvCan, DFO, NRCan, CFIA)

The evaluation findings relating to the research and monitoring stream of the BPC Initiative demonstrate how horizontal coordination in support of science-based regulatory decision-making can work, and enables HC-PMRA to benefit from the expertise and knowledge resident among its 6NR partners. The experience with developing this collaborative approach also demonstrates that effective horizontal coordination and integration across the federal government requires a clear vision, sustained effort and transparent processes.

A number of challenges or opportunities are apparent with regard to the future operation of the 6NR structure. The first is that of sustaining the level of horizontal integration and information sharing now that the previously dedicated BPC funding has been converted to ongoing A-base funding in each of the participating departments and agencies.

The second is that of strengthening the funding base to enable the 6NR partners to better respond to HC-PMRA's priority needs and address gaps in the understanding of post-market effects of pesticides on the environment and human health. Comments made by the program leads indicate that the potential demand for research and monitoring information exceeds what can be undertaken with current BPC funding even after combining these activities with other departmental research or environmental monitoring initiatives. These program leads also identified opportunities to further develop collaborative approaches between EnvCan, DFO and NRCan; measure and monitor the environmental effects of additional pesticides; conduct research into the incidence and effects of mixtures of pesticides; and hold regular face-to-face meetings to review HC-PMRA's information needs and the findings from research and monitoring work. They also cautioned that any expansion of funding for research and monitoring work should include provisions to add permanent FTEs to strengthen and maintain capacity in their respective fields.

Finally, external stakeholders suggested that research and monitoring findings be shared beyond the 6NR partners to help other stakeholders, such as provincial and territorial levels of government and registrants, better understand the environmental effects of pesticides in use.

Five evaluation questions relating to the performance of the research and monitoring stream were investigated.

-
1. To what extent and in what ways has collaboration among HC-PMRA and its 6NR partners in support of pesticide risk analysis changed as a result of the BPC Initiative?
-

According to the program managers and leads involved in the research and monitoring components of the BPC Initiative, the quality of the collaboration and integration of 6NR work planning has evolved significantly since the inception of the Initiative and more so since the formative evaluation in 2006. This evolution was shaped by such factors as:

- The evolution of a more integrated approach to work planning where the various 6NR partners ask each other for input to their project selection and planning activities and HC-PMRA is able to more readily tap into the knowledge and expertise of the 6NR partners.
- An increased level of understanding among the 6NR partners of the way HC-PMRA uses scientific information in its risk assessment and risk management work. In parallel, HC-PMRA gained a better understanding of the lead time and steps involved in establishing and conducting research projects and monitoring programs.
- Establishment of a DG-level committee to provide strategic guidance and direction for the work of the 6NR Working Group, which is the principal mechanism for integrating and coordinating the work of the six participating departments and agencies.

The pesticide research and monitoring work of the 6NR partners has, to a large extent, been embedded within more extensive departmentally-mandated activities. In many instances, this means that these departments and agencies have been able to combine their pesticide-related work with other departmental research or environmental monitoring initiatives and thereby gain leverage on their BPC funding.

-
-
2. Has there been an improvement in the quantity of useful information on the presence and effects of pesticides to support registration and re-evaluation of pesticides?
 - (a) Has there been an improvement in sharing of monitoring data that contributes to pesticide regulatory decision making?
 - (b) How has this information been used to support pesticide risk management?
-
-

Comments and supporting documentation provided by program leads responsible for the research and monitoring of the environmental effects of pesticides, demonstrates that there has been an improvement in the quantity of useful information on the presence and effects of pesticides to support registration and re-evaluation of pesticides. This improvement is a function of the further integration of the 6NR work planning and information sharing practices and the increased availability of information as research and monitoring projects reach the point where meaningful information for input to risk analysis and management can be generated.

-
-
3. To what extent has there been an improvement in risk management of pesticides as a result of BPC program activities?
-
-

The degree to which the risk management of pesticides has improved can only be inferred in that the breadth and depth of information on the environmental presence and effects of pesticides is strengthened and results in better informed risk assessments and risk mitigation strategies. It is too soon to be able to measure any discernible change in the environmental effects of pesticides that can be attributed to changes in the availability of post-market information for consideration in HC-PMRA's approach to risk management. Further long-term research and monitoring work will be necessary to determine if the environmental presence and effects of pesticides is reduced.

HC-PMRA managers responsible for aspects of the Agency's risk assessment work believed that the availability of 6NR research and monitoring data had improved the quality of their risk assessments and aided decision-making to determine if various active ingredients subject to re-evaluation should be subject to more stringent conditions of use or removed from all use in Canada. These views are supported by the documentation on a range of recent decisions that include references to the use of data from monitoring work enabled by the BPC Initiative in the supporting rationale and risk analyses.

-
-
4. To what extent has compliance with guarantee and residue standards by food and fertilizer industry sectors been enhanced?
 5. Has the safety of foods, fertilizers and fertilizer-pesticide combinations available to Canadians increased as result of the CFIA's monitoring programs?
-
-

As a result of the BPC Initiative, the CFIA (and HC-PMRA) has obtained a better understanding of the extent to which pesticide residues are present on processed food products typically consumed by children. Similarly, the CFIA has expanded its capability to verify the presence of pesticide levels in fertilizer-pesticide combination products and the incidence of pesticide contamination in fertilizers. Awareness of compliance rates has been enhanced through contacts with food and fertilizer companies in the course of program delivery as well as the associated industry associations.

In the case of residues on food products, compliance rates by Canadian manufacturers and importers of children's food products have been consistently high dating back to the time of the first CFIA monitoring survey in 2003/04. The snapshots provided by the CFIA's surveys of pesticide residues on processed food products typically consumed by children show that the majority of the sampled products have consistently been within established legal limits for the presence of pesticide residues, with over 98% of the samples in each of the surveys having either no detectable residues present or residues below the applicable Maximum Residue Limits (MRLs). These results suggest that children's foods have a high degree of compliance and thus are likely to be "safe" in the sense of limiting inadvertent exposure to pesticides.

With regard to fertilizers and fertilizer-pesticide combinations, low compliance rates (below 70% in recent years for fertilizer-pesticide guarantee verification and below 90% for pesticide contamination monitoring) have prompted the CFIA to engage with the fertilizer industry to improve quality control procedures, to target companies and products with repeat infringements.

Recommendations relating to the research and monitoring stream

The 6NR partners, under the leadership of HC-PMRA, to:

- 1. Develop a joint strategy to maintain and strengthen the focus of their pesticide-related research and monitoring work in support of HC-PMRA priority needs, and determine the associated funding requirements.**
- 2. Investigate the feasibility of sharing the findings from the 6NR research and monitoring work, and a summary of planned future work under the integrated 6NR work plans, with interested external stakeholders. This information sharing should be used to increase awareness of the environmental effects of pesticide use among external stakeholders.**

E. Effectiveness of the strengthened pesticide regulation stream (HC-PMRA)

Accelerated rate of re-evaluation of pesticides registered prior to 1995

-
-
1. As a result of the BPC funding, what proportion of active ingredients registered prior to 1995 has been re-evaluated?³ Of these,
 - (a) What proportion required amendments for continued registration?
 - (b) What proportion did HC-PMRA take action to remove from the market place?
 2. What progress has been made to ensure that only those pest control products that meet modern standards remain registered?
-
-

Data provided by the re-evaluation program show that in 2003/04 final decisions had been issued for 80 of 401 pesticides, or 20% of the total. By the end of 2008/09 the total had risen to 252 or 63% of the total, and 270 by the end of 2009/10. The breakdown of these outcomes was:

³ The evaluation questions originally used the term "products". "Active ingredients" has been substituted to recognize that the re-evaluation program measures the number of active ingredients (or "pesticides") that are re-evaluated.

- Continued registration with no changes to the label requirements: 9 of the 252 (4%) at the end of 2008/09, and 10 of the 270 (4%) at the end of 2009/10.
- Continued registration with changes to the label requirements: 153 (61%) and 169 (63%).
- Phase-out at the instigation of HC-PMRA: 7 (3%) in both years.
- Discontinuation or withdrawal by the registrant: 83 (33%) and 84 (31%).

In addition, substantial progress had been made on the re-evaluation of another 90 products at the end of 2009/10, as evidenced by the issuance of proposed decisions or re-evaluation notes for public consultation prior to final decision making. This means that re-evaluations of the last 41 active ingredients had not progressed to the point where proposed decisions could be made and that work on these re-evaluations will likely continue through 2010/11 and 2011/12, in addition to work on the finalization of the 90 proposed or pending decisions outstanding at the end of 2009/10.

Starting in 2010/11, HC-PMRA will initiate work on the re-evaluation of active ingredients that were registered in 1995 or later, which is a requirement of the *PCP Act*, while completing the re-evaluation of the outstanding older active ingredients. The Agency will need to forecast the workloads and resource requirements for both of these areas of re-evaluation work and factor them into its budgeting. Additional workload demands, such as the need to review confirmatory risk studies requested of registrants as a requirement in re-evaluation decisions, and research and develop policies to keep HC-PMRA's risk assessments and risk management consistent with current scientific knowledge and standards, will also need to be factored into resource planning for the re-evaluation program.

Pesticide incident reporting system

-
1. Has there been an improvement in the quantity of useful information on the presence and effects of pesticides to support registration and re-evaluation of pesticides?
 - (a) Has there been an improvement in sharing of monitoring data that contributes to pesticide regulatory decision making?
 - (b) How has this information been used to support pesticide risk management?
 2. To what extent has there been an improvement in risk management of pesticides as a result of BPC program activities?
-

The implementation of the Pesticide Incident Reporting system in April 2007 provides the foundation for the collection of "raw" post-market information on possible unintended or unexplained effects of pesticide use following registration. This information provides only a starting point, however, for identifying possible health and environment effects of pesticides. In order to provide useful information to inform pesticide risk management, further investigation of both individual incidents and broader patterns by HC-PMRA is necessary, both into the context in which incidents occurred and the science of the active ingredient(s) involved.

Both HC-PMRA's program leads and the majority of the external stakeholders interviewed believe that the incident reporting system will provide HC-PMRA with a new source of post-market information on the effects of pesticides and improved pesticide risk management. Early experience with the investigations of particular incidents and the identification of broader patterns and trends in incidents also support this view.

Both external key informants and survey participants suggested that public understanding of the incident reports on HC-PMRA's Public Registry would benefit from the inclusion of supporting contextual information explaining the differences between possible associations and causal relationships between pesticide use and health or environmental effects.

Implementation of the Formulants Policy

-
1. Has the formulants program contributed to an increased awareness, by registrants, of Canadian formulant requirements?
-

The integration of the formulants regulatory process into the product registration, amendment and renewal process ensures that registrants are made aware of the requirements of the policy at the time their products become due for mandatory renewal or a registration/amendment action takes place. However, awareness levels are not formally measured or tracked by the Agency.

-
2. What progress has been made to ensure that only those pest control products that meet modern standards remain registered?
-

A key objective of the formulants policy is to identify and phase out formulants that pose unacceptable risks to health and the environment and replace them with lower risk formulants. Formulants of greatest concern have been identified and actions have been taken to remove these products from use in pest control products. Only two List 1 formulants of toxicological concern are in use compared to nine in 2004, and the number of pest control products using these formulants is now down to five compared to 72 in 2004.

The HC-PMRA product registration renewal and registration amendment processes enable HC-PMRA to update its information on the use of different formulants. This renewal process means that HC-PMRA can check the compliance status of product formulations on a regular basis (at least every five years) and ensure that the formulants used meet currently applicable standards.

However, HC-PMRA has not yet set target time frames for gathering and reviewing information on the potentially adverse effects of 100 List 2 formulants (potentially toxic formulants) and over 800 remaining List 3 formulants (of unknown toxicity), and re-classifying or discontinuing these products.

Provision of Material Safety Data Sheets (MSDS) in the workplace (HC-PMRA)

-
1. To what extent has work under the BPC Initiative increased the availability of MSDS in workplaces?
 2. Has employee awareness of pesticide safety and hazard information increased as a result of the requirement for provision of WHMIS/MSDS data to workplaces?
-

The current state of implementation of a WHMIS/MSDS regulation means that the intended outcomes from this component of the BPC Initiative are yet to be achieved.

HC-PMRA anticipates going to Gazette 1 with an updated version of the proposed regulation in late-2010. Once introduced it will take up to five years to fully implement the final regulation as it is phased in through the pesticide registration renewal process. Research conducted by HC-PMRA in relation to the development of the draft regulation found that MSDS are already available for an estimated 73% of pesticide products in the Canadian marketplace. HC-PMRA also hopes to coordinate the introduction of the MSDS regulation with the introduction of changes to MSDS requirements for other chemical products under the *Hazardous Products Act*.

Overall impact

The expected final outcome from the measures to strengthen the pesticide regulatory system is improved protection of health and the environment, in combination with the outcomes from the research and monitoring stream of the BPC Initiative. The measures taken under the strengthened pesticide regulation stream of the BPC Initiative mean that products that pose risks to either health or the environment when assessed against current standards are progressively being made subject to more stringent conditions of use or removed from the market, and HC-PMRA has better information to inform its risk assessment and risk mitigation strategies. This suggests, by inference, that protection of health and the environment will ultimately be enhanced.

Recommendations relating to the strengthened pesticide regulation stream

1. **With regard to the re-evaluation of older active ingredients, HC-PMRA should:**
 - **Prepare a work plan forecasting the anticipated timing of proposed re-evaluation decisions for the active ingredients first registered prior to 1995 and the initial group of active ingredients subject to 15-year re-evaluation, and associated workload and resource requirements, for use in the planning and management of the re-evaluation program.**
 - **Publish an annual summary identifying the active ingredients that HC-PMRA will be re-evaluating in the coming year, the anticipated timing of proposed decisions for the active ingredients, and the progress made in the prior year.**
2. **With regard to the application and maintenance of the formulants policy, HC-PMRA to:**
 - **Publish an up-to-date breakdown of the formulants in each of the five risk-based categories of such products on a regular basis, either annually or biennially.**
 - **Develop and publish a strategy and time frame for gathering and reviewing information on the potentially adverse effects of the remaining potentially toxic formulants on List 2 and List 3 products for which HC-PMRA does not have information to determine which of the other four lists these formulants should be categorized to.**
3. **HC-PMRA's pesticide incident reporting system, accessed through the Public Registry, should include supporting contextual information explaining the differences between possible associations and causal relationships between pesticide use and health or environmental effects.**
4. **With regard to the provision of MSDS in the workplace, HC-PMRA to finalize and implement regulations under the *PCP Act* as a matter of priority to ensure that consistent MSDS are available for all pest control products available for use in Canada.**

F. Effectiveness of the pest management strategies stream (HC-PMRA, AAFC, NRCan)

-
1. Have the Minor Use and Risk Reduction Programs improved access to, and increased awareness of, safer pest management products and practices? How, and to what extent?
 2. Has the adoption of safer pest management practices and products for the agricultural and forestry sectors increased?
-

HC-PMRA and the AAFC Pest Management Centre (PMC) jointly deliver the pest management strategies stream of the BPC Initiative. Two programs are delivered: the Minor Use Pesticides Program, to facilitate access to new minor use pesticides for Canadian growers, and the Pesticide Risk Reduction Program, to support the development and implementation of reduced risk pest management solutions for both major and minor crops. In addition, NRCan undertakes work to develop and support the use of reduced risk pesticides and biopesticides in forestry, and develop alternative forest pest management strategies. This work is performed by the Canadian Forest Service's network of Forestry Centres and in cooperation with the PMC.

a) Pesticide Risk Reduction Program

The principal outputs from the Pesticide Risk Reduction Program with potential for direct application by growers are strategies for addressing priority pest management issues, and associated products, tools and practices to better manage pests. A total of 160 risk reduction implementation projects have been initiated by the Program since 2003/04 to develop reduced risk pest control products, practices and tools for application in the agricultural and forestry sectors.

Awareness of risk reduction products, tools and practices was promoted through demonstration projects, field days hosted by AAFC facilities, presentations at key industry meetings and distribution of information through such channels as the PMC newsletter, distribution of fact sheets, and website, plus communications to growers by provincial ministries, grower associations and registrants. However, levels of interest and subsequent rates of adoption and sustained use have not been measured nor the impacts on rates of pesticide use.

The key targets and stakeholders for the Program are growers, grower groups, provincial/territorial pest management organizations and registrants. Substantial majorities of these stakeholder representatives who participated in the survey or external key informant interviews believed that the Pesticide Risk Reduction Program had made either a "substantial" or a "small" positive contribution to the achievement of its two intended short-term outcomes and two of the three intended medium-term outcomes:

- Improving access to, and adoption of, reduced risk pesticides (76% positive rating among survey respondents).
- Increasing awareness of safer pest management practices and products (70%),
- Increasing the rate of adoption of safer pest management practices and products (70%).
- Improved crop protection practices (64%).

These external stakeholders were less likely to view the Program as making a positive contribution to the achievement of a third medium-term outcome – improving the management of pesticide resistance (54%) – and intended final outcome – improving the competitive parity of the agricultural and forestry sectors with regard to pest management (40%). In their comments the external stakeholders noted that more

training and demonstration projects are needed to increase the rate of adoption among growers, and that growers need information on reduced risk pest management alternatives to understand how (or if) they are economically viable.

b) Minor Use Program

The Minor Use Program focuses on registration of new minor uses of pesticides in accord with annual priorities established through a consensus process involving growers, grower groups, provincial/territorial pest management coordinators and pesticide manufacturers. Priorities for joint registration projects with the U.S. IR-4 (equivalent to the AAFC PMC) are also determined, leading to parallel registrations of new minor uses in Canada and the U.S.

A total of 638 minor use registration projects were initiated by the PMC between 2002/03 and the end of December 2009, and 234 (37%) projects were completed and submitted to HC-PMRA for registration review. Of these, 160 were accepted for use, 8 were rejected, and 66 were still undergoing review.

Submissions generated by the PMC since 2003/04 led to 454 registrations of new minor uses of pesticides, which represents 15% of the total number of new minor use registrations by HC-PMRA between 2003/04 and the end of 2009. The remaining 2,671 registrations were submissions made by provincial Minor Use Coordinators and non-minor use registration submissions by registrants outside of the BPC-funded Minor Use Program.

Differences in the way AAFC counts and tracks projects and the way HC-PMRA counts and tracks new minor use registrations mean that PMC projects do not equate directly to minor use registration submissions and subsequent registrations. This lack of direct comparability between PMC and HC-PMRA data is a weakness in the current performance reporting between the AAFC and HC-PMRA.

Substantial majorities of the survey respondents and external key informants believed the Minor Use Program had made either a “substantial” or a “small” positive contribution to the achievement of the four of the Program’s five intended outcomes:

- Improving access to and adoption of minor use and biopesticide products, particularly reduced risk pesticides (75% of the survey respondents rated the Program’s performance as making either a “substantial” or a “small” positive contribution).
- Increasing the rate of adoption and use of safer pest management practices and products (72%).
- Improving crop protection practices (68%).
- Increasing awareness of safer pest management practices and products (65%).

Survey respondents and key informants were less likely to believe the Program had made a positive contribution to improved management of pesticide resistance (60%) and improved competitive parity of the Canadian agricultural and forestry sectors with regard to pest management (56%). The key informants noted that there are insufficient products available to effectively manage pesticide resistance by rotating between different classes of products, especially given that resistance to narrow spectrum products tends to develop faster than resistance to older, broader-spectrum products.

In summary, both the internal and external key informants, as well as online survey respondents, perceive that awareness is being developed and safer pest management products and practices are available. The grower-driven nature of the minor use priority setting process means that awareness of new minor use registrations, including those for reduced risk products, is likely to be readily communicated by grower groups and provincial/territorial minor use coordinators and the products considered for use by growers in situations where growing conditions warrant their use.

3. Has pesticide resistance management improved?

AAFC and HC-PMRA program management and staff generally believe that the Minor Use Program has contributed to, or could potentially contribute to, improved management of pesticide resistance. However, the measurement of the contribution of the Risk Reduction and Minor Use Programs towards the achievement of improved pesticide resistance management is constrained by a lack of reliable data and difficulties in measuring the incidence and rate of development of pesticide resistance.

External key informants were less likely to believe that pesticide resistance management has improved as a result of the Pesticide Risk Reduction and Minor Use Programs. Factors that shaped their views typically related to the limited range of pest management options available to many growers, the faster rate at which resistance to the more targeted newer products develops, and the impact of the re-evaluation program. They also noted that the re-evaluation program has resulted in the removal of some products, and changes to the permitted uses and conditions of use of others that may have otherwise played an important role in the resistance management strategies of growers. Participants in the survey had a more positive view regarding the impact of the pest management strategies work on the management of pesticide resistance, with 54% of those who were familiar with the Pesticide Risk Reduction Program, and 60% of those who were familiar with the Minor Use Program, of the view that the programs has made either a “substantial” or “small” positive contribution.

4. Has the competitive parity of the agricultural sector been strengthened?

The Minor Use Program staff interviewed believe the Program has made a contribution in addressing the “technology gap” faced by Canadian growers that gave rise to the Program. This gap is the difference in access to pesticide products and approved uses in Canada compared to access for growers in other countries, most notably the U.S. Measuring the size of the gap is difficult due to such factors as the possible combinations of active ingredients, end-uses and MRLs, and the dynamic nature of growing conditions and pest management challenges encountered by growers. As a result, there are no currently available data indicating if, and at what rate, the gap is being closed.

External key informants were more concerned that Canadian growers continued to face a significant technology gap compared to U.S. growers even though the Minor Use Program has been successful in increasing the rate of new use registrations. They were also concerned that the rate of new product and new minor use registrations was not keeping up with the rate of removal of older products or application of more stringent conditions on their use under the re-evaluation program.

5. Has the forestry sector adopted pesticide risk reduction strategies and increased its use of reduced risk and biological pesticides?

It is not possible to make a definitive conclusion as to whether the forestry sector adopted pesticide risk reduction strategies and increased its use of reduced risk and biological pesticides at this point in time. This is largely due to a lack of available data on the extent to which the forestry and ornamental sectors are using reduced risk products and tools. Qualitative information presented by federal and provincial forestry ministries and industry at pest management meetings, such as the annual Forest Pest Management Forum, suggests that a range of reduced risk practices have been applied in forestry management, such as widespread use of reduced risk pesticides and biopesticides targeting specific insect pests for forest pest control in preference to aerial spraying of broad-scale pesticides.

Recommendations relating to the pest management strategies stream

AAFC, HC-PMRA and NRCan to:

1. Periodically measure and report on the level of awareness and rate of application of risk reduction strategies, practices and tools developed by the PMC, NRCan and HC-PMRA among intended users. Provincial/territorial pest coordinators and grower groups should be involved in the development and application of the data collection methods.
2. Identify the cost and revenue parameters of risk reduction tools and practices developed by the Pesticide Risk Reduction Program to enable growers to estimate impacts from applying these tools and practices. This information should be made available to growers and other interested stakeholders as part of the promotion and demonstration of these tools and practices.
3. Assess the current size and structure of the minor use technology gap facing Canadian growers, and to periodically update this analysis and report on the extent to which the gap is being addressed.
4. Develop an integrated approach to the measurement and reporting of the numbers of potential new minor use registrations involved in the PMC's projects and the associated numbers of minor use registration submissions reviewed by HC-PMRA and new minor uses registered.

G. Effectiveness of the enhanced transparency and engagement stream (HC-PMRA)

1. Have opportunities for public and stakeholder engagement in the regulatory decision-making process increased? If so, how and to what degree of satisfaction?
-

HC-PMRA has established the following mechanisms to increase transparency and enable stakeholder and public engagement in pesticide regulatory decision-making as required by the new *PCP Act*:

- **Public Registry** which provides information on pesticides and the pesticide regulatory system on the HC-PMRA website.
- **Reading Room** which allows members of the public to inspect confidential test data that supports a product registration, major amendment, re-evaluation or special review decision.
- **Expanded opportunities to provide comments** on proposed registration and re-evaluation decisions, and other consultations, which HC-PMRA must respond to in its final decisions.
- **Notices of Objection** which can be filed by anyone seeking the reconsideration of a major registration decision when they believe there is a scientific basis for requesting reconsideration, such as health or environmental risks, or value and efficacy assessments that raise doubt as to the scientific validity of decisions.
- **Requests for Special Reviews of decisions.** If new scientific evidence that raises a concern regarding a registered pesticide becomes available, members of the public can submit that evidence and request a special review of that pesticide.

Overall, the majority of stakeholders who participated in interviews or the survey indicated that these mechanisms were effective at enabling access to pesticide regulatory information, and increasing opportunities to provide input to regulatory decision-making **among stakeholders**. The contribution of the mechanisms to improving access and opportunities for input **among the public** was perceived by the stakeholders as being significantly lower due to much lower levels of interest in pesticide regulation compared to stakeholders.

-
2. To what extent are stakeholders and the Canadian public aware of increased opportunities to access pesticide regulatory information or/and opportunities to provide input to regulatory decision making?
-

(a) Stakeholders

Awareness of the opportunities to access pesticide regulatory information and opportunities to provide input to regulatory decision making was generally quite high among stakeholders who participated in the evaluation fieldwork. These stakeholders were more aware of the availability of information on registered products on the Public Registry and opportunities to provide comments on proposed registration and re-evaluation decisions but less aware of the provision to request Special Reviews or to inspect Confidential Test Data in the Reading Room.

The most frequently used transparency mechanism is that of commenting on proposed re-evaluation and, to a lesser extent, proposed registration decisions. Proposed re-evaluation decisions are believed to generate more comments because the active ingredients subject to re-evaluation have been in use for long periods of time and stakeholders are more likely to be aware of their patterns of use and performance. Comments are received from a broad spectrum of stakeholders that includes registrants, non-governmental organizations with interests in human health or the environment, provincial governments, users, and the general public. Comments on proposed registration decisions are most often received from registrants and users.

(b) Public

Public awareness of pesticide regulation and decision-making is low according to the results of various public opinion research studies reviewed for the evaluation, and suggests that awareness of HC-PMRA's transparency mechanisms would also be low. A 2004 Ipsos-Reid study on public views on pesticides indicated that the majority of the public are not aware of HC-PMRA and a 2006 Decima Research study found that many people believe there is much less regulation in place than actually exists. In another study (Compass, 2004), pesticide awareness was ranked low compared to other food safety issues. A fourth study, by Ekos Research investigated the influence of media reports on public confidence in Canada's food safety system. This study, which would likely apply equally to pesticide regulation, observed a decline in confidence in Canada's food safety system following substantial media attention to food safety issues.⁴

⁴ Ipsos-Reid, **Public Views on Pesticides**, conducted for Health Canada, 2004. Decima Research, **Investigating Canadian Attitudes and Behaviours Surrounding Chemicals in Consumer Products**, conducted for Health Canada, 2006. Compass Public Opinion and Customer Research, **Food for Thought**, conducted for Health Canada, 2004. Ekos Research Associates, **Measuring Stakeholder Satisfaction in the Federal Pesticide Regulatory System**, 2009.

Recommendations relating to the enhanced transparency stream

HC-PMRA to:

1. **Continue to enhance its web presence to provide better access to information on all aspects of the pesticide regulatory system, including the findings from the research and monitoring work of HC-PMRA's partners in the BPC Initiative.**
2. **Conduct an assessment of the effectiveness of current methods used to strengthen awareness and understanding of the pesticide regulatory system, the health and environmental effects of pesticides, and status of proposed decisions and other regulatory initiatives, and implement changes and refinements to address any identified gaps.**

H. Overall relevance and performance of the BPC Initiative

1. Is there a continued rationale for the BPC Initiative as it is defined? To what extent:
 - (a) Does the rationale for the BPC Initiative reflect current needs?
 - (b) Does the BPC Initiative (and its constituent programs) continue to support federal and departmental objectives for the 6NR departments?
 - (c) Have the needs of stakeholders been addressed?
-

As noted earlier, the federal government has the authority to regulate the import, manufacture, sale and use of pesticides in Canada, and the PCP Act provides for the exercise of this authority. Implementation of many provisions in the new PCP Act, which received Royal Assent in December 2002, was enabled by BPC Initiative funding and the need for ongoing administration of these requirements was recognized by the conversion of BPC funding for many of the program elements to A-base at the end of the 2007/08.

Particular provisions of the PCP Act that continue to drive demand for the services included in the BPC Initiative include:

- Provision of MSDS (Section 8(3)).
- Re-evaluation of older pesticides (Section 16).
- Incident reporting (section 13).
- Conduct of special reviews (Sections 17 and 18).
- Public consultation regarding proposed registration and re-evaluation decisions (Sections 28 and 42).
- Notices of objection (Sections 35 to 40).
- Access to information in the Register of Pest Control Products (Sections 42-44).

While progress has been made against most of the intended medium-term outcomes from the BPC Initiative, their full achievement and the achievement of the intended final outcomes, will require sustained long-term effort. As well, the underlying needs for information on the environmental and health effects of pesticides, provision of risk reduction strategies for growers and registration of additional minor use products, and stakeholder and public engagement are not static, meaning that the needs addressed by the BPC Initiative continue to be relevant. Needs of stakeholders are also being addressed, as demonstrated by the findings from the key informant interviews and stakeholder survey presented in other

sections of this report. These findings also suggest that between two-thirds and three quarters of stakeholders who are aware of, or involved with, various program components of the BPC Initiative feel that it is having a positive impact on stakeholder confidence in pesticide regulation.

The design and delivery of the BPC Initiative also continues to support the objectives of the six participating departments and agencies, and achievement of federal whole of government outcomes. Strategic outcomes and expected results in the departmental performance reports and reports on plans and priorities for the two departments with the largest roles in the BPC Initiative, Health Canada and AAFC, make reference to the role of BPC-supported activities and their contribution to managing environmental and health risks. The strategic outcomes and expected results of EnvCan, DFO and NRCan that are engaged in research and monitoring activities highlight the importance of these types of activities in identifying and managing environmental risks and sustainability. The CFIA highlights the protection of food safety risks and sustainability of the plant resource base through the use of methods that include product monitoring surveys. In turn, the BPC partners' strategic outcomes are aligned with four Government of Canada Outcome Areas: a clean and healthy environment, healthy Canadians, strong economic growth, and an innovative and knowledge-based economy.

2. To what extent does the design of the BPC Initiative support achievement of its objectives?

The design of the BPC Initiative, particularly the horizontal approach to the research and monitoring, and pest management streams, recognizes unique capabilities across the federal government. This approach taps into existing capabilities and fosters the coordination and integration of the partners' efforts to achieve the BPC Initiative's objectives.

The research and monitoring, and pest management strategies streams of the BPC Initiative require coordinated work by at least two departments or agencies to achieve their intended outcomes. The research and monitoring stream plays to the strengths of EnvCan, DFO, NRCan and the CFIA in conducting research and monitoring work that is linked to their core mandates while making additional information and data available to HC-PMRA to aid regulatory decision-making. The key to the success of this approach is the effective functioning of the coordination and information sharing activities to ensure PMRA's needs are understood and factored into the design of research and monitoring work, and the results shared with both HC-PMRA and the 6NR partners. HC-PMRA does not possess the capabilities and resources to undertake the research and monitoring work performed by its 6NR partners.

Similarly, the design of the pest management strategies stream plays to the respective capabilities and strengths of the AAFC PMC and HC-PMRA. The current level of capability was developed over the initial years of the BPC Initiative, and built upon the unique combination of AAFC's national network of research stations and farms and the regulatory knowledge and expertise of HC-PMRA. Both organizations had to add additional staff to undertake the tasks required for this stream and establish their consultation and priority setting process, building on existing links to grower groups, provincial/territorial ministries, registrants and other stakeholders. The AAFC sites also had to obtain GLP (Good Laboratory Practice) accreditation to undertake residue studies. The involvement of growers, provincial pest management coordinators and other stakeholders in the setting of the PMC's priorities, particularly for the Minor Use Program, also means that it is highly responsive to the needs of growers across Canada. NRCan was also able to co-locate their coordinator for forestry minor use work at the PMC and thereby provide a linkage between the NRCan forestry research centres and the PMC's operations and infrastructure for agricultural minor use registrations.

-
-
3. To what extent could the BPC Initiative be delivered with equal or better effectiveness, by other players and/or improved design?
-
-

It is unlikely that other organizations could deliver the various streams and program elements of the BPC Initiative with equal effectiveness or economy, except possibly the activities of the AAFC's PMC.

HC-PMRA activities in the strengthened pesticide regulation and enhanced stakeholder and public engagement streams are mandated to the Agency by the PCP Act and are linked to, or integrated with, the broader range of regulatory activities undertaken by HC-PMRA. The knowledge of pesticides and expertise in assessing the health and environmental effects and efficacy of pesticides resident in the Agency is likely to be unique within Canada.

HC-PMRA's partners in the research and monitoring stream have been able to "add on" their pesticide-related work to an existing infrastructure and knowledge base, and gain leverage on the relatively limited BPC funding allocated to EnvCan, DFO, NRCan and the CFIA. The economies gained through this approach mean that the BPC's research and monitoring stream could not be performed as cost-effectively at the national level by other public or private organizations in Canada. As noted in section D, above, the program leads for these activities all emphasized that the current levels of BPC research and monitoring activity provide a minimum level of data and information to support HC-PMRA's risk analysis work. Additional value-added could be obtained by expanding the breadth and depth of this information.

With regard to the PMC, external stakeholders surveyed were more likely to express concerns about the timeliness of the PMC's risk reduction and minor use projects with staff shortages and gaps being identified as a contributing factor. Data on actual versus allocated funding for the PMC's programs show a consistent pattern of spending shortfall, which is consistent with comments from program leads about delays in staffing the PMC and a build-up in the backlog of projects.⁵ This sub-optimal performance has been recognized by the PMC's management and actions taken to expand resource levels and reduce the backlog in recent years.

Some external stakeholders suggested that the work of the AAFC PMC could be performed by a third party organization. This is possible in theory but the practical reality is that a third party organization would likely encounter difficulties in securing sufficient sustainable funding (outside of sustaining funding from the federal government) and may be perceived to be less equitable or objective if it were operated by a particular industry group or partnership. More importantly, any change in funding and delivery structures would lead to interruptions and delays in project selection and performance as any new structure would have to establish the necessary infrastructure, obtain GLP (Good Laboratory Practice) accreditation, establish processes and working arrangements with HC-PMRA, and staff its operations.

⁵ TBS Horizontal Initiatives Database, (www.tbs-sct.gc.ca/hidb-bdih/home-accueil-eng.aspx).

I. Progress toward the achievement of intended final outcomes

The logic model for the BPC Initiative defines three longer-term outcomes from the BPC Initiative:

- Increased public and stakeholder confidence in the pesticide regulatory system.
- Improved competitive parity of agricultural and forestry sectors with regard to pest management.
- Improved protection of health and the environment.

The evaluation issues included one question for each of these long-term outcomes:

1. Is there still a need to increase public and stakeholder confidence in the pesticide regulatory system?
2. Do the agricultural and forestry sectors still need to increase their competitive parity as it relates to pest management?
3. To what extent has there been an improvement in the protection of health and the environment as a result of the BPC research and monitoring activities?

Based on the findings from the various lines of enquiry it can be concluded that, while changes have been made in the way in which pesticide regulatory decisions are made and opportunities for increased transparency established, continuing needs exist with regard to the intended long-term outcomes of increased stakeholder and public confidence in the pesticide regulatory system, and improved competitive parity of the agricultural and forestry sectors. With regard to the third of the above questions, continued research and monitoring work will be necessary to determine if the environmental presence and effects of pesticides is reduced, and by inference, protection of health and the environment enhanced.

I. INTRODUCTION

This report presents the findings from a summative evaluation of the *Building Public Confidence in Pesticide Regulation and Improving Access To Pest Management Products Initiative* (BPC Initiative). The evaluation was conducted over the period from December 2008 to February 2010, and examined the relevance and rationale for the Initiative, the extent to which intended outcomes have been achieved (focusing primarily on the short and medium-terms outcomes), and the efficiency and economy of the activities performed.

The BPC Initiative is an ambitious horizontal initiative established by the federal government in 2002/03 with three long-term goals: increase public and stakeholder confidence in the pesticide regulatory system, improve protection of health and the environment, and improve the competitive parity of the agri-food and forestry sectors with regard to pest management. Progress towards the achievement of these three long-term outcomes was to be achieved through coordinated actions by six federal departments and agencies directed towards three principal lines of activity:

- (a) Involving, consulting, and informing public and stakeholders on pesticide registrations leading to increased public confidence in pesticide regulation.
- (b) Studying and monitoring pesticides to strengthen health and environmental protection.
- (c) Developing and implementing pest management strategies leading to improved grower access to reduced risk and minor use pesticides, and sustainable pest management strategies.

The six federal partners in the BPC Initiative are Health Canada's Pest Management Regulatory Agency (HC-PMRA), Agriculture and Agri-Food Canada (AAFC), Environment Canada, Department of Fisheries and Oceans (DFO), Natural Resources Canada (NRCan) and the Canadian Food Inspection Agency (CFIA). Total funding approved for the BPC Initiative was \$185.7 million over six years.

The Initiative responds to the conclusions from a number of Parliamentary and stakeholder reviews of the pesticide regulatory system. Parliamentary reports by the House of Commons Standing Committee on the Environment and Sustainable Development (2000) and the Standing Committee on Agriculture and Agri-Food (2002) called for action in response to public concerns about the long-term impacts of pesticide use, plus concerns among users of pest control products regarding the level of access to reduced risk and minor use pesticides compared to competing jurisdictions.

The federal government accepted the principles advanced by these reports and subsequently introduced the new *Pest Control Products Act* (PCP Act), which received Royal Assent in December 2002 and came into force in June 2006. Selected elements of the BPC Initiative enabled HC-PMRA to implement key provisions of the new PCP Act and strengthen the overall pesticide regulatory system.

II. EVALUATION OBJECTIVES

A. Objectives of the evaluation

The objectives of the summative evaluation of the BPC Initiative were to:

1. Assess key areas of relevance and performance (effectiveness, efficiency and economy);
2. Highlight achievements and lessons learned, as well as any challenges that were experienced;
3. Determine the degree to which the management action plan commitments in response to the formative evaluation recommendations were met;
4. Address accountability requirements of the commitments made in the original submission to Treasury Board; and
5. Address broad performance measurement needs of senior management in support of management decision making with respect to the future of the programs.

In addressing these objectives, the evaluation was expected to answer a series of evaluation issues relating to the Initiative's rationale and relevance, achievement of short and medium term intended outcomes, and the extent to which the long-term outcomes are likely to be achieved. The evaluation is also required to assess the degree to which commitments made in response to the formative evaluation were met (as per objective #3, above). The Management Action Plan for the formative evaluation plan called for the partners to:

- Adopt a revised logic model as part of the preparation of a revised Results-Based Management and Accountability Framework (RMAF).
- Adopt a performance measurement framework in tandem with the revised logic model which:
 - Identifies and defines a concise set of measures for elements of the revised logic model;
 - Replaces current performance measurement strategies of the AAFC, HC-PMRA, JMC and 5NR (now 6NR) WG;
 - Is integrated with the performance measurement strategies of partner departments/agencies;
 - Shows responsibility for data collection and reporting; and
 - Focuses on BPC outcomes and generating the data required for the summative evaluation.
- Develop an integrated work plan for the research and monitoring elements that are the joint responsibility of the 6NR departments and agencies.
- Participate in the planning of the summative evaluation and formulation of a strategy for supporting the pesticide regulatory system beyond the current (BPC) funding agreement.
- Establish a committee of Directors General (DGs) from each of the 6NR participants to guide the future strategy for cross-government pest management issues, which will include not only research and monitoring but other science and technology programs.
- For HC-PMRA and AAFC to include the BPC Initiative as a strategic consideration in their strategic communications frameworks.⁶

⁶ Based on the Management Action Plan for the Formative Evaluation, November, 2006. pp 2-5

B. Context for the evaluation

The evaluation examined the performance of activities over the period for which funding was specifically allocated to the BPC Initiative by Treasury Board, from 2002/03 to the end of 2007/08 plus outputs and results produced up to the most recent periods for which such data is available. This approach recognized that, while the Initiative had a six-year term, a significant amount of ongoing funding for various program components (\$20 million per year) was added to the A-base of the participating departments at the end of the initial six-year term to enable ongoing provision of the majority of activities started under the Initiative. Long lead times for many of the outputs and outcomes also mean that the full realization of the impacts of many BPC activities occurs some years beyond the end of the six-year term of the Initiative. Readers should also note that the implementation of some required BPC activities under HC-PMRA's authority, such as, the pesticide incident reporting system and measures intended to increase transparency and engagement, were dependent on the *PCP Act* coming into force, which happened later than expected, in June 2006, and thus, have had a more limited time period for outcomes to be achieved.

C. Evaluation issues

The Terms of Reference for the evaluation included a set of preliminary evaluation issues that were then refined by the project team drawing on the content of the proposed BPC Performance Measurement Framework and input from the partners in the BPC Initiative. This final set of evaluation issues and questions is shown in Exhibit II-1 along with links from the issues to the applicable components of the BPC Initiative.

Exhibit II-1

Evaluation issues and questions

A. Rationale and Relevance of the Initiative and Final Outcomes:

1. Is there a continued rationale for the BPC Initiative as it is defined? To what extent:
 - (a) Does the rationale for the BPC Initiative reflect current needs?
 - (b) Does the BPC Initiative (and its constituent programs) continue to support federal and departmental objectives for the 6NR departments?
 - (c) Have the needs of stakeholders been addressed?
 2. To what extent does the design of the BPC Initiative support achievement of its objectives?
 3. To what extent could the BPC Initiative be delivered with equal or better effectiveness, by other players and/or improved design?
 4. Is there still a need to increase public and stakeholder confidence in the pesticide regulatory system?
 5. Do the agricultural and forestry sectors still need to increase their competitive parity as it relates to pest management?
 6. To what extent has there been an improvement in the protection of health and the environment as a result of the BPC research and monitoring activities?
-

B. Achievement of Medium Term Outcomes:

7. To what extent has there been an improvement in risk management of pesticides as a result of BPC program activities?
(*Research and monitoring – HC-PMRA, EnvCan, DFO, NRCan, CFIA; Incident reporting – HC-PMRA*)
 8. What progress has been made to ensure that only those pest control products that meet modern standards remain registered?
(*Re-evaluation, Formulants – HC-PMRA*)
 9. Has the safety of foods, fertilizers and fertilizer-pesticide combinations available to Canadians increased as result of the CFIA's monitoring programs?
(*Food and fertilizer monitoring – CFIA*)
 10. Has employee awareness of pesticide safety and hazard information increased as a result of the requirement for provision of WHMIS/MSDS data to workplaces?
(*WHMIS/MSDS requirements – HC-PMRA*)
 11. As a result of the BPC Initiative:
 - (a) Has the adoption of safer pest management practices and products for the agricultural and forestry sectors increased?
 - (b) Has pesticide resistance management improved?
 - (c) Has the competitive parity of the agricultural sector been strengthened?
 - (d) Has the forestry sector adopted pesticide risk reduction strategies and increased its use of reduced risk and biological pesticides?
(*Pest management strategies – HC-PMRA, AAFC, NRCan*)
 12. Have opportunities for public and stakeholder engagement in the regulatory decision-making process increased? If so, how and to what degree of satisfaction?
(*Enhanced transparency and engagement – HC-PMRA*)
-

C. Achievement of short-term outcomes:

13. To what extent and in what ways has collaboration among HC-PMRA and its 6NR partners in support of pesticide risk analysis changed as a result of the BPC Initiative?
(*Research and monitoring – HC-PMRA, EnvCan, DFO, NRCan, CFIA*)
 14. Has there been an improvement in the quantity of useful information on the presence and effects of pesticides to support registration and re-evaluation of pesticides?
 - (a) Has there been an improvement in sharing of monitoring data that contributes to pesticide regulatory decision making?
 - (b) How has this information been used to support pesticide risk management?
(*Research and monitoring – HC-PMRA, EnvCan, DFO, NRCan, CFIA; Incident reporting – HC-PMRA*)
 15. As a result of the BPC funding, what proportion of active ingredients registered prior to 1995 has been re-evaluated?⁷ Of these,
 - (a) What proportion required amendments for continued registration?
 - (b) What proportion of re-evaluated products did HC-PMRA take action to remove from the market place?
(*Re-evaluation – HC-PMRA*)
 16. Has the formulants program contributed to an increased awareness, by registrants, of Canadian formulant requirements?
(*Formulants – HC-PMRA*)
 17. To what extent has compliance with guarantee and residue standards by food and fertilizer industry sectors been enhanced?
(*Food and fertilizer monitoring – CFIA*)
 18. To what extent has work under the BPC Initiative increased the availability of MSDS in workplaces?
(*WHMIS/MSDS requirements – HC-PMRA*)
 19. Have the Minor Use and Risk Reduction Programs improved access to, and increased awareness of, safer pest management products and practices? How, and to what extent?
(*Pest management strategies – HC-PMRA, AAFC, NRCan*)
 20. To what extent are stakeholders and the Canadian public aware of increased opportunities to access pesticide regulatory information or/and opportunities to provide input to regulatory decision making?
(*Enhanced transparency and engagement – HC-PMRA*)
-

⁷ The evaluation questions originally used the term “products”. “Active ingredients” has been substituted to recognize that the re-evaluation program measures the number of active ingredients (or “pesticides”) that are re-evaluated.

D. Data collection methodology

The focus in this summative evaluation was on determining the extent to which the BPC Initiative has achieved its intended outcomes, and in doing so, assessing aspects of relevance, impacts and cost-effectiveness. The time period under consideration was from the Initiative's inception in April 2002, to March 2009 (and taking more recent performance data into account, where available).

The methodology for the evaluation is described in the following sections.

1. Literature review

A literature review was used to investigate peer reviewed and other published information on methods used in other jurisdictions to improve the effectiveness of pesticide regulation. More broadly, the investigation identified best practices in promoting public confidence in a wide range of science-based regulatory initiatives when these practices have direct implications for regulatory approaches for pesticides. As such, the literature review findings were most directly applicable to the assessment of evaluation questions concerning the rationale for the BPC Initiative and its design.

Readers should note that few of the elements of the literature dealt directly with aspects of pesticide regulation covered by the BPC Initiative. Many of the references did, however, deal with such issues as pesticide risks and benefits, trust aspects of risk regulation, best practices in pesticide regulation and food safety policy. As a result, the core conclusions of this line of enquiry are inferential as opposed to reflecting direct evidence related to the BPC Initiative.

2. Review of BPC documents

A structured review of BPC-related documentation was undertaken with the purpose of identifying material relating to the rationale for the BPC, its execution, and outputs and outcomes. Findings were used to inform the assessment of BPC outputs and (to a lesser extent) outcomes as well as supporting the design of other data collection tools, principally guides for internal and external interviews and an online survey questionnaire. These documents pertained to the approval to establish and fund the BPC Initiative, descriptions of activities undertaken, regulatory documents published in the Canada Gazette, and performance reports on outputs produced and (to the extent available) outcomes achieved.

3. Key informant interviews

Two separate sets of key informant interviews were used to obtain information and insights into the effectiveness and impacts of the various BPC elements from program managers at each of the participating departments and agencies, and representatives of selected external key stakeholders. The focus in both sets of interviews was on determining the extent to which intended outputs have been produced, the extent to which they have been applied or taken-up by the intended beneficiaries, and the results achieved or expected to accrue in the future. Information gaps, especially relating to the identification of outcomes for each of the BPC elements were also identified and reviewed through these interviews.

Internal interviews with 31 BPC program leads used an interview guide that featured extensive use of open-ended questions and provided extensive opportunities to further explore and qualify points of views. The majority of these interviews were conducted in-person.

Interviews with external key informants used a more structured approach that used rating scales to capture the participants' perceptions as to the effectiveness of BPC approaches and outcomes in combination with open-ended follow-up questions to understand the reasons for ratings. The wide ranging nature of the various elements of the BPC Initiative meant that few of the external (and internal) key informants were able to speak to all or even a majority of the BPC elements. In recognition of this likelihood, these interviews were structured to provide participants with a choice of answering questions relating to one or more thematic groupings of the BPC elements and targeted outcomes.

Targets for these interviews were representatives of the range of different stakeholders that participate in the pesticide-related work of HC-PMRA and its BPC partners. Fourteen external key informant interviews were interviewed, broken down as follows:

- Provincial/Territorial government ministries of agriculture, environment or natural resources (2 interviews).
- Federal government researchers supporting environmental regulatory programs (1).
- Municipal government (1).
- Agricultural production associations with key interests in the availability and use of pest control products and strategies ("growers/users") (4).
- Manufacturers and distributors of pest control products (2).
- Environmental and public health advocacy organizations ("NGOs") (2).
- University-based researchers working in such fields as toxicology and the environmental sciences (2).
- The U.S. Interregional Research Project No. 4 (IR-4), which is the model for, and works closely with, the AAFC Pest Management Centre on minor use projects (1 interview with 2 participants).

4. Online survey of external stakeholders

An online survey of stakeholders was used to complement and extend the investigation of views on the effectiveness of the BPC Initiative among external stakeholders who felt they had at least some awareness and understanding of one or more of the major streams of work covered by the Initiative. The survey questionnaire used the same four thematic groups shown in Exhibit II-1 and was structured to allow for the findings from the external key informants to complement and extend the findings from the survey analysis.

This survey used a convenience sample compiled from contact information maintained by HC-PMRA, the AAFC Pest Management Centre and suggestions from participants in the internal key informant interviews. The survey was not intended to provide a statistically reliable estimate of awareness of the BPC Initiative but to investigate perceptions among knowledgeable stakeholders regarding the effectiveness of the approaches used to achieve the intended outcomes set for the Initiative and their judgements as to whether these outcomes are being, or have been, achieved.

Readers should note that this was not a survey of randomly selected members of the public, but a survey of stakeholders who had requested that they be kept informed of pesticide regulation or minor use and risk reduction matters by HC-PMRA and AAFC, respectively, or who were actively involved in such activities. The stakeholder representatives who responded to the survey were also asked to rate how effective they thought the Initiative has been in building public confidence (in addition to their own confidence) in the pesticide regulatory system as a form of proxy measure of public confidence.

The starting sample for the survey contained 1,425 email addresses. Invitations to participate were emailed on October 13, 2009 and the survey remained open until November 2, 2009. Potential respondents were also e-mailed two reminders. A total of 282 individuals completed the survey for a response rate of 20%, which is considered to be in the normal range of response rates for a survey of this kind. The representation from the different stakeholder groups of interest was as follows:

Types of Stakeholders	# of Responses	% of Total Responses
Provincial/Territorial government	70	25%
User of pest control products or association representing interests of users	57	20%
Registrant or association representing interests of registrants	55	20%
Federal government department (excluding managers and staff of BPC program elements)	51	18%
University or other publicly funded research institution	18	6%
Public interest or advocacy group (NGO)	8	3%
Food processor/manufacturer or association representing food processors/manufacturers	4	1%
Other	19	7%
Total	282	100%

E. Limitations

A number of data collection and analysis limitations need to be remembered when reviewing the findings from the various lines of enquiry, especially the findings from external key informant interviews and the online survey of external stakeholders.

Firstly, the small sample (15) of external key informant interviews with selected stakeholders was inherently non-random. The intention with these interviews was to explore the views of external stakeholders who were well informed as to the nature of various activities performed as part of the overall BPC Initiative rather than to be representative of the overall population of potential stakeholders. Within this group of stakeholders the number who could provide informed comments on the various program components varied. The discussion of findings includes the numbers of external key informants who provided comments on each of the BPC streams that demonstrates this variability.

Secondly, the sample for the online survey of external stakeholders was mostly composed of representatives of organizations that had at least some level of awareness or involvement with one or more of the four streams of activity within the BPC Initiative, and had requested HC-PMRA or AAFC to keep them informed about pest management. As a result, the sample members were predominantly representatives of stakeholder groups with most at stake with pesticide regulation, be it from an economic perspective, such as growers and registrants, or regulatory and industry support perspective, such as representatives of provincial government ministries of agriculture, environment and natural resources.

Thirdly, participants in the survey were asked to self-select which streams of the BPC Initiative they were familiar with, so that they could focus on the subject areas that they could make informed comments on. This approach was also designed to minimize, as much as possible, the time required to complete the survey questionnaire. Even so, relatively high proportions of respondents opted for “don’t know” answers in various sections of the survey. The incidence of “don’t know” answers is highlighted in the discussion of findings in this report, where applicable.

This approach to the survey also meant that the sample sizes for the different sections of the survey, which correspond to the different streams of activity in the BPC Initiative, were quite varied. With only 282 responses in total, and sub-samples by BPC stream as low as around 100, it was not possible to make meaningful comparisons between the various types of stakeholders in the sample, for most questions. At best, these types of comparisons are only indicative or illustrative.

Finally, the design of the data collection activities did not permit investigation of the awareness of the features of pesticide regulatory system pertaining to the BPC Initiative directly with members of the public. Instead, the analysis relied on a combination of findings from other public opinion research investigating awareness and attitudes toward federal regulatory systems, such as the pesticide regulatory system, and judgements from the stakeholders who participated in the survey or interviews as to the likely impacts of the BPC Initiative on public confidence, as a form of “proxy measure”.

III. OVERVIEW OF THE BPC INITIATIVE

A. Context for pesticide regulation in Canada

Responsibilities for pesticide regulation are split between the federal, provincial/territorial and municipal levels of government in Canada. The federal government regulates pesticides proposed for manufacture or import prior to their commercial sale and use, under the *Pest Control Products Act (PCP Act)* and regulations. Under authority of the Act, HC-PMRA:

- Conducts science-based evaluations of new pesticide active ingredients and products to ensure risks to health and the environment are acceptable prior to their registration for use in Canada, and the products are efficacious.
- Re-evaluates the pesticides currently on the market on a 15-year cycle to ensure the products meet current scientific standards.
- Promotes sustainable pest management.

HC-PMRA’s role is to determine if pesticides can be used safely when label directions are followed and will be effective for their intended use. HC-PMRA also promotes and verifies compliance with the PCP Act and enforces it in situations of non-compliance warranting action.

Provincial and territorial governments may regulate the sale, use, storage, transportation and disposal of registered pesticides in their jurisdictions as long as the measures they adopt are consistent with any conditions, directions and limitations imposed under the *PCP Act* or other federal legislation. Amongst other things, this means that they may impose additional conditions or restrictions on the use of registered pesticides but are not permitted to authorize the use of products that have not been approved under the *PCP Act* nor to reduce or limit the conditions of use imposed on registered pesticides by HC-PMRA. Provincial/territorial programs typically span the range of classification of pesticides for sale and use; education and training; licensing and certification of pesticide applicators, vendors and users; issuing of permits for certain uses; and, provision of advice on pest management strategies as part of their agricultural extension services.

At the municipal level, provincial/territorial legislation may permit municipal governments to set further restrictions or conditions on the use of pesticides. In this regard, a large number of municipalities have introduced restrictions on “non-essential” or “cosmetic” use of pesticides in urban areas, as have the provinces of Quebec and Ontario.

B. Objectives, structure and governance of the BPC Initiative

The BPC Initiative was created to increase public confidence in pesticide regulation and improve access to pest management products by:

- (a) Involving, consulting, and informing the public and stakeholders on pesticide registrations;
- (b) Studying and monitoring pesticides on an ongoing basis; and
- (c) Developing and implementing pest management strategies.

Delivery of the BPC Initiative is via thirteen component programs distributed amongst the six BPC partner departments and agencies. For the purposes of the evaluation these various components have been grouped into four distinct, but inter-related, groupings: Research and Monitoring, Strengthened Pesticide Regulation, Pest Management Strategies, and Enhanced Transparency and Engagement. The purpose of each of the thirteen program components is as follows:

➤ Research and monitoring:

- *Linking regulation and research* – improve coordination and cooperation between pesticide regulatory and research functions within Government. (HC-PMRA is the lead department/agency)
- *Monitoring and research of presence and effects of pesticides in the environment* – Enhance the federal government’s knowledge base for environmental protection and conservation through research and monitoring on the environmental fate and effects of pesticides in Canada. (EnvCan)
- *Monitoring and research of presence and effects of pesticides in marine and freshwater ecosystems* – Enhance conservation and protection of fish and fish habitat through an improved pesticide regulatory decision making process based on Canadian environmental exposure data. (DFO)
- *Monitoring and research of presence and effects of pesticides in the forest environment* – Research and monitor the presence and effects of pesticides in the forest environment. (NRCan)
- *Enhanced monitoring and enforcement of pesticide residue limits in foods and feed* – Increase the monitoring of imported and domestic foods in order to assure increased compliance with current and future residue standards for specific residues in foods.⁸ (CFIA)
- *Enhanced monitoring and enforcement of pesticide residues in fertilizers and pesticide guarantees in fertilizer-pesticide combinations* – Increase activities to monitor compliance of fertilizer-pesticide combinations and other fertilizers with the requirements of the *Fertilizers Act* and/or *PCP Act* for enhanced consumer and environmental protection. (CFIA)

⁸ Under the BPC Initiative, the CFIA monitors the incidence of pesticide residues in foods consumed by children and infants. This activity supplements work by the CFIA monitoring the presence of chemical residues in the food supply under the National Chemical Residue Monitoring Program (NCRMP).

- Strengthened pesticide regulation
 - *Accelerated and priority re-evaluation of older pesticides* – Ensure unacceptable risks to human health and the environment are prevented by accelerating the re-evaluation of older pesticides. (HC-PMRA)
 - *Tracking pesticide incidents* – Design a framework and implement a system for the collection and reporting of any unintended or unexpected effects to human health, domestic animal health or the environment, resulting from exposure to, or use of, pesticides. (HC-PMRA)
 - *Updating processes to regulate pesticide formulants* – Update processes for regulating pesticide formulants by implementing a new formulants policy. (HC-PMRA)
 - *Meeting Workplace Hazardous Material Information System (WHMIS) objectives for pesticides* – Ensure WHMIS objectives are met for pesticides and thereby provide workers with relevant safety and health information on materials so that they can take the necessary precautions to avoid injury, illness and premature death. (HC-PMRA)
- Pest management strategies:
 - *Developing and implementing commodity specific risk reduction strategies* – Develop pest management risk reduction strategies for agricultural commodities, including improved availability of reduced risk and minor use pest control products; make pesticide registration and re-registration decisions in the context of commodity specific pest management risk reduction strategies; work cooperatively with stakeholders to ensure that the strategies can be implemented; develop alternative approaches for risk reduction; and, expedite the review of submissions to register reduced risk and minor use products for the agriculture and agri-food sector. (AAFC and HC-PMRA)
 - *Developing and facilitating use of reduced risk pesticides and biological pesticides for forestry* – Develop and facilitate the use of reduced risk control products and biological pesticides for forest pest management to prevent pollution. (NRCan)
- Enhanced transparency and engagement:
 - *Consultation on and reconsideration of registration decisions, access to regulatory information, sharing confidential information* – Increase the openness and transparency of the pest management regulatory system. (HC-PMRA)

A number of additional activities undertaken by partners to the BPC, while not funded under the BPC Initiative, contribute to the achievement of its objectives. In particular:

- Health Canada's Food Directorate has allocated A-Base funding to address specific questions and data gaps raised by HC-PMRA over the course of the BPC Initiative, the average of which was \$84 thousand dollars annually.
- HC-PMRA's Re-evaluation and Use Analysis Section collects and analyses pesticide use data to facilitate the Agency's pesticide re-evaluation activities.
- \$1 million was allocated in 2002/03 from the AAFC Canadian Adaptation and Rural Development Fund to facilitate and accelerate the introduction of BPC-related initiatives and to assist farm and commodity groups in contributing to their development and implementation. A further \$2 million was allocated annually from AAFC's A-Base to support the work of the Pest Management Centre by expanding the capacity of AAFC to conduct field trials at six locations across Canada and generate data to support pesticide registration submissions.

Governance of the BPC Initiative is provided by three bodies, with common involvement by HC-PMRA as the lead agency in all three:

- 6NR – Interdepartmental Working Group on Pesticides and Pest Management (also known as the 6NR WG due to the involvement of six natural resources departments and agencies). The mandate of the 6NR is to coordinate, promote and foster closer cooperation between the federal research and regulatory communities working on pesticides and pest management issues. The 6NR was initially established as a working group to facilitate joint planning and information sharing. Following the formative evaluation, the working group was upgraded to the level of a DG committee with a role to monitor progress and discuss future strategies for the conduct of cross-government pesticide research and monitoring, and linkages to pesticide regulation.
- JMC – HC-PMRA/AAFC Joint Management Committee, responsible for joint-direction- setting, planning, budgeting, monitoring and reporting on the performance of AAFC and HC-PMRA’s work to develop and implement pest management strategies.
- HC-PMRA’s Agency Management Committee.

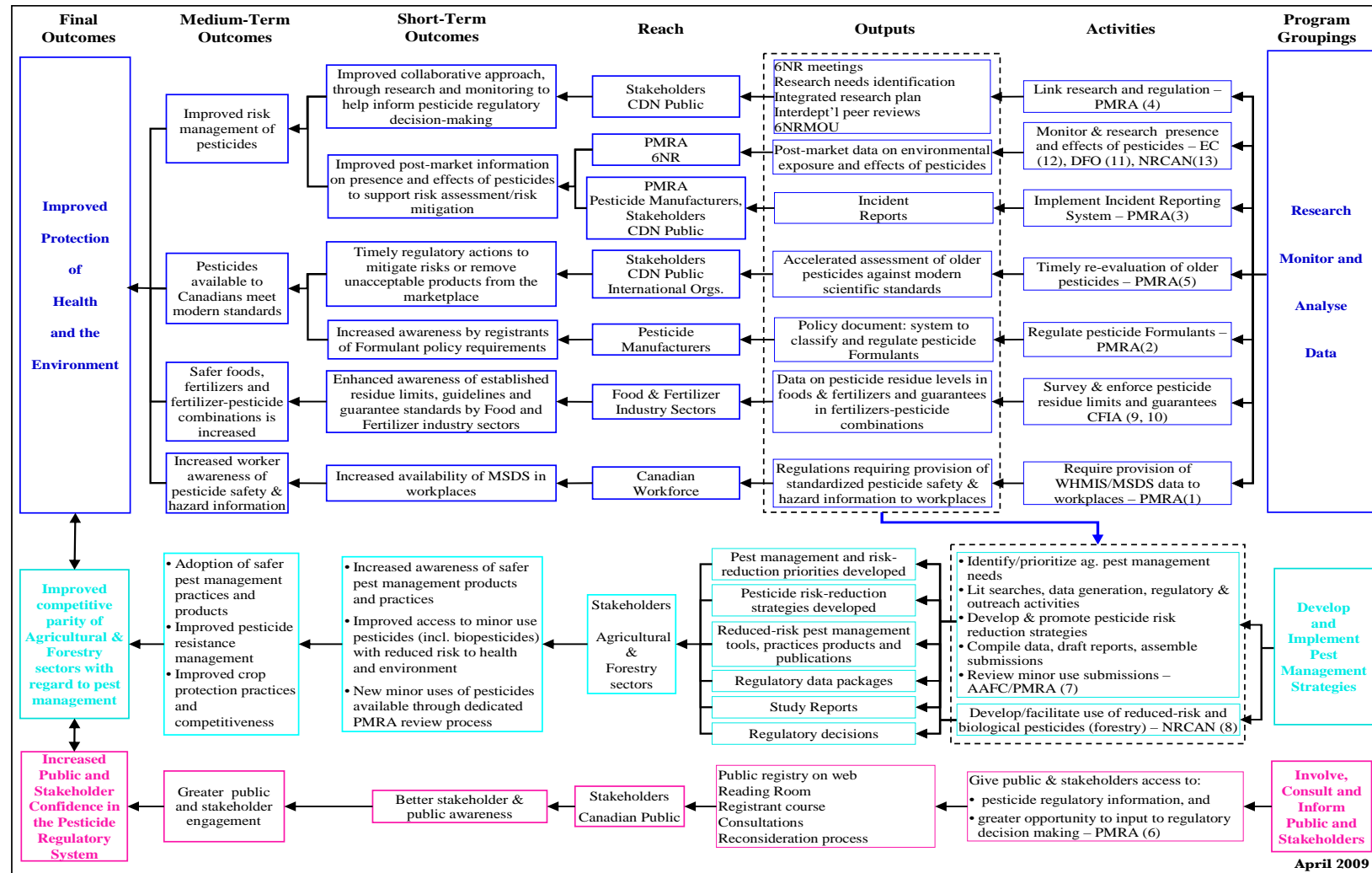
C. BPC logic model

The current logic model for the BPC Initiative is shown in Exhibit III-1. This is a revised model that incorporates changes made in response to the recommendations of the formative evaluation in 2006 while remaining true to the intent of the program objectives. This updated logic model:

- Emphasizes the distinction between HC-PMRA’s public and stakeholder involvement programs and the other horizontal components of the initiative;
- Recognizes the interdependencies between the research and monitoring, and pest management programs under BPC; and
- Modifies the final outcomes so that they can be more readily attributed to the impacts of the various BPC program activities.

Exhibit III-1

Logic model for the BPC Initiative



D. Funding allocated to the BPC Initiative

The breakdown of funding allocated to the BPC Initiative by Treasury Board is summarized in Exhibit III-2.

Exhibit III-2

Breakdown of funding allocated to the BPC Initiative

Program Area	2002/03	2003/04	2004/05	2005/06	2006/07	2007/08	TOTAL (\$,000)	2008/09 & Ongoing
A. Research and Monitoring								
<i>Linking regulation and research</i>	\$ 100	\$ 100	\$ 800	\$ 800	\$ 800	\$ 800	\$ 3,400	\$ 800
<i>Monitoring - EC</i>	\$ 2,000	\$ 2,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 8,000	\$ 1,000
<i>Monitoring - DFO</i>	\$ 1,000	\$ 1,900	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 6,900	\$ 1,000
<i>Monitoring - NRCan</i>	\$ 500	\$ 500	\$ 500	\$ 500	\$ 500	\$ 500	\$ 3,000	\$ 500
<i>Monitoring - Foods</i>	\$ 850	\$ 850	\$ 250	\$ 250	\$ 250	\$ 250	\$ 2,700	\$ 250
<i>Monitoring - Fertilizers</i>	\$ 450	\$ 450	\$ 250	\$ 250	\$ 250	\$ 250	\$ 1,900	\$ 250
Sub-Total	\$ 4,900	\$ 5,800	\$ 3,800	\$ 3,800	\$ 3,800	\$ 3,800	\$ 25,900	\$ 3,800
B. Strengthened Pesticide Regulation								
Re-evaluation	\$ 1,900	\$ 1,900	\$ 2,500	\$ 2,500	\$ 2,500	\$ 2,500	\$ 13,800	\$ 2,500
Incident Reporting	\$ 800	\$ 800	\$ 1,100	\$ 1,100	\$ 1,100	\$ 1,100	\$ 6,000	\$ 1,100
Formulants	\$ 1,500	\$ 1,500	\$ 1,500	\$ 1,500	\$ 1,500	\$ 1,500	\$ 9,000	\$ 1,500
MSDS	\$ -	\$ 900	\$ 900	\$ 900	\$ 900	\$ 900	\$ 4,500	\$ 900
Sub-Total	\$ 4,200	\$ 5,100	\$ 6,000	\$ 6,000	\$ 6,000	\$ 6,000	\$ 33,300	\$ 6,000
C. Pest Management Strategies								
<i>Risk Reduction/Minor Use - AAFC</i>								
Risk Reduction	\$ 3,300	\$ 3,500	\$ 2,500	\$ 2,500	\$ 2,500	\$ 2,500	\$ 16,800	\$ 2,500
Minor Use	\$ 1,200	\$ 6,500	\$ 6,500	\$ 6,500	\$ 6,500	\$ 6,500	\$ 33,700	\$ -
Research & Monitoring	\$ -	\$ 1,000	\$ 1,000	\$ 1,000	\$ 2,000	\$ 3,000	\$ 8,000	\$ -
<i>Risk Reduction/Minor Use - PMRA</i>								
Risk Reduction	\$ 1,700	\$ 4,000	\$ 4,000	\$ 4,000	\$ 4,000	\$ 4,000	\$ 21,700	\$ 4,000
Minor Use	\$ 800	\$ 4,000	\$ 4,000	\$ 4,000	\$ 4,000	\$ 4,000	\$ 20,800	\$ -
Research & Monitoring	\$ -	\$ 300	\$ 500	\$ 600	\$ 900	\$ 1,200	\$ 3,500	\$ -
<i>Risk Reduction/ Biopesticides - NRCan</i>	\$ 600	\$ 1,000	\$ 500	\$ 500	\$ 500	\$ 500	\$ 3,600	\$ 500
Sub-Total	\$ 7,600	\$20,300	\$19,000	\$19,100	\$20,400	\$21,700	\$108,100	\$ 7,000
D. Enhanced Transparency								
Transparency & engagement	\$ 1,000	\$ 3,000	\$ 3,600	\$ 3,600	\$ 3,600	\$ 3,600	\$ 18,400	\$ 3,600
Sub-Total	\$ 1,000	\$ 3,000	\$ 3,600	\$ 3,600	\$ 3,600	\$ 3,600	\$ 18,400	\$ 3,600
TOTAL - BPC Initiative	\$17,700	\$34,200	\$32,400	\$32,500	\$33,800	\$35,100	\$185,700	\$20,400

Source: TB Submission for the BPC Initiative, Annex 1: Summary of Financial Requirements.

The Research and Monitoring stream of the Initiative was allocated 14% of the total funding, Strengthened Pesticide Regulation 18%, Pest Management Strategies 58%, and Enhanced Transparency 10%. Total allocations by department/agency over the six-year term of the Initiative were as shown in Exhibit III-3.

Exhibit III-3

Allocation of BPC funding by department/agency, 2002/03 to 2007/08

Department/Agency	Amount Allocated (\$,000)	% of Total
HC-PMRA	\$101,100	54.4%
AAFC	58,500	34.5%
Environment Canada	8,000	4.3%
Fisheries & Oceans Canada	6,900	3.7%
Natural Resources Canada	6,600	3.6%
Canadian Food Inspection Agency	4,600	2.5%
Total	\$185,700	100%

The relatively small scale of the funding allocated to EnvCan, DFO, NRCan and the CFIA means that their pesticide research and monitoring work is, to a large extent, embedded within more extensive departmentally-mandated activities. In many instances, this means that these departments and agencies have been able to combine their pesticide-related work with other departmental research or environmental monitoring initiatives and thereby gain significant leverage on their BPC funding.

Ongoing A-base funding of \$20.4 million per year, starting in 2008/09, was also allocated to enable continuation of activities by the partners to the BPC. The breakdown of this funding by program element is shown in the right-hand column of Exhibit III-2. In addition, funding was allocated under the AAFC *Growing Forward* initiative for the period from 2009/10 to 2012/13 in support of risk reduction and minor use activities - \$9.9 million annually to the AAFC's Pest Management Centre and \$3.9 million to HC-PMRA.

E. Organization and presentation of the evaluation findings

The following chapters of the report present the findings, conclusions and recommendations for each of the four streams of work under the BPC Initiative. They are followed by a final chapter that assesses the overall relevance of the Initiative and the extent to which progress is being made toward the achievement of the long-term outcomes.

IV. RESEARCH AND MONITORING IN SUPPORT OF PESTICIDE REGULATION

A. Purpose of the BPC research and monitoring activities

The intended short and medium-term outcomes from the BPC research and monitoring activities are:

- **Short-term outcomes:**
 - Improved collaborative approach through research and monitoring to help inform pesticide regulatory decision-making.
 - Improved post-market information on the presence and effects of pesticides to support risk assessment and risk management.
 - Enhanced awareness of established residue limits, guidelines and guarantee standards by the food and fertilizer industry sectors.
- **Medium-term outcomes:**
 - Improved risk management of pesticides.
 - Safety of foods, fertilizers and fertilizer-pesticide combinations is increased.

The achievement of these outcomes is made possible through the production of three distinct outputs:

- Identification of research needs leading to the development of an integrated research plan.
- Post-market data on the environmental exposure and effects of pesticides.
- Data on pesticide residue levels in foods and fertilizers, and guarantees for fertilizer-pesticide combination products.

The principal research and monitoring departments/agencies are EnvCan, DFO, NRCan and the CFIA. AAFC is also a partner in the 6NR with a role to conduct research and share findings that support the introduction of reduced risk strategies and minor use products, as well as research on environmentally beneficial agricultural production and management practices as an element in the National Agri-Environmental Standards Initiative (NAESI). These activities were evaluated as part of the overall pest management strategies stream of the BPC Initiative (Chapter VI).

Five evaluation issues were considered in examining the extent to which the above outcomes from the research and monitoring stream have been achieved:

1. To what extent and in what ways has collaboration among HC-PMRA and its 6NR partners in support of pesticide risk analysis changed as a result of the BPC Initiative?
2. Has there been an improvement in the quantity of useful information on the presence and effects of pesticides to support registration and re-evaluation of pesticides?
 - (a) Has there been an improvement in sharing of monitoring data that contributes to pesticide regulatory decision making?
 - (b) How has this information been used to support pesticide risk management?

3. To what extent has there been an improvement in risk management of pesticides as a result of BPC program activities?
4. To what extent has compliance with guarantee and residue standards by food and fertilizer industry sectors been enhanced?
5. Has the safety of foods, fertilizers and fertilizer-pesticide combinations available to Canadians increased as result of the CFIA's monitoring programs?

B. Research and monitoring activities

Activities undertaken by HC-PMRA, EnvCan, DFO, NRCan and the CFIA for this component of the BPC Initiative span:

- Identification by HC-PMRA of research needs, based on input from the Agency's Environmental Assessment, Health Evaluation, Efficacy and Sustainability Assessment, and Compliance, Lab Services and Regional Operations Divisions.
- Sharing of these needs through the 6NR Working Group to enable the development of research and monitoring work plans.
- Identification of needs for, and development of, analytical methods and protocols to enable the presence and/or effects of priority pesticides and mixtures of pesticides to be measured and assessed in field and laboratory studies.
- Conduct of research and monitoring projects.
- Data analysis and preparation of reports, presentations and research papers summarizing findings.
- Sharing of findings with BPC partners and publication of papers in peer reviewed journals.
- Provision of comments and advice to HC-PMRA regarding the interpretation and application of research and monitoring findings in the Agency's risk analyses and proposed regulatory decisions.

Findings from the research and monitoring activities of the 6NR partners are used as inputs to HC-PMRA's risk analysis and risk assessment work, particularly in relation to re-evaluation of older pesticides. As such, the outputs from the work of HC-PMRA's 6NR partners provides the Agency with an additional source of information that complements data provided by registrants and other sources, such as provincial governments.

The nature of the specific activities and outputs of the work performed by EnvCan, DFO, NRCan and CFIA is summarized in the following sections.

1. Environment Canada – Pesticide Science Fund

In 2003, EnvCan established a Pesticide Science Fund (PSF) to select and fund research by EnvCan researchers into the presence and effects of pesticides in the Canadian environment. According to the most recent report summarizing the results of that work (2007), over 30 research projects have received contributions from the PSF. These projects have spanned the *monitoring of environmental concentrations of in-use pesticides in water and air, and study of the effects of pesticides on fish, invertebrate, amphibian, bird, mammal, and plant species in Canada.*⁹

⁹ Environment Canada, **Pesticides in the Canadian Environment**, Ottawa, 2007, p.ix.

Specific areas of focus in this work were:

- Water – six regional studies that monitored 144 currently used pesticide products and their degradation products in sensitive water bodies, which provide a baseline for EnvCan and HC-PMRA, as well as other federal and provincial agencies, to measure the impacts of risk management strategies.
- Air – a three-year study that used sampling programs to provide measures of the spatial and temporal distributions of currently used pesticides, and provided insights into the atmospheric transport of pesticides.
- Mammals, birds, amphibians and plants – a series of projects were undertaken to examine the direct and indirect impacts of pesticides on native plants and wildlife species, and provided information for use in protecting and conserving these species.
- Aquatic life – support was provided for studies of the effects of pesticides on aquatic life under naturalistic settings and different types of exposure conditions, and research into the effects of different agricultural production practices on the concentration and toxicity of pesticides in adjacent water sources.¹⁰

2. Fisheries and Oceans – Centre for Environmental Research on Pesticides

DFO established its Winnipeg-based Centre for Environmental Research on Pesticides (CERP) to act as the focal point for research into the environmental effects of pesticides on fish and fish habitat. CERP's field research and monitoring work under the BPC Initiative is centred on Twenty Mile Creek in southern Ontario, which is used as a model system for examining the effects of pesticides on wild fish and invertebrate populations, and laboratory-based research investigating and characterizing the effects of pesticide exposure by small bodied fish. In addition, DFO also maintains a research fund that supports pesticide research addressing the department's regional priorities and HC-PMRA's research priorities, which has supported work by DFO's Arctic Research Division.

CERP researchers collaborate with Environment Canada's Canada Centre for Inland Waters to facilitate their work at Twenty Mile Creek and to access the results of EnvCan's water monitoring work in that area. Other collaborations enable CERP staff to access EnvCan's pesticide monitoring data for prairie ecosystems (from EnvCan's Saskatchewan office), and to work with the Ontario Ministry of Natural Resources, Ontario Conservation Authority, and the University of Manitoba's Department of Soil Science.¹¹ CERP has also developed an innovative "mesocosm" to complement and link its field and laboratory work. The mesocosm is expected to function as an "artificial stream" that will enable scientists to simulate actual field conditions while controlling for such factors as flow rates of water and the size and age of fish.¹²

DFO's current Five-Year Research Plan (2008-2013) notes that *CERP's current research on high priority urban pesticides (e.g., 2-4 D, Mecoprop, Glyphosate, Diazinon, Imidacloprid) includes field research to identify environmentally relevant concentrations of these pesticides and laboratory studies to provide scientifically defensible data on the impacts of these pesticides both in single and combination exposure experiments.*¹³

¹⁰ Ibid, pp.x-xiii.

¹¹ This summary of the nature and scope of DFO's research and monitoring work draws on material in CERP's **Effects-Based Pesticide Research – Annual Report, 2007**.

¹² DFO, **In the lab, in the field and in between: The Centre for Environmental Research on Pesticides takes a multi-faceted approach**, Feature Articles series, May 2009. (Accessed at: www.dfo-mpo.gc.ca/science/publications/article/2009/04-20-09-eng.htm)

¹³ Fisheries and Oceans Canada, **Five-Year Research Plan** (2008-2013), Ottawa, 2008, p.12.

3. Natural Resources Canada

NRCan established the Enhanced Pest Management Methods S&T Program in 2002/03 to address the two components of the Department's BPC work – monitoring pesticides in the forest environment (development of tools, techniques and information for environmental assessment of impacts of pest control products) and sustainable pest management to prevent pollution (development and facilitation for the use of reduced risk and biological pesticides). This dual role meant that work conducted under the BPC research and monitoring stream could be more directly linked to work on the development of reduced risk pest control products and integrated pest management techniques that fall under the pest management strategies stream of the BPC. The Program was funded using a combination of existing Canadian Forestry Service (CFS) A-base funding (~67% of the total) and the additional funding allocated under the BPC Initiative (~33%).¹⁴

Pesticide-related research and monitoring work is performed through the Great Lakes Forestry Centre in Sault Ste Marie, as the main centre for the five CFS Forestry Centres. The focus in this work is on monitoring pesticide persistence and impacts in forest environments, and research to support the development and registration of new pest control products and better manage the risks posed by existing products. The program lead for this work described the CFS' approach to monitoring as being very "micro", focused on specific pesticides and problems compared to the more "macro" approach in EnvCan's environmental monitoring work. Examples of the CFS' monitoring projects include:

- Environmental fate and ecological effects of a systemic insecticide for control of exotic wood boring insect pests.
- Knowledge synthesis and decision support for aerial pesticide applications in forestry, and the development, validation and application of Spray Safe Manager (SSM7) as a decision support system application.
- Advanced methods for monitoring impacts of pest control products on key microbial communities of forest soils.¹⁵

4. Canadian Food Inspection Agency – pesticide residues on food products

CFIA is responsible for monitoring the food supply for chemical residues (pesticides, veterinary drugs and other agricultural chemicals as well as metals) in food under the National Chemical Residue Monitoring Program (NCRMP). Under this program, which has been in place since 1978, the Agency monitors fresh fruits and vegetables, processed products and meats for compliance with established residue limits. Under the BPC Initiative, the CFIA undertakes supplementary monitoring of agricultural chemical residues in foods consumed by children, including processed food products in addition to the raw agricultural products typically monitored under the NCRMP. To put this BPC funding into context, the NCRMP has an annual cost of approximately \$10.8 million, including ongoing BPC funding of \$250,000.

The CFIA's monitoring work provides snapshots or case studies of the extent to which food products more commonly consumed by children contain pesticide residues. As such, it does not *gather statistically valid information on the type and levels of chemical residues or contaminants in children's foods and due to the limited scope of this study and the limitations of the design, no correlation between the number of samples taken of a particular food and the relative importance of this type of food in the typical diet can*

¹⁴ Natural Resources Canada – Canadian Forestry Service, **Enhanced Pest Management Methods S&T Program Review – 2002-2006**, pp.2-3.

¹⁵ Natural Resources Canada – Canadian Forest Service, **Enhanced Pest Management Methods S&T Program Review – 2002-2006**.

*be made.*¹⁶ Trend analysis of this nature and an ability to relate the sampling and findings to the typical diets of children would require analysis of the prevalence and rates of consumption of foods commonly consumed by children and many more samples for testing.

Depending on the year, CFIA purchased and analyzed between 350 and 1523 processed food samples, with tests conducted to determine the presence or absence of between 260 and 285 different pesticide compounds in each of its four surveys between 2003/04 and 2007/08. During 2007/08 the CFIA also developed and/or validated new testing methods for additional pesticide residues, taking the total number of compounds being tested for in the 2008/09 samples to approximately 400. The selection of food samples focused on processed fruit and vegetable products, and grain and dairy-based products, with priority given to selecting products with advertising and/or packaging geared towards children.¹⁷

5. Canadian Food Inspection Agency – pesticides in fertilizers and fertilizer-pesticide combinations

The CFIA also verifies the presence of pesticides at the levels guaranteed on the product labels of fertilizer-pesticide combinations, and monitors fertilizer products for contamination by pesticides.

CFIA's approach to this verification and monitoring has evolved since the inception of the BPC, to respond to changes in the distribution and packaging of fertilizers and fertilizer-pesticide products. The sampling approach also includes a risk-based element where companies that were non-compliant in prior years are more likely to be re-sampled. Starting in 2008/09, the annual sampling coverage was expanded to include products used by lawn care companies.

C. Findings from internal interviews and documents

1. Outputs and immediate outcomes from the 6NR process

The intended immediate outcome from the 6NR process is an improved collaborative approach to research and monitoring to help inform pesticide regulatory decision-making.

The program leads responsible for HC-PMRA's involvement with the 6NR Working Group were strongly of the view that the quality of the collaboration and integration of 6NR activities has evolved significantly since the inception of the BPC Initiative. They noted that, at the outset, HC-PMRA established a set of research and monitoring priorities which the various partners used as the basis for developing their own research and monitoring plans. The relationship evolved as the 6NR partners came to better understand the way HC-PMRA uses scientific information in its risk assessment and risk management work, and HC-PMRA developed its understanding of the time and steps necessary to generate high quality monitoring data and research information. Now, the partners ask HC-PMRA for input to the design and/or selection of projects (for example, HC-PMRA participates in the committees that select research projects to be funded by EnvCan and DFO), and HC-PMRA is able to tap into the partners' expertise and knowledge for advice on risk management and science questions.

¹⁶ Canadian Food Inspection Agency, **Children's Food Chemical Residues Project Report on Sampling for 2007-2008**, Ottawa, 2009, p.7

¹⁷ Ibid, p.9

Program leads from EnvCan, DFO, NRCan and the CFIA confirmed this pattern of development in the level of collaboration among the 6NR partners as well as noting improvements in the identification of research priorities and better notice of planned re-evaluations of active ingredients. In turn, the program leads at EnvCan and DFO, in particular, felt that the improved flow of information enables them to better focus their research projects and ongoing monitoring and surveillance work.

They also noted that opportunities exist for the research and monitoring partners to undertake joint or complementary work rather than largely seeking to satisfy aspects of HC-PMRA's information needs independently. Instances of data sharing and coordinated work do occur, and were highlighted by both EnvCan and DFO, but these situations appear to have been driven more by serendipity than design. Further evolution of the 6NR work planning should lead to better coordinated and rigorous approaches to the planning and conduct of work and provide an opportunity to obtain further leverage on the relatively limited levels of BPC funding allocated to research and monitoring.

One simple way of facilitating such collaboration that was suggested by many of the program leads would be for regular face-to-face meetings of program managers and lead researchers over and above the 6NR Working Group meetings, to engage in more detailed presentation and discussion of the partners' respective research and monitoring strategies and findings. It was also suggested that such meetings would benefit HC-PMRA officials by giving them a much better sense of the conditions under which pesticide products are used and, in return, build understanding of regulatory processes and methods among the researchers. The value of such information exchange meetings within 6NR partners' own departments as a means of facilitating information sharing and identifying areas of need and/or collaboration was also highlighted, such as, the annual Forest Pest Management Forum organized by the Canadian Forestry Service and the DFO's participation in the annual Aquatic Toxicity Workshop. However, the cost to undertake such an annual meeting of the 6NR partners is currently beyond the funding levels allocated to this BPC stream due the costs of travel and numbers of researchers who could potentially be involved.

The program leads also noted that the level of BPC funding available for research and monitoring work under the BPC Initiative forces each of the 6NR partners to make careful choices as to how much monitoring work they can do, what they can monitor and what research needs are most important. They have also looked for ways to leverage their BPC funding by running intra-departmental competitions for research funding that include expectations for researchers to bring access to additional capacity or resources to their projects (for example, BPC funds may be used to cover the costs of data collection and sample testing with the costs of salaries and access to supporting facilities coming from existing resource allocations). Both DFO and EnvCan highlighted needs for research into the incidence and effects of mixtures of pesticides and the ongoing development of capacity to measure and analyze the effects of both new and existing pesticides. CFIA highlighted the opportunity to improve the design of its food monitoring work and expand its sampling to enable the analysis of residues on children's food from annual "snapshots" to produce statistically valid trend data, thereby providing HC-PMRA with a truer representation of dietary exposure to pesticide residues.

Views regarding the establishment of the 6NR Directors General committee, which was a recommendation of the formative evaluation, were generally supportive. A number of program leads qualified their comments by reference to the time taken to develop and sign-off on the MOU creating the committee and noted that the full benefit of their participation had yet to be fully realized as participation by DGs is only quite recent. They felt that the DGs were committed to the work of the 6NR and, if they are not able to participate directly on meetings do make sure they have people attending who have the authority to commit their organizations to agreed actions (as opposed to having to go back to their

departments/agencies for decisions/commitments). Many of the program leads also noted that the effectiveness of the 6NR Working Group was continuing to develop with the increasing flow of results from research and monitoring projects and the associated degree of interaction between partners.

Some program leads felt that the involvement of DGs had made (or could make) the Working Group more “strategic”, through the annual reviews and updates to the integrated work plan. Another benefit noted was that DG involvement helps to build recognition and acceptance of the work by the 6NR partners on pesticides within the partner departments and agencies and to reinforce the linkages between pesticide work and strategic priorities of the partner departments and agencies. Looking forward, some were concerned that the interest of their DGs may wane if HC-PMRA does not take a leadership position on any new MC or TB submission seeking resources to renew and reinforce the role of pesticide research and monitoring in support of a government-wide approach to understanding the effects of pesticides.

2. Generation of improved post-market information on the presence and effects of pesticides and improved risk management of pesticides

The second immediate outcome from the BPC research and monitoring stream is improved post-market information on the presence and effects of pesticides to support risk assessment and risk management. In turn, this information is intended to contribute to the intermediate outcome of improved risk management of pesticides.

Program leads from the 6NR partners all agreed that the research and monitoring activity has resulted in improved post-market information and advice being made available to HC-PMRA which in turn, was enabling improved risk management. The sharing of information on the presence and effects of pesticides takes place through sharing of monitoring data, research findings and peer-reviewed papers as well as more informal advice provided in less formal communications and responses to ad hoc requests. Program leads at HC-PMRA described the main uses of the outputs from the BPC research and monitoring work in such terms as:

- Research and monitoring data that enables the key assumptions and risk drivers in assessment models to be validated and refined (to improve confidence in the tools used in regulatory decision making), and to provide insights into emerging issues and public concerns, for example, residues in drinking water, children’s health, species at risk
- Generation of monitoring data to address data gaps identified in recent re-evaluations and to respond to data needs for pending future re-evaluations of active ingredients.
- Assessment and development of label statements for pesticide products, for example, to understand the “real world” circumstances under which pest control products are applied in forestry and agriculture, and to establish revised guidelines and requirements for label conditions, for example, in such areas as no spray and buffer zone requirements.

Research and monitoring projects typically require data collection and analysis over several years before useful findings and conclusions can be drawn from the analysis. This means that post-market information from this work has only really become available during the most recent years of the BPC Initiative. For example, the formative evaluation (2006) noted that findings from work by EnvCan, DFO and NRCan (as well as AAFC work with a bearing on HC-PMRA risk assessments) was only starting to become available and shared with HC-PMRA.

Tangible evidence of the application of research and monitoring findings since that time can be found in HC-PMRA’s documentation regarding proposed re-evaluation decisions for active ingredients that were registered prior to 1995. Selected examples of this include:

- **Proposed Acceptability for Continuing Registration – Re-evaluation of Atrazine (Environmental Assessment)**, issued in 2007, referred to the use of monitoring data generated by work funded under the EnvCan Pesticide Science Fund in 2003 - 2004 (that is, work made possible by BPC funding) as well as published sources and provincial monitoring data.¹⁸
- **Re-evaluation Note – Preliminary Risk and Value Assessments of Endosulfan**, issued in 2007, made reference to water monitoring data collected by EnvCan and an analysis of data on the bioaccumulation of endosulfan in Arctic biota.¹⁹
- **Re-evaluation Decision – Triallate**, issued in 2008, drew upon unpublished water and air quality monitoring data compiled by EnvCan Pesticide Science Fund projects.²⁰
- **Proposed Re-evaluation Decision – Trifluralin**, issued in 2008, referenced pesticide air sampling and water monitoring data compiled through support from the EnvCan Pesticide Science Fund among the information sources considered in performing the environmental risk assessment. In addition, DFO's Pacific region made unpublished water, sediment, air and biota monitoring data on trifluralin and chlorpyrifos available for the re-evaluation.²¹
- **Proposed Re-evaluation Decision – Formetanate Hydrochloride**, issued in 2008, refers to the use of food residue data collected by the CFIA under the National Chemical Residue Monitoring Program, including data on infant dietary exposure.²²
- **Proposed Re-evaluation Decision – Carbofuran**, issued in 2009, drew upon water monitoring data compiled by EnvCan under work supported by the Pesticide Science Fund as one of a number of sources of monitoring data on drinking water.²³
- **Proposed Re-evaluation Decision – Simazine**, issued in 2009, included unpublished water monitoring data and a study on the presence of pesticides in Canadian aquatic ecosystems compiled with support for the EnvCan Pesticide Science Fund as sources of additional information considered.²⁴
- **Re-evaluation Decision – Diazinon**, issued in 2009, references unpublished water monitoring data collected in BC with support from the Pesticide Science Fund.²⁵
- **Re-evaluation of Lindane – EnvCan** work on modelling the atmospheric persistence and movement of **Lindane** drew on findings from the air sampling program supported by the Pesticide Science Fund was considered by HC-PMRA for the re-evaluation of *Lindane*.²⁶

In addition, CFIA monitoring data provides for a more realistic understanding of residue levels in foods available to Canadians and is considered in the re-evaluation of existing pesticides.

¹⁸ Health Canada, **Proposed Acceptability for Continuing Registration, Re-evaluation of Atrazine (Environmental Assessment)**, HC-PMRA: PACR2007-05, 2007, p.8.

¹⁹ Health Canada, **Re-evaluation Note - Preliminary Risk and Value Assessments of Endosulfan**, HC-PMRA: REV2007-13, p.13 and p.14.

²⁰ Health Canada, **Re-evaluation Decision – Triallate**, HC-PMRA: RVD2008-04, p.11.

²¹ Health Canada, **Proposed Re-evaluation Decision – Trifluralin**, HC-PMRA: PRVD2008-22, 2008, p.34, 61, 63, 64.

²² Health Canada, **Proposed Re-evaluation Decision – Formetanate Hydrochloride**, PRVD2008-26, pp.18-19.

²³ Health Canada, **Proposed Re-evaluation Decision – Carbofuran**, HC-PMRA: PRVD2009-11, p.101

²⁴ Health Canada, **Proposed Re-evaluation Decision – Simazine**, HC-PMRA: PRVD2009-12, p.50.

²⁵ Health Canada, **Re-evaluation Decision – Diazinon**, HC-PMRA: RVD2009-18, p.53

²⁶ Information provided in internal key informant interviews.

3. Results of CFIA's monitoring of pesticide residues on food products and verification of pesticides in fertilizers and fertilizer-pesticide combinations

CFIA's work on monitoring pesticide residues on food products, and the verification of pesticide levels in fertilizers and fertilizer-pesticide combinations has one intended immediate outcome, to enhance awareness of established residue limits, guidelines and guarantee standards by the food and fertilizer industry sectors. Achievement of this outcome is expected to then contribute to an intermediate outcome of increased safety of foods, fertilizers and fertilizer-pesticide combinations.

a) Pesticide residues on food products

CFIA has prepared four reports on the collection and analysis of domestic and imported processed food products typically consumed by younger Canadians. Compliance rates, that is, the extent to which pesticide residues were either not detected or were within the established Maximum Residue Levels (MRLs), were between 98.6% and 100% for each of these studies. The extent to which pesticide residues were detected on samples (including samples where the residue level was below the established MRL) varied between 3.5% and 24.3%.

Highlights from each of the studies were as follows:

- 2003/04 report:
 - Focused on foods typically consumed by children under 18 months of age.
 - Detected residues in 21 samples (3.5%) out of a total of 594 and all were within the applicable MRLs.²⁷
- 2004-2006 report:
 - Examined foods typically consumed by children between the ages of 6 months and 15 years.
 - Found 80.8% of the 1,523 samples to have no detectable residues.
 - Eighteen (1.2%) of the samples had residues in excess of the applicable MRLs. CFIA performed risk assessments of these residues to assess their potential impact on the health of Canadians and concluded that none represented a risk to Canadians of any age, including children in the age range studied. The CFIA also notified the manufacturers/importers of these products of the non-compliance results and followed up to improve future compliance.²⁸
- 2006/07 report:
 - Also examined foods consumed by children between 6 months and 15 years.
 - Found no measureable residues in 316 of the 350 samples tested (90.3%) and all 34 samples with residues present were in compliance with their applicable MRL.²⁹
- 2007/08 report:
 - An overall compliance rate of 98.6% for 836 samples of foods consumed by children between 3 and 15 years of age.
 - Of these, almost 25% (203 samples) had a detectable but compliant residue (that is, within the established maximum residue limits (MRLs)).

²⁷ CFIA, **Young Children's Food Chemical Residues Project: Report on Agricultural Pesticides Residues, 2003-2004.**

²⁸ CFIA, **Children's Food Chemical Residues Project: Foods Aimed at Children 6 Months to 15 Years, Report on Sampling for 2004-2006.**

²⁹ CFIA, **Children's Food Chemical Residues Project: Report on Sampling for 2006-2007.**

- In 12 samples (1.4%) the level of pesticide residue was higher than the applicable MRLs. Risk assessments were performed by CFIA for these residues to estimate their potential impact on the health of Canadians and concluded that *none of the residues observed represented a health risk to Canadians of any age including children in the specified age groups*.³⁰
- The number of samples with at least two distinct residues was 27 (out of 215 with measurable residues), with eight containing three different residues and one with four.³¹

While the results of each of the studies cannot be compared directly to provide trend insights they do provide an indication of the general level of safety of processed food products consumed by children.

b) Pesticides in fertilizers and fertilizer-pesticide combinations

The findings from the CFIA's monitoring of pesticide contamination in fertilizers and pesticide guarantee verification in fertilizer-pesticide combinations provide annual snapshots of the level of compliance but do not provide evidence of statistically valid trends in the two areas due to the varying nature of the sampling approaches and sample sizes. Percentage of samples found to be compliant and associated sample sizes for each year between 2002/03 and 2007/08 (Exhibit IV-1) show that compliance rates for the fertilizer-pesticide guarantee program have varied within a range from 61% to 70% (excluding 2002/03 due to the small sample size). Compliance rates (that is, the proportion with no detectable pesticide residues) for fertilizers subject to pesticide contamination monitoring increased from 2004/05 to 2005/06 (from 74% to 83%) and have remained relatively stable from 2005/06 to 2007/08.

Exhibit IV-1

CFIA fertilizer-pesticide guarantee verification and pesticide contamination monitoring programs – observed compliance rates

Year	Fertilizer-Pesticide Guarantee Verification		Pesticide Contamination Monitoring	
	% of Samples Compliant	(Sample Size)	% of Samples Compliant	(Sample Size)
2002/03	82%	(38)	88%	(26)
2003/04	69%	(126)	76%	(55)
2004/05	70%	(97)	74%	(81)
2005/06	61%	(107)	83%	(47)
2006/07	69%	(132)	87%	(63)
2007/08	65%	(97)	84%	(105)

Source: Annual summaries of sampling outcomes for Fertilizer Program 5A (Fertilizer-Pesticide Guarantee Verification Sampling) and 5B (Pesticide Contamination Monitoring) provided by CFIA.

Actions taken in response to non-compliance include the issuance of warning letters, product detention and follow-up visits to seek out any remaining non-compliant product and discuss potential sources of the non-compliance. The CFIA has worked with the fertilizer-pesticide industry in particular, to help identify potential sources of non-compliance, such as quality assurance procedures and analytical testing methodology, in order to better detect pesticide levels, improve formulation and manufacture compliant products. More recently, HC-PMRA announced in early February 2010 that, effective December 31, 2012, fertilizer-pesticide combinations would no longer be approved for lawn and turf uses. This decision to “uncouple fertilizer-pesticide combination products” was made in conjunction with the CFIA and followed consultation with stakeholders.

³⁰ CFIA, *Children's Food Chemical Residues Project: Report on Sampling for 2007-2008*, p.34.

³¹ Ibid, p.16.

c) Contribution to intended outcomes

Achievement of the intended immediate outcome for CFIA's work, to enhance awareness of established residue limits, guidelines and guarantee standards by the food and fertilizer industry sectors, is achieved through contacts with food and fertilizer industry members in the course of program delivery. In the case of residues on food products, the CFIA follows up with food processors and importers when samples display residues in excess of the applicable MRL to ensure they are aware of the regulatory requirements and to determine if any systemic risks exist.

With regard to fertilizers and fertilizer-pesticide combinations, the CFIA has engaged more actively with industry groups to find ways to improve compliance rates. For example, the CFIA's 2007/08 Departmental Performance Report noted the following, with regard to these outcomes:

Low compliance levels within the fertilizer program over the past few years had prompted the Agency to further engage with stakeholders and adjust fertilizer sampling and monitoring strategies to target areas of chronic non-compliance. ... The CFIA has been in discussions with the Canadian Fertilizer Products Forum (CFPF) for the past several years to identify root causes of non-compliance and options for improvement. The CFIA will continue working with the CFPF and industry to ensure that compliance rates continue to improve. ³²

Program leads at CFIA and HC-PMRA indicated that findings from the CFIA's monitoring of residues on food products provide a useful additional source of information on dietary exposure, which may be considered in HC-PMRA's product registration and re-evaluation decision-making. HC-PMRA also noted that data on pesticide residues on food from CFIA is a critical source of information for modelling and assessing probabilistic distribution models of MRLs.

D. Findings from external sources

Two principal sources of information were used to identify and explore the perspectives of external stakeholders: key informant interviews with representatives of selected stakeholders and a complementary online survey of stakeholder representatives who felt that they were familiar with the scope of the BPC research and monitoring activities and outcomes.

1. Effectiveness of the 6NR process and outputs

a) Research and monitoring of environmental effects of pesticides

Research and monitoring work conducted by HC-PMRA, EnvCan, DFO and NRCan among external stakeholders has an internal focus, with HC-PMRA being the client for the products of the work undertaken by the partner departments and agencies. As a result, few external stakeholders are aware of the scope and results of such work. Amongst the 15 external key informants interviewed only two appeared to have a reasonable degree of understanding of this BPC stream, one from a registrants' group and the other a federal government researcher.

The key informant from the registrants group was critical that the 6NR process was "closed" with no opportunities for registrants and other external stakeholders to comment on project selection and design nor opportunities to see the results. This key informant suggested that wider availability of findings could help registrants to identify areas for improvement in their products and/or conditions of use. The federal

³² Canadian Food Inspection Agency, **2007-2008 Performance Report**, Ottawa, 2008, p.45.

government researcher had contributed to the research and monitoring work of EnvCan and DFO, and felt that the approach taken was highly effective and suggested that the limited public availability of findings was an area of weakness.

External stakeholders who participated in the online survey also exhibited low levels of awareness of the BPC Initiative's research and monitoring activities. Claimed familiarity with the activities of the participating research and monitoring departments/agencies (as measured by "some knowledge", "substantial knowledge" or "very familiar" responses) among the 42% who stated they were familiar was highest for CFIA (83%), followed by EnvCan (73%), DFO (46%) and the CFS (NRCan), at 37%.

These survey respondents were asked to rate the effectiveness of a range of aspects of the 6NR work on a department-by-department basis. Exhibit IV-2 shows the percentages of each of these groups who rated their performance as either effective ("highly" or "somewhat" effective) or ineffective ("highly" or "somewhat" ineffective). Note that these responses do not distinguish clearly between BPC-related pesticide research and monitoring and the activities of each of these departments that predate or are performed outside of the BPC as well as the high incidences of "don't know" responses. "Effective" ratings consistently exceeded "ineffective" ratings although not always by large margins. (Readers should also note that many of these cells had very small numbers of responses.)

Exhibit IV-2

Ratings of the effectiveness of research and monitoring work conducted by the 6NR partners

Activities	EnvCan	DFO	NRCan	CFIA
Priority setting and work planning				(n=99)
Effective	29%	14%	17%	28%
Ineffective	8%	5%	6%	14%
Don't Know	55%	80%	72%	47%
Integration & coordination of efforts between the PMRA & each of the 6NR partners				(n=99)
Effective	22%	19%	23%	26%
Ineffective	21%	8%	11%	20%
Don't Know	48%	73%	64%	43%
Integration & coordination of activities between the 6NR partners				
Effective	27%	15%	26%	24%
Ineffective	22%	10%	9%	18%
Don't Know	45%	71%	60%	43%
Design and conduct of data collection and analysis activities				
Effective	31%	17%	26%	31%
Ineffective	16%	5%	9%	12%
Don't Know	46%	69%	64%	44%
Reporting and sharing of findings				
Effective	33%	24%	28%	31%
Ineffective	22%	12%	9%	12%
Don't Know	39%	61%	57%	44%
Timeliness of projects and reporting				
Effective	26%	14%	26%	18%
Ineffective	18%	8%	6%	21%
Don't Know	51%	75%	64%	49%
(Sub-sample size)	86)	54)	(44)	(98) (Except where noted)

Base: Respondents who indicated familiarity with the research and monitoring stream (Q.G2).

Respondents were further asked if they believed there were opportunities to improve the effectiveness or efficiency of the BPC research and monitoring activity, and if so, how. Almost one-third of the survey respondents (30%) felt there were “some” or “substantial” opportunities for improvement. One of the common themes in the respondents’ suggestions was that there should be more sharing of the findings from the BPC research and monitoring as well as opportunities for stakeholder consultation or participation. In addition to these themes, which were also suggested by the external key informants, the survey respondents suggested that more resources were needed, especially for field work, and reinforced the need for strong horizontal collaboration and integration of findings in to regulatory decision-making.

b) Monitoring of pesticide residues on food products and fertilizers, and verification of pesticide guarantees in fertilizer-pesticide combinations by CFIA

Seven of the external key informants indicated that they were familiar with the CFIA’s food residue monitoring work and all or most rated the Agency as being either “somewhat” or “highly effective” in achieving the intended outcomes from the CFIA’s verification and monitoring work. When asked if there were areas in which the approach to monitoring of residues on food products could be improved the key informants suggested:

- Results of the monitoring work should be communicated more widely (and, in the view of several of the key informants, building on the CFIA’s effectiveness and credibility in communicating food safety information).
- Increase the level of funding for residue monitoring and enable the Agency to expand the breadth and frequency of its sampling.
- Consider providing more training/communications to growers to reinforce the requirement for pesticides to be used in accord with the uses and instructions on the label (which would be a provincial/territorial responsibility rather than HC-PMRA).

Respondents to the online survey who indicated they were familiar with the CFIA’s approach to monitoring residues on food products were also asked if they thought CFIA’s approach was the best that could be taken. A relatively large percentage of these stakeholders (42%) felt opportunities existed. In addition to making suggestions similar to those provided by the external key informants noted above, they suggested that more attention should be paid to monitoring imported food products and to improve the transparency of the program and timeliness of reporting.

A similar question was asked regarding the CFIA’s approach to the monitoring of pesticide contamination in fertilizers and fertilizer-pesticide guarantee verification, with one third of the respondents suggesting that changes could be made. The most common themes in their suggestions related to increasing the resources allocated and scale of sampling, and discontinuing the marketing of fertilizer-pesticide combination products.³³

2. Views on the achievement of intended outcomes

a) Research and monitoring of environmental effects of pesticides

Ratings of the effectiveness of the BPC research and monitoring activity were provided by five external key informants who had some degree of familiarity with the BPC research and monitoring activity. Three rated the performance as “somewhat” or “highly effective” and two rated it as “somewhat ineffective”.

³³ Note that the survey was conducted prior to the HC-PMRA’s announcement that, starting in January, 2013, pesticide-fertilizer products would no longer be approved for lawn and turf uses.

Those stakeholders who gave low ratings expressed concerns that data and information produced by the 6NR partners was not available to industry and external researchers, and were not convinced that such information was being used or having an impact on risk management.

Respondents to the online survey who indicated that they were familiar with the research and monitoring activities of one or more of EnvCan, DFO, NRCan and the CFIA (42% of the total) were asked to rate the effectiveness of the BPC's cross-government approach in achieving the intended outcomes of the research and monitoring stream. The responses to this question are summarized in Exhibit IV-3.

Note, once again, that relatively high percentages of the respondents opted for a "don't know" response. The remaining respondents were more likely to rate the 6NR partners as being "somewhat" or "highly" effective in improving the availability of information on the presence and effects of pesticides and improving risk assessments and risk management of pesticides, but less confident about their performance in improving collaboration to help inform decision making for pesticides. This latter result may reflect the fact that the 6NR collaboration is internal to the 6NR partners with no external participation or consultation.

Exhibit IV-3

Effectiveness of the BPC research and monitoring stream in achieving intended outcomes

Intended Outcomes	Highly or Somewhat Effective	Neither Effective nor Ineffective	Highly or Somewhat Ineffective	Don't Know
Improving collaboration to help inform regulatory decision-making for pesticides	39%	20%	19%	21%
Improving the quality of information on the presence and effects of pesticides to support risk assessments and risk mitigation	53%	15%	18%	15%
Improving risk assessments and risk management of pesticides	52%	13%	18%	18%

Base: Respondents who were familiar with research and monitoring on the presence and effects of pesticides (Q.1); n=108)

b) Monitoring of pesticide residues on food products and fertilizers, and verification of pesticide guarantees in fertilizer-pesticide combinations by CFIA

Respondents who indicated they were familiar with the monitoring work of the CFIA (35% of the total sample) were also asked to rate CFIA's effectiveness in achieving intended outcomes for its food and fertilizer monitoring activities. The results of these questions are shown in Exhibit IV-4.

Exhibit IV-4

Effectiveness of the BPC research and monitoring stream in achieving intended outcomes

Intended Outcomes	Highly or Somewhat Effective	Neither Effective nor Ineffective	Highly or Somewhat Ineffective	Don't Know
Monitoring pesticide residues on food products:				
Enhancing awareness of maximum residue limits (MRLs) among food producers	56%	13%	16%	14%
Enhancing rates of compliance with established MRLs	44%	14%	16%	26%
Increasing the safety of food products	61%	11%	13%	14%

Intended Outcomes	Highly or Somewhat Effective	Neither Effective nor Ineffective	Highly or Somewhat Ineffective	Don't Know
Monitoring of pesticide contamination in fertilizers and fertilizer-pesticide guarantee verification:				
Enhancing awareness among fertilizer manufacturers of tolerance levels for pesticide residues in fertilizers, and of pesticide guarantees for fertilizer-pesticide combinations	28%	6%	13%	53%
Enhancing rates of compliance of fertilizers with established pesticide residue tolerance levels	27%	5%	13%	56%
Enhancing rates of compliance with pesticide guarantees for combined fertilizer-pesticides	27%	6%	13%	54%

Base: Respondents who were familiar with CFIA's monitoring work (Q.G1); n=98)

The incidence of "don't know" ratings in Exhibit IV-4 shows that perceived awareness of the CFIA's monitoring of pesticide residues on foods is much higher than awareness of its fertilizer monitoring and fertilizer-pesticide verification work. Respondents who did rate the effectiveness of the CFIA's monitoring and verification work (that is, excluding the "don't knows") were consistently likely to rate the Agency's performance as effective across all three intended outcomes.

The views of external key informant who were familiar with the CFIA's work monitoring residues on food products views differed slightly from the survey respondents. They were more likely to rate CFIA's performance at enhancing awareness of MRL limits among producers and enhancing rates of compliance as being either "somewhat" or "highly effective" but less likely to see a linkage from monitoring MRLs to increasing the safety of food products.

E. Conclusions and recommendations

1. Conclusions regarding the BPC research and monitoring stream

Five evaluation issues related directly to the research and monitoring stream of the BPC Initiative. These issues are listed below, accompanied by our summary conclusions against each.

-
1. To what extent and in what ways has collaboration among HC-PMRA and its 6NR partners in support of pesticide risk analysis changed as a result of the BPC Initiative?
-

Awareness of the BPC research and monitoring stream, particularly the 6NR process, is quite low among external stakeholders, which likely reflects the fact that the 6NR process is internal to the partner departments and agencies with no external participation or consultation. Accordingly, the conclusions drawn in regard to this evaluation issue are based principally on the feedback from the program leads at each of the 6NR partner departments and agencies.

These program leads were consistently of the view that the quality of the collaboration and integration of 6NR work planning has evolved significantly since the inception of the Initiative and more so since the formative evaluation in 2006. They attributed this improvement to:

- The evolution of a more integrated approach to work planning, which was a recommendation of the formative evaluation. The 6NR partners characterized this evolution as going from each department/agency choosing how to respond to HC-PMRA's priorities independently to a situation where the various 6NR partners ask each other for input to their project selection and planning activities and HC-PMRA is able to more readily tap into the knowledge and expertise of the 6NR partners.

- Increasing the level of understanding among the 6NR partners of the way HC-PMRA uses scientific information in its risk assessment and risk management work. In parallel, HC-PMRA gained a better understanding of the lead time and steps involved in setting up research projects and surveillance and monitoring programs, and the subsequent generation of high quality monitoring data and research information. This improvement in shared understanding underpinned the evolution of the more integrated approach to work planning.
- Upgrading the 6NR Working Group to a DG-level committee was thought to have helped the collaborative process to a certain extent. This impact was due to such factors as making the Working Group a little more “strategic”, ensuring that participants in meetings of the Working Group had the authority to commit their organizations to agreed actions, and the enhancement of the credibility of pesticides-related research and monitoring within the partner departments.

The relatively small scale of the funding allocated to EnvCan, DFO, NRCan and the CFIA (in the range of \$250,000 to \$1 million per year per partner) means that their pesticide research and monitoring work has, to a large extent, been embedded within more extensive departmentally-mandated activities. In many instances, this means that these departments and agencies have been able to combine their pesticide-related work with other departmental research or environmental monitoring initiatives and thereby gain leverage on their BPC funding.

Looking forward, the 6NR program leads identified opportunities to foster additional collaboration and add to the value of the 6NR work. Areas of opportunity include further integration of work plans between the 6NR partners (particularly EnvCan, DFO and NRCan which have common areas of interest), holding face-to-face meetings of the 6NR program managers and researchers in these organizations to exchange information on the results of their work and the nature of HC-PMRA’s needs, and seeking additional funding for pesticide research and monitoring work. Current funding levels for research and monitoring work are quite low (in the range of \$250,000 to \$1 million per year per program) relative to the cost of data collection and analysis, and limit the extent to which the 6NR can respond to emerging needs and monitoring of the effects of new pest control products.

-
2. Has there been an improvement in the quantity of useful information on the presence and effects of pesticides to support registration and re-evaluation of pesticides?
 - (a) Has there been an improvement in sharing of monitoring data that contributes to pesticide regulatory decision making?
 - (b) How has this information been used to support pesticide risk management?
-

The nature of regulatory decision making regarding the re-evaluation and registration of pesticides is such that the “quantity” of information required or used cannot be readily measured. However, based on the comments and supporting documentation provided by program leads responsible for the research and monitoring of the environmental effects of pesticides, it can be concluded that there has been an improvement in the availability of useful information on the presence and effects of pesticides to support registration and re-evaluation of pesticides. This improvement is a function of the further integration of the 6NR work planning and information sharing practices, and the increased availability of information as research and monitoring projects reach the point where meaningful information can be generated.

Program leads from the 6NR partners all agreed that the 6NR activity has increased the breadth and depth of useful information on the presence and effects of pesticides for use in conjunction with data from existing sources, such as registrants, provincial government ministries and academic research. The lead

time required for project selection and planning, establishment of data collection methods and processes, and time required to build data bases with multi-year data obviously means that it has only been in the more recent years of the BPC Initiative (starting around 2006) that more extensive data have been available to HC-PMRA from the BPC partners.

The provision of information to HC-PMRA from the 6NR partners takes place through sharing of monitoring data, research findings and peer-reviewed papers as well as more informal advice provided in less formal communications and responses to ad hoc requests. Program leads at HC-PMRA identified a range of uses of research and monitoring results in the Agency's work, primarily related to the re-evaluation of existing active ingredients and products, in such areas as testing and validation of risk assessment assumptions and models, filling of gaps in existing data, development and refinement of risk models, and determination of conditions of use on product labels. Examples of explicit references to the use of data and information from the 6NR partners include proposed and final re-evaluation decisions for a range of active ingredients, such as, atrazine, trifluralin, diazinon, endosulfan, carbofuran and simazine.

-
-
3. To what extent has there been an improvement in risk management of pesticides as a result of BPC program activities?
-
-

The degree to which the risk management of pesticides has improved can only be inferred in that the breadth and depth of information on the environmental presence and effects of pesticides is strengthened and results in better informed risk assessments and risk mitigation strategies. It is too soon to be able to measure any discernible change in the environmental effects of pesticides that can be attributed to changes in the availability of post-market information for consideration in HC-PMRA's approach to risk management. Further long-term research and monitoring work will be necessary to determine if the environmental presence and effects of pesticides is reduced.

HC-PMRA managers responsible for aspects of the Agency's risk assessment work believed that the availability of 6NR research and monitoring data had improved the quality of their risk assessments and aided decision-making to determine if various active ingredients subject to re-evaluation should be subject to more stringent conditions of use or removed from all use in Canada. These views are supported by the documentation on a range of recent decisions that include references to the use of data from monitoring work enabled by the BPC Initiative in the supporting rationale and risk analyses.

Among the respondents to the online survey who were familiar with the BPC research and monitoring work, 63% rated its performance in improving risk assessments and risk mitigation as effective compared to 16% who felt it was neither effective nor ineffective and 22% ineffective (after excluding "don't know" responses).

-
-
4. To what extent has compliance with guarantee and residue standards by food and fertilizer industry sectors been enhanced?
 5. Has the safety of foods, fertilizers and fertilizer-pesticide combinations available to Canadians increased as result of the CFIA's monitoring programs?
-
-

The evidence obtained from our key informant interviews, review of documentation and survey of external stakeholders suggests that, as a result of the BPC Initiative, the CFIA (and HC-PMRA) has obtained a better understanding of the extent to which pesticide residues are present on processed food products typically consumed by children. Similarly, the CFIA has expanded its capability to verify the presence of pesticide levels in fertilizer-pesticide combinations and the incidence of pesticide contamination in fertilizers. Awareness of compliance rates has been enhanced through contacts with food and fertilizer companies in the course of program delivery as well as the industry associations for these sectors.

a) Pesticide residues on food products

In the case of residues on food products, compliance rates by Canadian manufacturers and importers of children's food products have been consistently high dating back to the time of the first CFIA monitoring survey in 2003/04. The design of CFIA's monitoring of pesticide residues on children's food products has varied from one survey to another since the first such survey in 2003/04 and, as such, does not provide a definitive basis for looking at trends in the extent to which such products are compliant with limits on the presence of pesticides.

The snapshots provided by these surveys do suggest that the majority of children's food products have consistently been within established legal limits for the presence of pesticide residues, with over 98% of the samples in each of the surveys having either no detectable residues present or residues below the applicable MRLs. These results show that children's foods have a high degree of compliance and thus are likely to be "safe" in the sense of limiting inadvertent exposure to pesticides.

In cases where applicable MRLs have been exceeded, follow-up investigations by the Agency have determined that the non-compliant products have not posed systemic concerns. In the event that more significant risks are found the Agency has the authority to conduct follow-up inspections of the manufacturers and importers, and if necessary, to require the recall and removal of hazardous foods from the marketplace.

b) Pesticides in fertilizers and fertilizer-pesticide combinations

With regard to fertilizers and fertilizer-pesticide combinations, low compliance rates (below 70% in recent years for fertilizer-pesticide guarantee verification and below 90% for pesticide contamination monitoring) have prompted more intensive engagement with the industry by CFIA. The CFIA's 2007/08 Performance Report noted that lower than desired compliance levels for fertilizers and fertilizer-pesticide combinations were a concern and it had initiated actions with the industry to improve quality control procedures, and to target companies and products with repeat infringements. The Agency also introduced a new sampling element in 2008/09 to include testing of lawn fertilizer treatments used by lawn care companies. The CFIA and HC-PMRA also announced in February 2010 that fertilizer-pesticide combinations intended for lawn and turf use would be "decoupled" and may no longer be sold after December 31, 2012. Significant reductions in the risk of inadvertent pesticide exposure (in the case of fertilizers) or inappropriate concentrations of pesticides (in fertilizer-pesticide combinations), as measured by the CFIA, have yet to be realized.

2. Recommendations

The evaluation findings relating to the research and monitoring stream of the BPC Initiative are generally very positive and provide a good example of how horizontal coordination in support of science-based regulatory decision-making can work. The experience with developing this collaborative approach clearly demonstrates that effective horizontal coordination and integration across the federal government requires a clear vision, sustained effort and transparent processes. The challenge going forward, now that the previously dedicated funding allocated under the BPC Initiative has been converted to ongoing A-base funding in each of the participating departments and agencies, will be to sustain the degree of horizontal

integration and information sharing that has been gained. In addition, if this current level of ongoing funding for research and monitoring does not enable HC-PMRA's priority needs to be satisfied, the 6NR partners will need to determine what level is most appropriate and develop a supporting rationale for such funding.

The 6NR partners, under the leadership of HC-PMRA, to:

- 1. Develop a joint strategy to maintain and strengthen the focus of their pesticide-related research and monitoring work in support of HC-PMRA priority needs, and determine the associated funding requirements.**
- 2. Investigate the feasibility of sharing the findings from the 6NR research and monitoring work, and a summary of planned future work under the integrated 6NR work plans, with interested external stakeholders. This information sharing should be used to increase awareness of the environmental effects of pesticide use among external stakeholders.**

V. STRENGTHENED PESTICIDE REGULATION

A. Program description

The BPC Initiative's activities to strengthen pesticide regulation include a series of measures designed to make Canada's regulation of pesticide products more effective and in this way contribute to improved protection of health and the environment. HC-PMRA is solely responsible for these four elements of the BPC Initiative to strengthen pesticide regulation. The nature and purpose of these activities are:

- **Timely re-evaluation of older pesticides** – The purpose of the HC-PMRA re-evaluation program is to determine if currently registered pesticides remain acceptable for use in Canada based on updated information, modern scientific approaches and standards. Under the BPC Initiative, funding was provided to HC-PMRA to accelerate the rate of re-evaluation of pesticides registered prior to December 31, 1994 by increasing the resources engaged in this work. The intended outcomes from this work are:
 - Timely regulatory actions to mitigate risks or remove unacceptable products from the marketplace. (Short-term outcome.)
 - Pesticides available to Canadians meet modern standards. (Medium-term outcome.)

Two evaluation issues are directly applicable to this element of the BPC Initiative:

1. As a result of the BPC funding, what proportion of products registered prior to 1995 has been re-evaluated? Of these, what have been the results of re-evaluation?
2. What progress has been made to ensure that only those pest control products that meet modern standards remain registered?

The performance of the re-evaluation program is also a consideration under a third evaluation issue related to the achievement of the long-term outcome from the pest management strategies stream (Chapter VI) of the BPC Initiative: has the competitive parity of the agricultural sector been affected?

- **Pesticide Incident Reporting System** – The Pest Control Products Incident Reporting Regulations introduced a mandatory incident reporting requirement for registrants of pesticides in Canada and applicants wishing to register new pesticides in Canada. As of April 2007, registrants and applicants are required by law to report incidents, including adverse effects to health and the environment or value ³⁴of their products, to HC-PMRA within a set time frame. The intended outcomes from the incident reporting system are:
- Improved post-market information on presence and effects of pesticides to support risk assessment/mitigation. (Short-term outcome.)
 - Improved risk management of pesticides. (Medium-term outcome.)

Both of these BPC outcomes are shared with the research and monitoring stream.

- **Implementation of a formulants policy** – HC-PMRA is implementing a policy on formulants (any component of a pest control product that is added intentionally and is not an active ingredient) with the purpose of ensuring that information on formulants is accurate and these components of pesticides meet current scientific standards. The expected outcomes from the formulants activities are:
- Increased awareness by registrants of formulant policy requirements. (Short-term outcome.)
 - Pesticides available to Canadians meet modern standards. (Medium-term outcome, shared with re-evaluation activity.)
- **Availability of MSDS data for all registered pesticide products** – Section 8 (3) of the new PCP Act requires product safety information, including a material safety data sheet (MSDS) to be provided to workplaces where a pest control product is manufactured or used, as a condition of the product's registration. Under the BPC Initiative HC-PMRA is developing and implementing a regulation establishing standardized information requirements for pesticide MSDS consistent with the national WHMIS (Workplace Hazardous Materials Information System) hazard communication standard. The expected outcomes for this BPC element are:
- Increased availability of MSDS in workplaces. (Short-term outcome.)
 - Increased worker awareness of pesticide safety and hazard information. (Medium-term outcome.)

Each of the above four measures to strengthen the pesticide regulatory system is expected to contribute to a final (long-term) BPC outcome of improving protection of health and the environment.

B. Re-evaluation of older pesticides

1. Activities and outputs

The basis for the HC-PMRA re-evaluation program was established in HC-PMRA Regulatory Directive DIR2001-03, HC-PMRA Re-evaluation Program, published in March 2001. The key features of that Directive included:

³⁴ Value is defined in the PCP Act as: "value: the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact."

- All pesticide active ingredients registered prior to December 31, 1994 and their currently registered end-products are subject to re-evaluation against current scientific standards for product registration.
- A total of 405 active ingredients were affected out of a total of approximately 550 registered active ingredients. This number was later reduced to 401 as four were disinfectants and no longer subject to the PCP Act.
- In order to complete the re-evaluations of these active ingredients in a timely manner and make efficient use of the Agency's re-evaluation resources, HC-PMRA decided to use foreign reviews, particularly those conducted by the U.S. Environmental Protection Agency (EPA), where available and suitable. The EPA's reregistration initiative (equivalent to Canada's re-evaluation program) commenced in 1986 and had already called in an extensive number of studies of active ingredients generated by registrants.
- Active ingredients subject to re-evaluation were assigned to one of four sub-programs:
 - Program 1 – pest control products for which the EPA had already published a Risk Assessment Document or Reregistration Eligibility Decision (RED). The expectation was that the Canadian review could be based on this information without undertaking substantial additional in-house work, and that registrants would not have to generate a significant number of new studies for HC-PMRA.
 - Program 2 – pest control products that do not have suitable EPA review documents and require a detailed in-house re-evaluation covering the full range of assessments of risks to human health and the environment as well as consideration of value. Products with unique use situations in Canada and product types subject to ongoing re-evaluation³⁵ were also included in Program 2.
 - Program 3 – pest control products that were scheduled for reassessment in the U.S. under the *Food Quality Protection Act*. A central area of focus for these products was the safety of food residues considering cumulative exposure from all sources, common mechanism of toxicity and susceptible subgroups, such as children.
 - Program 4 – targeted re-evaluations (Special Reviews) initiated to address particular concerns identified for specific pest control products.
- In addition to drawing on data generated by registrants, HC-PMRA draws upon available monitoring data from provincial and territorial ministries, and other federal departments, such as that compiled by Environment Canada and Fisheries and Oceans, as well as EPA review documents. HC-PMRA and EPA also work together, where possible, to plan for and conduct joint re-evaluation reviews.
- At the time the Re-evaluation Directive was issued the EPA's target for completion of its product reregistrations was August, 2006 and HC-PMRA proposed to complete the Canadian re-evaluations within the same time frame. In 2004, the EPA target was modified when the U.S. *Pesticide Registration Improvement Act* came into effect, with re-registration decisions for pesticides with food uses and/or tolerances (MRLs) to be completed by August 2006 and decisions for all non-food use pesticides by October 2008. In May, 2005, HC-PMRA announced that it intended to complete the re-evaluation of Canadian products by June, 2009. The April 2009 to March 2010 Workplan published in September, 2009, extended the target completion date for publishing proposed or final decisions and re-evaluation notes for the outstanding active ingredients to March, 2010. Note that "completion" was defined in these documents as being the

³⁵ Seven product types were listed in Appendix 1 to the Directive: chlorophenols, 2,4-D, fumigants, MCPA, personal insect repellents, antispasms, and heavy duty wood preservatives. Re-evaluations of these products were initiated between 1979 and 1992.

issuance of a final re-evaluation decision, a proposed re-evaluation decision or a re-evaluation note, including preliminary risk assessments.³⁶ Changes to the registration, MRL or label requirements can only be made, however, after the issuance of a final re-evaluation decision or re-evaluation note.

In 2003, the Commissioner of the Environment and Sustainable Development (CESD) noted in her report on managing the pesticide regulatory activities that progress on re-evaluations (up to and including 2002) had been very slow, due partly to the limited resources assigned to the program as well as the rate of progress of the U.S. Environmental Protection Agency's (EPA) own re-registration program and associated availability of data supporting U.S. decisions for use in Canadian re-evaluations. Prior to 1999/00 HC-PMRA expected that efficiencies in the conduct of new product registration reviews would enable resources to be freed up to undertake re-evaluation reviews. However, the anticipated efficiencies were not fully realized and the volume of submissions for new and amended registrations increased sharply (from an average of about 2,050 in 1998/99 and 1999/00 to about 3,300 per year from 2000/01 to 2002/03). In response, the 1999 and 2000 federal budgets increased the level of resources available for re-evaluation, and the BPC Initiative provided funding in 2002/03 for a further increase in re-evaluation resources, beginning with an additional 20 FTEs in 2002/03 and rising to 26 in 2004/05.

According to resource data provided by HC-PMRA, the direct FTEs involved in the Agency's re-evaluation activities rose from 30 in 1999/00 to 57 in 2002/03, which would appear to be attributable to the additional funding allocated in the 1999 and 2000 federal budgets. Treasury Board gave its approval for the BPC Initiative to proceed late in fiscal 2002/03, which meant that 2003/04 was the first full year of its implementation. Direct FTE's working on re-evaluation increased to 75 in 2003/04 but fell back to 61 in 2004/05 and have remained relatively stable since, at 55 in 2005/06, 63 in 2006/07, and 68 in 2007/08.

The extent to which the BPC-funded FTEs accelerated the rate of re-evaluation cannot be readily isolated from the impacts of earlier increases in re-evaluation resources. Timelines and workloads for each individual pesticide re-evaluation are highly variable. This variability is a function of such factors as the complexity of each active ingredient's science; complexity of potential health and environmental effects; numbers of end-use products and approved uses; whether EPA and other foreign review documents are available; and the timeliness of registrant responses to data requests.

As an illustration of this, the start and completion dates for 60 products for which a final re-evaluation decision was released during 2007/08 and 2008/09 (comprised of 48 continuing registrations with label modifications, eight discontinuations by registrants, three continuing registrations with no label modifications, and one phase-out) were reviewed. The median re-evaluation time for this sample was 35 months with a range from zero (for three products) to 121 months (after excluding one extreme outlier, atrazine, of 234 months). Median time from initiation to issuance of a proposed decision for the 53 products for which this data was available was 28 months, and median time from issuance of a proposed decision to a final decision was 5 months (data for 56 products). These time frames included periods of 45 or 60 days for public comment on formal consultation documents issued during the re-evaluation process – Re-evaluation Notes and Proposed Re-evaluation Decisions (Proposed Acceptability for Continuing Registration prior to July, 2007).

2. Achievement of outcomes

The HC-PMRA re-evaluation program activity leads to decisions regarding the continued availability for use, or otherwise, of older active ingredients. Products using these active ingredients may be withdrawn

³⁶ **HC-PMRA Re-evaluation Program** (April 2005 to June 2009), REV2005-04, May 2005.
HC-PMRA Re-evaluation Workplan (April 2009 to March 2010), REV2009-07, September 2009.

by registrants, phased out at the request of HC-PMRA, subject to altered conditions of use (label changes), or continue to be marketed with no changes to the conditions of use. In addition, these decisions may give rise to transition strategies that provide for the phased introduction of new conditions of use or removal of active ingredients that have an impact on the activities of users and registrants. Both types of impacts are considered in this section, in the context of the short and medium-term outcomes set for the re-evaluation activities in the BPC logic model:

- Timely regulatory actions to mitigate risks or remove unacceptable products from the marketplace.
- Pesticides available to Canadians meet modern standards.

In turn, these outcomes are expected to contribute the long-term intended outcome of improved protection of health and the environment.

a) Re-evaluation decisions

Annual breakdowns of the number of final re-evaluation decisions issued by HC-PMRA are shown in Exhibit V-1. This information shows that many registrants chose to discontinue or withdraw pesticide registrations during the initial years of the period examined, in preference to undertaking the data generation required to support re-evaluation reviews. The combined number of final, proposed and pending decisions in each year rose from 2003/04 to 2005/06 in response to the increases in resources allocated to the program and remained relatively stable thereafter.

As previously noted, the re-evaluation program tends to measure its rate of progress by looking at the number of pending, proposed and final decisions in total, given that the greatest amount of effort involved in re-evaluating each active ingredient occurs prior to the determination of proposed decisions. However, from an external, or public, perspective the result that matters most is the timing of final decisions or re-evaluation notes that lead to actual changes in the conditions of registration, MRLs or label requirements of these older active ingredients, that is, the point at which their use is consistent with current scientific standards and regulatory requirements.

Exhibit V-1

Annual breakdowns of re-evaluation decision making

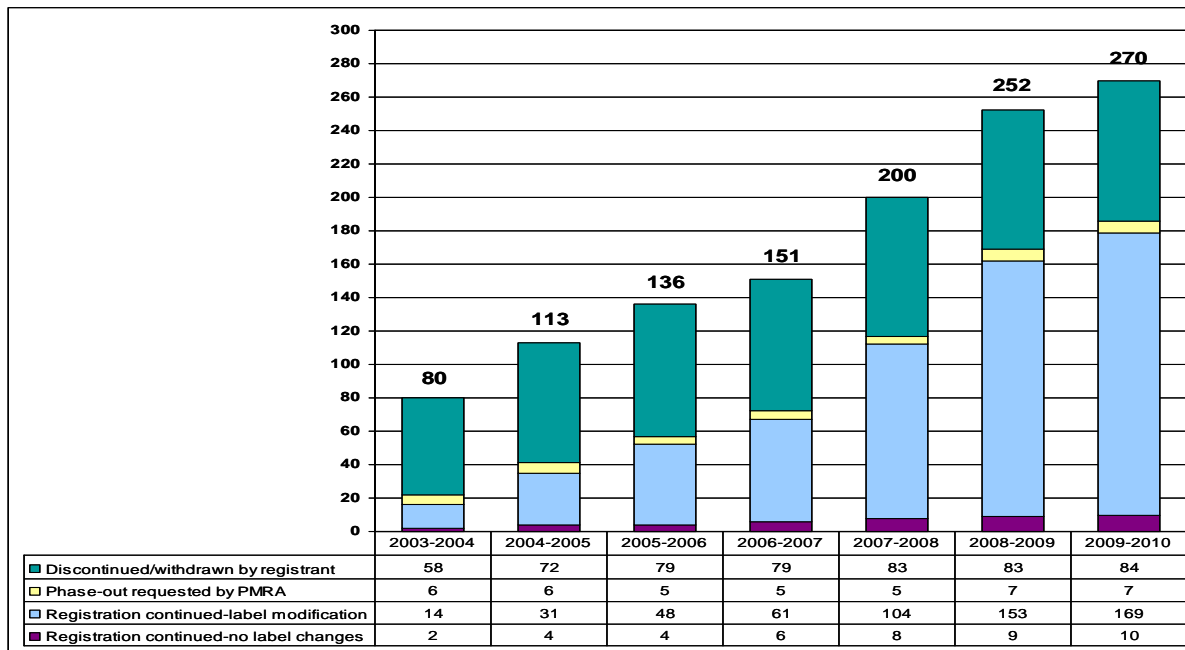
Final Decision Outcomes	2003/04		2004/05		2005/06		2006/07		2007/08		2008/09		2009/10	
	#	%	#	%	#	%	#	%	#	%	#	%	#	%
Discontinued/withdrawn by registrant	23	79%	14	42%	7	30%	0	0%	4	8%	0	0%	1	6%
Phase-out requested by HC-PMRA	2	7%	0	0%	-1	-4%	0	0%	0	0%	2	4%	0	0%
Registration continued – label modifications	2	7%	17	52%	17	74%	13	87%	43	88%	49	94%	16	89%
Registration continued – no label changes	2	7%	2	6%	0	0%	2	13%	2	4%	1	2%	1	6%
Sub-Total – Final Decisions	29	100%	33	100%	23	100%	15	100%	49	100%	52	100%	18	100%
Proposed and Pending Decisions at Year-end	55		69		97		93		74		78		90	
Total – Final, Proposed and Pending Decisions	84		102		120		108		123		130		108	

Source: HC-PMRA Annual Reports, HC-PMRA reports to the House of Commons Standing Committee on Agriculture and Agri-Food, and data provided by the HC-PMRA Re-evaluation Program.

Cumulative data on the numbers of final re-evaluation decisions for the period from 2003/04 to 2008/09 are summarized in Exhibit V-2 and show the extent to which decisions for the 401 active ingredients subject to re-evaluation have been finalized. This data show that final decisions had been issued for 80 of the 401 active ingredients (20%) by the end of 2003/04. By the end of 2008/09 the total had risen to 252 or 63% of the total, and 270 (67%) by the end of 2009/10.

Exhibit V-2

Cumulative numbers of final re-evaluation decisions



Source: HC-PMRA Annual Reports, HC-PMRA reports to the House of Commons Standing Committee on Agriculture and Agri-Food, and data provided by the HC-PMRA Re-evaluation Program.

At the time of the data collection for the evaluation (second half of 2009) HC-PMRA expected to issue proposed evaluation decisions, re-evaluation notes and final decisions for the 149 active ingredients outstanding at the end of 2008/09 by the end of 2009/10. Decisions for 78 of these active ingredients (from Exhibit V-1) were proposed or pending which suggested that a substantial number of re-evaluations would have been finalized by the end of 2009/10.

However, data compiled by HC-PMRA in mid-2010 showed that this expectation was not realized. At the end of 2009/10 270 final decisions had been issued and work on another 90 was sufficiently advanced to the point where decisions were proposed or pending, leaving 41 in process.

This data suggests that the issuance of final decisions to complete the re-evaluation of pesticides first registered prior to 1995 will likely continue through 2010/11 and 2011/12, based on the median elapsed times for the conduct of reviews and issuance of proposed and final decisions noted in the previous section (28 months to the issuance of a proposed decision plus 5 months from the proposed to the final decision).

Starting in 2010/11, the Agency will have to commence re-evaluation reviews of pesticides first registered in 1995 or later, consistent with a requirement in the *PCP Act* that re-evaluation should be initiated for all registered pest control products no later than one year after 15 years of registration has elapsed. The number of these “Phase 2” re-evaluations to be initiated each year – of the order of 15 per year on average – will be much lower than the numbers of active ingredients reviewed in the initial re-evaluation program.

Projected workloads to complete the re-evaluation of the active ingredients registered prior to 1995 will need to be determined by the re-evaluation program in its planning and budgeting for the Phase 2 re-evaluation work over the 2010/11 to 2012/13 period to ensure that the Agency is able to complete both streams of work on a timely basis. Program officials also identified a number of other requirements that will need to be addressed in the work planning and budgeting for the Agency’s ongoing re-evaluation activity. In particular, they identified needs to review confirmatory risk studies requested of registrants for a proportion of the past re-evaluation decisions to better understand and confirm the nature of possible risks, and develop new and updated policies (for example, relating to bee/pollinator protection) to guide the application of modern science and standards to the evaluation of older active ingredients. Both of these activities contribute to the strengthening of pesticide regulation and improving the protection of human health and the environment.

b) External views on the effectiveness of the re-evaluation program

Participants in seven of the fourteen key informant interviews indicated that they were involved or familiar with the activities of the re-evaluation program. Six of these seven provided ratings of the effectiveness of HC-PMRA in achieving the intended outcomes of the re-evaluation activity. All six rated HC-PMRA’s performance on each of the three intended outcomes – more timely action to mitigate the risks posed by older pesticides, pesticides approved for use meet modern science and regulatory standards, and improved protection of health and the environment – as being either “somewhat” or “highly effective”, except for one participant who gave a “don’t know” rating on the impact on human health and the environment.

A further area of questioning with the external key informants was that of the impact of removing some older pesticides and changes to the conditions of use for others on the availability of pest management options for users, which has an impact on the competitive parity of Canadian users of pesticides. Themes in these comments related to:

- Re-evaluation outcomes in Canada are generally consistent with re-evaluation outcomes in the U.S. However, sometimes there are short-term differences in the timing of such decisions that can mean that pesticides available in the U.S. are not available in Canada or vice versa.
- A greater concern for growers is that Canadian growers start with fewer pest control alternatives and means of minimizing the development of pesticide resistance than U.S. growers. Many newer pesticide products are quite specialized and targeted, and typically resistance to these products develops faster than the older, broader spectrum products. Re-evaluation decisions that result in the removal or more restricted conditions of use for these older active ingredients then reduce the pest management options available to growers.
- The rate of removal of existing pesticides or tighter restrictions on the use of existing pesticides under the re-evaluation program are perceived to be happening at a faster rate than the registration of new minor uses and active ingredients. (The combinations of pest control substances and crops covered means that there are no readily available data to actually make this comparison.) As a result, growers may have very limited alternatives available for rotating pesticide products and minimizing the rate at which resistance develops. Transition strategies for re-evaluated pesticides are intended to respond to such situations and the efforts by HC-PMRA to

accommodate such needs were recognized and acknowledged. In some situations the transition strategies developed with the aid of stakeholder input are effective; in other cases they are less effective, particularly if there are no effective alternatives to the pesticides that are being removed, or do not adequately accommodate the long lead times involved in developing new active ingredients.

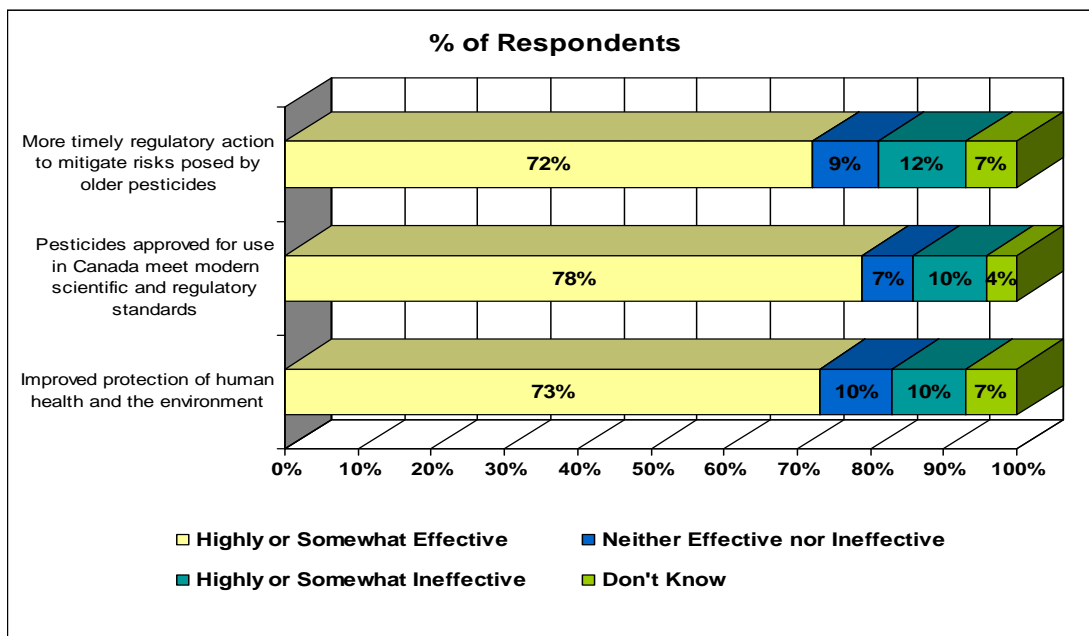
- In rare instances, Canadian growers may have pesticides available that are not available to U.S. growers. However, if the EPA has not established tolerances (MRLs) for these pesticides then Canadian growers are precluded from exporting produce that may contain residues of these pesticides.

Participants in the online survey who indicated they had either “some” or a “substantial knowledge” or were “very familiar” with the HC-PMRA re-evaluation program (172 or 61% of the 282 survey participants), were asked about the effectiveness of the re-evaluation program and suggest opportunities for improvements. Ratings of HC-PMRA’s performance against the three intended outcomes from the re-evaluation program are summarized in Exhibit V-3.

As can be readily seen from the exhibit, the surveyed stakeholders were highly likely to think that HC-PMRA has been effective in achieving the intended re-evaluation outcomes. Comparison of the breakdowns by type of stakeholder, while indicative only, suggest that provincial/territorial government representatives and users of pesticides were more likely to believe HC-PMRA was effective.

Exhibit V-3

Ratings of the effectiveness of the re-evaluation program by participants in the online survey



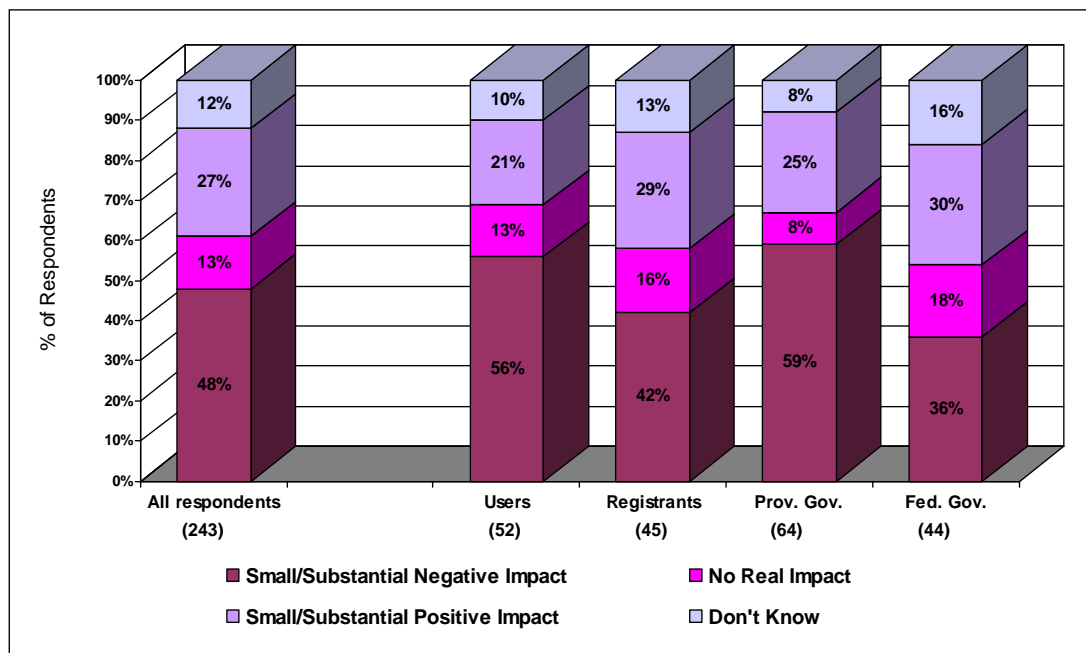
Base: Respondents who were familiar with the HC-PMRA re-evaluation program (QC2); n=172.

These survey respondents were also asked to rate the impact of the re-evaluation program outcomes on the competitive parity of Canadian agricultural producers and forestry managers, with the results summarized in Exhibit V-4. Although not an objective of re-evaluation, unintended impacts of this type

are possible. This exhibit shows that almost half (48%) of the survey respondents believed that re-evaluation has had either a “small” or “substantial” negative impact on the competitive parity of Canadian growers versus 27% who believed that it had either a “small” or “substantial” positive impact. Users and provincial government representatives (the majority of whom were from provincial ministries of agriculture or environment) were the most likely to perceive a negative effect on competitive parity.

Exhibit V-4

Impact of re-evaluation on competitive parity



Base: Respondents who were familiar with the pest management strategies activities (QA7); n=243.

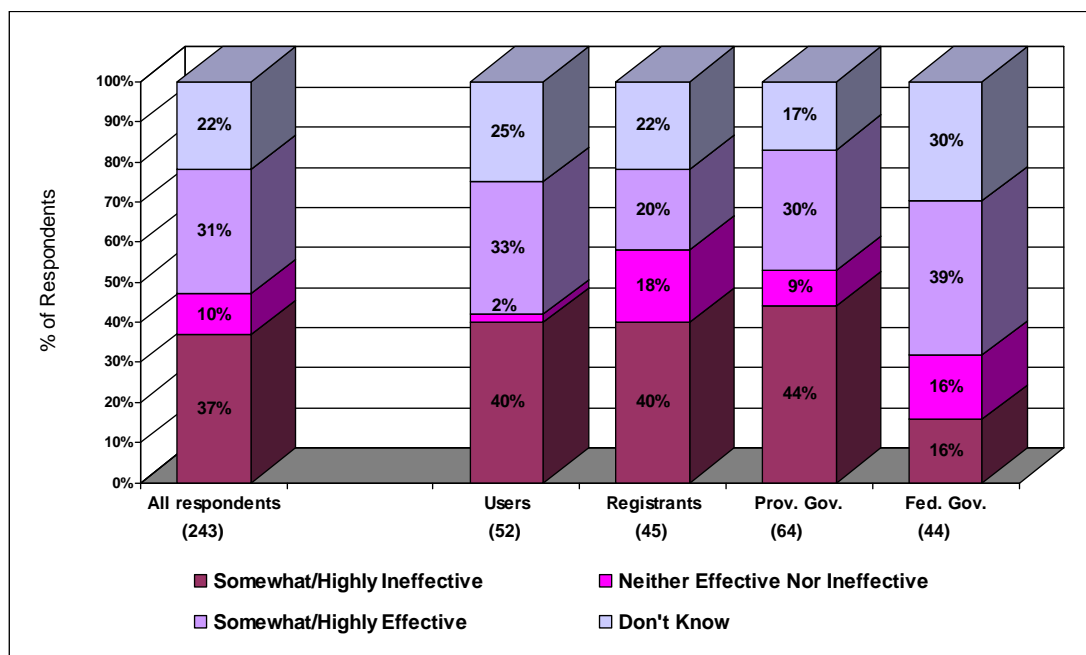
These same survey respondents were then asked how effective they thought the transition strategies applied when older pesticides are removed or the conditions of use are made more restrictive. The results for this question are shown in Exhibit V-5. The key points to note from Exhibit V-5 are:

- A relatively high proportion of the survey respondents were not in a position to provide an effectiveness rating either way (22% of the total), with slightly higher incidence rates among users (25%) and federal government representatives (30%).
- After excluding these “don’t know” responses the proportion of respondents viewing the transition strategies as effective is slightly lower (40%) than those viewing them as ineffective (47%), and the balance believing they were neither effective nor ineffective.

Overall, these results suggest a very mixed view among the various stakeholder groups as to the effectiveness of transition strategies. Findings from the key informant interviews suggest that this situation may be a function of the extent to which stakeholder representatives have been directly affected by changes in the availability or conditions of use applied to re-evaluation products. The extent of impact can vary substantially depending on the circumstances facing individual growers and which pest control issues are involved.

Exhibit V-5

Perceived effectiveness of transition strategies



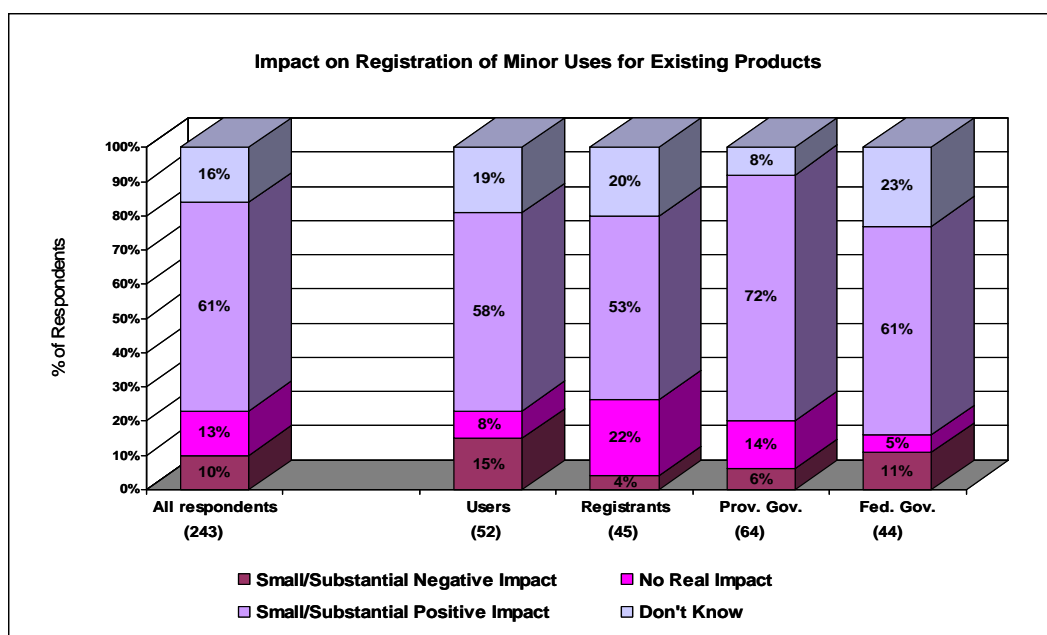
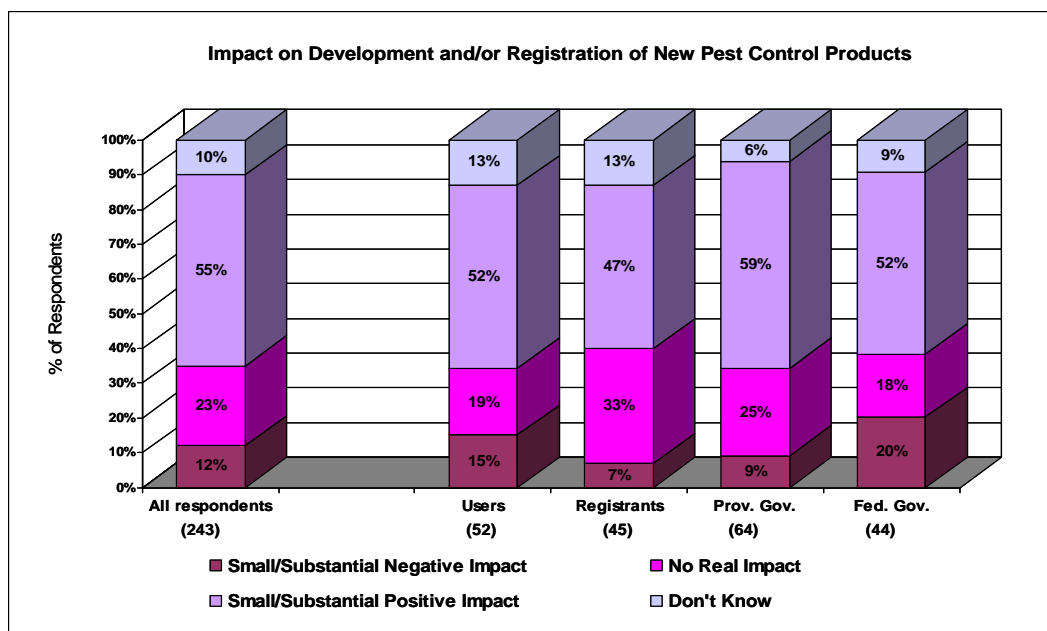
Base: Respondents who were familiar with the pest management strategies activities (QA9); n=243.

Perceptions of the broader effects of the re-evaluation program – in terms of the program’s impact on the development and/or registration of new pest control products, and on the registration of minor uses for existing products – were also investigated. Respondents’ ratings of the program’s impacts on these two dimensions are summarized in Exhibit V-6 and show that:

- With regard to the impact on the rate of development and/or registration of new pesticide products, registrants (who should be in the best position to indicate if re-evaluation has influenced their decision-making) were less likely than other stakeholder groups to believe that re-evaluation had had a positive impact (47% versus 52% - 59% for other stakeholder types) and more likely to believe it had had no impact either way (33%).
- Respondents were more likely to believe that re-evaluation had had a positive effect on the rate of minor use registrations versus the rate of new product development (61% compared to 55%). Registrants were less likely than other stakeholders to believe re-evaluation had had a positive impact and more likely to believe it had had no real impact. Relatively high proportions of respondents – especially among users, registrants and federal government representatives – were not in a position to provide a rating and selected the “don’t know” option.

Exhibit V-6

Impact of product re-evaluations on new pesticide development and minor use registrations



Base: Respondents who were familiar with the pest management strategies activities (QA10); n=243.

Both the external key informants and survey respondents were asked if they thought there were opportunities to improve the effectiveness or efficiency of the re-evaluation program. Almost two-thirds (66%) of the respondents to the survey questions on the re-evaluation program felt that opportunities existed to improve the re-evaluation program whereas only 10% were of the opinion that no improvements were necessary (with the balance opting for “don’t know”).

The most commonly mentioned themes in these suggestions related to:

- Improving communications to stakeholders and the public regarding re-evaluation, for example, to address possible concerns that re-evaluation was concerned with actions to fix past/existing safety problems rather than being “good risk management” and providing regular updates explaining the status of completed and in-process re-evaluations.
- Improvements to HC-PMRA’s approach to re-evaluation, in such areas as:
 - Greater coordination with the EPA and other countries with re-evaluation programs, given that decisions made in one jurisdiction are generally consistent with decisions made in Canada and other jurisdictions.
 - Strengthening consultations with stakeholders and the public regarding proposed decisions and associated proposals regarding transition strategies for active ingredients subject to discontinuation, phase out or more restricted conditions of use.
 - Draw as much as possible on practical experience with the use of pesticides subject to re-evaluation as part of the risk analysis process.
 - Consider the cumulative effects of combinations of pesticides that may occur rather than assessing active ingredients individually, and apply a more precautionary approach.
 - Expand the testing requirements to include consideration of the effects of chronic or sub-lethal levels of pesticides, and expand the coverage of species included in environmental testing.

3. Conclusions – accelerated rate of re-evaluation

Two evaluation issues are related directly to the HC-PMRA re-evaluation program and the use of BPC Initiative funding to accelerate the rate of assessment of pesticides registered prior to 1995. A third issue, related to competitive parity under the pest management strategies stream, is indirectly affected by the outcomes from the program.

-
1. As a result of the BPC funding, what proportion of active ingredients registered prior to 1995 has been re-evaluated? Of these,
 - (a) What proportion required amendments for continued registration?
 - (b) What proportion did HC-PMRA take action to remove from the market place?
 2. What progress has been made to ensure that only those pest control products that meet modern standards remain registered?
-

The HC-PMRA Re-evaluation Program directive issued in March 2001, set a target of completing re-evaluations of all pesticide active ingredients registered prior to December 31, 1994 in parallel with the U.S. EPA’s re-registration program, which had a target completion date of August 2006. Following delays related to changes in the EPA role in these re-evaluations, HC-PMRA in May, 2005 announced that it intended to complete the re-evaluation of the 401 active ingredients subject to re-evaluation by June, 2009. HC-PMRA defines completion in this context as the issuance of a final re-evaluation decision, a proposed re-evaluation decision, or a re-evaluation note for an active ingredient. HC-PMRA’s *Workplan for April 2009 to March 2010*, published in September 2009, extended this target completion date to March 2010.

Data provided by the re-evaluation program show that in 2003/04 final decisions had been issued for 80 of 401 pesticides, or 20% of the total. By the end of 2008/09 the total had risen to 252 or 63% of the total, and 270 by the end of 2009/10. The breakdown of these outcomes was:

- Continued registration with no changes to the label requirements: 9 of the 252 (4%) at the end of 2008/09, and 10 of the 270 (4%) at the end of 2009/10.
- Continued registration with changes to the label requirements: 153 (61%) and 169 (63%).
- Phase-out at the instigation of HC-PMRA: 7 (3%) in both years.
- Discontinuation or withdrawal by the registrant: 83 (33%) and 84 (31%).

In addition, substantial progress had been made on the re-evaluation of another 90 products at the end of 2009/10, as evidenced by the issuance of proposed decisions or re-evaluation notes for public consultation prior to final decision making. This means that re-evaluations of the last 41 active ingredients had not progressed to the point where proposed decisions could be made and that work on these re-evaluations will likely continue through 2010/11 and 2011/12, in addition to work on the finalization of the 90 proposed or pending decisions outstanding at the end of 2009/10.

Starting in 2010/11, HC-PMRA will need to complete the re-evaluation of the 401 oldest active ingredient registrations in parallel with the re-evaluation of active ingredients that have been registered for 15 years, which is a requirement of the *PCP Act*. The Agency will need to forecast the workloads and resource requirements for both of these areas of re-evaluation work and factor them into its budgeting. Other demands, such as the need to review confirmatory risk studies requested of registrants as a requirement in re-evaluation decisions, and research and develop policies to keep HC-PMRA's risk assessments and risk management consistent with current scientific knowledge and standards, will also need to be factored into resource planning for the re-evaluation program.

External key informants who were familiar with the re-evaluation program were asked to rate the effectiveness of the program in achieving the intended outcomes of the re-evaluation activity – more timely action to mitigate the risks posed by older pesticides, pesticides approved for use meet modern science and regulatory standards, and improved protection of health and the environment. These six external key informants felt that the Agency's performance against each of these outcomes was either "somewhat" or "highly effective" (with one providing a "don't know" rating against the impact on human health and the environment).

A majority of the participants in the online survey of stakeholders who indicated they were familiar with the re-evaluation program also believed that it was either "somewhat" or "highly" effective: 72% for the timeliness of actions to mitigate the risks posed by older pesticides, 78% for ensuring that pesticides approved for use meet modern science and regulatory standards, and 73% for improving protection of health and the environment.

3. Has the competitive parity of the agricultural sector been affected?

A possible side effect of the re-evaluation program is that the competitive parity between Canadian and U.S. producers is affected by the rate of progress with the re-evaluation of older pesticides. This may occur if re-evaluation removes pest control products that no longer meet modern standards and the rate of removal is not offset or exceeded by the rate of registration of new pest control products and registration of new minor uses through such initiatives as the AAFC/HC-PMRA Minor Use Program.

External key informants who commented on the impact of decisions to remove older pesticides or restrict their use most commonly noted that Canadian growers start with fewer pest control alternatives and means of minimizing the development of pesticide resistance than U.S. growers. These key informants also noted that many newer pesticides are quite specialized and targeted, and typically resistance to these pesticide products develops faster than with older, broader spectrum pesticides. Re-evaluation decisions that result in the removal of these older pesticides or the application of more restricted conditions of use then reduce the pest management options available to growers. The key informants also perceived that re-evaluation decisions to remove older pesticides or apply more stringent conditions of use was happening at a faster rate than the registration of new minor uses and active ingredients. The combinations of pest control substances and crops covered means that there are no readily available data to actually make this comparison, and the extent of impact can vary substantially depending on the circumstances facing individual growers and which pest control issues are involved.

Amongst the survey respondents who indicated they were familiar with the re-evaluation program, almost half (48%) believed the re-evaluation of older active ingredients has had either a “small” or “substantial” negative impact on the competitive parity of Canadian growers versus 27% who believed that it had either a “small” or “substantial” positive impact. A similar pattern was apparent when these survey respondents were asked to rate the effectiveness of transition strategies applied when older pesticides are removed or the conditions of use are made more restrictive, albeit with a narrower gap between the proportions with negative and positive views (47% versus 40% after excluding the “don’t know” answers).

Findings from the key informant interviews suggest that this pattern of responses may, in part, be a function of the extent to which the surveyed stakeholders have been directly affected by changes in the availability or conditions of use applied to re-evaluation products when seeking pest control solutions.

C. Pesticide incident reporting system

1. Activities and outputs

Regulations establishing HC-PMRA’s reporting system for suspected pesticide incidents came into force and began operating in April 2007. These regulations established a mandatory requirement for registrants to report to HC-PMRA, within set timeframes, any pesticide incidents – where incident means an incident described in the Act whose effects relate to the health or environmental risks or the value of a pest control product.³⁷ Members of the public and medical professionals and organizations are encouraged to report any pesticide incidents they experience or become aware of to registrants who are then required to report these incidents to the Agency. Incidents may also be reported directly to the Agency.

Key features of the system include:

- Incidents received are allocated to one of six categories listed below and, within each category, assigned a degree of severity:
 - Effects on humans.
 - Effects on domestic animals.
 - Effects on the environment (that is, plants and wildlife).
 - Residues in food.
 - Packaging failure.
 - Effects identified in scientific studies.

³⁷ Pest Control Products Incident Reporting Regulations – Section 1: Interpretation, **Canada Gazette**, Vol. 140, No. 23 — November 15, 2006.

- Registrants are required to report all incidents that occur in both Canada, as well as a subset of incidents that occur in the U.S.
- Timeframes for reporting incidents vary between 15 days and 12 months, depending on the category and degree of severity. For example, an incident that results in a human death, an incident that occurs in Canada and has a major effect on a human, or an incident that has a major effect on the environment must be reported within 15 days of the registrant receiving such information.
- All incident reports are placed in the Public Registry (on the HC-PMRA section of the Health Canada website), excluding any personal information and confidential business information.

The inclusion of an incident in the Public Registry does not indicate that causality has been established, only that a pesticide may be associated with a health or environmental situation, the effects of which may be reviewed. As noted on the Public Registry, *additional scientific investigations are required to validate signals from the database and to establish a cause and effect relationship between a pesticide and an adverse effect. Assessment of causality must include other factors such as the frequency, severity, plausibility, quality of the information contained in the report, amount of pesticide used, underlying diseases, etc.*³⁸

The reporting system was designed to be harmonized with the comparable U.S. requirements under the *Federal Insecticide, Fungicide, and Rodenticide Act* (FIFRA) administered by the U.S. Environmental Protection Agency (EPA) to the extent possible. The Canadian approach was built on the U.S. experience with the EPA's system, which was introduced some years prior to the Canadian system, and added some new features, including requirement for electronic submission of incident reports and public access to incident reports via the HC-PMRA Public Registry.

The Public Registry is a living database to which new reports are added on a regular basis. As of July 30, 2009, the database contained 2,563 separate individual reports; by December 29, 2009, the number had increased to 3,368 (of which 18 were incidents that involved two incident categories), broken down as follows:

Category	# of Incident Reports	% of Total
Human	781	23%
Domestic Animals	2304	68%
Environment	178	5%
Food Residues	1	0.03%
Packaging Failure	85	3%
Scientific Studies	37	1%
Total:	3386	100%

Three-quarters of the human effects reports, and 48% of the domestic animal reports were incidents that occurred within Canada.

³⁸ HC-PMRA Public Registry, **Pesticide Incident Reporting Database**, accessed at: pr-rp.HC-PMRA-arla.gc.ca/portal/page?_pageid=34,6928,34_51552:34_59552&_dad=portal&_schema=PORTAL

HC-PMRA officials interviewed emphasized that the incident information included in the Public Registry is not verified prior to posting and should be viewed as the starting point for analysis to identify patterns and trends for consideration in the Agency's risk analysis and re-evaluation work. BPC funding allowed HC-PMRA to recruit an epidemiologist to design and perform analyses of the incident data in conjunction with verification work by the Agency's health and environmental effects specialists. As such, the incident data reports are "raw outputs" from the reporting system. More time will be required before more refined outputs – in the form of investigations of trends and patterns, input to HC-PMRA's risk assessments, and published evaluations of incidents posing particular risks to health or the environment – can be generated on a regular basis. Some early examples of these types of outputs have been produced and are described in the next section. However, Agency officials expect that it will be some years before the system's value as a tool for supporting risk assessment and mitigation measures will be fully realized.

2. Achievement of outcomes

The expected immediate outcome from the incident reporting system is improved post-market information on the presence and effects of pesticides to support risk assessment/risk mitigation (which is shared with the research and monitoring stream of the BPC Initiative). This short-term outcome is expected to lead to improved risk management of pesticides in the medium-term and ultimately contribute to improved protection of health and the environment.

Program leads believe that the incident reporting system has started to contribute to the achievement of the short and medium-term outcomes but, as noted above, it may be some time before these risk assessment and mitigation measures are fully implemented. As evidence of the value of the incident reporting system, they cited several examples of the way in which information in the system is used:

- HC-PMRA conducted an investigation of one incident (2007-5671) in which an agricultural worker using a hand sprayer was subsequently hospitalized with respiratory distress. HC-PMRA's investigation concluded that the worker's ill health was probably due to exposure through inhalation of one of the pesticides present in the mixture that she was applying. The Agency's review also concluded that workers using the product in question should wear a respirator to avoid inhalation. The product label was amended to require the use of a respirator when the product was being handled, mixed, loaded and applied.³⁹
- HC-PMRA identified an increase in the frequency of incidents involving spot-on products for flea and tick control on pet dogs and cats between 2007 and 2008 in both Canada and the U.S. This led to the issuance of public advisory notices by both the EPA and HC-PMRA to alert users to the possible risk and advise them to follow product instructions. Both agencies also initiated actions to conduct further analysis of the possible risks in consultation with the registrants of the products in question to determine if further risk mitigation measures are required.⁴⁰
- HC-PMRA conducted an investigation of an incident related to the environmental effects of water run-off from a fire at a pesticide packaging facility in Ontario (2007-5800, 2007-5823 and 2009-0719). In this case, HC-PMRA's investigation concluded that the concentrations of two pesticides in the run-off water may have caused fish kills in a nearby creek but that regulatory action was not required due to the accidental nature of the exposure.

³⁹ HC-PMRA, **Evaluation of Incident Report 2007-5671**, accessed at: www.hc-sc.gc.ca/cps-spc/pubs/pest/_decisions/epir-edirp2007-5671/index-eng.php.

⁴⁰ Health Canada, **Health Canada Advises Consumers to Follow Label Directions on Flea and Tick Pest Control Products for Use on Cats and Dogs**, accessed at: www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2009/2009_60-eng.php.

- In another incident, HC-PMRA investigated the possibility that indoor use of a pesticide close to a heat source had produced carbon monoxide and may have been associated with fatalities in the building in question (2008-5998). The investigation in this case concluded that there was insufficient information to link the pesticides used and the alleged fatalities, and that if the products had been used as required they should not produce carbon monoxide if used in close proximity to an electric heater.⁴¹

Program leads noted that the incident reporting system can (or will be) used to identify “triggers” for further targeted risk analysis work. In addition to conducting statistical analyses of the incidents data and investigations of specific incidents, HC-PMRA is also looking at the extent to which different products are named in incident reports and checking this against the sales of these products as reported to HC-PMRA, to obtain additional context.⁴² The Agency’s compliance group is using the incident data in conjunction with sales data as an input to their risk-based approach to outreach, education and monitoring work. The program responsible for the incident reporting system intends to prepare annual summaries of the types of data received, HC-PMRA’s analysis of the data, and what actions have been taken in response to findings. These summaries will be made publicly available via the HC-PMRA website.

External key informants who rated the effectiveness of the incident reporting system (five of fourteen) viewed it as being either “somewhat” or “highly effective” in contributing to improvements in post-market information on the presence and effects of pesticides and their risk management. Most also cautioned that it was a little too soon to be able to fully assess the effectiveness and impacts of the system and, as such, their ratings related to the initial establishment of the system in combination with their expectations of future effectiveness. Several also highlighted the recent experience with the over-the-counter flea and tick control products as a good example of how the incident reporting system could be used to monitor and respond to unintended impacts of pesticides between registration and re-evaluation points, including the ability to coordinate the analysis and response to issues of concern with the EPA.

Most of these key informants also cautioned that incident reports as presented in the Public Registry could have a negative effect on public confidence rather than demonstrating how post-market information is used to monitor and strengthen the effectiveness of the pesticide regulatory system. That is, if all the public sees and reacts to is the sheer number of incidents listed without considering the context (extent to which causality is determined) and, in the future, reading the annual summaries, then confidence in the regulatory system may be diminished.

Participants in the online survey of stakeholders who had at least some knowledge of or familiarity with the pesticide incident reporting system (155 respondents out of 282 (55%)) were asked similar questions to those discussed with the external key informants. Registrants were the most likely to have “substantial knowledge” or to be “very familiar” with the system.

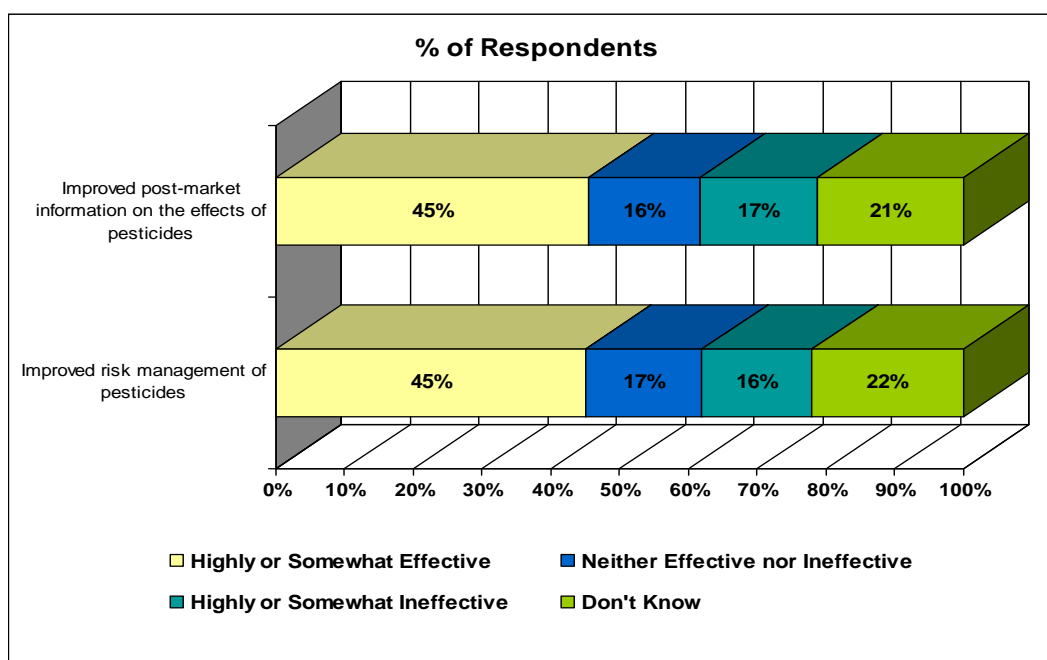
⁴¹ HC-PMRA, **Evaluation of Pesticide Incident Reports 2007-5800, 2007-5823 and 2009-0719, and Evaluation of Pesticide Incident Report 2008-5998**, accessed at: www.hc-sc.gc.ca/cps-spc/pubs/pest/_decisions/index-eng.php.

⁴² The new PCP Act required the HC-PMRA to implement a system whereby registrants are required report information related to annual sales of their products. Development, implementation and operation of these regulations is outside of the BPC Initiative.

Ratings of the effectiveness of the incident reporting system (Exhibit V-7) show that slightly less than half of the respondents (45%) believe the system is effective in improving post-market information on the effects of pesticides and improving risk management of pesticides. This uniformity of ratings between both outcomes continued for other rating choices. Note also that approximately a fifth of the respondents (21% and 22% respectively) chose “don’t know” as their response, suggesting that the reach of this initiative might be extended. In some instances these less-supportive ratings appeared to be due to a view that it was “too soon to tell” how effective the system will be.

Exhibit V-7

Ratings of the effectiveness of the pesticide incident reporting system



Base: Survey respondents who indicated they had some familiarity with the pesticide incident reporting system (Q.D2); n=155.

Suggestions for improvements to the reporting system were also offered by survey respondents, with three themes apparent:

- Incident reports should be validated or supported by contextual information. For example:

The incident reporting system appears to be showing a tremendous number of pesticide incidents. As you read the reports, it is quickly evident that a number of the supposed incidents are more about pre-existing or other medical issues than the effect of the pesticide. There should be some form of triage activity and only the incidents where it is “likely that the pesticide caused an adverse affect” are posted on the website.
- Awareness of the program should be increased, in two areas:
 - Firstly, to be sure that as many incidents as possible are reported, especially those that come to the attention of physicians and poison control centres.
 - Secondly, to increase public awareness of the information being collected, listed, investigated and reported on by HC-PMRA.

3. Conclusions – pesticide incident reporting system

Two evaluation issues relate directly to the establishment and operation of HC-PMRA's pesticide incident reporting system, one of which relates to the intended short-term outcome from incident reporting and the other to the intended medium-term outcome; both are shared with the research and monitoring stream of the BPC Initiative.

-
1. Has there been an improvement in the quantity of useful information on the presence and effects of pesticides to support registration and re-evaluation of pesticides?
 - (a) Has there been an improvement in sharing of monitoring data that contributes to pesticide regulatory decision making?
 - (b) How has this information been used to support pesticide risk management?
 2. To what extent has there been an improvement in risk management of pesticides as a result of BPC program activities?
-

The implementation of the Pesticide Incident Reporting system in April 2007 provides the foundation for the collection of "raw" post-market information on possible unintended or unexplained effects of pesticide use following registration. However, the information obtained through the reporting system is only a starting point and, in order to provide useful information to support pesticide risk management, requires further investigation by HC-PMRA, both into the context in which incidents occurred and into the science of the active ingredient(s) involved.

Both HC-PMRA's program leads and the majority of the external stakeholders interviewed believe that the incident reporting system will provide HC-PMRA with a new source of post-market information on the effects of pesticides and improved pesticide risk management. Early experience with the investigations of particular incidents and the identification of broader patterns and trends in incidents also support this view. HC-PMRA's investigation of one incident with a major human health effect resulted in modifications to the label of the product in question to require users to wear a respirator to avoid accidental inhalation. HC-PMRA has also been able to identify a possible issue with the use of consumer products to treat fleas and ticks on domestic pets, working in conjunction with the EPA, based on their respective analyses of patterns and trends in reported incidents.

However, awareness and/or support for the view that the incident reporting system will potentially improve pesticide risk management was not as strongly supported by stakeholders who participated in the survey. Only 45% of those who indicated they were familiar with the incident reporting system believed it was effective and another 16-17% felt it had been neither effective nor ineffective.

External key informants and survey participants both suggested that public understanding of the incident reports on HC-PMRA's Public Registry would benefit from the inclusion of supporting contextual information explaining the differences between possible associations and causal relationships between pesticide use and health or environmental effects.

D. Implementation of a policy on formulants

Formulants are defined as *any substance or group of substances other than the active ingredient that is intentionally added to a pest control product to improve its physical characteristics (e.g., sprayability, solubility, spreadability and stability)*.⁴³ Implementation of a formulants policy was a commitment made by the federal government in response to the recommendations of the Pesticide Registration Review in 1990. The purpose of the policy is to define how formulants in pest control products are regulated. In regulating formulants it is necessary to ensure that information on formulations and identification of formulants are accurate and meet current regulatory requirements. Formulants identified as being toxic are to be eliminated from pest control products unless registrants provide data to support their continued use. Under the BPC Initiative, HC-PMRA was to develop and implement this policy and supporting processes.

1. Activities and outputs

The initial requirements of the HC-PMRA Formulants Policy were established in a 2004 Regulatory Directive, and updated in 2006 with the issuance of Regulatory Directive 2006-02, *Formulants Policy and Implementation Guidance Document*. The key features of the policy are summarized below.

- The requirements of the policy were based on the approach used by the U.S. EPA to regulate inerts (formulants) in the U.S. As such, the policy provided for a high degree of harmonization, recognizing that registrants seek to use common product formulations in both Canada and the U.S., and enables HC-PMRA to draw upon the EPA's analyses and decisions regarding the regulation of formulants.⁴⁴
- Existing formulants contained in registered pest control products in Canada are assigned to one of five lists based on the level of concern with respect to human health and the environment:
 - **List 1** – formulants identified as being of significant concern with respect to their potential adverse effects on health and the environment. These formulants meet defined criteria for carcinogenicity, neurotoxicity, chronic effects, adverse reproductive effects and ecological effects as well as Track 1 substance criteria as defined under the Toxic Substances Management Policy (TSMP) or are substances designated under the Montreal Protocol.
 - **List 2** – formulants that are considered potentially toxic, based on structural similarity to List 1 formulants or on data suggestive of toxicity.
 - **List 3** – formulants that do not meet the criteria of any of the other lists, that is, are of unknown toxicity.
 - **List 4A** – formulants that appear on the EPA's Minimum Risk Inerts List, which are generally regarded to be of minimal toxicological concern, as well as substances commonly consumed as foods.
 - **List 4B** – formulants, some of which may be toxic, for which there are sufficient data to reasonably conclude that the specific use pattern of the pest control product will not adversely affect public health and the environment.

⁴³ HC-PMRA, **Formulants Policy and Implementation Guidance Document**, Regulatory Directive DIR2006-02, May 2006, p.2.

⁴⁴ According to HC-PMRA, at the time the formulants policy was developed and implemented the approach was harmonized with the US EPA with respect to list categorization. However, the EPA subsequently completed a reassessment of all food-use inert ingredients and changed their categorization system. As a result, Canada is no longer as harmonized as it was with the US EPA. The HC-PMRA is currently investigating the implications of the US changes and looking at ways of becoming more harmonized.

The initial set of lists compiled by HC-PMRA, with assistance from registrants, contained 1,517 formulators, 9 on List 1, 101 on List 2, 1,038 on List 3, 149 on List 4A and 220 on List 4B.

- Prior to the introduction of the formulators policy, and dating back to 1990, it was HC-PMRA's practice (and the practice of its predecessor departments) to ask registrants to substitute or remove formulators that were on List 1 of the EPA's List of Inert Ingredients. Label disclosure requirements were applied if no suitable substitute was available. Starting in 2001, the Agency undertook to remove all List 1 formulators from pest control products and introduced the regulatory requirements applicable to List 1 in Exhibit V-12, and these requirements were carried over to the Regulatory Directive.
- The requirements of the policy were phased in over three years. Starting in January 2005 all applications by a registrant to register a new product, amend an existing registration (including changes to the formulant(s)), renew a registration (required every five years from date of registration or amendment) or conduct research with a pest control product were to be accompanied by a Statement of Product Specification Form (SPSF) disclosing the identity and concentration of the formulant(s) used with the product.

Exhibit V-12

Regulatory actions applicable to different lists of formulators

Formulators Lists	Applicable Regulatory Actions
List 1 – Formulators of Toxicological Concern	<ul style="list-style-type: none"> Discontinuation of formulation (that is, the pest control product), or Substitution or removal of List 1 formulators from product formulations, or Submission of data or rationale to support continued use. Disclosure on product labels for all products containing a List 1 formulant.
List 2 – Potentially Toxic Formulators with a High Priority for Testing	<ul style="list-style-type: none"> High priority for re-assessment, including coordinated re-assessment with the EPA, and re-classification to List 1, 4A or 4B. Registrants with product formulations that use List 2 substances encouraged to amend formulations by substituting lower (3, 4A or 4B) formulators.
List 3 – Formulators That Do Not Meet the Criteria of Lists 1, 2, 4A and 4B	<ul style="list-style-type: none"> Formulators that do not have information to demonstrate they meet the criteria for any of the other lists. Subject to future reassessment and possible data call-in (post reassessment of List 1 and 2 formulators), and re-categorization.
List 4A – Formulators of Minimal Toxicological Concern	<ul style="list-style-type: none"> Considered acceptable in pest control products for both food and non-food uses with no further data necessary for the formulant alone. No further regulatory action is anticipated.
List 4B – Formulators of Minimal Concern under Specific Conditions of Use	<ul style="list-style-type: none"> Available data indicate that the specific use pattern of the pest control product will not adversely affect public health and the environment. No further regulatory action is anticipated unless the specific use pattern is changed.

Source: HC-PMRA, Formulators Policy and Implementation Guidance Document, Regulatory Directive DIR2006-02, May 2006.

According to information provided by HC-PMRA, List 1 formulators have been virtually eliminated from pest control products. List 1 now contains two formulators compared to nine in 2002 and the number of products containing List 1 formulators has been reduced from 72 to five. Of the two remaining List 1 formulators, one is in the process of being re-classified to 4B. The lists of formulators themselves are updated as changes are made and copies of the lists published in Regulatory Notes from time-to-time. The most recent such note (2007) highlights that 26 formulators were re-classified to List 2 (24 from List 3 and 2 from List 4B) as a result of potential concerns identified during the categorization of products on the Domestic Substances List by Health Canada and Environment Canada under the requirements of the *Canadian Environmental Protection Act, 1999*.

The review of formulants is integrated into the Agency's overall processes for reviewing new/amended product registrations and reviewing registration renewals. The design of the registration renewal process means that registrants are aware of the requirements of the formulants policy as their products fall due for renewal. Information on formulant requirements is also included in the content of the pesticide regulation course that HC-PMRA conducts for interested industry representatives from time to time (see chapter VII), and key formulant documents are posted on the HC-PMRA website.

The registration renewal process, in particular, provides a regular means of reviewing details of formulants in use and ensuring the requirements of the formulants policy are met. The renewal process is used to verify product specifications and label details against what was approved at the time of registration or last amendment, and against the requirements of more recent regulatory directives.

An interviewee at HC-PMRA noted that registration renewal reviews have found instances of "formulation creep" (unapproved formulation changes) that triggered requirements for registration amendments, as well as divergences for other registration requirements. For example, approximately 9% of the renewals in 2008/09 included product changes on the SPSF that differed from the most recent product registration or amendment. These unapproved changes do not pose unacceptable risks to the environment or human health. Such products typically receive a one-year renewal and registrants are required to submit an amendment request within 90 days. Continuing enforcement by HC-PMRA means that products not following these review requirements cannot be sold.

2. Achievement of outcomes

The expected outcomes for the formulants initiative under the BPC Initiative are:

- Increased awareness by registrants of formulant policy requirements. (Short-term outcome).
- Pesticides available to Canadians meet modern standards. (Medium-term outcome, shared with the BPC research and monitoring stream).

The integration of the formulants regulatory process into the product registration, amendment and renewal process means that registrants are being made aware or reminded of the requirements of the policy at the time their products become due for renewal or a registration/amendment action takes place and helps ensure compliance. However, awareness levels are not formally measured or tracked by the Agency. The opportunity to check the compliance status of product formulations on a regular basis allows HC-PMRA to verify whether the formulants used in pesticides meet currently applicable standards. However, HC-PMRA does not appear to have set target time frames for gathering and reviewing information on the potentially adverse effects of the 100 List 2 formulants (those that are potentially toxic) and over 819 List 3 formulants (down from 101 and 1,038 products, respectively, in 2004), and re-classifying or discontinuing the use of these formulants.

Only four of the fourteen external key informants commented on the effectiveness of the formulants initiative. Three of the four rated the effectiveness of the formulants activity in achieving the two intended outcomes as either "somewhat" or "highly effective" while the fourth noted that it was probably too soon to assess its effectiveness.

3. Conclusions – formulants policy implementation

Two evaluation issues are applicable to the actions under the BPC Initiative to develop and implement the HC-PMRA formulants policy.

-
-
1. Has the formulators program contributed to an increased awareness, by registrants, of Canadian formulant requirements?
-
-

The integration of the formulators regulatory process into the product registration, amendment and renewal process provides an opportunity for registrants to be made aware of the requirements of the policy at the time their registered products become due for mandatory renewal or a registration/amendment action takes place. However, awareness levels are not formally measured or tracked by the Agency.

Other factors including the following have likely also contributed to increased industry awareness of formulant requirements:

- Publication of the initial and revised Formulators Policy directive and associated List of Formulators, and List of Pest Control Products Formulators and Contaminants of Health or Environmental Concern.
- Updates/presentations on the Formulators Policy requirements provided to industry associations, including CropLife, the Canadian Consumer Specialty Products Association and the Chemical Producers and Distributors Association (US) as well as training courses provided to industry.
- Pre-submission consultations with applicants regarding the registration of new pest control products.

-
-
2. What progress has been made to ensure that only those pest control products that meet modern standards remain registered?
-
-

One important objective of the formulators policy is to identify and phase out formulators that pose unacceptable risks to health and the environment and replace them with lower risk formulators. Formulators of greatest concern have been identified and actions have been taken to remove them from use in pest control products. Only two List 1 formulators of toxicological concern are in use compared to nine in 2004, and the number of pest control products using these formulators is now down to five compared to 72 in 2002.

The HC-PMRA product registration renewal and registration amendment processes enable HC-PMRA to update its information on the use of different formulators. This renewal process means that HC-PMRA can check the compliance status of product formulations on a regular basis (at least every five years) and ensure that the formulators used meet currently applicable standards.

However, HC-PMRA has not yet set target time frames for gathering and reviewing information on the potentially adverse effects of the 100 List 2 formulators (which are potentially toxic substances) and 819 List 3 formulators (of unknown toxicity), and re-classifying or discontinuing these formulators. Recent EPA formulant risk assessments could be a useful tool for re-categorizing by considering these results for formulators used in both the U.S. and Canada. In addition, the following actions have contributed to this outcome:

- Extensive updating to the formulators database to ensure that HC-PMRA has complete information on all formulators and can clearly identify formulators that are acceptable for use in pest control products.
- A change in how HC-PMRA assesses new formulators as a result of the policy, which are now assessed individually as well as being assessed as part of a pest control product formulation.

E. Provision of Material Safety Data Sheets (MSDS) data to workplaces

The final BPC component related to the strengthening of the pesticide regulatory system is the implementation of requirements for Material Safety Data Sheets (MSDS) to be made available in workplaces where pesticides are manufactured, handled or used, and thereby bring pesticides into line with WHMIS (Workplace Hazardous Materials Information System) requirements. Implementation of this requirement is expected to lead to increased availability of pesticide MSDS in the workplace and, in the medium-term, to increased worker awareness of pesticide safety and hazard information.

1. Activities and outputs

Section 8 (3) of the *PCP Act* created a requirement for product safety information, including a MSDS, to be provided to workplaces where pest control products are used or manufactured as a condition of product registration. Prior to this change, pesticides were excluded from WHMIS requirements under the *Hazardous Products Act* (HPA) although MSDS are available for many pesticides due to the application of the industry-driven Warehousing Standards Certification Program in Canada and requirements in other jurisdictions where these pesticides are sold for the provision of MSDS for pesticides. Note that pesticides are still excluded under the HPA, as they were before and after the *PCP Act* changes.

As a first step, HC-PMRA issued a discussion document, *Preliminary Consultation on a Proposal to Implement Elements of WHMIS for Pest Control Products*, in May 2003 that presented the proposed content of the new regulation and solicited comments from interested stakeholders. The key features of the proposed regulation included:

- Applications to register new pest control products, and to renew the registration of existing products, would need to include an MSDS. HC-PMRA would check to ensure the hazard information contained on the MSDS was consistent with that identified in the Agency's assessment of the product's health and environmental risks.
- The MSDS requirements would take effect six months after the regulation comes into force. Linking the MSDS requirement to the registration renewal requirements would mean that MSDS for all registered products would be in place no more than five years after the regulation went into effect.
- An MSDS to be included with each container of a Commercial, Restricted or Manufacturing Class pest control product, and with the container of a technical grade active ingredient that is used or manufactured in Canada. Domestic class products would not be subject to the MSDS requirements.
- Full disclosure on the MSDS of the identity and concentration of all active ingredients and of any formulators and contaminants of health or environmental concern. In turn, the application of the requirement for the disclosure of formulators of concern depended on the implementation of the regulatory directive on formulators (which took effect in January 2005).
- Disclosure on the MSDS of hazard information on both the pest control product and on individual active ingredients and formulators.
- Transmittal of a current MSDS to purchasers of Commercial, Restricted and Manufacturing Class pest control products that use refillable containers, unless the purchaser has a current copy on hand.
- Information on the MSDS to be in English and in French.

- HC-PMRA would be responsible for ensuring compliance with the requirement for MSDS to be provided with each container of subject product that is manufactured or imported. Provincial/territorial governments would be responsible for enforcing WHMIS requirements for employers to provide workers with access to the MSDS and labels of pesticide products handled as well as training on associated health and safety information.⁴⁵

In considering the potential impact and effectiveness of the MSDS requirements it is important to remember that the provision of MSDS with pesticides is not the only source of information on safe handling and use available in workplaces. First of all, the new product registration process and processes for post-market amendment and re-evaluation of registrations provide the primary means of assessing health and environmental effects, and applying risk mitigation strategies. Secondly, pesticide labels contain legal requirements for the safe use and handling of pesticides, including hazard information and precautions. Finally, provincial and territorial governments are responsible for regulating the sale, distribution, use and disposal of pesticides, and training, certification and licensing of applicators. As such, the requirement for MSDS adds a further source of information on pesticide safety and use in a form that is (or should be) familiar to people in workplaces that manufacture, handle or use hazardous materials, including pesticides. In addition, many registrants provide MSDS voluntarily, where available, although the form and content of these documents varies.

In July 2004, the proposed regulation and supporting Regulatory Impact Analysis Statement (RIAS) was published in Gazette 1. The proposed regulation was modified to allow a single MSDS to be included with each shipment of a pesticide rather than for an MSDS to be attached to each container, in response to industry concerns regarding the costs for this documentation and potential for wastage, with provision for additional copies to be provided on request. The six-month lead-time for the labelling requirements to take effect was also extended to one-year to enable registrants to integrate production of MSDS with the printing of product labels.

Action to finalize and take the proposed regulation to Gazette 2 was put on hold while HC-PMRA addressed other regulatory actions and priorities until 2008 when a survey of registrants was conducted in order to collect up-to-date information on the likely costs to registrants to implement the proposed regulation. This survey found a wide range in the estimated cost to produce and make MSDS available. Equally important, the findings enabled HC-PMRA to estimate the proportion of products for which MSDS are already available (73%), the extent to which they are available in both English and French (89% of the 73%), and the type of format used (80% used the Globally Harmonized System 16 heading format). Note that these percentages were not weighted to reflect the significance of the sales volumes of the various products covered in the sample.

HC-PMRA now anticipates publishing an updated version of the regulation and RIAS in Gazette 1 in late-2010, depending on the progress of other regulation change projects that the Agency has in progress. A related consideration in the timing is that of pending revisions to the *Hazardous Products Act* to provide for the change from the current “9 heading” WHMIS format for MSDS to the “16 heading” Globally Harmonized System (GHS) format.

2. Achievement of outcomes

The current state of implementation of a WHMIS/MSDS regulation means that the intended outcomes from this component of the BPC Initiative are yet to be achieved.

⁴⁵ HC-PMRA, **Preliminary Consultation on a Proposal to Implement Elements of WHMIS for Pest Control Products**, Discussion Document DIS2003-02, May 2003.

Given that HC-PMRA does not anticipate going to Gazette 2 until late-2010 and that it will take up to five years to fully implement the final regulation it will not be possible to assess the immediate impacts for some years yet. However, the nature of the registration and registration renewal processes at HC-PMRA will mean that all registrants will be notified of the MSDS requirements and the availability of MSDS in the workplace should increase from the current level of approximately 73% of registered products to 100%.

Determining the extent to which the medium-term outcome – to increase worker awareness of pesticide safety and hazard information – will be more challenging, and will require some form of pre- and post-measurement of awareness among workers handling or using pesticides.

F. Overall conclusions and recommendations

The four components of the BPC Initiative concerned with the strengthening of the post-registration of pesticides – re-evaluation, incident reporting, formulants regulation, and provision of MSDS – have required a significant amount of work by HC-PMRA. BPC funding for re-evaluation enabled HC-PMRA to accelerate the rate at which work was being performed, and funding for the other three components enabled the Agency to extend the regulatory system into new areas required by the *PCP Act*.

The extent to which the intended short and medium-term outcomes for each of these four program components of the BPC Initiative have been achieved varies. In particular:

- **Re-evaluation of pesticides registered prior to 1995.** The rate at which regulatory actions to mitigate risks or remove unacceptable products from the marketplace under the re-evaluation program has progressed at a slower rate than anticipated. Achievement of the first target date, of August 2006, was delayed by changes in the timing of the equivalent EPA program but the more recent target completion date of June 2009 has slipped. HC-PMRA work re-evaluating the 41 active ingredients outstanding at the end of 2009/10 and finalization of the 90 for which proposed decisions were issued or pending will now run through 2010/11 and 2011/12. This means that the re-evaluation of these oldest active ingredients will overlap with the commencement of re-evaluation reviews of pesticides first registered in 1995 or later, as required by the *PCP Act*.
- **Pesticide incident reporting.** Mandatory reporting of incidents (unintended or unexpected effect to human health, domestic animal health or the environment, resulting from exposure to, or use of, a pesticide) that come to the attention of registrants, and voluntary reporting by the public and medical professionals and organizations, is expected to contribute to both improved post-market information on the presence and effects of pesticides, and risk management. Many stakeholders cautioned, however, that listing incident reports on the Health Canada website without providing contextual information to explain the difference between reported and verified incidents, and information describing how incidents are verified or analyzed, could potentially reduce rather than enhance public confidence in the regulatory system.

The HC-PMRA incident reporting system has only been operating for a relatively short period of time (since April 2007) and program leads and many external stakeholders consider that it is too soon to tell how effective it will be. Early experiences with the investigation of selected incidents and patterns in the overall mix of incidents suggest that the system can make an effective contribution to the improved risk management of pesticides.

- **Implementation of formulators regulation.** The regulation of formulators is also intended to contribute to ensuring that pesticides available to Canadians meet current regulatory requirements in the medium term by evaluating formulators as a separate component of pest control products. The design of the formulators policy should ensure that registrants are aware of the requirements of the policy due to its integration into HC-PMRA's processes for registration of new products and post-market registration amendments and renewals, and means the maximum time between reviews to verify the formulant(s) in use for a product is five years. However, HC-PMRA does not appear to have set target time frames for gathering and reviewing information on the potentially adverse effects of the formulators on List 2 (potentially toxic formulators) and List 3 products (formulators of unknown toxicity), and re-classifying or discontinuing these products.
- **Provision of MSDS data to workplaces.** Requirements for registrants to make MSDS available for the estimated 27% of products for which MSDS are not currently available, and to ensure consistent presentation and distribution of MSDS for all registered products, have yet to be implemented. However, a proposed regulation has been drafted and comments sought from external stakeholders, and HC-PMRA anticipates republishing in Gazette 1 in late-2010. As such, it is premature to conclude whether the BPC activities related to the availability of MSDSs will promote greater worker awareness of the safety and hazard information for pesticides. A possible consideration in the finalization and implementation of regulations for the provision of MSDS will be the timing of revisions under the *Hazardous Products Act* to bring MSDS for all chemical products into line with the structure of the Globally Harmonized System (GHS) format.

The expected final outcome from the measures to strengthen the pesticide regulatory system is improved protection of health and the environment, in combination with the outcomes from the research and monitoring activities examined in Chapter IV. The measures taken under the strengthened pesticide regulation stream of the BPC Initiative mean that products that pose risks to either health or the environment when assessed against current standards are progressively being made subject to more stringent conditions of use or removed from the market, and HC-PMRA has better information to inform its risk assessment and risk mitigation strategies. This suggests, by inference, that protection of health and the environment will ultimately be enhanced as a result of the measures reviewed in this chapter.

Recommendations

1. With regard to the re-evaluation of older active ingredients, HC-PMRA should:
 - Prepare a work plan forecasting the anticipated timing of proposed re-evaluation decisions for the active ingredients first registered prior to 1995 and the initial group of active ingredients subject to 15-year re-evaluation, and associated workload and resource requirements, for use in the planning and management of the re-evaluation program.
 - Publish an annual summary identifying the active ingredients that HC-PMRA will be re-evaluating in the coming year, the anticipated timing of proposed decisions for the active ingredients, and the progress made in the prior year.
2. With regard to the application and maintenance of the formulators policy, HC-PMRA to:
 - Publish an up-to-date breakdown of the formulators in each of the five risk-based categories of such products on a regular basis, either annually or biennially.
 - Develop and publish a strategy and time frame for gathering and reviewing information on the potentially adverse effects of the remaining potentially toxic formulators on List 2 and List 3 products for which HC-PMRA does not have information to determine which of the other four lists these formulators should be categorized to.

3. **HC-PMRA's pesticide incident reporting system, accessed through the Public Registry, should include supporting contextual information explaining the differences between possible associations and causal relationships between pesticide use and health or environmental effects.**
4. **With regard to the provision of MSDS in the workplace, HC-PMRA to finalize and implement regulations under the PCP Act as a matter of priority to ensure that consistent MSDS are available for all pest control products available for use in Canada.**

VI. PEST MANAGEMENT STRATEGIES

A. Purpose of the BPC pest management strategies stream

The development and implementation of pest management strategies is delivered through two programs jointly administered by HC-PMRA and AAFC Pest Management Centre: the Pesticide Risk Reduction Program, and the Minor Use Pesticides Program. The terms of this joint work, and the role of the associated AAFC/HC-PMRA joint management committee (JMC) were established in a Memorandum of Understanding between AAFC, HC-PMRA and Treasury Board Secretariat in 2003. The goals of the Memorandum were to:

- Develop and implement commodity-based risk reduction strategies for the agriculture and agri-food sector.
- Improve access to agricultural minor-use pesticides, and reduced-risk pesticides for agricultural use.
- Conduct research to support the introduction of minor-use pesticides that pose a reduced risk to the environment.

In addition, the Enhanced Pest Management Methods S&T Program in the Canadian Forestry Service (CFS) at NRCan is responsible for developing and facilitating the use of reduced risk pesticides and biopesticides in forestry and developing alternative forest pest management strategies.

The intended outcomes from the pest management strategies stream of the BPC Initiative are:

- **Short-term or immediate outcomes:**
 - Increased awareness of safer pest management practices and products.
 - Improved access to minor use pesticides (including biopesticides) with reduced risk to health and the environment.
 - New minor uses of pesticides available through dedicated HC-PMRA review processes.
- **Medium-term outcomes:**
 - Adoption of safer pest management practices and products.
 - Improved pesticide resistance management.
 - Improved crop protection practices and competitiveness.
- **Final outcome:** improved competitive parity of agricultural and forestry sectors with regard to pest management.

Five evaluation issues were considered in the evaluation of this stream of the BPC Initiative:

1. Have the Minor Use and Risk Reduction Programs improved access to, and increased awareness of, safer pest management products and practices? How, and to what extent?
2. Has the adoption of safer pest management practices and products for the agricultural and forestry sectors increased?
3. Has pesticide resistance management improved?
4. Has the forestry sector adopted pesticide risk reduction strategies and increased its use of reduced risk and biological pesticides?
5. Has the competitive parity of the agricultural sector been strengthened?

The activities, outputs and outcomes achieved by the Pesticide Risk Reduction and Minor Use Pesticides Programs are evaluated separately in the following sections followed by our conclusions and recommendations with regard to the above evaluation issues.

B. Pesticide Risk Reduction Program

1. Program purpose

The Pesticide Risk Reduction Program aims to reduce the risks to the environment and human health posed by the use of pesticides in agriculture by:

- Helping address growers' needs to achieve effective and sustainable pest management.
- Preparing crop profiles that provide national analyses of crop production and pest management information on a commodity basis.
- Establishing priorities and developing strategies to address pest management issues identified in consultation with stakeholders.
- Commissioning research projects to develop, test and demonstrate risk reduction tools and practices, and generate data to support the preparation of reduced risk pesticide registrations.
- Facilitating the registration of reduced-risk pesticides.
- Supporting the development and provision of comprehensive information on integrated pest management strategies to growers.⁴⁶

AAFC and HC-PMRA work with provincial/territorial governments, growers and grower associations, registrants, government and academic researchers, the pesticide industry and other stakeholders to develop pesticide risk reduction strategies.

NRCan has a more limited budget to undertake risk reduction and minor use activities under the BPC Initiative, and focuses on developing reduced risk forest pest control approaches, including biopesticides, and integrated pest management techniques. In addition to undertaking work at its network of Forestry Research Centres, the CFS Forestry Minor Use Coordinator is co-located with the AAFC Pest Management Centre to facilitate access to the operations and infrastructure for agricultural minor use registrations, and provide support for forestry-related risk reduction initiatives.

⁴⁶ AAFC/HC-PMRA, **Fact Sheet on the Pesticide Risk Reduction Program**.

2. Pesticide Risk Reduction Program outputs

a) AAFC and HC-PMRA risk reduction outputs

The principal outputs from AAFC and HC-PMRA's work on pesticide risk reduction are:

- Crop profiles that provide national analyses of crop production and pest management information on a commodity basis, based on input from growers, provincial ministries and other interested stakeholders. These crop profiles provide baseline for the development of pesticide risk reduction strategies.
- Priorities and strategies for addressing identified pest management issues. These commodity-based pesticide risk reduction strategies identify gaps and barriers in current pest management approaches, define realistic and measurable goals to bridge these gaps, and specify the expertise, actions and resources required to achieve these goals. The process of preparing these strategies includes consultation with commodity groups to identify commodity-specific pest management issues and risk reduction opportunities.
- Research projects to develop, test and demonstrate new risk reduction tools and practices.
- Research projects to enable the registration and introduction of reduced risk products including biopesticides. The Pesticide Risk Reduction Program and HC-PMRA provide regulatory support to facilitate the preparation of registration submissions and registration of these products and uses.

Projects undertaken under the program span such activities as research and demonstration trials, workshops, strategy support (for example, literature reviews, development of strategic plans, measurement of risk reduction), and the implementation of reduced-risk pest management solutions. The following exhibits list the different crop profiles prepared (Exhibit VI-1); projects initiated, by commodity (Exhibit VI-2); and the various approaches to risk reduction involved in these projects (Exhibit VI-3).

Exhibit VI-1

Crop profiles prepared by the Pesticide Risk Reduction Program

Year Completed						
2002/03	2003/04	2004/05	2005/06	2006/07	2007/08	2008/09
Ornamentals (container) Ornamentals (field)		Apple Bean (dry) Canola Carrot Grape Rutabaga Tomato (greenhouse)	Broccoli Cabbage Pepper (greenhouse) Strawberry Wheat	Blueberry (highbush) Cherry (sweet) Corn (field) Corn (sweet) Cucumber (greenhouse) Lettuce (greenhouse) Peach Potato Raspberry Soybean	Chickpea Cranberry Lentil Pea (field)	Blueberry (wild)

Source: AAFC Pest Management Centre (www4.agr.gc.ca/AAFC-AAC/display-afficher.do?id=1181157779290&lang=eng)

Exhibit VI-2

Breakdown of implementation projects by commodity

Commodity	Number of Projects Initiated							Total
	2003/04	2004/05	2005/06	2006/07	2007/08	2008/09	2009/10	
Apple	3	2	9	4	6	-	-	24
Bean (dry)	1	-	-	-	-	1	-	2
Blueberry	1	-	-	-	2	1	1	5
Broccoli and cabbage	-	-	-	1	-	1	1	3
Canola	3	1	2	2	1	2	1	12
Carrot	1	-	-	3	3	-	1	8
Cherry	1	-	-	-	-	-	-	1
Chickpea	1	-	-	-	1	-	-	2
Corn	2	-	-	2	3	-	-	7
Corn (sweet)	1	-	-	-	3	-	-	4
Cranberry	1	-	-	-	-	-	-	1
Field crops	1	-	-	-	2	1	-	4
Field vegetables	2	-	-	2	-	1	2	7
Ginseng	-	-	-	1	-	-	-	1
Grape	-	-	1	1	2	-	1	5
Greenhouse vegetables	1	-	6	8	2	-	-	17
Lentil	-	-	-	-	1	-	-	1
Livestock	-	-	-	-	1	-	-	1
Mushroom	2	-	-	-	-	-	-	2
Nursery landscape – conifers	-	-	-	1	-	-	-	1
Onion	-	-	1	-	-	1	-	2
Ornamentals	-	-	-	-	-	-	-	-
Pea	2	-	-	2	3	-	1	8
Peach	-	-	-	4	-	-	-	4
Potato	1	-	-	-	1	-	-	2
Pulse crops	-	-	-	-	1	-	-	1
Rangeland	8	-	1	5	9	1	1	25
Raspberry	7	-	1	2	3	-	-	13
Soybean	1	-	-	-	-	-	-	1
Strawberry	-	-	-	-	4	-	-	4
Tomato	-	-	-	5	2	-	1	8
Vegetables, leafy	1	-	-	3	4	-	-	8
Wheat	2	-	-	1	1	-	-	4
Other	-	-	-	-	1	-	-	1
	1	-	-	2	1	1	2	7
	-	-	1	-	-	-	-	1
Total Number of Projects	31	3	22	42	41	8	13	160

Source: AAFC Pest Management Centre. Note that some projects relate to two or more commodities.

Exhibit VI-3

Major types of implementation projects commissioned

Type of Approach to Risk Reduction	Number of Projects Initiated							Total
	2003/04	2004/05	2005/06	2006/07	2007/08	2008/09	2009/10	
Biopesticide	-	-	3	10	12	3	9	37
Minor use research	13	-	-	8	3	-	-	24
Development of reduced risk solutions	18	3	19	22	19	1	4	86
Screening of reduced risk pest control products	-	-	-	2	7	4	-	13
Total Number of Projects	31	3	22	42	41	8	13	160

Source: AAFC Pest Management Centre.

Recent examples of the range of projects funded through the Pesticide Risk Reduction Program include:

- **Biopesticide:** investigation of the management of lowbush blueberry insect pests, onion thrips, and downy mildew on cucumber with biopesticides.
- **Risk reduction projects:** facilitating the adoption of reduced risk approaches to pest management in apples, development/demonstration of an IPM toolbox for cabbage maggot in Brassica crops, and carrot trimmer implementation for white mould management.
- **Minor use:** development of new pesticide formulations for reduced risk management of wireworms in potatoes.

In addition to supporting the Pesticide Risk Reduction Program's work in the areas described above, HC-PMRA also participates in the work of the NAFTA Working Group on Pesticides to enable the conduct of joint reviews and registration of reduced risk products, and has worked with the US EPA on such reviews and registrations. Joint reviews enable Canadian growers to access products that otherwise may not have been registered for use in Canada.⁴⁷

Until 2007/08, many of the pesticide risk reduction strategies were specific to a particular commodity and pest. In late 2007 a new approach was adopted following an internal review of the Pesticide Risk Reduction Program. This approach shifted the emphasis from identifying and responding to commodity-specific "pest management issues" to broader "pesticide risk issues" emphasizing risks to health and environment, and commonalities across crops and pests (versus the commodity-specific approach). Approaches to the communication of results will be developed during the planning of responses to priority risk issues rather than being considered as an afterthought. Going forward, HC-PMRA will focus more on the regulatory issues and needs associated with pesticide risks, with four main areas of activity: stakeholder consultations, risk reduction strategies, transition strategies for pesticides phased due to re-evaluation, and regulatory support. The PMC will continue to focus its activities on the development of crop profiles, development of pesticide risk reduction strategies, support for biopesticide submissions, and the implementation of risk reduction strategies through demonstration projects and supporting outreach activities.⁴⁸

⁴⁷ North American Free Trade Agreement Technical Working Group on Pesticides, **Accomplishments Report for the period of 2003–2008**, 2009

⁴⁸ Agriculture and Agri-Food Canada, **Re-engineering of the AAFC Role in the Pesticide Risk Reduction Program (PRRP)**, Ottawa, November 23, 2007.

b) NRCan activities and outputs

The CFS' network of five forestry research centres undertakes work on risk reduction strategies for forestry, building on its work on monitoring the environmental effects of pesticides used in forestry to ensure their safe and effective deployment, with a major role played by the Great Lakes Forestry Centre in Sault Ste Marie. In selecting projects for this work, the CFS draws on inputs from provincial and territorial ministries of natural resources that regulate and control most forest product land. These ministries also nominate a single minor use coordinator for forestry to provide forestry perspectives in the work of the pesticide minor use coordinators.

In addition, NRCan has a forestry minor use coordinator based at the AAFC PMC in Ottawa who supports NRCan's risk reduction work and acts as a liaison between the CFS, PMC and HC-PMRA. The risk reduction work of the CFS is closely tied to its work under the research and monitoring stream of the BPC Initiative as well as responding to needs related to the production of ornamentals. Examples of projects undertaken included:

- Integrated programs for the control of sawfly forest pests.
- Development of tools for use in IPM programs against gypsy moth.
- Integrating forest and pest management of the Blackheaded Budworm in regenerating forests.⁴⁹

3. Internal perspectives on the performance of the Pesticide Risk Reduction Program

a) Production of outputs

Interviews with program leads and staff at HC-PMRA, AAFC and NRCan were used to obtain further information about the intended program outputs and the extent to which these outputs (and the associated outcomes) have been achieved. These key informants indicated that before any risk reduction projects could be initiated, a significant amount of upfront work by staff at HC-PMRA and the PMC was required to identify priority crops, prepare and publish crop profiles, identify and prioritize pest management issues, and consult with stakeholders to develop risk reduction strategies. They indicated that the first two years of the program were spent on these planning and prioritization activities, which included meetings with early adopters, and continued work on associated projects, such as those undertaken for potatoes, and other start-up activities. Start-up of the Pesticide Risk Reduction Program was also affected by the time required to staff the PMC following its establishment in 2003 and expand HC-PMRA's risk reduction capacity.

Nevertheless, the Pest Management Centre initiated a series of 12 research projects related to reduced risk minor use pesticides and 19 research projects related to the development of commodity-based risk reduction strategies. No further major projects were commissioned until 2006/07 although a number of short-term projects to support strategy implementation were funded in 2004 and 2005.

Broader engagement of stakeholders for the development of risk reduction strategies began following the initial two-year start-up period. Stakeholder buy-in to the risk reduction concept was obtained through ongoing consultation on priorities, communication activities, and demonstration projects. For example, consultations with stakeholders took place to identify and obtain additional information on priority crops and pest management issues. Communications with, and presentations to, grower groups and the pesticide industry leveraged existing forums such as the annual Minor Use priority setting workshops, the Western Forum on Pest Management, and the Canadian Horticultural Council Annual General Meeting.⁵⁰

⁴⁹ NRCan Canadian Forest Service, **Enhanced Pest Management Methods S&T Program Review – 2002-2006**.

⁵⁰ AAFC-HC-PMRA Pesticide Risk Reduction Program - Joint Management Committee of AAFC and HC-PMRA, Nov. 23, 2007.

b) Achievement of outcomes

As part of annual performance reporting to the Joint Management Committee (JMC), both AAFC and HC-PMRA identify the outputs/results created that are intended to contribute to the achievement of outcomes from the development and implementation of pest management strategies. However, these reports, and the annual BPC performance reports posted on the Treasury Board website, provide little data against which to measure outcomes (versus descriptive information and data on activities and outputs).

The first step in the achievement of increased adoption of safer pest management practices – awareness creation amongst interested growers and other interested stakeholders – has been fostered through demonstration projects, field days hosted by AAFC facilities, farm tours showcasing individual projects, presentations at key industry meetings and distribution of information using such channels as the PMC newsletter, factsheets and website. However, the subsequent rates of adoption and sustained use of risk reduction products, tools and strategies are not known and their measurement is a weakness for the Pesticide Risk Reduction Program.

Program managers and staff interviewed believe that the Pesticide Risk Reduction Program has achieved significant growth in awareness of risk reduction issues and solutions. Staff indicated that adoption by growers could be increased if the economic benefits for doing so were demonstrated. They also indicated that proprietary pesticide-use data has been purchased recently and will be used to infer rates of adoption of integrated pest management practices. According to key informants, another challenge to measuring adoption is that sales data obtained from the pesticide industry does not specify the use for which a product was purchased which means that levels of and trends in, use by commodity cannot be tracked. HC-PMRA is also working on the development of a risk indicator model that will incorporate pesticide use data and, longer term, demonstrate trends associated with pesticide use.

Statistics Canada and AAFC, with participation by HC-PMRA, conducted a pilot crop protection survey in 2005 to investigate the use of this method to provide baseline data on pest management practices used by apple, carrot and grape growers in response to insect, plant disease and weed pressures during the 2005 growing season. The initial public report on the survey findings provided information on the extent to which integrated pest management (IPM) practices are being used on the apple growing acreage in Canada to help control insects, diseases and weeds, and estimates of pesticide use.⁵¹ However, the time and cost involved with this survey resulted in the PMC concluding that it will not be possible to fund similar baseline and follow-up surveys across a full range of commodities from the current funding allocation for the operation of the reduced risk program.

4. External perspectives on the performance of the Pesticide Risk Reduction Program

a) Effectiveness of activities and production of outputs

Both external key informants and participants in the stakeholder survey who indicated they were familiar with the work of the Pesticide Risk Reduction Program were asked to rate the effectiveness of the key activities performed. The survey participants (160 (57%) of the 282 respondents) were more likely to be representatives of growers/users (and associations representing users) and provincial ministries while the key informants (11 of 14) were composed of representatives of provincial government ministries of agriculture, growers, registrants, academic researchers, and public interest groups.

Ratings of the effectiveness of the main activities of the Pesticide Risk Reduction Program provided by the survey respondents were quite consistent with those provided by the key informants, for the most part. The aggregated ratings from the survey are shown in Exhibit VI-4.

⁵¹ Statistics Canada, **Pesticide Use and Pesticide Management Practices of Canadian Apple Growers, 2005**, Agriculture and Rural Working Paper Series, Ottawa, August 2008.

Exhibit VI-4

Ratings of the effectiveness of Pesticide Risk Reduction Program activities

Program Activities	Highly or Somewhat Effective	Neither Effective nor Ineffective	Highly or Somewhat Ineffective	Don't Know
a) Consultations with stakeholders to set priorities	73%	8%	12%	8%
b) Identification and definition of preferred risk reduction solutions (products, practices, tools)	68%	13%	13%	7%
c) Preparation of crop profiles and identification of pest management issues and potential solutions	62%	13%	10%	16%
d) Development of risk reduction solutions and implementation action plans	63%	11%	13%	14%
e) Promotion of risk reduction solutions and support for their adoption, such as demonstration projects	53%	16%	14%	17%
f) Regulatory advice and decision making by HC-PMRA	58%	11%	17%	14%
g) Timelines for the selection, development and conduct of strategies and projects	46%	13%	26%	16%
h) Overall program management and coordination	55%	13%	19%	13%

Base: Respondents who participated in risk reduction activities (Q.A3); n=160

Key points to note from the survey results and the key informant interviews:

- Four areas of activity were rated as “somewhat” or “highly effective” by relatively large majorities of these survey respondents:
 - Consultations with stakeholders to set priorities (73%). However, a majority of the external key informants were less positive about performance in this area due to such factors as a perceived lack of opportunity for stakeholders to have a say or a lack of broadly-based consultation, difficulty in getting priority for and attention to particular commodity groups (e.g., ornamentals), and a lack of regular communication regarding the process and progress of projects.
 - Identification and definition of preferred risk reduction solutions (68%)
 - Preparation of crop profiles and identification of pest management issues and potential solutions (62%). The external key informants acknowledged that the preparation of crop profiles requires a significant amount of time and effort, and to be most useful, need to be kept up-to-date to reflect the evolution of growing practices and emerging pest control issues.
 - Development of risk reduction solutions and implementation action plans (63%). The key informants cited opportunities for growers to be involved and the level of cooperation between Pest Management Centre staff and growers as areas of particular effectiveness.
- Only a slight majority (53%) believed the promotion of risk reduction solutions and support for their adoption, such as demonstration projects, was effective. In this regard, the external key informants suggested that promotion of risk reduction solutions is impeded due to insufficient information reaching growers demonstrating the effectiveness of these strategies, a lack of attention to the economic feasibility and cost-effectiveness of proposed solutions, and that more demonstration projects on key grower farms are needed rather than on experimental stations.

- Less than half (46%) believed the timelines for project selection, development and conduct were effective, and 26% rated this aspect of performance as ineffective. The external key informants who provided ratings of performance in this area were evenly split on the Pesticide Risk Reduction Program's effectiveness. Those who provided positive ratings typically noted that performance had improved considerably while those with negative views were concerned about the time taken for projects and administration of project approval and funding processes, for example, one noted, *funding for projects is approved at the last minute; growers and researchers then must rush to make up the time lost to be (ready) for the growing season.*

With regard to overall program management and coordination, some external key informants commented favourably on the accessibility of staff and effectiveness of coordination while others suggested that this had been an area of weakness but was now improving, for example, as one noted *it's improving significantly, more staff are needed, and the new leadership appears to be making a difference.*

Suggestions by both key informants and survey respondents for improving the effectiveness of program design and delivery were quite consistent and mainly related to:

- **Improving stakeholder communications and consultations processes**, to improve understanding of the program and its outputs, and to gain a better understanding of pesticide risk issues facing different grower groups and locations. It was also suggested that the Pest Management Centre needed stronger outreach to reach potential users of risk reduction tools and practices directly in addition to communicating through grower groups and provincial ministries. For example, it was suggested that HC-PMRA could work with grower associations and provincial jurisdictions that have existing mechanisms to disseminate information to growers and thereby facilitate adoption of risk reduction strategies.
- **Improving processes for developing and maintaining crop profiles, and associated risk reduction strategies.** Key informants suggested that a more efficient approach was needed to ensure profiles are updated to reflect the evolution of crops and to expand the range of research projects supported. For example, basic biology research is needed for certain crops to identify reduced risk solutions, and funding for these projects is not available elsewhere. Grower representatives also suggested that a better approach to fostering the development of risk reduction strategies is required for crops that are a high priority for certain grower groups but have not attracted broadly-based support in the priority setting process.

b) Achievement of risk reduction outcomes

Ratings of the extent to which the Pesticide Risk Reduction Program was believed to have achieved its intended outcomes by external key informants and survey respondents were also very similar. The breakdowns of the ratings by the survey respondents are summarized in Exhibit VI-5.

Key points to note from the survey responses and the key informants' comments are:

- Respondents were most likely to perceive that the program had made a "substantial" or "small" positive contribution to:
 - Improving access to, and adoption of, reduced risk pesticides (76% positive rating).
 - Increasing awareness of safer pest management practices and products (70%),
 - Increasing the rate of adoption of safer pest management practices and products (70%).

Exhibit VI-5

Ratings of the contribution of the Pesticide Risk Reduction Program to intended outcomes

Program Activities	Substantial or Small Positive Contribution	No Real Contribution	Substantial or Small Negative Contribution	Don't Know
Short-term outcomes:				
a) Increased awareness of safer pest management practices and products	70%	19%	3%	8%
b) Improved access to, and adoption of, minor use and biopesticide products, particularly reduced risk pesticides	76%	14%	4%	6%
Medium-term outcomes:				
c) Increased rate of adoption and use of safer pest management practices and products	70%	19%	3%	9%
d) Improved management of pesticide resistance	54%	27%	5%	14%
e) Improved crop protection practices	64%	19%	4%	13%
Final outcome:				
f) Improved competitive parity of the Canadian agricultural and forestry sectors with regard to pest management	40%	24%	13%	24%

Base: Respondents who indicated they were familiar with the pest management strategies stream of the BPC Initiative (Q.A4); n=243.

According to the key informants, information on safer pest management practices and products is most likely to reach growers through a variety of indirect sources and channels, such as provincial/territorial government contacts, grower associations, registrants, agricultural dealers, agronomists and registrants. Many of the key informants also believed that many growers are unaware of these improved products and practices, and those that do receive these communications materials may not recognize AAFC and HC-PMRA as the source.

They also indicated that more training and demonstration projects are needed to increase the rate of adoption among growers, and that growers need information to understand how (or if) reduced risk pest management alternatives are economically viable.⁵² Additionally, they highlighted the need for growers to have more than one solution per crop to allow growers to alternate products and practices including continuing to use currently available pesticides and established pest management practices.

- Conversely, respondents were much less likely to perceive that the program had made a positive contribution to the remaining medium-term outcomes of improving management of pesticide resistance (54%) and improving crop protection practices (64%), and the long-term outcome of improving the competitive parity of the Canadian agricultural and forestry sectors (40%).
- The incidence of “don’t know” ratings increased as the time frame for outcomes went from the short-term to the medium and long-term outcomes, going as high as 24% when asked to rate the contribution to improving competitive parity.

Survey respondents who were grower representatives, provincial officials or federal officials were more likely to perceive that the Pesticide Risk Reduction Program had made a positive contribution to the achievement of the intended outcomes, and registrant representatives were less likely.

⁵² These comments and suggestions are consistent with a set of lessons learned identified in a report prepared for the Pesticide Risk Reduction Program in 2007 by the PMC-Provincial IPM Adoption Working Group, Appendix 3.

C. Minor Use Pesticides Program

1. Program scope

The AAFC, HC-PMRA, and NRCan are partners in the delivery of the Minor Use Pesticides Program (Minor Use Program). Candidates for minor use pesticide registrations are those where the active ingredient and the end-use product are already registered in Canada, the registrant supports the addition of new uses to the label, and there is sufficient information available to assess the safety, merit and value of the proposed new use. In addition, the anticipated volume of sales in Canada must be insufficient for the registrant to otherwise register the new use or the proposed new use is for a major crop but is only needed on an occasional basis by growers or is limited to a small percentage of the total production area.

AAFC's Pest Management Centre and HC-PMRA work together to:

- Conduct research to support the introduction of minor use pesticides that pose a reduced risk to the environment.
- Improve access to agricultural minor-use pesticides, and reduced risk pesticides for agricultural use.

NRCan's principal activity is to develop and facilitate the use of reduced risk pesticides and biopesticides for forestry. The nature of pesticide use in forestry management means that all uses of pest control products are categorized as minor uses.

The delivery of the Minor Use Program involves the following key steps and activities:

- Identification of pest problems and potential solutions.
- Establishment of annual national weed, insect and disease priorities.
- Identification of data requirements for registration of prospective solutions.
- Performance of field trials and laboratory analysis to generate data.
- Preparation of minor use registration submissions and their submission to HC-PMRA.
- Review of registration submissions by HC-PMRA.
- Decisions on the registration of a pesticide for minor use.

AAFC's Pest Management Centre also works collaboratively on minor use registrations with a long-standing similar program in the U.S. known as the Interregional Research Project No. 4 (IR-4). The IR-4 is a joint initiative of the U.S. Department of Agriculture and the State Agricultural Experiment Stations. The principal function of the IR-4 is to facilitate the registration of sustainable pest management products and practices for specialty crops and minor uses in the U.S. The Pest Management Centre and the IR-4 work cooperatively in establishing priorities and sharing test results. This close relationship leads to cost savings on field trials and facilitates the registration of minor use pesticides in both Canada and the U.S. and establishment of harmonized MRLs for registered uses of these pesticides in both jurisdictions.⁵³

⁵³ The IR-4 Project, **2008 Annual Report**, Rutgers University, Princeton, NJ, pp.1-2.

A key element in this process is the establishment every year of a national list of pest priorities and potential pesticide solutions using a consensus approach that builds on priorities and potential solutions identification at provincial levels using input from growers, grower groups, provincial/territorial pest management coordinators and pesticide manufacturers. At the annual minor use priority-setting workshop, the participating stakeholders reach a consensus on national priorities for the coming year in each of three pest categories – weeds and growth regulators, entomology (insects) and pathology (diseases). Each year between 30 and 40 national priorities are chosen (2009 – 38, 2008 – 44) plus five regional priorities and one to two organic priorities.⁵⁴ Additionally, up to 15 priorities are identified for cooperative projects with the U.S. IR-4 program. These priorities then provide the starting point for selecting and designing minor use registration projects. Stakeholders who participate in these workshops include producers, provincial minor use coordinators, pesticide industry representatives, provincial and federal specialists and representatives from the U.S. IR-4 program.

Following the priority setting process, data requirements for product registration are determined by HC-PMRA based on literature search reports (pre-submission packages) submitted by the PMC. Field trials and lab analyses are then organized and conducted by the PMC in consultation with the pesticide industry, grower representatives, and other government organizations. Subsequently, a registration package is prepared and submitted to HC-PMRA for review and a registration decision. The typical time required to conduct field trials and prepare a minor use registration for review by HC-PMRA is about three years from the time of trial initiation.

HC-PMRA's activities in relation to the Minor Use Program relate to:

- Review of pre-submission packages and provision of data requirements as needed.
- Review of submission packages and issuance of regulatory decisions on minor use expansions.
- Incorporation of new minor use expansions on product labels of registered products.
- Participation in harmonization and regulatory projects (joint reviews, data requirements, crop groupings, MRL promulgation).
- Participation in regulatory projects on joint submissions and reviews, such as the development of a NAFTA work plan to enhance the conduct of joint HC-PMRA/EPA minor use reviews, including joint reviews of AAFC/IR-4 submissions.

As experience with the data requirements and preparation of submissions has grown, HC-PMRA has been able to streamline or refine its data requirements and their collection, for example, by taking more streamlined approaches to value assessment. In addition, the PMC prepares a pre-submission report for review by HC-PMRA to help ensure that submissions meet HC-PMRA requirements.

2. Outputs from the AAFC-HC-PMRA Minor Use Program

Minor use submission project reports prepared by the PMC provide the principal mechanism for translating minor use priorities into submissions to register new minor uses of registered pesticides. Between 2001/02 and the end of 2009 the PMC had initiated 638 minor use projects. The outcomes of the completed projects and status of projects in process is summarized in Exhibit VI-6.

Note that the period of funding of the Minor Use Program under the BPC Initiative was from 2002/03 to the end of 2007/08; since then funding for the Minor Use Program has come from the AAFC Growing Forward initiative. However, the exhibit shows results up to the end of 2009 as many of the projects finalized since 2007/08 were initiated during the BPC-funded period of the Minor Use Program.

⁵⁴ AAFC/HC-PMRA JMC Meeting: Minor Use Pesticide Program Report, January 22, 2010, slide 5.

Exhibit VI-6

Outcome status of minor use projects managed by the Pest Management Centre

Project Status	Year Of Project Inception / Numbers of Projects									Total
	01/02	02/03	03/04	04/05	05/06	06/07	07/08	08/09	As of Jan. 1, 2010	
Project initiated	-	-	-	-	-	4	6	11	33	54
Data generation	-	4	7	14	18	23	43	41	19	169
Reporting phase	-	35	17	12	10	9	10	4	1	98
Preparing submission	-	3	2	2	-	3	-	2	-	12
Data with registrant for submission	1	1	3	-	-	-	-	-	-	5
Submitted to HC-PMRA	-	9	17	7	4	8	4	4	13	66
Accepted for use ¹	3	42	29	28	26	19	11	2	-	160
Rejected ²	-	1	3	-	1	3	-	-	-	8
Withdrawn ³	-	13	10	6	2	4	10	4	1	50
On hold		7	1	-	-	3	5	-	-	16
Total	4	115	89	69	61	76	89	68	67	638

Source: Data provided by the Pest Management Centre.

¹ – Including those where HC-PMRA review has been completed and final label approval is pending, including projects submitted by the PMC for registrant's Category A submissions (for new active ingredients and major new uses).

² – Submissions are typically rejected by HC-PMRA due to insufficient data on health and/or environment risks.

³ – Withdrawals of submissions may be due to such reasons as lack of pest pressure or withdrawal of support by the registrant, and as such, are outside the control of HC-PMRA.

The data in Exhibit VI-6 show a number of facets of the minor use activity since the inception of the BPC Initiative in 2002/03. Firstly, the number of minor use registration projects that were **initiated** in each year was highest in year one (2002/03) at 115, when the PMC took over a large number of priority projects previously selected by the provinces and growers, and then dropped to between 61 and 89 new projects per year.

Secondly, the rate at which the PMC is able to bring projects to fruition within the expected typical time frame for a minor use project of three years can also be discerned from this data. Amongst the projects that were initiated prior to 2006/07 (and thus equal to or older than the typical three-year period required for minor use projects), 37% are still in the data collection and preparation of their registration submissions stages, 11% are undergoing review by HC-PMRA, and 49% have resulted in a final outcome (acceptance or rejection by HC-PMRA or withdrawal of support for the submission by the registrant), including acceptance of Category A submissions by registrants that were prepared with assistance from the PMC. This suggests that the program was being overly ambitious in taking on so many projects in the early years when it was still ramping up its staffing, establishing the infrastructure required to conduct field trials and obtaining the GLP (Good Laboratory Practice) accreditation required for sites that conduct residue studies.

According to the key informants from the Minor Use Program, the PMC has implemented a number of measures to enable it to clear the backlog of older minor use projects that are still “in the pipeline” involving a combination of improvements to the field work and data analysis elements of the minor use process and an increase in the number of resources in the Minor Use Program.

AAFC's goal under the Minor Use Program is to submit reports on at least 40 **completed** projects to HC-PMRA per year. Actual numbers of completed projects submitted since 2003-04 and outcomes of these projects are shown in Exhibit VI-7. Note that Exhibit VI-7 is based on the numbers of projects completed by the PMC and the years in which they were submitted to HC-PMRA for registration review whereas the data in Exhibit VI-6 relates to the numbers of projects started by the Minor Use Program, by year.

Exhibit VI-7

Numbers of minor use projects submitted to HC-PMRA and outcomes

Outcome Status of Projects	Numbers of Projects Submitted to HC-PMRA, by Year Submitted							Total
	2003/04	2004/05	2005/06	2006/07	2007/08	2008/09	As of Jan. 1, 2010	
1. Data provided to registrant for submission to HC-PMRA	-	-	-	4	1	-	-	5
2. Submitted; HC-PMRA review in process	-	-	-	1	-	13	52	66
3. HC-PMRA review completed; waiting for final label approval	-	-	-	-	4	19	1	24
4. Accepted for use (new uses registered)	1	10	32	37	41	12	3	136
5. Rejected	-	-	-	1	4	3	-	8
Total	1	10	32	43	50	47	56	239

Source: Data provided by the Pest Management Centre.

The data in Exhibit VI-7 show that the PMC has achieved its target of 40 or more completed projects submitted to HC-PMRA in each of the years since 2006/07. The exhibit also provides a sense as to how long the HC-PMRA review and registration decision requires, with almost all of the projects currently in review being submitted in 2009/10 (79% of those currently in review) or 2008/09 (20%).

Readers should note that the PMC projects do not equate to individual new minor use registrations that are evaluated by HC-PMRA and a single submission considered by HC-PMRA may draw on the results of a number of projects. HC-PMRA indicated to us that the 234 projects submitted to the Agency by the PMC were equivalent to 158 separate minor use registration submissions.

Communications with stakeholders are particularly important to manage expectations regarding the progress of projects according to key informants interviewed. Staff and management interviewed indicated that the principal fora for feedback to participating stakeholders (provincial/territorial partners, user groups, registrants) are the annual AAFC Minor Use Priority Setting workshop, the Federal/Provincial Territorial Working Group on Minor Use, participation in the Minor Use Technical Working Groups or PMC Advisory Committee, and periodic electronic newsletters from the PMC as well as postings on the PMC and HC-PMRA websites.

2. NRCan activities and outputs

NRCan has responsibility for developing and facilitating the use of reduced risk pesticides and biopesticides for forestry including accelerated research to permit registration of pest control products for which no or limited registrations exist, or for expanded approval of current labels to allow managers to use products already registered for other crops or pests⁵⁵. NRCan undertakes the following minor use activities:

⁵⁵ Enhanced Forest Pest Management Strategies Research Program: Call for proposals (2007-08), NRCan.

- Conduct or fund, monitor and report on research projects on reduced risk pesticides and biopesticides for forestry at regional centres.
- Collaborate with AAFC and HC-PMRA through the Forestry Minor Use Advisor at PMC to facilitate registration of pest control products for forestry and woody ornamental applications.
- Coordinate preparation of registration submissions for forest pest control products.
- Support the annual National Forest Pest Management Forum.
- Coordinate and integrate activities with 6NR partners and stakeholders.
- Collaborate in the development of the National Forest Pest Strategy.

The CFS' Forestry Minor Use Coordinator based at the AAFC PMC in Ottawa works to facilitate the registration of minor use pesticides and advises CFS scientists and managers on pest control products, regulations and other pest control regulatory issues⁵⁶. Locating the coordinator at the PMC enabled linkages to be established between the NRCan forestry research centres and the PMC's operations and infrastructure for agricultural minor use registrations. Work on registering minor use products for use with woody ornamentals has been a main area of focus for the coordinator's work. Between 2003 and 2006, seventeen minor use registration projects were for forestry and ornamentals uses⁵⁷.

Examples of minor use priority projects undertaken for forestry include examination of minor uses for:

- Spruce spider mites on Christmas trees.
- Downy mildew on outdoor woody ornamentals.
- Japanese beetle and European chafer on field woody ornamentals.
- Weeds in poplar plantations.

3. External perspectives on the effectiveness of the Minor Use Program

Respondents to the online survey and external key informants who indicated they had participated in one or more activities involved in the performance of the Minor Use Program activities provided feedback on the effectiveness of the activities performed under the Minor Use Program. The ratings provided by survey respondents are summarized in Exhibit VI-8.

As can be seen from the exhibit, substantial majorities of the survey respondents believed the program was either "highly" or "somewhat" effective. Similar views were expressed by the external key informants. Key points to note from the exhibit are:

- The two areas of activity that respondents were most likely to feel were performed effectively were:
 - Consultation with stakeholders to set priorities (85%).
 - Selection of minor use registration projects (80%).
- Timelines for the selection, development and conduct of strategies and projects were more likely to be rated as "somewhat" or "highly ineffective" (24%) versus just over half perceiving this activity to be performed effectively (57%). The key informants identified past mistakes in the design and conduct of data collection activities that required work to be repeated, a shortage of experienced staff at AAFC and HC-PMRA, and the elapsed time between priority setting in April

⁵⁶ NRCan Canadian Forest Service, Enhanced Pest Management Methods S&T Program Review – 2002-2006.

⁵⁷ Ibid. Page 4

of each year and the subsequent initiation of projects as key reasons for longer than necessary timelines. These stakeholders also emphasized that significant progress has been made in the timelines for preparation of minor use registration packages by the PMC, particularly recent steps to improve the throughput of registration packages.

- The provision of regulatory advice and decision making by HC-PMRA, and overall program management and coordination, also had somewhat higher rates of “ineffective” ratings (16% and 15%, respectively).

Exhibit VI-8

Ratings of the effectiveness of the Minor Use Program activities

Program Activities	Highly or Somewhat Effective	Neither Effective Nor Ineffective	Highly or Somewhat Ineffective	Don't Know
Consultations with stakeholders to set priorities	85%	4%	7%	3%
Design and conduct of MU research projects	77%	3%	10%	10%
Selection of MU registration projects	80%	6%	7%	7%
Preparation assistance for submission of minor use and biopesticide registration packages to PMRA	67%	8%	7%	18%
Regulatory advice and decision making by PMRA	68%	6%	16%	10%
Timelines for selection, development and conduct of strategies and projects	57%	9%	24%	10%
Overall program management and coordination	67%	7%	15%	10%

Base: Respondents who had participated in Risk Reduction Program activities (Q.A1b); n=176.

Survey respondents were also asked to identify potential opportunities for improvement in the Minor Use Program. More than half of all respondents felt that “some” or “substantial” opportunities existed to improve the minor use activities. The main themes running through these suggestions were to increase the funding for field work to generate data, increasing the involvement of growers, increasing harmonization with the U.S., and improving the timeliness of submission reviews.

Almost all of the key informants who commented on the minor use activities described the priority-setting workshops as an effective and equitable approach to identifying priorities, as well as enabling networking and sharing of information about minor use products and registrations among participants from across the country and sectors. They also endorsed the approach to designing and conducting minor use research projects as effective, and noted that some problems experienced in the past due to a poor selection of contractors that led to poorly executed field work have been addressed. Concerns were also expressed about the level of ongoing communication and consultation with stakeholders following the minor use priority setting workshops. Although stakeholders are consulted during the priority setting process, they felt they were insufficiently involved and informed on the conduct of minor use research projects.

4. Achievement of minor use outcomes

a) Increased availability of and access to new minor use registrations

Short-term outcomes of the Minor Use Program are increased availability of and access to new minor uses of pesticides, including biopesticides. The principal means of measuring the achievement of these outcomes are through the number of new registrations made. In considering these numbers, it is important to note that each minor use project submission that goes to HC-PMRA from the PMC does not constitute a separate registration submission (which is a weakness in the comparability of the current performance reporting between the AAFC and HC-PMRA). Equally, each registration submission may result in multiple new uses being added to the applicable pesticide labels.

Data provided by HC-PMRA shows that submissions generated by the PMC since 2003/04 had led to 454 new registrations of new minor crop uses, as shown in the table below. New minor uses originating from the work of the PMC accounted for 15% of the total number of such registrations by HC-PMRA between 2003/04 and the end of 2009. (The balance were submissions from provincial Minor Use Coordinators and non-minor use registration submissions by registrants outside of the BPC-funded Minor Use Program).

Year	Number of New Minor Uses Registered by HC-PMRA	
	From AAFC Submissions	Total Number Registered
2003/04	-	302
2004/05	1	65
2005/06	94	374
2006/07	55	663
2008/09	76	702
200-/10	172	717
(To Jan 1/10)	57	302
TOTAL	454	3,125

Source: Data provided by HC-PMRA

Informal feedback to the PMC from provincial/territorial government and grower/user group representatives suggests the new minor use registrations meet the demonstrated needs of growers and product use occurs following registration as applicable pest management needs arise. This outcome is consistent with the design intent of the program, with priority setting and project selection being driven by grower/user groups and supported by provincial/territorial minor use coordinators.

The Program has also been effective in identifying and performing joint work with the U.S. IR-4. For example, the IR-4's 2008 Annual Report noted that it had conducted 19 cooperative studies with the Pest Management Centre. In doing so, 47 field trials were conducted in Canada and 137 field trials in the U.S. This joint work improves the productivity of both organizations and enables new minor uses to be registered simultaneously in Canada and the U.S.⁵⁸

Measurement of progress against medium-term outcomes is constrained by data availability challenges. In particular, data on resistance management can only be compiled or synthesized through extensive online searches and data mining of relevant literature. HC-PMRA and the PMC have established a working group to improve data requirements and availability in this area and HC-PMRA has begun to track the extent to which minor use registrations may enable improvements in resistance management. Beginning in 2008, sales information was obtained that can be used to track changes in the use of certain types of products over time but is limited in the extent to which data on minor use applications can be separately identified. An interactive tool is being developed as part of the On-Farm Food Safety Program to collect data on actual product use but it will be several years, at least, before the PMC will have any data providing insights into rates of access and use of minor use products.

⁵⁸ In this regard the IR-4's 2008 Annual Report noted: "This shared workload saves both countries significant resources. More importantly the cooperation leads to internationally harmonized pesticide tolerances for the US and Canada." The IR-4 Project, **2008 Annual Report**, Rutgers University, Princeton, NJ, pp.1-2. (Note that while harmonization is a shared goal it is not always possible to achieve this due to differences in risk assessments between the Canada and U.S.)

In some instances, NRCan is the registrant for forestry applications of products, and then seeks private company partners to market and support these uses. This approach provides NRCan with a way of responding to the needs of foresters and overcoming the reluctance of pest control companies to register and market minor use products for the forestry sector in Canada. Qualitative information presented by provincial forestry ministries in fora such as the annual Forest Pest Management Forum suggest that a range of reduced risk practices have been applied in forestry management, such as widespread use of reduced risk and biopesticides targeting specific insect pests for forest pest control in preference to aerial spraying of broad-spectrum pesticides.

With regard to improving the competitive parity of the agricultural and forestry sectors, the minor use staff interviewed perceived that nearly all registrations improve competitive parity since most of the product uses that are the subject of PMC submissions are already registered for use in the U.S. As such, the Minor Use Program has made progress in addressing the “technology gap” – the difference in access to pesticide products and approved uses in Canada compared to access for growers in other countries, most notably the U.S. – that gave rise to the establishment of the Program. As noted in the earlier section on the HC-PMRA re-evaluation program, the combinations of pest control products and crops covered means that there are no readily available data to actually make this comparison, and the extent of impact can vary substantially depending on the circumstances facing individual growers and which pest control issues are involved. This complexity of the technology gap is a function of such factors as the possible combinations of active ingredients, end-uses and MRLs, and the dynamic nature of growing conditions and pest management challenges encountered by growers.

b) External perspectives on the achievement of minor use outcomes

In general, the survey respondents and external key informants who were familiar with the Minor Use Program perceived that it had had a positive impact on the achievement of the intended short and medium-term outcomes. Ratings of the perceived contribution of the Minor Use Program to the applicable intended outcomes are summarized in Exhibit VI-9.

Exhibit VI-9

Ratings of the contribution of the Minor Use Program in achieving intended outcomes

Program Activities	Substantial or Small Positive Contribution	No Real Contribution	Substantial or Small Negative Contribution	Don't Know
Short-term outcomes:				
a) Increased awareness of safer pest management practices and products	65%	20%	1%	14%
b) Improved access to, and adoption of, minor use and biopesticide products, particularly reduced risk pesticides	75%	7%	4%	14%
Medium-term outcomes:				
c) Increased rate of adoption and use of safer pest management practices and products	72%	13%	1%	14%
d) Improved management of pesticide resistance	60%	19%	2%	20%
e) Improved crop protection practices	68%	13%	1%	18%
Final outcome:				
f) Improved competitive parity of the Canadian agricultural and forestry sectors with regard to pest management	56%	11%	7%	26%

Base: Respondents who indicated they were familiar with pest management strategies stream of the BPC Initiative (Q.A4); n=243.

Key points to note from the exhibit and the key informants' comments include:

- Survey respondents were most likely to rate the program as making a positive contribution to four of the five intended short and medium term outcomes:
 - Improving access to and adoption of minor use and biopesticide products, particularly reduced risk pesticides (75%).
 - Increasing the rate of adoption and use of safer pest management practices and products (72%).
 - Improving crop protection practices (68%).
 - Increasing awareness of safer pest management practices and products (65%).
- External key informants had similar views to the survey respondents. Their comments provided supporting insights into the thinking behind the ratings of the Minor Use Program's performance:
 - With regard to improving access to and adoption of minor use and biopesticide products, they noted that the program has provided access to more sophisticated products and new delivery methods, with most of the reduced risk products being provided by smaller registrants. Although the program was deemed relatively effective in providing access to these products, some stakeholders expressed concern that it has resulted in more toxic substances being used. Some also suggested that the rate of adoption (compared to the process of registering new minor uses) was driven more by the marketing and outreach programs of registrants and provincial/territorial ministries and grower groups, which is a logical expectation given the involvement of these stakeholders in determining growers' needs and the establishment of priorities for the PMC's work.
 - Many of the external stakeholders who participated in the key informant interviews (and participants in the survey) expressed concerns that Canadian growers face a significant technology gap, as defined above, compared to U.S. growers even though the Minor Use Program has been successful in increasing the rate of new use registrations. They also believed that the rate of new product and new minor use registrations was not keeping up with the rate of removal of older products or application of more stringent conditions on use as a result of re-evaluation decisions.
 - Many of the key informants also noted that the Program had a positive impact on crop protection practices. Effective stakeholder and user consultations and priority setting, research on safer practices and alternatives, and information on crop rotation and resistance management were cited as areas of particular effectiveness. On the negative side, some felt that the Program was not timely (although it must be noted that the time requirements for field trials and data generation are largely outside the control of the Program), insufficient numbers of new registrations, and the relative difficulty of registering biopesticides in Canada versus the U.S.
- Both survey respondents and key informants were less likely to believe the Program had made a positive contribution to improved management of pesticide resistance. Key informants noted that improved labelling and involvement of stakeholders were cited as factors that contributed to the Program having a positive impact on outcomes. However, there are few facilities for growers to determine whether poor crop results may be due to pesticide resistance or other factors, such as poor coverage. In addition, the key informants noted that there are insufficient products available to effectively manage pesticide resistance by rotating between different classes of products, especially given that resistance to narrow spectrum products tends to develop faster than resistance to older, broader-spectrum products.

- Survey respondents were less likely to believe that the Program had contributed to improving the competitive parity of the Canadian agricultural and forestry sectors. Just over half (56%) of the respondents rated the Program as making a “small” or “substantial” positive contribution, another 11% believed that it had made no real contribution, and a relatively large proportion (26%) were unable to provide a rating. External key informants were also more circumspect on this outcome, due to concerns that Canadian growers continued to face a significant technology gap, as defined above, compared to U.S. growers even though the Minor Use Program has been successful in increasing the rate of new use registrations. They were also concerned that the rate of new product and new minor use registrations was not keeping up with the rate of removal of older pesticides or application of more stringent conditions on their use under the re-evaluation program.

A further area of questioning with the external key informants was that of the impact of removing certain older products and changes to the conditions of use for others as a result of the re-evaluation program. Themes in these comments related to:

- Re-evaluation outcomes in Canada – removal of some pesticides, more stringent conditions of use or fewer uses on others – are generally consistent with re-evaluation outcomes in the U.S. However, sometimes there are short-term differences in the timing of such decisions.
- A greater concern for growers is that Canadian growers start with fewer choices in terms of pest control alternatives and means of minimizing the development of pesticide resistance than U.S. growers. Many newer pesticides are quite specialized and targeted, and typically resistance to these products develops faster than the older, broader spectrum pesticides. Re-evaluation decisions that result in the removal or more restricted conditions of use for these older pesticides then reduce the pest management options available to growers.
- The rate of removal of existing pesticides or tighter restrictions on the use of existing pesticides under the re-evaluation program is perceived to be happening at a faster rate than the registration of new minor uses and active ingredients. As a result, growers continue to have limited alternatives available for rotating pesticides and minimizing the rate at which resistance develops. Efforts by HC-PMRA to accommodate such situations in developing transition strategies were recognized and acknowledged.

Examination of the breakdowns of the ratings in Exhibit VI-9 by key stakeholder group point to noticeable differences between these groups. Note that these results are based on small sample sizes and are indicative at best. In particular:

- Growers, who are the primary beneficiaries of the Minor Use Program, and provincial officials were generally more positive about the Program’s contributions to the achievement of the intended outcomes than registrants and federal officials. Positive ratings of performance by these stakeholders were highest for increasing awareness of safer pest management products and practices, increasing the rate of adoption and use of safer pest management practices and products.
- Larger proportions of registrants (between 13% and 38%, depending on the particular outcome) were more likely to believe that the Minor Use Program was making no real contribution to the achievement of the intended Program outcomes compared to other groups. At the same time, however, there appeared to be a relatively large group of registrants (between 20% and 27%) who felt they were not in a position to make any judgement and opted for “don’t know”.

- Federal government officials were consistently more likely than the other stakeholders to believe the Program was making a positive contribution to each of the pest management strategies outcomes, although this group also had a relatively large proportion of don't know ratings. A final question asked of these survey respondents relating to the pest management streams asked for their ratings of how the regulatory environment now compares to the situation before the inception of the Risk Reduction and Minor Use Programs in 2002/03. Almost three-quarters (72%) felt the regulatory environment was now "somewhat" or "much better". The sub-sample of users within the overall sample was slightly more likely to rate the situation as being "neither better nor worse" (19% versus 12%). Note that this user sub-sample was quite small so this difference is indicative only.

D. Conclusions and recommendations

1. Conclusions regarding the development and implementation of pest management strategies

External stakeholders generally view the pest management strategies stream of the BPC Initiative as making a positive contribution to increasing the availability of minor use products to Canadian growers and, to a lesser extent, fostering the development of pesticide risk reduction strategies. However, the partners in the pest management strategies stream – AAFC's Pest Management Centre, NRCan and HC-PMRA – do not have a clear understanding of the degree to which growers may be aware of pesticide risk reduction strategies nor the extent to which strategies developed with the support of the Pesticide Risk Reduction Program are being used. With regard to the Minor Use Program, it appears that there are widespread concerns among stakeholders, particularly growers and provincial/territorial ministries, regarding the rate at which the technology gap facing Canadian growers is being addressed.

Five evaluation issues related directly to this stream of the BPC Initiative. Our conclusions against each of these are presented below.

-
1. Have the Minor Use and Risk Reduction Programs improved access to, and increased awareness of, safer pest management products and practices? How, and to what extent?
 2. Has the adoption of safer pest management practices and products for the agricultural and forestry sectors increased?
-

a) Pesticide Risk Reduction Program

The principal outputs from the Pesticide Risk Reduction Program with potential for direct application by growers are strategies for addressing priority pest management issues, and products, tools and practices to better manage pests. A total of 160 risk reduction implementation projects have been initiated by the Program since 2003/04 to develop these reduced risk pest control products, practices and tools for application in the agricultural and forestry sectors. However, awareness levels and rates of adoption of risk reduction products, tools and practices developed by the PMC have not been measured, nor have the impacts on rates of pesticide use.

Program staff believe that the Program has achieved significant growth in awareness of risk reduction issues and solutions. This view was also supported by substantial majorities of the survey respondents and external key informants who believed that the Pesticide Risk Reduction Program had made either a "substantial" or "small" positive contribution to the achievement of its two intended short-term outcomes and two of the three intended medium-term outcomes:

- Improving access to, and adoption of, reduced risk pesticides (76% positive rating among survey respondents).
- Increasing awareness of safer pest management practices and products (70%),
- Increasing the rate of adoption of safer pest management practices and products (70%).\
- Improved crop protection practices (64%).

The survey respondents and external key informants were less likely to agree that the Pesticide Risk Reduction Program was making a positive contribution to improving the management of pesticide resistance (54%) and improving the competitive parity of the agricultural and forestry sectors with regard to pest management (40%). Almost one quarter of the respondents (24%) were unable to say whether they thought the Program had made any contribution (positive or negative) to improving competitive parity.

According to the key informants, information on safer pest management practices and products is most likely to reach growers through a variety of indirect sources and channels, such as provincial/territorial government contacts, grower associations, registrants, agricultural dealers, agronomists and registrants. Key informants also believed that many growers are unaware of these improved products and practices, and those that do receive information through these sources may not recognize the PMC as the developer. They also indicated that more training and demonstration projects are needed to increase the rate of adoption among growers, and that growers need information to understand how (or if) reduced risk pest management alternatives are economically viable. Additionally, they highlighted the need for growers to have more than one solution per crop to allow growers to alternate products/practices including continuing to use currently available pesticides and established pest management practices.

b) Minor Use Program

The Minor Use Program focuses on registration of new minor uses of pesticides in accord with priorities jointly identified by growers, grower groups, provincial/territorial pest management coordinators and pesticide manufacturers. Priorities for joint registration projects with the U.S. IR-4 (equivalent to the AAFC PMC) are also determined, leading to parallel registrations of new minor uses in Canada and the U.S.

A total of 638 minor use registration projects were initiated by the PMC between 2001/02 and the end of December 2009, and 234 (37%) projects were completed and submitted to HC-PMRA for registration review. Of these, 160 were accepted for use (including 24 where the HC-PMRA review was complete and final label approval was pending), 8 were rejected, and 66 were still undergoing review. Readers should note that each of these PMC projects do not necessarily equate to individual new minor use registration submissions; HC-PMRA indicated that these 234 projects were equivalent to 158 separate minor use submissions.

A substantial number of PMC projects have been in progress for longer than the three-year period typically required from the time field trials are initiated, for example, 43 current projects were initiated in 2002/03 and another 29 in 2003/04. The PMC implemented a number of measures to enable it to clear this backlog of older minor use projects in 2008/09.

Data provided by HC-PMRA shows that submissions generated by the PMC since 2003/04 led to 454 registrations of new minor uses of pesticides, which represents 15% of the total number of new minor use registrations by HC-PMRA between 2003/04 and the end of 2009. (The remaining 2,671 registrations were made as a result of submissions made by provincial Minor Use Coordinators and registrants.)

Differences in the way AAFC counts and tracks projects and the way HC-PMRA counts and tracks new minor use registrations mean that PMC projects do not equate directly to minor use registration submissions. This lack of direct comparability between PMC and HC-PMRA data is a weakness in the comparability of the current performance reporting between the AAFC and HC-PMRA.

In general, the survey respondents and external key informants who were familiar with the Minor Use Program perceived that it had had a positive impact on the achievement of the intended short and medium-term outcomes. Majorities of the survey respondents and external key informants believed the Minor Use Program had made either a “substantial” or “small” positive contribution to the achievement of four of the Program’s five intended outcomes:

- Improving access to and adoption of minor use and biopesticide products, particularly reduced risk pesticides (75% of the survey respondents rated the Program’s performance as making either a “substantial” or “small” positive contribution).
- Increasing the rate of adoption and use of safer pest management practices and products (72%).
- Improving crop protection practices (68%).
- Increasing awareness of safer pest management practices and products (65%).

Survey respondents and key informants were less likely to believe the Program had made a positive contribution to improved management of pesticide resistance. Key informants noted that improved labelling and involvement of stakeholders were cited as factors that contributed to the Program having a positive impact on outcomes. However, there are few facilities for growers to determine whether poor crop results may be due to pesticide resistance or other factors, such as poor coverage. In addition, the key informants noted that there are insufficient products available to effectively manage pesticide resistance by rotating between different classes of products, especially given that resistance to narrow spectrum products tends to develop faster than resistance to older, broader-spectrum products.

In summary, both the internal and external key informants, as well as online survey respondents, perceive that awareness is being developed and safer pest management products and practices are available. The grower-driven nature of the minor use priority setting process means that awareness and product use of new minor use registrations, including those for reduced risk products, is likely to be readily communicated by grower groups and provincial/territorial minor use coordinators and the products considered for use by growers in situations where growing conditions warrant their use.

3. Has pesticide resistance management improved?

AAFC and HC-PMRA Program management and staff generally believe that the Minor Use Program has contributed to, or could potentially contribute to, improved management of pesticide resistance. This belief is based on the fact that an increasing number of minor use products are becoming available and thereby increasing the options available to growers. HC-PMRA reports that the Agency is currently working with stakeholders and the U.S. EPA to identify approaches and strategies to improve the management of pesticide resistance. However, the measurement of the contribution of the Risk Reduction and Minor Use Programs towards the achievement of improved pesticide resistance management is constrained by a lack of reliable data and difficulties in measuring the incidence and rate of development of pesticide resistance.

External stakeholders were less likely to believe that pesticide resistance management has improved as a result of the Pesticide Risk Reduction and Minor Use Programs. Factors that shaped their views typically related to the limited range of pest management options available to many growers, the faster rate at which resistance to the more targeted newer pesticides develops, and the impact of the re-evaluation program. They also noted that the re-evaluation program has resulted in the removal of some pesticides, and changes to the permitted uses and conditions of use of others that may have otherwise played an important role in the resistance management strategies of growers. Participants in the survey rated the impact of the pest management strategies work on this outcome more favourably. About sixty per cent of respondents rated the Minor Use Program as contributing to improved management of pesticide resistance.

4. Has the competitive parity of the agricultural sector been strengthened?

The Minor Use Program staff interviewed believe the Program has made a contribution in addressing the “technology gap” faced by Canadian growers that gave rise to the Program. This gap is the difference in access to pesticide products and approved uses in Canada compared to access for growers in other countries, most notably the U.S. Measuring the size of the gap is difficult due to such factors as the possible combinations of active ingredients, end-uses and MRLs, and the dynamic nature of growing conditions and pest management challenges encountered by growers. As a result, there are no currently available data indicating if, and at what rate, the gap is being closed.

Fewer survey respondents and external key informants believed that the Program was making a positive contribution to the achievement of the intended final outcome – improved competitive parity of the Canadian agricultural and forestry sectors with regard to pest management. Only a slight majority (56%) of survey respondents supported this view and another 26% were unable to provide a rating and opted for “don’t know”. External key informants were also more circumspect on this outcome, due to concerns that Canadian growers continued to face a significant technology gap compared to U.S. growers, even though the Minor Use Program has been successful in increasing the rate of new use registrations. They were also concerned that the rate of new pesticide registrations and approval of new minor uses was not keeping up with the rate of removal of older pesticides or application of more stringent conditions on their use under the re-evaluation program.

However, when asked how the current regulatory environment compares to the situation before the inception of the Minor Use Program (and Pesticide Risk Reduction Program) in 2002/03 almost three quarters (72%) of the survey respondents indicated that they believed it was “somewhat” or “much” better.

5. Has the forestry sector adopted pesticide risk reduction strategies and increased its use of reduced risk and biological pesticides?

Qualitative information presented by federal and provincial forestry ministries and industry in pest management meetings such as the annual Forest Pest Management Forum, suggests that a range of reduced risk practices have been applied in forestry management, such as widespread use of reduced risk and biopesticides targeting specific insect pests for forest pest control in preference to aerial spraying of broad-scale pesticides. However, it is not possible to make a definitive conclusion as to whether the forestry sector adopted pesticide risk reduction strategies and increased its use of reduced risk and

biological pesticides at this point in time. This is largely due to the same reasons cited above regarding the adoption of safer pest management practices and products, that is, a lack of available data on the extent to which the forestry and outdoor ornamental sectors are using reduced risk products and tools.

NRCan, in cooperation with the AAFC and HC-PMRA, has developed a number of reduced risk pest control products and tools, and registered minor use products for use in the forestry sector. This activity has resulted in:

- Conduct of seventeen minor use registration projects for forestry and ornamentals uses between 2003 and 2006.
- Development of reduced risk products and tools for application in the forestry sector.
- In some cases, NRCan registers products and seeks private company partners to market and support these uses.

External stakeholders interviewed did not have any observations on adoption that were specific to the forestry sector but commented more broadly on the adoption of pesticide risk reduction strategies and use of reduced risk and biological pesticides across the agricultural and forestry sectors. As described above, the majority of key external informants interviewed perceived an increased rate of adoption and use of safer pest management practices and products among growers as a result of the Pesticide Risk Reduction and Minor Use Programs. This perception was echoed by the survey respondents.

2. Recommendations

AAFC, HC-PMRA and NRCan to:

- 1. Periodically measure and report on the level of awareness and rate of application of risk reduction strategies, practices and tools developed by the PMC, NRCan and HC-PMRA among intended users. Provincial/territorial pest coordinators and grower groups should be involved in the development and application of the data collection methods.**
- 2. Identify the cost and revenue parameters of risk reduction tools and practices developed by the Pesticide Risk Reduction Program to enable growers to estimate impacts from applying these tools and practices. This information should be made available to growers and other interested stakeholders as part of the promotion and demonstration of these tools and practices.**
- 3. Assess the current size and structure of the minor use technology gap facing Canadian growers, and to periodically update this analysis and report on the extent to which the gap is being addressed.**
- 4. Develop an integrated approach to the measurement and reporting of the numbers of potential new minor use registrations involved in the PMC's projects, and the associated numbers of minor use registration submissions reviewed by HC-PMRA and new minor uses registered.**

VII. ENHANCED TRANSPARENCY AND ENGAGEMENT

A. Purpose of the enhanced transparency stream

The new *PCP Act* included a requirement for the Minister of Health to consult the public, and provincial government departments and agencies. In particular, the Minister must consult stakeholders whose interests are affected before making a decision on registering or amending the registration of a pest control product, and registration of a pest control product following re-evaluation or special review. In particular, the Minister is required to:

- Provide a public notice of consultation that invites comments from the public.
- Provide a consultation statement that includes reports of the evaluation of the health and environmental risks and value of the pest control product, the proposed decision and reasons, and any other necessary information.
- Consider comments prior to making a decision.
- Make a public decision statement that includes the decision, reasons for the decision, and summary of comments received.
- Make confidential test data available if considered to be in the public interest.

The *PCP Act* also requires the Minister to establish and maintain a register of pest control products including information about applications, registrations, re-evaluations and special reviews, as well as consultation statements and decision statements.

The *PCP Act* also provides for an appeals process for the reconsideration of major registration decisions. In particular, any person may file with the Minister a notice of objection to a decision within 60 days after the decision statement is made public. In addition, any person may request a special review of the registration of a pest control product by making a request to the Minister in the form and manner directed by the Minister. Such reviews are conducted if there are reasonable grounds to believe that the health or environmental risk associated with a product, or its value, is unacceptable.

The intended outcomes from this stream of the BPC Initiative are to achieve: (1) better stakeholder and public awareness (short-term outcome), and (2) greater public and stakeholder engagement (medium-term outcome). In turn, achievement of these outcomes is expected to contribute to the achievement of the long-term outcome of increased public and stakeholder confidence in the pesticide regulatory system. This chapter of the evaluation examines the extent to which these two short and medium-term outcomes are on track to being achieved while the next chapter includes consideration of the progress towards the long-term outcome.

Two evaluation issues were considered in examining the achievement of the above intended outcomes:

1. Have opportunities for public and stakeholder engagement in the regulatory decision-making process increased? If so, how and to what degree of satisfaction?

2. To what extent are stakeholders and the Canadian public aware of increased opportunities to access pesticide regulatory information or/and opportunities to provide input to regulatory decision making?

B. Enhanced transparency and engagement activities

HC-PMRA's provisions for enhanced transparency took effect when the *PCP Act* came into force in June 2006. These transparency provisions enable the public to:

- Obtain information about applications to register or amend a product.
- Provide comments on proposed decisions before they are finalized.
- Review evaluation reports and final decision documents.
- Inspect Confidential Test Data (CTD) after a final registration decision.
- Appeal major registration decisions under certain conditions by submitting a notice of objection to a registration decision, or requesting a special review of a pesticide.⁵⁹

Actions taken to meet these requirements are summarized in the following sections.

1. Public Registry

HC-PMRA provides information on pesticides and the pesticide regulatory system on the Public Registry found on the Health Canada website. Specific types of information posted include:

- Pesticide Product Information Database (PPID), which contains a listing of registered products and labels, applications to register or amend the registration of a pesticide, products under re-evaluation, and active ingredients. The database also provides a listing of programs and special actions such as research authorizations, pesticide products under reconsideration, and minor use applications, as well as incident reports.
- Policies, guidelines and codes of practice relating to the registration and regulation of pesticides.
- Consultation documents for proposed registration and re-evaluation decisions, and final decision documents that discuss evaluations of the health and environmental risks and value of registered pest control products (described in Exhibit VII-1).
- Regulatory proposals, directives or discussion documents for public consultation and stakeholder engagement in the development of new policies, strategies and programs.
- Guidance to the public on the basis for and way in which:
 - Comments on proposed registration and re-evaluation decisions can be submitted.
 - Special Reviews of a pesticide registration in light of scientific evidence of health or environmental risks or unacceptable product value can be requested.
 - Notices of Objection to registration, re-evaluation and Special Review decisions can be submitted.

⁵⁹ HC-PMRA, Getting Involved in Canada's Pesticide Regulatory Process Fact Sheet.

Exhibit VII-1

HC-PMRA Documents related to Pesticide Registration Decisions

Type of Document	Purpose
Proposed Registration Decision	<ul style="list-style-type: none">To consult the public and stakeholders before a registration decision is made on a new active ingredient or major use for a registered active ingredient.
Proposed Re-evaluation Decision	<ul style="list-style-type: none">To consult the public and stakeholders before a decision regarding the re-evaluation of an active ingredient. (Prior to July 2007 these were called Proposed Acceptability for Continuing Registration documents).
Registration Decision	<ul style="list-style-type: none">Summarizes HC-PMRA's decision on a new active ingredient or major new use for a registered active ingredient.Includes a summary of responses to comments received.
Re-evaluation Decision	<ul style="list-style-type: none">Summarizes HC-PMRA's decision regarding the re-evaluation of an existing active ingredient and reasons for the decision.Includes a summary of responses to comments received.
Re-evaluation Note	<ul style="list-style-type: none">To present updates, forward plans of the Re-evaluation program or address individual active ingredients.
Evaluation Report	<ul style="list-style-type: none">Summarizes HC-PMRA's review of data supporting an application to register a new active ingredient and reasons for a conditional registration decision.
Special Review Documents	<ul style="list-style-type: none">Make special review announcements and inform of decisions.

Source: C-PMRA, Reading Room Pilot Project (Draft Report), November 2008.

2. Reading Room

The Reading Room, located at HC-PMRA's headquarters in Ottawa, allows members of the public to inspect (subject to conditions of access and use) confidential scientific data that supports a product registration, major amendment, re-evaluation or special review decisions. The objective of the reading room is to facilitate the understanding of regulatory decisions concerning pesticide by interested persons and for the purpose of requesting the reconsideration of a registration decision.⁶⁰

In order to access the Reading Room, a formal application must be made and an affidavit or statutory declaration signed committing the reader to maintaining the confidentiality of the data they are permitted to view. If they wish, individuals can submit a notice of objection to a decision based on their review of this data. This confidential test data is made available for inspection in an electronic format and may not be removed from the Reading Room. The data supporting any decision made after June 27, 2006, the date when the PCP Act came into force, can be inspected.

3. Opportunities for stakeholders and the public to provide input

Stakeholders and members of the public have the opportunity to provide comments on proposed registration decisions, file Notices of Objection, and request a Special Review of decisions.

a) Comments

Registrants receive notices of proposed registration and re-evaluation decisions as do individuals who have registered for e-mail notifications, and may submit comments on these proposed decisions. A 45 or 60-day time period is provided following the publication date of proposed registration and re-evaluation decision documents for the submission of comments.

⁶⁰ HC-PMRA, Transparency: Consultation Documents, Public Registry, Reading Room, February 2008.

Before making its final decisions, HC-PMRA considers all comments received in response to these consultation documents. HC-PMRA then publishes a final decision document that includes the decision, the reasons for that decision, a summary of comments received on the proposed decision, and HC-PMRA's response to these comments.

b) Notices of Objection

A Notice of Objection can be filed by anyone for a major registration decision to be reconsidered if they believe there is a scientific basis for requesting reconsideration. A notice of objection can be filed within 60 days following the date a registration decision is made public. People requesting reconsideration of a major decision are required to provide or refer to evidence for the notice, which can include confidential test data inspected in the Reading Room and scientific reports, and how this evidence raises scientifically founded doubts as to the validity of the evaluations leading to registration decisions.⁶¹ In particular, Notices of Objection must be based on information related to health or environmental risks, or value and efficacy assessments that raise doubts as to the scientific validity of decisions. HC-PMRA must review each Notice of Objection and determine whether the advice of a panel of external scientific experts needs to be obtained in relation to the objection. A panel is established if the information in the notice raises scientifically founded doubt and if the advice of expert scientists would assist in addressing the content of the objection.⁶²

c) Special Review

The *PCP Act* requires that the Minister initiate a special review if there are reasonable grounds to believe that the health or environmental risk associated with a product, or its value, is unacceptable. Any person may request a special review of the registration of a pest control product by making a request to the Minister in the form and manner directed by the Minister. Special reviews focus on a specific health or environmental concern, whereas re-evaluations examine each aspect of a pesticide to provide a broader, more complete assessment.

Special reviews can also be triggered by information supported by scientific evidence received from other federal or provincial departments, or from a member country of the OECD. If scientific evidence regarding a registered pesticide becomes available, regardless of source, that provides reasonable grounds to believe that the health or environmental risk associated with a product, or its value, is unacceptable, HC-PMRA reviews the new scientific evidence and decides on an appropriate course of action.⁶³

Three requests for special reviews have been submitted since the *PCP Act* came into force in 2006. In all three cases HC-PMRA declined to conduct special reviews as the requests either dealt with re-evaluations that were already underway or provided insufficient scientific evidence to warrant the initiation of a special review. Special reviews typically focus on a specific health or environmental concern, whereas re-evaluations examine each aspect of a pesticide, providing a broader and more complete assessment.

⁶¹ HC-PMRA, *Reconsideration of Decisions Under the New Pest Control Products Act*, October 1 2007.

⁶² *Ibid*, page 3

⁶³ HC-PMRA, *Getting Involved in Canada's Pesticide Regulatory Process Fact Sheet*.

4. Canadian Pesticide Regulation Course

HC-PMRA provides periodic education and training on pesticide registration and regulation for registrants as a means of supporting transparency and engagement. In particular, HC-PMRA periodically hosts the Canadian Pesticide Regulation Course (CPRC) which provides an overview of the Canadian pesticide regulatory process for new and experienced regulatory staff of registrants. The CPRC is meant to help them prepare complete and accurate submissions and in turn allow for a more efficient review and quicker decision.⁶⁴

The course is offered on an irregular basis, usually every 4-6 years, with the most recent session held in February 2008. Past courses were planned by a CPRC Organizing Working Group consisting of representatives from HC-PMRA plus the two main industry associations representing registrants, CropLife and the Canadian Consumer Specialty Products Association. The course consists of an overview of the submission process and regulatory programs, and the scientific evaluation and decision-making process for pest control products.⁶⁵ The CPRC is an efficient way of helping ensure registrants are kept current on regulatory changes, as well as the steps involved and requirements for registration submissions.

C. Achievement of intended outcomes

The enhanced transparency and engagement stream of the BPI Initiative has two intended outcomes, a short-term outcome of better stakeholder and public awareness, and a medium-term outcome of greater public and stakeholder engagement. Evidence to assess progress toward the achievement of these outcomes was obtained from a combination of HC-PMRA documents, public opinion research studies commissioned by Health Canada, internal and external key informant interviews, and the complementary survey of stakeholders.

1. Evidence from internal sources

Program managers and staff from HC-PMRA were interviewed to obtain their perceptions on the activities to support the enhanced transparency and engagement stream of the BPC Initiative and their effectiveness in achieving intended outcomes. These key informants indicated that HC-PMRA gave greater priority to increasing awareness and understanding of the pesticide regulatory system among stakeholders, compared to awareness among, and engagement with, the Canadian public. This prioritization reflects the degree of ongoing involvement with the regulatory system by such key stakeholders as registrants, grower organizations, and environmental and public health advocacy organizations. These organizations have a direct interest in the design and functioning of the regulatory system, and commit resources to monitoring regulatory performance and providing input to proposed policies, regulations and decisions. In contrast, the broader Canadian public is, for the most part, much less engaged or concerned with pesticide regulation unless an incident or disclosure occurs that has, or may potentially have, a direct impact on their lives (discussed in more detail in Chapter VIII). While HC-PMRA's consultation processes enable anyone to participate, the Agency's finite resources for communications and outreach are largely committed to communicating with, and responding to, those stakeholders who are most directly affected by regulatory proposals and actions.

a) Public Registry

Internal key informants indicated that rates of access to and downloading of information on the Public Registry would normally provide a general indicator of the level of usage or demand for regulatory information and decision-making, and changes over time. However, in 2008 the HC-PMRA website was

⁶⁴ HC-PMRA, Introduction and Overview of Canadian Pesticide Regulation Course, February 2008.

⁶⁵ Ibid, page 9.

integrated into the overall Health Canada website and changes were made to the way in which information is organized and presented. As a result, measures of web activity would not be comparable pre and post website integration. According to the internal informants, this change appears to have had a major negative impact on the patterns of use (and was also noted by respondents to the survey of stakeholders). Changes have subsequently been made to the website to improve the ease of use and access to material as a result of user feedback.

b) Use of the Reading Room

A pilot test of the Reading Room was conducted in November 2007 to determine if access and review of CTD facilitates the understanding of a decision and contributes to enhanced transparency. Four members of the Pest Management Advisory Committee (PMAC), which included researchers in medicine, epidemiology, and environmental sciences, as well as a representative active in the area of environmental law, were invited to inspect the CTD.

In their feedback, these testers indicated that access to CTD, on its own, was not likely to be very useful in helping someone understand the background to a regulatory decision if they had no appropriate scientific training. These reviewers also noted that specialists contracted to review and provide feedback on CTD would probably be the most likely users of the Reading Room rather than members of the general public.⁶⁶ However, these comments need to be placed in context. The documentation supporting a registration or re-evaluation decision, for example, is both complex and extensive, and as such, requires a high level of training to be able to fully understand and interpret the scientific data. Equally, if the intended purpose of reviewing the CTD for a decision is to determine if there are suitable grounds to request a special review, then the person or organization seeking access to CTD must have a reasonably well-developed understanding of pesticide science.

According to the Program leads interviewed, one review of confidential test data in the Reading Room has taken place which subsequently led to a Notice of Objection. This rate of usage is consistent with what HC-PMRA expected, based on the experiences of pesticide regulatory agencies in other jurisdictions that provide similar access opportunities, such as the U.K. and U.S.

c) Notices of Objection

According to the Program leads interviewed, the requirement for Notices of Objection to have a sound scientific basis is not always well-understood by respondents. They also noted that understanding of the scientific basis for regulatory decisions is not widespread amongst the public and stakeholder organizations.

According to information reviewed on the Pesticide Product Information Database, a total of nine Notices of Objection (NO) to HC-PMRA decisions have been submitted between June 2006 and the end of 2008/09, including one subsequent to a review of CTD in the Reading Room, as noted in the previous section. These NOs related to three active ingredients – one active ingredient accounted for four of the nine NOs, the remaining two active ingredients accounted for two NOs each. The NOs were received from registrants (2), applicators of pesticides (3), provincial governments (2), a physician (1), and a researcher in the area of public health and safety (1). HC-PMRA chose not to consider one NO, has provided responses to seven out of the nine NOs, and a response to the ninth (received in June 2008) is pending. For the NOs where HC-PMRA issued a response, none led to the creation of an expert panel to review the decision; however, four led to label amendments.

⁶⁶ HC-PMRA, Reading Room Pilot Project (Draft Report), November 2008.

d) Comments provided on proposed re-evaluation and registration decisions

According to the internal key informants, comments on the scientific basis for, or interpretation of, scientific data considered in arriving at proposed decisions are managed and responded to on an individual basis. The comments received may lead to justified changes in the nature of decisions in some instances, for example, changes to transition strategies or conditions of use on labels that reflect actual patterns of use compared to assumed patterns that may have been used in conducting risk assessments and developing proposed re-evaluation decisions.

The Program staff interviewed also noted that:

- The majority of proposed decisions (primarily proposed registration and re-evaluation decisions) receive between zero and ten comments.
- A small number of proposed decisions generate large numbers of comments, for example, the proposed 2,4-D re-evaluation decision, due to higher levels of stakeholder and public awareness and/or levels of use of these products.
- Proposed re-evaluation decisions generate more comments than proposed registration decisions, which reflect the greater availability of data on the health and environmental effects of existing products versus proposed new products.
- The majority of comments on proposed registration decisions are from registrants.

To illustrate the distribution of comments, 12 registration and 31 re-evaluation decisions for 2008/09 were reviewed to determine the number for which comments were received. Comments were received by HC-PMRA on three of the proposed registration decisions (25%) and 18 of the proposed re-evaluation decisions (58%). Of the total 21 decision documents that included stakeholder comments, 17 received less than ten comments, while four received more than 25 comments. Re-evaluation decisions received the most comments.

Comments on proposed re-evaluation decisions were received from a broad spectrum of stakeholders including registrants, non-governmental organizations with interests in human health or the environment, provincial governments, pesticide users, and the general public. Comments made by registrants were identified in two-thirds of all re-evaluation decision documents that received comments. These comments generally related to the product chemistry, human and animal toxicology, residues, exposure, environmental impacts, product value and efficacy, application instructions, buffer zones, precautionary statements and re-entry periods. Changes were made to two of the 18 proposed decisions in response to comments; both were changes to the required label statements.

All comments made regarding proposed registration decisions for new products – the majority of which were provided by the applicants – were either to indicate that a decision was perceived to be too restrictive or conservative or to point out typographical errors. Specifically, stakeholders felt that application instructions were too restrictive, and that toxicology endpoints were too conservative.

In addition to the comments made, the time to address comments received prior to issuing a final decision document was analyzed. Proposed registration and re-evaluation decisions that generate comments require longer periods of time for decision-making. The amount of time required to issue a re-evaluation decision was, on average, 221 days longer when comments were received from stakeholders. A minimum of about 78 days were needed to issue a decision when comments were made versus a minimum of about 66 days when no comments were received. This difference may be more due to the nature of the product being examined rather than the absolute number of comments received.

The average time needed for final re-evaluation decisions was skewed by the extended time periods for a small number of decisions, particularly those that received widespread public coverage and interest, and generated the most comments. For example, HC-PMRA required 1180 and 755 days to issue final decisions for 2,4-D and MCPA, respectively, following the issuance of its proposed decisions. These two re-evaluations were atypical in that they were conducted in two phases; the first phase evaluated lawn and turf uses and the second phase evaluated agricultural use. Both phases involved stakeholder consultations and preparation of responses to a large volume of comments, particularly for 2,4-D, as part of the process. The final decisions were rendered after the completion of the second phase

2. External perspectives

a) Insights from public opinion research on awareness of pesticide risk regulation

In 2004, Health Canada commissioned an Ipsos-Reid report titled *Public Views on Pesticides*. When respondents were asked about their awareness of HC-PMRA, 1% indicated they were “very familiar” with another 10% being “somewhat familiar.” The largest category (58%) was “not at all familiar”. These responses suggest that at that time, there was likely very low or no public awareness of the BPC Initiative. In addition, about 60% of respondents (including those not familiar with HC-PMRA) agreed that HC-PMRA was doing a good job in ensuring pesticides are safe. The HC-PMRA-commissioned report by The Strategic Counsel, *Focus Testing of Pesticide Messages and Labels* (2007)⁶⁷, provided information from focus groups, including members of the public, that are relevant to the BPC Initiative. The results included a finding that participants were surprised by Health Canada’s announcement that it is in the process of re-evaluating older pesticides against modern standards. They had assumed that this was being done on an ongoing basis, i.e., that as new information is obtained, and standards evolve, all existing products on the market are continuously monitored for conformity. These two reports suggest that members of the general public may assume that pesticide regulation is effective unless they hear otherwise.

Other studies suggest there is limited awareness among the public of the role of HC-PMRA in regulating pesticides. As part of a Decima Research (2006) attitudes study, a report was provided to Health Canada titled *Investigating Canadian Attitudes and Behaviours Surrounding Chemicals in Consumer Products*. This report presents the findings of an online national survey with 1899 respondents, supplemented by the results of ten focus groups held in various locations across Canada. The survey and focus groups indicated that there is very limited knowledge about the responsibility in government for regulating a wide variety of potentially hazardous products. The study observed a belief that there is much less regulation in place than actually exists, which is somewhat at odds with the finding of the 2004 study (above) that members of the public believe product registrations are continuously updated in response to new scientific knowledge. This study concluded that the gap in perceptions of risk regulation relative to actual regulatory practices means that more risk communication is required.

A continuing series of assessments of public opinion are provided in Health Canada’s reports in 2005 titled *Eye on Health: Public Opinion Research Quarterly Report*. The 2005 survey results provide information on food safety issues and concerns, some of which are pesticide-related. One issue of the quarterly report supported the general finding that focus group and survey respondents “tend to have a lack of knowledge and familiarity with Canada’s regulatory system”.⁶⁸ The Compas (2004) survey titled *Food for Thought* also provides information related to food safety issues. One component of this report focused on awareness of a variety of food issues and themes including pesticides. Respondents were asked how much they had heard about a series of food-related subjects. Pesticide awareness was ranked relatively low (eight out of 11) compared to other food safety subjects.

⁶⁷ The Strategic Counsel, *Focus Testing of Pesticide Messages and Labels*, HC-PMRA, 2007.

⁶⁸ *Eye on Health: Public Opinion Research Quarterly Report*, Spring Issue, 2005, page 2.

The literature review also examined the potential influence of media reports in affecting public confidence in pesticide regulation. Ekos Research Associates carried out a number of public opinion research studies in a report titled *Security Monitor*⁶⁹ between 2005 and 2007 where pesticide risks and related risk perception questions were asked. In one component of the study, a decline was observed in respondents reporting that they were very confident in Canada's food safety system, which followed substantial media attention to publicized food safety issues. Another study by Krewski et al.⁷⁰ provides data and analysis related to public perceptions of population health risks in Canada and sources of information about these risks. The study authors suggest that lifestyle factors may have had particularly high risk rankings because of extensive media coverage of such risks. People are likely to rank events differently if there has been recent media exposure.

b) Insights from stakeholder opinion research on satisfaction with pesticide regulation

In 2009, HC-PMRA commissioned a study by Ekos Research Associates titled *Measuring Stakeholder Satisfaction in the Federal Pesticide Regulatory System*.⁷¹ This study was intended to reflect the views of all stakeholders, including registrants/applicants, industry representatives, pesticide users, not-for-profit/non-government groups in the health and environmental sectors plus representatives from all three levels of government.

- The study showed there to be a high level of awareness of the Public Registry (81%) and varying rates of use (although approximately 85% of those who were aware had used it at least once). Stakeholders cited a number of reasons for using the registry including acquiring pesticide information (81%), examining regulatory and policy documents and guidelines (63%), obtaining information on active ingredients (61%), obtaining information on the re-evaluation of pesticides (54%), and providing comments related to registrations.
- Although aware of the Registry, many users were not aware of the variety of features on this system. Less than half indicated they were aware of the ability to request a reconsideration of a decision (45%), or knew the Public Registry offered users the ability to request an inspection of confidential test data (42%). Only 39% indicated they were aware of the ability to request a special review through the Public Registry.
- High satisfaction ratings were given to the ability to access regulatory and policy documents and guidelines (66% satisfied), and product information on pesticide products (61%) on the HC-PMRA website (prior to its integration into the Health Canada site).
- Nearly three quarters of respondents were aware of the HC-PMRA training courses and 45% had taken a course. Most registrants who had taken a course reported that it was either "very" useful or "somewhat" useful (89%).
- Seventy one percent of registrant respondents were aware of pre-submission consultations. Among those who were aware, more than half said that they either never or only rarely participated in these consultations. Delays in pre-submission appointments were cited as a reason for not using this service which was rated as useful or very useful by nearly 60% of those who had used it.

⁶⁹ Ekos Research Associates, *Security Monitor*, Waves 8 and 11 in 2005 and Waves 4 and 5 in 2007.

⁷⁰ Krewski, D. et al. "Public Perception of Population Health Risks in Canada: Health Hazards and Sources of Information", *Human and Ecological Risk Assessment*, v.12, pp. 626-644, 2006.

⁷¹ Ekos Research Associates, *Measuring Stakeholder Satisfaction in the Federal Pesticide Regulatory System*, 2009

- Approximately two-thirds of respondents were familiar with HC-PMRA's electronic mailing list and more than 70% had subscribed to it. Approximately 85% of users rated it as "very" or "somewhat" useful.

c) External key informants and survey respondents

External key informants and survey respondents were both asked about their familiarity with the various mechanisms established under the *PCP Act*, and how effective the various mechanisms have been in producing intended outcomes among the public and stakeholders. They were also asked how HC-PMRA's current approach to transparency and stakeholder engagement with regard to pesticide regulation compares to the situation prior to the *PCP Act* coming into force in 2006, and whether there were opportunities to improve that approach.

Awareness and use of transparency and engagement mechanisms

Exhibit VII-2 shows the extent to which external key informants and survey respondents who indicated they were familiar with the increased transparency and engagement stream (n=13) reported being familiar with each of the main elements of this stream of the BPC Initiative. All of these external key informants were aware of information available through the PPID and knew that policies, guidelines and other information related to regulation of pesticides were available on the HC-PMRA website. However, less than half actually used that information. The majority commented that the inclusion of the previously separate HC-PMRA website within the overall Health Canada website made it more difficult to find information and access documents, especially for people who may have only occasional need to obtain information on pesticide regulation matters.

The majority of these external key informants were also aware of opportunities to provide input into the regulatory process. Almost all (12) informants were aware of opportunities to provide comments on proposed registration decisions, inspect CTD, and file Notices of Objection. Fewer were aware of the opportunity to request a Special Review. In particular:

- External key informants were most involved in providing comments on proposed registration and re-evaluation decisions. However, several mentioned that it is difficult to find relevant information in consultation documents and to understand the information. Several were also unsure how their comments were subsequently used.
- Several informants had had some involvement with the establishment of the Reading Room, and one had used the Reading Room to review data. Several echoed the comments of internal informants, and the findings of the Reading Room pilot evaluation, that the data is difficult to interpret in the form provided in the Reading Room.
- Generally, external key informants were aware or have taken advantage of the opportunity to file Notices of Objection to decisions but had few comments on the effectiveness of this mechanism.
- One third of informants were not aware of the opportunity to request a Special Review.
- Almost all informants were aware of the education and training on pesticide registration and regulation available to registrants through the Canadian Pesticide Regulation Course. They perceived that large registrants are more aware of the training available whereas smaller registrants or those new to the Canadian market may not be, and may require additional support. Several informants noted that in-person training on pesticide registration and regulation is more effective than registrants contacting HC-PMRA individually for guidance. As a side benefit, the CPRC provides an opportunity for informal knowledge transfer between participants and HC-PMRA staff members.

A high proportion of the survey respondents appeared to be familiar with the Pesticide Product Information Database on the Health Canada website (92%), policies guidelines and codes of practice relating to the registration and regulation of pesticides (86%), and opportunities to provide comments on proposed registration and re-evaluation decisions (89%). They were less familiar with mechanisms to enable third parties to inspect confidential data supporting registration and re-evaluation decisions in the Reading Room (53%), file notices of objection of registration decisions by HC-PMRA (59%), and to request Special Reviews (50%).

Exhibit VII-2

Familiarity with enhanced transparency and engagement mechanisms

Activity	% of External Key Informants	% of Survey Respondents
Make information on specific pest control products publicly available using an online Pesticide Product Information Database on the Health Canada website	100%	92%
Policies, guidelines and codes of practice relating to registration and regulation of pesticides made available on the HC-PMRA website	100%	86%
Opportunities to provide comments on proposed registration and re-evaluation decisions	92%	89%
Opportunities to inspect confidential test data supporting proposed pesticide registration and re-evaluation decisions in HC-PMRA's Reading Room	92%	54%
Opportunities to request a Special Review of a pesticide registration in light of scientific evidence of health/ environmental risks/ unacceptable product value	69%	50%
Opportunities to file Notices of Objection to registration, re-evaluation and Special Review decisions	92%	59%
Education and training on pesticide registration and regulation for registrants	92%	67%

Bases: Respondents who were familiar with the enhanced transparency and engagement stream of the BPC (n=13 for external key informants and n=144 for survey respondents familiar with the enhanced transparency and engagement stream (Q.B1).

Survey respondents were asked how HC-PMRA's current approach to transparency and stakeholder engagement with regard to pesticide regulation compares to the situation prior to the *PCP Act* coming into force in late-June, 2006. Nearly two-thirds (66%) of the respondents indicated that the current approach is either "somewhat" or "much" better.

Reasons cited for the effectiveness of the current approach by the stakeholders who participated in the survey included:

- Greater grower engagement with registration process and feeling of improved responsiveness to needs.
- Tools are in place for the public to access information and more input is invited from the public.
- Information supporting registration decisions is available and is useful to stakeholders to understand pesticides.

- Transparency has improved through the public registry, the reading room, and documents being published in plain language.
- HC-PMRA staff are open and more approachable. HC-PMRA has a more favourable attitude to providing information.
- Information is provided through the e-mail distribution list about registered products and uses, as well as opportunities for stakeholders to provide input.

Areas of concern identified through comments related to the difficulties experienced in finding information on the HC-PMRA website; that HC-PMRA has minimal involvement with the public; a lack of awareness among the public regarding how pesticides are regulated; and that the Reading Room is difficult to access for stakeholders located outside of Ottawa.

Perceptions regarding the achievement of intended outcomes

The majority of key informants (10 or more of the 13), perceived the transparency and engagement mechanisms to be either “somewhat” or “highly effective” in achieving outcomes among stakeholders. Generally, the ratings were the same across all outcomes assessed. Activities and mechanisms that were perceived to positively impact outcomes were making information available on the HC-PMRA website; providing regular updates through the stakeholder mailing list; the process to receive input from stakeholders; and a culture of approachability at HC-PMRA.

Areas of concern identified by the external informants included the integration of the HC-PMRA website into the Health Canada website, which made it less effective; the complexity of the consultation process; and the complexity of the consultation documents which may require an intermediate party to interpret the data for growers. Challenges in achieving outcomes were perceived to be communication of information to those who are not aware of the website or mailing list; and responding to misinformation in the media.

Survey respondents who were familiar with the enhanced transparency and engagement stream of the BPC Initiative also rated the effectiveness of each of the mechanisms in contributing to intended outcomes. The results of these ratings are shown in Exhibit VII-3. The majority of respondents indicated that the mechanisms were effective in producing the intended outcomes among **stakeholders**. The contribution of the mechanisms to immediate outcomes was deemed to be effective by the highest number of respondents, and slightly lower for longer term outcomes. In particular, over 70 per cent indicated that mechanisms were effective in enabling stakeholder and public access to pesticide regulatory information, and increasing opportunities for stakeholders and public to provide input to regulatory decision-making.

Less than half of the survey respondents perceived the mechanisms to be effective in achieving intended outcomes among the public. Almost half (49% and 43%, respectively) of stakeholders surveyed perceived that they were effective in enabling public access to pesticide regulatory information, and increasing opportunities for the public to provide input to regulatory decision-making. However, less than a third of respondents (27%) believed the mechanisms were effective in achieving the longer term outcome of increasing public confidence, equal to the proportion who believed they were “somewhat” or “highly ineffective”, and 37% who perceived them to be “neither effective nor ineffective”.

Exhibit VII-3

Effectiveness of transparency mechanisms in contributing to intended outcomes among stakeholders and the public (as perceived by stakeholders)

Intended Outcomes	Stakeholders				Public			
	Highly or Somewhat Effective	Neither Effective nor Ineffective	Highly or Somewhat Ineffective	Don't Know	Highly or Somewhat Effective	Neither Effective nor Ineffective	Highly or Somewhat Ineffective	Don't Know
Increasing stakeholder and public awareness of the basis for pesticide regulation	66%	18%	13%	3%	32%	36%	24%	9%
Enabling stakeholder and public access to pesticide regulatory information	73%	17%	8%	3%	49%	28%	14%	9%
Increasing opportunities for stakeholders and the public to provide input to regulatory decision making	71%	13%	11%	5%	43%	30%	16%	11%
Increasing stakeholder and public confidence in the Canadian pesticide regulatory system	51%	28%	15%	6%	27%	37%	27%	10%

Base: Survey respondents who were aware of Enhanced Transparency and Stakeholder Engagement activities (Q.B2); n=142.

External key informants were less positive, compared to the survey respondents, in their perceptions of the impacts of HC-PMRA's enhanced transparency and engagement mechanisms on the Canadian public. They were most positive about the impact of the extent to which the actions taken by HC-PMRA had improved access to pesticide regulatory information (rated as "highly" or "somewhat" effective by 9 of 13), and increased opportunities to provide input to regulatory decision making (7 of 13). Views on the effectiveness of actions to increase awareness of the pesticide regulatory system were mixed, and a majority (8 of 13) believed that the BPC Initiative had been "highly" or "somewhat" ineffective in increasing public confidence in pesticide regulation.

Opportunities to Improve Transparency and Engagement

External key informants' suggestions for improving the effectiveness of HC-PMRA's approach to increasing the transparency and engagement related to:

- Increasing the transparency of pesticide regulation, for example, by creating a more user-friendly HC-PMRA website, providing the complete text of documents on the website, providing materials that can be easily understood by the public and stakeholders, and making HC-PMRA representatives available to attend meetings of stakeholders and the public related to pesticide regulation.
- Reinforcing the science behind HC-PMRA's decision-making in communications to stakeholders and the public, and to defend the scientific basis of the federal pesticide regulatory system.
- Increasing stakeholder and public engagement with regard to decision making on pesticides by, for example, undertaking consultations with each province to better understand regional differences, following up with stakeholders after consultation, providing regular information/updates, and consulting stakeholders on the implications of decisions made.

- Undertaking more proactive communications and outreach to broaden the Agency's reach among stakeholders and groups that are not usually engaged.

About two-thirds (68%) of the survey respondents also indicated that they thought there were “some” or “substantial opportunities” to improve the effectiveness of the approach to enhancing transparency and engagement. Suggestions by these respondents mirrored those identified by the external key informants.

However, evidence from the risk communications literature (which is discussed in Chapter VIII) suggests that it is difficult to engage a majority of the public unless a major issue linked to regulatory decision-making with a potential to have some public impact occurs. These findings suggest that, rather than undertake more intensive public communications activities, it would be better to conduct a detailed assessment of the effectiveness of current communications methods and, if appropriate, implement targeted communications to public and stakeholder groups to strengthen understanding of the pesticide regulatory system, the health and environmental effects of pesticides, and status of proposed decisions and other regulatory initiatives.

D. Conclusions and recommendations

1. Conclusions regarding the BPC enhanced transparency and engagement stream

Two evaluation issues related directly to the enhanced transparency and engagement stream of the BPC Initiative.

-
1. Have opportunities for public and stakeholder engagement in the regulatory decision-making process increased? If so, how and to what degree of satisfaction?
-

HC-PMRA has responded to the legislative requirements of the *PCP Act* that require the public and stakeholders to be consulted before making a decision on registering or amending the registration of a pest control product, and registration of a product following re-evaluation or special review. In particular, HC-PMRA created the following mechanisms to increase transparency and enable stakeholder and public engagement in pesticide regulatory decision-making:

- **The Public Registry** which provides information on pesticides and the pesticide regulatory system on the HC-PMRA website. A number of suggestions were made to improve the effectiveness of the Registry, including a more user-friendly organization of the website, a way to allow stakeholders to download all relevant documents on the website, and to be able to access documents from all departments involved in the BPC through one place. Some improvements have been made to the website subsequent to, and independent of, the conduct of the key informant interviews.
- **The Reading Room** which allows members of the public to inspect confidential test data that supports a product registration, major amendment, re-evaluation or special review decision, to inform their understanding of regulatory decisions concerning pesticides and to potentially provide evidence to support a request to reconsider a product registration decision. There has only been one instance of Confidential Test Data being reviewed in the Reading Room to date (excluding the pilot test) so it is not feasible to assess direct satisfaction with this particular transparency mechanism. External stakeholders commented that the data is difficult to understand in the form provided.

- **Opportunities to provide comments on proposed registration and re-evaluation decisions, and other consultations.** HC-PMRA provides a 45 to 60-day time period for comments following the publication of proposed decisions. HC-PMRA considers comments received and then publishes final decision documents including summaries of comments received, and HC-PMRA's responses to these comments. Although stakeholders felt the opportunity to provide comments was important, some indicated that consultation documents may be difficult to understand and, it may be inferred, limit engagement.
- **Opportunities to file Notices of Objection.** A Notice of Objection can be filed by anyone for the reconsideration of a major registration decision when they believe there is a scientific basis for requesting reconsideration, such as health or environmental risks, or value and efficacy assessments that raise doubt as to the scientific validity of decisions.
- **Opportunities to request a Special Review of a decision.** If new scientific evidence that raises a concern regarding a registered pesticide becomes available, the public can submit that evidence and request a special review of that pesticide. HC-PMRA reviews the new scientific evidence and decides on an appropriate course of action.
- **Training.** HC-PMRA also provides education and training on pesticide registration and regulation for registrants through the Canadian Pesticide Regulation Course. The course provides an overview of the Canadian pesticide regulatory process for regulatory staff of registrants to help them prepare complete and accurate submissions and in turn allow for a more efficient review and decision-making process.

Overall, the majority of stakeholders who participated in interviews or the survey indicated that these mechanisms were effective at enabling access to pesticide regulatory information, and increasing opportunities to provide input to regulatory decision-making among stakeholders. The contribution of the mechanisms to improving access and opportunities for input among the public was perceived by the stakeholders as being significantly lower due to much lower levels of interest in pesticide regulation compared to stakeholders.

-
2. To what extent are stakeholders and the Canadian public aware of increased opportunities to access pesticide regulatory information or/and opportunities to provide input to regulatory decision making?
-

a) Stakeholders

Generally, awareness among stakeholders interviewed and surveyed was high with respect to the opportunities to access pesticide regulatory information and opportunities to provide input to regulatory decision making. Although the majority of stakeholders were aware of almost all these opportunities, there was significant variation in the level of familiarity between the various mechanisms to provide these opportunities. A large majority were aware of the availability of information on registered products on the Public Registry (92%) and opportunities to provide comments on proposed registration and re-evaluation decisions (89%) but fewer were aware of the provision to request Special Reviews (50%) or to inspect Confidential Test Data in the Reading Room (54%).

One indicator of the awareness of opportunities to provide input to regulatory decision making is that of the incidence of comments on proposed registration and re-evaluation decisions. More proposed re-evaluation decisions receive comments than proposed new product registration decisions, and the proposed re-evaluation decisions are more likely to receive a greater number of comments. This is likely due to greater familiarity and experience with existing products versus proposed new products. Comments

are received from a broad spectrum of stakeholders that includes registrants, non-governmental organizations with interests in human health or the environment, provincial governments, users, and the general public. Generally, comments on proposed registration decisions are most often received from registrants and users rather than the general public.

b) **Public**

Public awareness of pesticide regulation and decision-making appears is lower than among other stakeholders. A 2004 Ipsos-Reid study on public views on pesticides indicated that the majority of the public are not aware of HC-PMRA, which would suggest there would be low awareness of the Agency's transparency mechanisms. A 2006 Decima Research study found that many people believe there is much less regulation in place than actually exists and concluded that the gap between perceptions of risk regulation versus actual regulatory practices means that more risk communication is required. In another study (Compass, 2004), pesticide awareness was ranked low compared to other food safety issues. Other opinion research that identifies the potential influence of media reports in affecting public confidence in Canada's food safety system which may also apply to pesticide regulation. For example, an Ekos Research study observed a decline in confidence in Canada's food safety system following substantial media attention to food safety issues.

2. Recommendations

HC-PMRA to:

- 1. Continue to enhance its web presence to provide better access to information on all aspects of the pesticide regulatory system, including the findings from the research and monitoring work of HC-PMRA's partners in the BPC Initiative.**
- 2. Conduct an assessment of the effectiveness of current methods used to strengthen awareness and understanding of the pesticide regulatory system, the health and environmental effects of pesticides, and status of proposed decisions and other regulatory initiatives, and implement changes and refinements to address any identified gaps.**

VIII. OVERALL RELEVANCE AND PERFORMANCE OF THE BPC INITIATIVE

This chapter examines the overall relevance and performance of the BPC Initiative, summarizes the evidence of progress toward the achievement of the intended long-term outcomes, and the extent to which management commitments in response to the formative evaluation were met.

A. Relevance and performance of the BPC Initiative

In the context of the federal government's 2009 Policy on Evaluation, relevance refers to the extent to which a program or initiative is appropriate to the federal government, addresses a demonstrable need, and is responsive to the needs of Canadians. Performance refers to the initiative's effectiveness, efficiency and economy.

1. Appropriateness of federal government involvement

Formal responsibility for the regulation of pesticides is shared between the federal and provincial/territorial levels of government. The federal government has the authority to regulate the import, manufacture, sale and use of pesticides under the *PCP Act* and regulations. The objective of the Act is to prevent unacceptable risks to people and the environment from the use of pest control products. BPC funding enabled HC-PMRA to implement and administer a range of requirements under the new *PCP Act*, which received Royal Assent in December 2002 and came into force in June 2006. These requirements related to provision of MSDS (Section 8(3)), incident reporting (Section 13), re-evaluation of older pesticides (Section 16), special reviews (Sections 17 and 18), public consultation (Sections 28 and 42), notices of objection (Sections 35 to 40), and access to information in the Register of Pest Control Products (Sections 42-44). BPC funding provided for the establishment of these services and functions by HC-PMRA as well as additional A-base funding starting in 2008/09 to enable their ongoing provision.

Provincial/territorial governments may regulate the sale, use, storage, transportation and disposal of registered pesticides in their jurisdictions as long as the measures applied are not less restrictive than the federal conditions of registration. Provincial/territorial governments also establish and apply requirements for education and training of users, licensing or certification of vendors and users (applicators and growers), and issuance of permits for certain uses of restricted class pesticides.

Responsibility for monitoring and compliance with the federal and applicable provincial/territorial legislation is also shared between these two levels of government.

Municipalities may also establish by-laws and land-use restrictions that include conditions on the use of pesticides, if permitted by provincial legislation. Many municipal governments have chosen to regulate the use of pesticides in recent years, for what has come to be known as “cosmetic use” (and some provinces, such as Ontario and Quebec, have introduced blanket provincial restrictions). As with the provincial/territorial regulation, municipalities are not permitted to apply less restrictive conditions than are applied at the federal level. The right of municipalities to establish such by-laws was confirmed by the Supreme Court in 2001 in a case between Spraytech (on behalf of landscaping and lawn care companies operating in Quebec) and the Town of Hudson.⁷²

2. Alignment with department and agency priorities

The focus of the BPC Initiative on improving protection of human health and the environment, increasing the availability of reduced risk and minor use pest control products, and thereby contributing to increased public and stakeholder confidence in the pesticide regulatory system is aligned to selected strategic outcomes and expected results of each of the participating departments and agencies. Exhibit VIII demonstrates this by summarizing the links between the involvement of the six BPC partners, the applicable strategic outcomes in their 2007/08 Departmental Performance Reports, and the associated Government of Canada Outcome areas. The 2007/08 reports were used because this was the last year of the BPC Initiative prior to conversion of funding for many of the program elements to department and agency A-bases.

⁷² 114957 Canada Ltée (Spraytech, Société d'arrosage) v. Hudson (Town), 2001 SCC 40, [2001] 2 S.C.R. 241, June 28, 2001. (Accessed at: <http://csc.lexum.umontreal.ca/en/2001/2001scc40/2001scc40.html>).

Exhibit VIII-1

Alignment of the BPC Initiative with federal and department/agency objectives

BPC Partners	BPC Streams	Associated Department/Agency Strategic Outcomes	GOC Outcome Areas
HC-PMRA	Research & Monitoring Strengthened Pesticide Regulation Pest Management Strategies Enhanced Transparency & Engagement	Strategic Outcome 3b: Reduced health and environmental risks from products and substances, and safer living and working environments. Expected Results: Access to safer pesticides. Improved transparency and knowledge dissemination.	Healthy Canadians
AAFC	Pest Management Strategies	Strategic Outcome: Health of the environment Performance Indicators: Number of minor use and reduced risk regulatory submissions made to HC-PMRA; Number of crop profiles, risk reduction strategies, research projects and new products, practices or technologies that can be utilized by growers	A clean and healthy environment
EnvCan	Research & Monitoring	Strategic Outcome 3: Canadians and their environment are protected from the effects of pollution and waste. Program Activity 3A – Planned Result: Risks to Canadians and impacts on the environment posed by toxic and other harmful substances are managed.	A clean and healthy environment
DFO	Research & Monitoring	Strategic Outcome: Healthy and productive aquatic ecosystems. Expected Result – Science: Science advice to inform the integrated management of healthy and productive aquatic ecosystems for the benefit and enjoyment of Canadians.	An innovative and knowledge-based economy
NRCan	Research & Monitoring	Strategic Outcome: Sustainable forest. Expected Result: Healthy forests continue to provide balanced social, environmental and economic benefits to Canadians. Intermediate Outcome: Forest losses are addressed through the provision of balanced social, economic and environmental information and advice.	Strong economic growth
CFIA	Research & Monitoring	Strategic Outcome (residues on food products): Protection from preventable health risks related to food safety or the transmission of animal diseases to humans. Expected Result: Food leaving federally registered establishments for interprovincial and export trade or being imported into Canada is safe and wholesome.	Healthy Canadians
		Strategic Outcome (fertilizers and fertilizer-pesticide combinations): A sustainable plant and animal resource base. Expected Result: Industry complies with federal acts and regulations regarding Canada's crops and forests.	Strong economic growth

Sources: 2007/08 Departmental Performance Reports for each department/agency.

The information in Exhibit VIII-1, and in the underlying department and agency performance reports, demonstrates a clear linkage from the activities and intended outcomes of the BPC Initiative to the strategic outcomes and expected results of the BPC partners. This alignment is most apparent for Health Canada and AAFC, the departments that were allocated the majority of the BPC Initiative's funding (54% to HC-PMRA and 32% to AAFC). The four partners who received funding for research and monitoring activities (EnvCan, DFO, NRCan and CFIA) all have strategic outcomes related to the identification and management of environmental risks and sustainability or, in the case of CFIA, protection of human health from food safety risks, that are also central to their roles in the BPC Initiative. In turn, the BPC partners'

strategic outcomes are aligned with four Government of Canada Outcome Areas: a clean and healthy environment, healthy Canadians, strong economic growth, and an innovative and knowledge-based economy. This emphasis on managing environmental and health risks is also reflected in the strategic outcomes in the Reports on Plans and Priorities and Departmental Performance Reports of the BPC partners for the years since 2007/08.

3. Responsiveness to demonstrated needs

The new *PCP Act*, which came into force in June 2006, was a response to evolving needs for strengthened protection of health and the environment from the risks posed by pesticides, and responded to widely based expressions of the need from Canadians generally, users and suppliers of pest control products and other stakeholders.

Two reports – one by the House of Commons Standing Committee on the Environment and Sustainable Development (2000) and the other by the Standing Committee on Agriculture and Agri-Food (2002) – drew upon public and stakeholder consultations and submissions in reaching their conclusions. Two major issues of concern were identified in these reports. Firstly, the public is concerned about the long-term impacts of pesticide use and more information should be made available, and secondly, users of pest control products in the agricultural and forestry sectors have limited access to reduced risk and minor use pesticides compared to Canada's international competitors, particularly U.S. growers.

The federal government accepted the principles advanced by these reports and subsequently introduced the new *PCP Act*. The BPC Initiative was introduced in 2002/03 to enable the implementation of key elements of the new Act and expand post-market monitoring of the impacts of pesticide products on the environment and health.

The findings from public opinion research commissioned by Health Canada, summarized in the previous chapter, suggest there are continuing levels of uncertainty regarding the nature of pesticide regulation and low awareness of the federal government's regulatory role. In this context, the awareness of particular components of the BPC Initiative aimed at increasing public awareness and transparency is probably even lower. The results of this public opinion research also highlight a fundamental challenge facing HC-PMRA; Canadians vary substantially in their risk perceptions and in how they believe their governments should deal with the risks that they face. This means that there is no single approach to risk regulation that will satisfy this diverse set of stakeholder risk preference policies. As such, there is a continuing need to build the awareness of understanding of the pesticide regulatory system among both stakeholders and the public.

4. Challenges in building public confidence and trust identified in the literature review

Our literature search and review examined "building public confidence" from a perspective that public confidence will ultimately be increased if regulatory procedures have been improved and the public recognizes that regulatory activities are more effective. This approach is in contrast to direct activities and initiatives to create more confidence in members of the public by explaining to them more clearly the strengths of the current system. Public confidence, following the approach described, is likely to increase if it can be demonstrated that Canada is moving in the direction of an improved regulatory environment for pesticides relative to innovative measures in the rest of the world. The literature pertaining to risk management was the most useful in understanding issues of public confidence and insights regarding the development or maintenance of confidence levels.

a) Public confidence and risk management

The issue of public confidence extends to many areas of risk regulation and includes public confidence or trust in science as it is communicated to the public. Concerns about risk regulation, including pesticide risk regulation are not unique to Canada. For the United Kingdom, the literature related to Bovine

Spongiform Encephalopathy (BSE) and the initial U.K. regulatory response to it highlights a number of issues that contributed to creating an environment in which there was a reduced degree of confidence in government risk regulation. The post-BSE situation in the U.K. has been described as one in which there was a “crisis of confidence”.⁷³

The BSE example is consistent with much of the literature in this area. “Objective” or expert assessments of risk often deviate from apparent public perceptions. The public appears to under-estimate risks associated with unregulated personal choices and to over-estimate risks associated with activities that are regulated by government. Developing effective pesticide policies is particularly challenging in a context in which there may be a discrepancy between the judgment of experts on pesticide risks and the judgment of consumers.

A further issue highlighted in the U.K. case is the treatment of scientific uncertainty by government risk regulators. This is clearly a central issue for risk regulators, including those responsible for pesticides. Regulatory decisions are generally made in the context of some uncertainty. Standards of “beyond reasonable doubt” imply some subjectivity to the public. In many such decisions, policy-makers may be faced with disagreements among experts and it is necessary in this situation to make the extent of the uncertainty clear to the public.

b) Risk communication

The findings from the literature review indicate that building or maintaining public confidence cannot be dealt with effectively solely by outreach campaigns to the public. At a time of reduced public confidence, more information from a source in which there is reduced confidence will not be productive. Instead, a process of institutional change is required, followed by more effective communications strategies. Success is unlikely if the issue is perceived solely as one of improved communication.

To improve the regulatory environment, the post-BSE U.K. response focused on communicating risk information but also dealt with other elements of risk management. The risk management approach employed in the U.K. up to and including the BSE issue was described as being a *pedagogic one-way communication approach*. The U.K.’s BSE review argued that regaining public confidence required regulators to *change existing institutional terms of reference and procedures to open them up to more substantial influence and effective inputs from diverse groups*.⁷⁴

These principles have much in common with what is being developed in the BPC Initiative. The conclusion in the assessments of the U.K. experience is that any public confidence initiative must have a long-term perspective and must effect institutional change. “Quick fix” approaches are as likely to exacerbate the problem.

More recent reviews of the BSE experience highlight the fact that government risk communication did not accurately portray the known scientific base. In addition, elements of scientific uncertainty known to regulators and risk communicators were concealed and there was insufficient public investment in research and the review process discouraged input from independent scientists.⁷⁵

⁷³ House of Lords Science and Technology Select Committee (2000), Science and Society, Report to the U.K. Parliament, London.

⁷⁴ House of Lords Science and Technology Select Committee (2000), Op cit.

⁷⁵ Millstone, E. and P. Van Zwanenberg (2007), “Mad Cow Disease- Painting Policy-Making into a Corner”, **Journal of Risk Research**, v. 10, no. 5, pp. 661-691.

Another example in this area relates to an investigation of risk perceptions and risk communication themes in Belgium in response to a suspected outbreak of avian influenza. The absence of established linkages between regulators and stakeholders prior to the crisis appears to have been the key determinant of weaknesses in the risk communications process. Confidence in public authorities, according to this research, requires continuing links with stakeholders as opposed to trying to establish new links at the time of a crisis.

Risk perception by the public is a critical issue in the area of risk regulation and public confidence. In abstract analyses of risk, the concept is clear and quantitative, in terms of a probability of a specific consequence. However, the evidence suggests that, while public perceptions do relate to statistical or quantitative risk, qualitative effects are also important. That is, the public may have a greater aversion to some risks than others, even if they are equal in likelihood and the same in terms of consequence. Qualitative or subjective elements include personal controllability and the degree of uncertainty.⁷⁶

Differences in risk tolerance based on context are found in evidence from the occupational health and safety field.⁷⁷ These results show that workers may readily accept workplace risks that they would find unacceptable if they or their families were exposed to the same risk outside of the workplace. In addition, this literature points to “risk amplification” as an over-estimation of specific risks with the single most important amplifying factor being the extent to which risk managers appear in control and are trusted. In the absence of such control and trust, amplification, often through the media, can be substantial.

c) Trust in regulatory structures and regulators

Risk managers, in most countries, face severe challenges. Traditional science-based systems of risk management are being challenged to become more open and to respond to a variety of pressures to regulate more effectively, including a requirement for more post-market surveillance. Some of the literature in this area refers specifically to public “trust” in regulatory structures and notes the asymmetry in trust relationships. It is much more difficult to re-establish public trust than it is to damage trust relationships. This has clear implications for measures of “success” for the BPC Initiative in influencing public trust. In general, issues in this category relate directly to the core concept of this Initiative of “building public confidence”.

Some of the literature highlights perception differences between professionals (toxicologists) and the public. The toxicologists by a large margin disagreed with the view that even very small amounts of exposure to harmful chemical substances pose a significant health risk. Pesticides were included in the substances that did pose significant health risks, according to the toxicologists. A majority of respondents was critical of both the media and regulators for not explaining chemical risk to the public in a balanced manner.⁷⁸

In terms of providing accurate information, toxicologists were concerned about both overstatement and understatement of some chemical risks. These assessments of accuracy varied across sources with many government sources scoring relatively highly but with the lowest scores generally attributed to the media for overstating risks.

⁷⁶ Slovic, P. (1987), “Perception of Risk”, *Science*, v. 236, pp. 280-285 and Slovic, P. (1993), “Perceived Risk, Trust and Democracy”, *Risk Analysis*, v. 13, pp. 675-685.

⁷⁷ Viscusi W.K. (1992) **Fatal Trade-Offs: Public and Private Responsibility for Risk**, New York, Oxford University Press.

⁷⁸ Centre for Health and Risk Communication, (2009), **Toxicologists’ Opinions on Chemical Risk: A Survey of the Society of Toxicology**, George Mason University

These results provide an insight into the views of professional toxicologists and, at the same time, highlight a fundamental challenge that faces the BPC Initiative and more generally faces risk regulators in Canada and elsewhere. Risk perceptions by the public do not necessarily correlate well with “unbiased” professional assessments of the same risks. This point is made in a number of the other references in this review but is highlighted starkly in the views of risk assessment professionals. For this reason, the “trust” elements of this review take on added importance and significance in assessing measures to improve Canada’s regulatory system for pesticides.

The literature indicates that in the areas of environmental, health, food and pesticide regulation, similar changes in regulatory frameworks are being made in a number of countries.⁷⁹ The traditional science-based approach, described as “scientific consensual”, is being modified in the direction of “participatory-transparent”. In the scientific consensual approach, regulators review scientific evidence and attempt to determine and manage objective risk. In the extreme form of this top-down model, regulators inform the public of risks and their regulation only following the completion of regulatory reviews. For a variety of reasons, generally referred to as the decline of public trust, this system is changing to one in which there is more widespread public and interest group involvement prior to making regulatory decisions. This literature has found that trust is a critical factor because a public that has become less trustful of risk regulators will become more risk averse, requiring that more resources be devoted to risk reduction.

The literature also indicates that various social and regulatory interactions will be more effective in a climate of trust and that risk perceptions among members of the public will be influenced by their confidence in regulators. Factors such as “perceived competence”, “objectivity”, “fairness” and “consistency” are typically related to trust levels.⁸⁰

Researchers in this field have proposed a concept of a “critical trust” that combines general trust with degrees of scepticism that can vary across the risk spectrum. The degree of scepticism increases with any negative public perception of the agency even if it is not directly risk-related. In their example, the British railway safety regulator generated negative sceptical reactions because of public dislike of elements of the railway system (“over-complicated and confusing rail structure”) not directly reflecting risks. Related research suggests that two factors – “accountability” and “a belief that the organization acts in the public interest” – are of primary importance in determining trust perceptions and relationships.⁸¹

Risk management controversies related to public trust and confidence and its determinants have developed in essentially all areas of risk management. The findings of the literature review suggest that many factors have combined to make risk management more difficult than in earlier time periods. Two lessons are suggested by the findings from this review. The first is that, in order for public confidence to be strengthened, institutional changes in the way risks are identified and managed should accompany (or, more likely, precede) the deployment of more effective communications strategies. The second is that risk managers should not expect that it will be straightforward to convince the public of the adequacy of reforms.

⁷⁹ Lofstedt, R. (2004), **Risk Communication and Risk Management in the 21st Century**, Washington, AEI-Brookings Joint Center for Regulatory Studies

⁸⁰ Poortinga, W. and N. Pidgeon (2003), “Exploring the Dimensionality of Trust in Risk Regulation” **Risk Analysis**, v. 23, no. 5, pp. 961-972. Walls, A. et al. (2004), “Critical Trust: “Understanding Lay Perceptions of Health and Safety Risk Regulation” **Health, Risk and Society**, v. 6, no. 2, pp. 133-150. Weyman, A. et al. (2006), “Exploring Comparative Ratings and Constituent Facets of Public Trust in Risk Regulatory Bodies and Related Stakeholder Groups”, **Journal of Risk Research**, v.9, no. 6, pp. 605-622.

⁸¹ Poortinga, W. and N. Pidgeon (2003), op cit. Walls, A. et al. (2004), op cit. Weyman, A. et al. (2006), op cit.

4. Continuing relevance and effectiveness of the BPC Initiative

-
1. Is there a continued rationale for the BPC Initiative as it is defined? To what extent:
 - (a) Does the rationale for the BPC Initiative reflect current needs?
 - (b) Does the BPC Initiative (and its constituent programs) continue to support federal and departmental objectives for the 6NR departments?
 - (c) Have the needs of stakeholders been addressed?
-

As noted earlier, the federal government has the authority to regulate the import, manufacture, sale and use of pesticides in Canada, and the PCP Act provides for the exercise of this authority. Implementation of many provisions in the new PCP Act, which received Royal Assent in December 2002, was enabled by BPC Initiative funding and the need for ongoing administration of these requirements was recognized by the conversion of BPC funding for many of the program elements to A-base at the end of the 2007/08.

Particular provisions of the PCP Act that continue to drive demand for the services included in the BPC Initiative include:

- Provision of MSDS (Section 8(3)).
- Re-evaluation of older pesticides (Section 16).
- Incident reporting (section 13).
- Conduct of special reviews (Sections 17 and 18).
- Public consultation regarding proposed registration and re-evaluation decisions (Sections 28 and 42).
- Notices of objection (Sections 35 to 40).
- Access to information in the Register of Pest Control Products (Sections 42-44).

While progress has been made against most of the intended medium-term outcomes from the BPC Initiative, their full achievement and the achievement of the intended final outcomes, will require sustained long-term effort. As well, the underlying needs for information on the environmental and health effects of pesticides, provision of risk reduction strategies for growers and registration of additional minor use products, and stakeholder and public engagement, are not static, meaning that the needs addressed by the BPC Initiative continue to be relevant. Needs of stakeholders are also being addressed, as demonstrated by the findings from the key informant interviews and stakeholder survey presented in other sections of this report. These findings also suggest that between two-thirds and three quarters of stakeholders who are aware of, or involved with, various program components of the BPC Initiative feel that it is having a positive impact on stakeholder confidence in pesticide regulation.

The design and delivery of the BPC Initiative also continues to support the objectives of the six participating departments and agencies, and achievement of federal whole of government outcomes. Strategic outcomes and expected results in the Departmental Performance Reports and Reports on Plans and Priorities for the two departments with the largest roles in the BPC Initiative, Health Canada and AAFC, make reference to the role of BPC-supported activities and their contribution to managing environmental and health risks. The strategic outcomes and expected results of EnvCan, DFO and NRCan that are engaged in research and monitoring activities, highlight the importance of these types of activities in identifying and managing environmental risks and sustainability. The CFIA highlights the protection of

food safety risks and sustainability of the plant resource base through the use of methods that include product monitoring surveys. In turn, the BPC partners' strategic outcomes are aligned with four Government of Canada Outcome Areas: a clean and healthy environment, healthy Canadians, strong economic growth, and an innovative and knowledge-based economy.

-
-
2. To what extent does the design of the BPC Initiative support achievement of its objectives?
-
-

The design of the BPC Initiative, particularly the horizontal approach to the research and monitoring and pest management streams, recognizes unique capabilities across the federal government. This approach taps into existing capabilities and fosters the coordination and integration of the partners' efforts to achieve the BPC Initiative's objectives.

The research and monitoring and pest management strategies streams of the BPC Initiative require coordinated work by at least two departments or agencies to achieve their intended outcomes. The research and monitoring stream plays to the strengths of EnvCan, DFO, NRCan and the CFIA in conducting research and monitoring work that is linked to their core mandates while making additional information and data available to HC-PMRA to aid regulatory decision-making. The key to the success of this approach is the effective functioning of the coordination and information sharing activities to ensure HC-PMRA's needs are understood and factored into the design of research and monitoring work, and the results shared with both HC-PMRA and the 6NR partners. HC-PMRA does not possess the capabilities and resources to undertake the research and monitoring work performed by its 6NR partners.

Similarly, the design of the pest management strategies stream plays to the respective capabilities and strengths of the AAFC PMC and HC-PMRA. The current level of capability was developed over the initial years of the BPC Initiative, and built upon the unique combination of AAFC's national network of research stations and farms and the regulatory knowledge and expertise of HC-PMRA. Both organizations had to add additional staff to undertake the tasks required for this stream and build their consultation and priority setting process, building on existing links to grower groups, provincial/territorial ministries, registrants and other stakeholders. The AAFC sites also had to obtain GLP (Good Laboratory Practice) accreditation to undertake residue studies. The involvement of growers, provincial pest management coordinators and other stakeholders in the setting of the PMC's priorities, particularly for the Minor Use Program, also means that it is highly responsive to the needs of growers across Canada. NRCan was also able to co-locate their coordinator for forestry minor use work at the PMC and thereby provide a linkage between the activities of the NRCan forestry research centres and the PMC.

5. Efficiency and Economy of the BPC Initiative

3. To what extent could the BPC Initiative be delivered with equal or better effectiveness, by other players and/or improved design?
-
-

It is unlikely that other organizations could deliver the various streams and program elements of the BPC Initiative with equal effectiveness, efficiency or economy, except possibly the activities of the AAFC's PMC.

HC-PMRA activities in the strengthened pesticide regulation and enhanced stakeholder and public engagement streams are mandated to the Agency by the PCP Act and are linked to, or integrated with, the broader range of regulatory activities undertaken by HC-PMRA. The knowledge of pesticides and expertise in assessing the health and environmental effects and efficacy of pesticides resident in the Agency is likely to be unique within Canada.

HC-PMRA's partners in the research and monitoring stream have been able to "add on" their pesticide related work to an existing infrastructure and knowledge base, and gain leverage on the relatively limited funding available for this BPC stream (between \$250,000 and \$1,000,000 per year per area of work). The economies gained through this approach mean that the BPC's research and monitoring stream could not be performed as cost-effectively at the national level by other public or private organizations in Canada.

The program leads for these activities at EnvCan, DFO, NRCan and CFIA all emphasized that the current levels of BPC research and monitoring activity provide a minimum level of data and information to support HC-PMRA's risk analysis work. Additional value-added could be obtained by expanding the breadth and depth of this information. Areas of opportunity they identified included the further development of collaborative and complementary approaches between EnvCan, DFO and NRCan; monitoring of the environmental effects of additional pesticides; research into the incidence and effects of mixtures of pesticides; and regular face-to-face meetings to review HC-PMRA's information needs and the findings from research and monitoring work. They also cautioned that any expansion of funding for research and monitoring work should enable the participating departments and agencies to add FTEs and thereby strengthen their capacity and the continuity of their work. In contrast, the funding provided under the BPC Initiative has a relatively high proportion of funding allocated to non-salary operating costs (for example, 66% of the funding allocated to research and monitoring in 2007/08).

With regard to the PMC, external stakeholders surveyed were more likely to express concerns about the timeliness of the PMC's risk reduction and minor use projects, with staff shortages and gaps being identified as a contributing factor. Data on actual versus allocated funding for the PMC's programs show a consistent pattern of spending shortfall, which is consistent with comments from program leads about delays in staffing the PMC and a significant build-up in the backlog of projects.⁸² This sub-optimal performance has been recognized by the PMC's management and actions taken to expand resource levels and reduce the backlog in recent years.

Some external stakeholders suggested that the work of the AAFC PMC could be performed by a third party organization. This is possible in theory but the practical reality is that a third party organization would likely encounter difficulties in securing sufficient sustainable funding (outside of sustaining funding from the federal government) and may be perceived to be less equitable or objective if it were operated by a particular industry group or partnership. More importantly, any change in funding and delivery structures would lead to interruptions and delays in project selection and performance as any new structure would have to establish the necessary infrastructure, obtain GLP (Good Laboratory Practice) accreditation, establish processes and working arrangements with HC-PMRA and staff its operations.

⁸² TBS Horizontal Initiatives Database, (www.tbs-sct.gc.ca/hidb-bdih/home-accueil-eng.aspx).

B. Progress towards intended final outcomes

The logic model for the BPC Initiative defines three longer-term outcomes from the mix of activities undertaken:

- Increased public and stakeholder confidence in the pesticide regulatory system.
- Improved competitive parity of agricultural and forestry sectors with regard to pest management.
- Improved protection of health and the environment.

The evaluation issues included one issue for each of these long-term outcomes:

1. Is there still a need to increase public and stakeholder confidence in the pesticide regulatory system?
2. Do the agricultural and forestry sectors still need to increase their competitive parity as it relates to pest management?
3. To what extent has there been an improvement in the protection of health and the environment as a result of the BPC research and monitoring activities?

Based on the findings from the various lines of enquiry it can be concluded that there is still a need to increase stakeholder and public confidence in the pesticide regulatory system, and to improve the competitive parity of the agricultural and forestry sectors. With regard to the third of the above three evaluation issues, continued research and monitoring work will be necessary to determine if the environmental presence and effects of pesticides is reduced, and protection of health and the environment enhanced.

The following sections summarize the key findings regarding progress toward the achievement of increased public and stakeholder confidence and recap the findings relating to competitive parity and protection of health and the environment.

1. Increased public and stakeholder confidence in the pesticide regulatory system

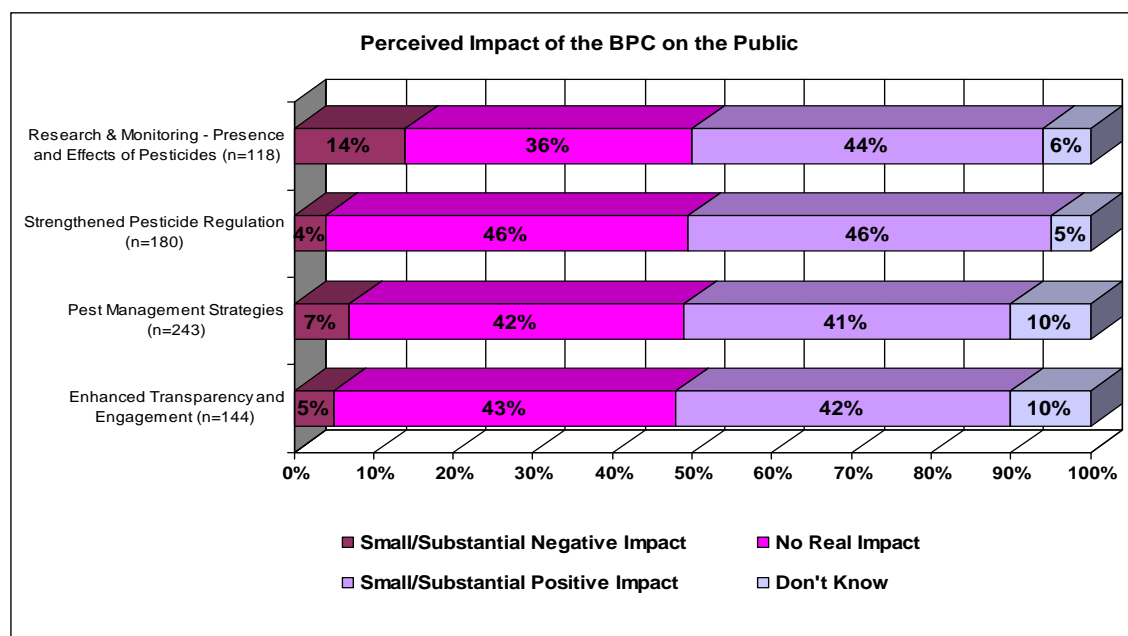
Survey participants were asked to rate the extent to which each of the four main streams of activity in the BPC Initiative had had an impact on public and stakeholder confidence at the outset of the survey. The ratings of the stakeholders' perceived impacts of the different streams on public confidence are summarized in Exhibit VIII-1. Note that the responses reflect the views of stakeholders about public confidence impacts gathered through key informant interviews and the survey and do not reflect data from the Canadian public.

Points to note from the exhibit:

- Stakeholders' judgements about the impact of the BPC Initiative on members of the public are quite consistent across all four streams of activity, with between 41% and 46% perceiving a "small" or "substantial" positive impact. Note that a large majority of these respondents believed the impact was "small" rather than "substantial".
- Similar proportions of respondents (between 36% and 46%) believed the various BPC streams have had "no real impact" on public confidence in pesticide regulation. This perception appears to reflect the primary focus on engagement with stakeholders in the BPC Initiative rather than the public per se.
- Only a small percentage perceived the BPC streams to have had a negative impact on public confidence to date.

Exhibit VIII-1

Ratings of the impact of the BPC Initiative on public confidence in pesticide regulation



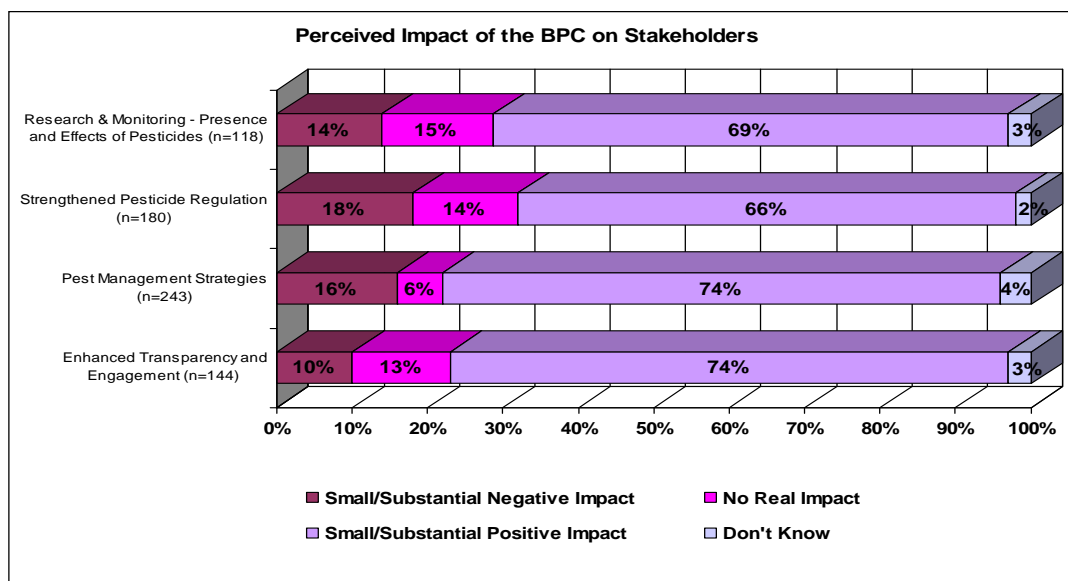
Base: Survey respondents who were aware of each of these BPC streams (Q.4a).

Exhibit VIII-2 summarizes the ratings of the impacts of the four BPC streams on stakeholder confidence in pesticide regulation. These ratings differ markedly from the ratings of perceived impacts on the public. In particular:

- Clear majorities of the respondents perceived the four BPC streams to have had either a “small” or “substantial” positive impact on stakeholder confidence (between 66% and 74%). A much smaller proportion of the survey respondents – of between 10% and 18% – believed the BPC streams to have had a negative impact on stakeholder confidence.
- Breakdowns by stakeholder type, which are indicative at best, suggest that:
 - Registrants and provincial and federal government representatives were more likely to rate the impact of research and monitoring as positive. Users were more likely to see this area of activity as having “no real impact”.
 - Provincial representatives were more likely to rate the impact of strengthened pesticide regulation as positive while registrants had a higher propensity to give a “no real impact” rating, and users and federal government representatives a negative impact rating.
 - Provincial representatives were also more likely to rate the impact of enhanced transparency and stakeholder engagement as positive.
 - Users and provincial government representatives were more likely to rate the impact of BPC activities related to pest management strategies as positive. The remaining users, however, were more likely to rate the impact as negative, as did the registrants.

Exhibit VIII-2

Ratings of the impact of the BPC Initiative on stakeholder confidence in pesticide regulation

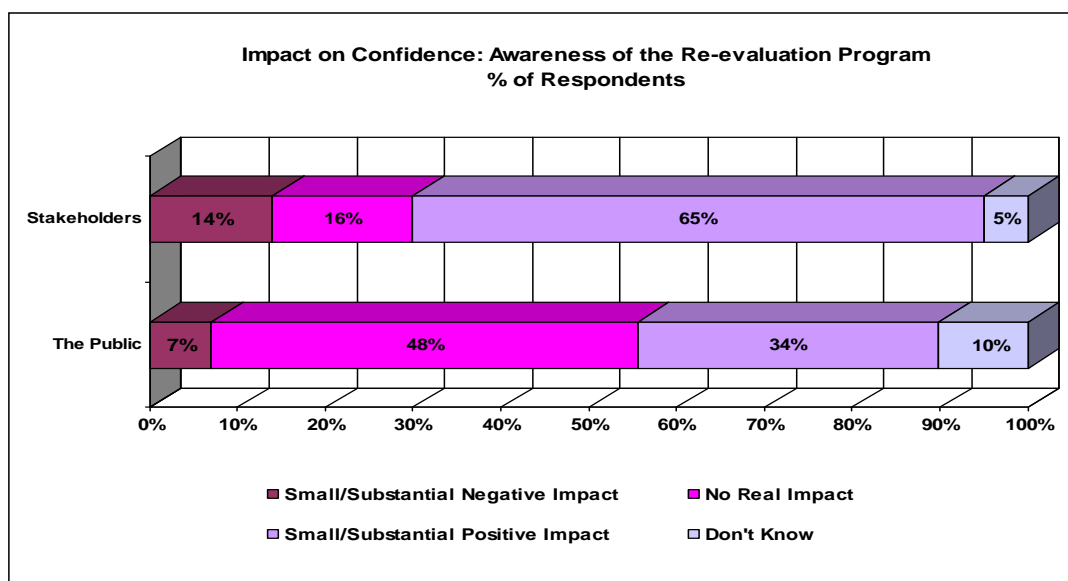


Base: Survey respondents who were aware of each of these BPC streams (Q.4b).

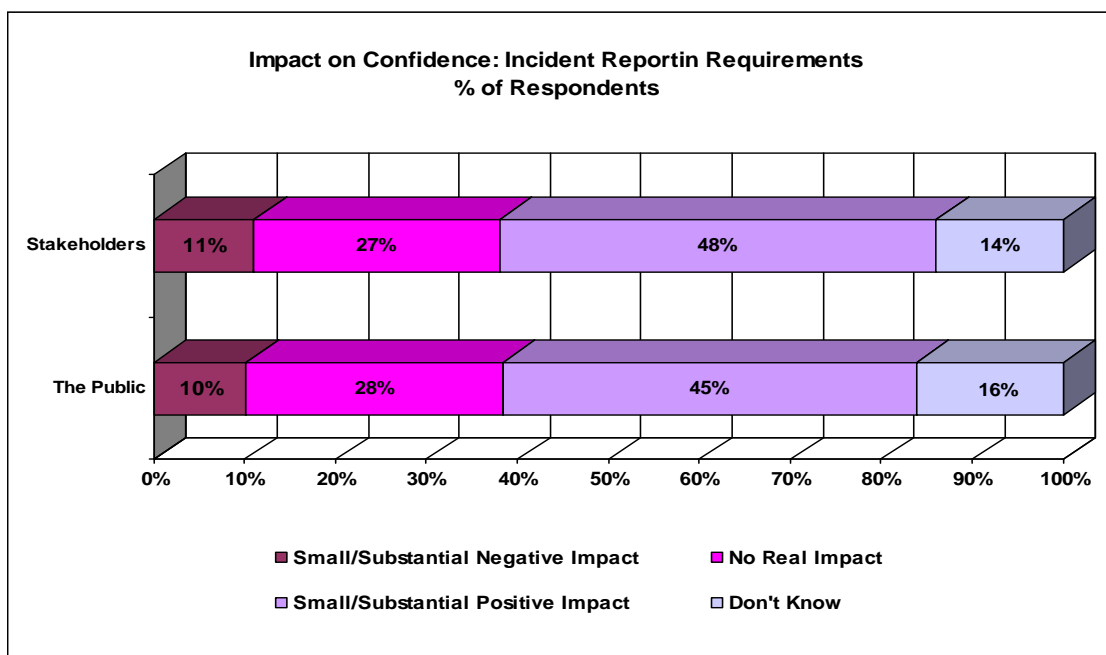
Stakeholders who participated in the survey were also asked to rate the impact of several specific program components on confidence – re-evaluation of older pesticides, the incident reporting system and enhanced transparency mechanisms – at other points in the online interviews. The results of these questions are shown in Exhibit VIII-3.

Exhibit VIII-3

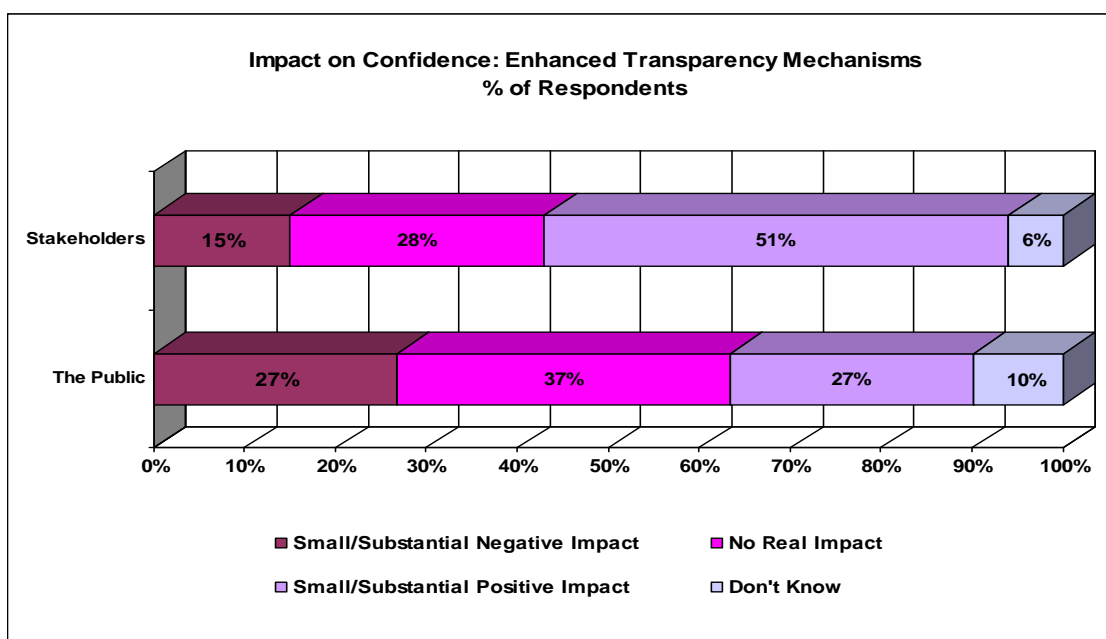
Ratings of the impact of selected components of the BPC Initiative



Base: Respondents who reported having at least some knowledge of the re-evaluation program (Q.C3); n=172.



Base: Respondents who reported having at least some knowledge of the incident reporting system (Q.D6); n=155.



Base: Respondents who reported having at least some knowledge of the re-evaluation program (Q.B2); n=142.

The information in Exhibit VIII-3 suggests:

- With regard to re-evaluation – which is a vehicle for ensuring that pesticides on the market meet modern scientific and regulatory standards and where the decision-making process includes opportunities for stakeholders and members of the public to comment on proposed re-evaluation decisions – the ratings of the impact on stakeholder confidence are almost identical to those for

the overall strengthened pesticide regulation stream. The pattern of perceived impacts on public confidence, however, is more conservative, with a slightly higher incidence rate of negative, “no real impact” and “don’t know” ratings.

- Ratings of the impact of the incident reporting system are almost identical between stakeholders and the perceived impacts on the public. Compared to the overall ratings of the impacts of the strengthened pesticide regulation stream, the incident reporting system was more likely to be viewed as having “no real impact” on stakeholders (27% versus 14%), and more likely to have had a negative impact on public confidence (10% versus 4%). “Don’t know” ratings were also higher for the ratings of the incident reporting system compared to the overall strengthening regulation stream (14% versus 2% for stakeholder ratings and 16% versus 5% for perceived impacts on the public).
- Respondents were also asked the reasons for their ratings of the impact of HC-PMRA’s incident reporting system on public and stakeholder confidence. These answers suggest:
 - Reporting of incidents may be, or is, useful but stakeholders question if anything has changed as a result.
 - Low public awareness of HC-PMRA and the incident reporting system reduces the potential impact of measures to improve transparency.
 - Public confidence may be weakened if reports of incidents are interpreted to say that HC-PMRA’s registration (and re-evaluation) reviews are inadequate.
- Ratings of the effectiveness of the enhanced transparency mechanisms on increasing confidence differ from the ratings of the impact of the overall transparency and engagement stream of the BPC Initiative. This comparison suggests that, while stakeholders generally believe the overall impact of enhanced transparency will be positive, they are more likely to believe that the mechanisms available for that purpose are “neither effective nor ineffective” or are more likely to be perceived by stakeholders to have a negative effect on public confidence.

Survey respondents were also asked to identify factors that they thought contributed most to the current state of public and stakeholder confidence. Factors perceived to have contributed most to developing or maintaining public confidence were improved communications with stakeholders and, to a lesser extent, with the public, improved transparency and openness, more effective research efforts to support risk analysis, and better harmonization with other jurisdictions. Offsetting factors related to perceptions among stakeholders of excessive closeness with industry groups, insufficient use of the precautionary principle, less transparency than is appropriate and not enough work by the Agency and its federal government partners related to environmental health issues.

In terms of possible improvements, many respondents called for more effective communication, particularly with the public, noting that, for example, “the general public barely knows you exist” and “the public should have a high degree of confidence but I think they are mostly unaware”. Other respondents referred to the influence of jurisdictional issues on public confidence, that is, the difficulty of building public confidence in a system when provincial and municipal levels apply restrictions on pesticide use over and above federally-determined conditions of product use.

2. Improved protection of health and the environment

The principal means of achieving improved protection of health and the environment are through the research and monitoring, and strengthened pesticide regulation streams of the BPC Initiative, which were examined in Chapters IV and V.

As noted in the conclusions to these chapters, the breadth and depth of information on the environmental presence and effects of pesticides has been strengthened and the availability of this information contributes to better informed risk assessments and risk mitigation strategies by HC-PMRA. Work undertaken by CFIA has provided deeper insights into the safety of food, and fertilizers and fertilizer-pesticide combinations, and led to initiatives by CFIA to improve the rate of compliance of these products with product guarantees and standards. Additionally, significant progress has been achieved with the implementation of the major measures under the strengthened pesticide regulation stream (re-evaluation, incident reporting system and strengthened requirements for formulants, but not the introduction of MSDS requirements) thus improving the degree to which pest control products on the market are compliant with current regulatory standards.

The rate of progress in the above areas suggests, by inference, that the foundation for achieving improved protection of health and the environment has been established. Further, long-term research and monitoring work will be necessary to determine if the environmental presence and effects of pesticides is reduced, and protection of health and the environment enhanced.

3. Improved competitive parity of the agricultural and forestry sectors with regard to pest management

As was noted in the conclusions to Chapter VII on the pest management stream of the BPC Initiative, the increased rate of registration of minor use products and development of reduced risk pest strategies should have contributed to an improvement in competitive parity between Canadian and U.S. growers by increasing the number of minor use products and pest management options available to Canadian growers. The extent to which the “technology gap” – the difference in access to pesticide products and approved uses in Canada compared to access for growers in other countries, most notably the U.S. – is narrowed as a result of these additional minor use registrations cannot be readily measured due to the need to consider combinations of active ingredients, end-uses and MRLs as well as the dynamic nature of growing conditions and pest control issues encountered by growers.

Both the internal and external key informants interviewed indicated that they had observed some improvement in competitive parity between Canada and the U.S. as a result of the Risk Reduction and Minor Use Programs. The main evidence in support of this view was the increased number of products and tools available to growers. Many external stakeholders were concerned that competitive gains realized through the Minor Use Program may be offset by re-evaluation decisions that result in the removal of older pesticides or more restrictive conditions of use (although such conditions should also improve the management of health and/or environmental risks). Support for this view was also apparent in the survey findings although a relatively large minority of respondents provided “don’t know” responses when asked to rate the effectiveness of the activities involved in the pest management strategies stream in improving competitive parity.

These findings suggest that, while the volume of minor use registration achieved by the Pest Management Centre (and the volume of such projects in the pipeline) means that the range of pest control options open to many growers should have increased, there is a significant backlog of demand for additional minor uses. Beyond this, a lack of readily available data on the scale and structure of the “technology gap” makes it difficult to determine whether this gap is narrowing, stable or growing.

C. Implementation of formative evaluation recommendations

The Management Action Plan for the formative evaluation committed the partners in the BPC Initiative to undertake the following actions. Our assessments of the extent to which these planned actions have been acted upon are shown against each of these.

- **Adopt a revised logic model as part of the preparation of a revised Results-Based Management and Accountability Framework (RMAF).**
A revised logic model for the BPC Initiative has been developed and was used to guide the planning and conduct of the summative evaluation. A revised RMAF has not been developed.
- **Adopt a performance measurement framework in tandem with the revised logic model which:**
 - Identifies and defines a concise set of measures for elements of the revised logic model;
 - Replaces current performance measurement strategies of the AAFC-HC-PMRA, JMC and 5NR (now 6NR) WG;
 - Is integrated with the performance measurement strategies of partner departments/agencies;
 - Shows responsibility for data collection and reporting; and
 - Focuses on BPC outcomes and generating the data required for the summative evaluation.

A draft performance measurement framework has been developed as an adjunct to the development of the revised logic model but has yet to be implemented.

- **Develop an integrated work plan for the research and monitoring elements that are the joint responsibility of the 6NR departments and agencies.**
An integrated work plan for the research and monitoring stream of the BPC Initiative was prepared by the 6NR partners. This work plan was, and continues to be, used to guide the planning for, and conduct of, the research and monitoring activities of each of the 6NR partners. Additionally, HC-PMRA prepares annual updates on its prioritised needs for research and monitoring information, and shares these priorities with the 6NR partners to facilitate the ongoing planning and management of their research and monitoring projects.
- **HC-PMRA will engage all partners in the planning of the summative evaluation and formulation of a strategy for supporting the pesticide regulatory system beyond the current (BPC) funding agreement.**
Partners in the BPC Initiative were all actively involved in the planning for the summative evaluation, with participation from representatives of the various program elements of the Initiative plus the evaluation groups of the departments and agencies. However, work on the formulation of a strategy regarding the continuation of BPC activities beyond the term of the then current funding agreement was put on hold until the summative evaluation is completed. The findings from the summative evaluation will be used to inform the development of this strategy.
- **Establish a committee of Directors General (DGs) from each of the 6NR participants to guide the future strategy for cross-government pest management issues, which will include not only research and monitoring but other science and technology programs.**
A DG-level committee was established to provide strategic direction to the 6NR Working Group and provide a senior-level linkage for the horizontal work of the BPC Initiative into the planning and management activities of the 6NR departments and agencies. The time taken to develop and

sign-off on the MOU creating the committee meant that the first meeting of the DG-committee did not take place until January 2009 and the anticipated benefits of their involvement have yet to be fully realized. As noted under the previous bullet, work on the future strategy for cross-government pest management issues was put on hold until the summative evaluation is completed

In brief, the DG committee is more strategic in nature, providing general direction to the WG, and providing a mechanism to feed into 6NR department and agency activities through senior managers.

➤ **For HC-PMRA and AAFC to include the BPC Initiative as a strategic consideration in their strategic communications frameworks.**

Communication of information relating to the nature of and results from the various BPC streams is incorporated into external communications for each of the various program components, as opportunities arise. As such, the programs and activities are not referred to under a “BPC Initiative brand”, which was not the intention of this recommendation from the formative evaluation. Instead, the intention was to increase the flow of information regarding the performance of program components that contribute to the various BPC outcomes and thereby increase awareness of the changes made to strengthen the pesticide regulatory system. Information about the performance of the various program components of the BPC Initiative is made available, for example, in the material published in HC-PMRA’s annual report, and is the subject of information disseminated using such communications vehicles as the Pest Management Centre’s electronic newsletter and the electronic dissemination of proposed and final re-evaluation and registration decisions to stakeholders who have registered their interest in receiving such material through the HC-PMRA website.