Health Canada and the Public Health Agency of Canada
Santé Canada et l'Agence de la santé publique du Canada

Evaluation of the Pesticide Program 2010-2011 to 2013-2014

Prepared by
Office of Audit and Evaluation
Health Canada and the Public Health Agency of Canada

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List of Acronyms

AAFC	Agriculture and Agri-food Canada
ADM	Assistant Deputy Minister
AMC	Agency Management Committee
AMP	Administrative Monetary Penalties
CBSA	Canada Border Services Agency
CESD	Commissioner of the Environment and Sustainable Development
CFIA	Canadian Food Inspection Agency
CLSROD	Compliance, Laboratory Services, and Regional Operations Directorate
CMP	Chemicals Management Plan
CVMA	Canadian Veterinary Medical Association
DFO	Department of Fisheries and Oceans Canada
DG	Directors General
EAD	Environmental Assessment Directorate
ED	Executive Director
EDO	Executive Director's Office
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency
FCSAP	Food and Consumer Safety Action Plan
FPT	Federal-Provincial-Territorial
HED	Health Evaluation Directorate
IRP	Incident Reporting Program
MOU	Memorandum of Understanding
MRL	Maximum residue limit
NAFTA	North American Free Trade Agreement
NGO	Non-governmental organizations
NPCP	National Pesticide Compliance Program
OECD	Organisation for Economic Co-operation and Development
OSC	Operations Sub-Committee
PAA	Program Alignment Architecture
PCPA	*Pest Control Products Act*
PCRAD	Policy, Communications, and Regulatory Affairs Directorate
PMAC	Pest Management Advisory Council
PCPR	Pest Control Product Regulations
PMF	Performance Measurement Framework
PMS	Performance Measurement Strategy
PMRA	Pest Management Regulatory Agency
POR	Public Opinion Research
PPE	Personal protective equipment
RAPB	Regions and Programs Bureau
RCC	Regulatory Cooperation Council
RD	Registration Directorate
SMC	Science Management Committee
SPFBOD	Strategic Planning, Financial and Business Operations Division
SWI	Single Window Initiative
US	United States
VAD	Value Assessment Division
VRD	Value Assessment and Re-Evaluation Management Directorate

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Executive Summary

The evaluation of the Pesticide Program focussed on the five-year period ending December 2014, although data outside this timeframe is included as appropriate. The evaluation was undertaken in fulfillment of the requirements of the *Financial Administration Act* and the Treasury Board of Canada's *Policy on Evaluation* (2009).

Evaluation Purpose and Scope

The purpose of the evaluation was to assess the relevance and performance (effectiveness, efficiency, and economy) of the Pesticide Program. The Pesticide Program consists of all regulatory activities carried out by the Pest Management Regulatory Agency (PMRA) of Health Canada, as well as pesticide-related activities carried out by the Regions and Programs Bureau (RAPB) of Health Canada. Although previous evaluations have examined aspects of Health Canada's regulatory activities for pesticides, this evaluation was the first time that the Pesticide Program as a whole was evaluated.

Program Description

The Pesticide Program consists of pre-market and post-market activities. Pre-market activities include the science-based assessment and registration of pesticides to ensure that these products do not pose unacceptable risks to human health and the environment, and have social and economic value, when used according to label directions; this process also includes the determination of maximum residue limits (MRL) for pesticides that are expected to remain on food products. Post-market activities include re-evaluations and special reviews of registered pest control products to ensure that they continue to meet modern scientific standards and their risks and value continue to remain acceptable; analysis of incident reports and sales reports; and compliance and enforcement activities, including compliance promotion, verification monitoring, inspections, investigations, and enforcement. In addition, outreach activities are carried out to support awareness building among stakeholders and to facilitate public access to relevant information in relation to pest control products and responsible pesticide use.

CONCLUSIONS – RELEVANCE

Continued Need

Pesticides offer important benefits to people, such as the control of agricultural pests and of organisms that cause disease in crop commodities, as well as control of pests in sectors such as forestry, industrial settings, buildings and other structures, and domestic uses. However, despite their benefits, pesticides can have detrimental effects on both human health and the environment if not used properly. New information on the impact of pesticides on human health and the environment is being continually generated, and scientific standards are continually evolving. For these reasons, the ongoing regulation of pesticides is required to ensure that the risks to human health and the environment associated with the use of these products remain acceptable and are appropriately managed.

Alignment with Government Priorities

The Pesticide Program is aligned with the priorities of the federal government, as they have been articulated in major federal initiatives in recent years, and with Health Canada's current strategic outcome #2, that "health risks and benefits associated with food, products, substances, and environmental factors are appropriately managed and communicated to Canadians."

Alignment with Federal Roles and Responsibilities

The activities carried out under the Pesticide Program are consistent with federal responsibilities under the *Pest Control Products Act* (PCPA). There is, however, concern among industry that provincial/territorial and municipal activities, such as restrictions on pesticide use and Ontario's plans to reduce the use of neonicotinoids in agriculture, can sometimes be inconsistent with regulatory decisions made by the PMRA.

CONCLUSIONS – PERFORMANCE

Implementation

The Pesticide Program addressed several interrelated challenges and issues during the period being evaluated (2010-11 to 2014-15), including the increased complexity and volume of pesticide regulatory activities, increased globalization and international trade, and evolving science. These issues have been addressed through emphasizing international collaboration and work sharing, and will be further addressed through pursuing a new cost recovery framework and initiating efforts to modernize electronic business support systems.

With respect to its core regulatory activities, during the period covered by the evaluation, PMRA implemented several measures to improve the efficiency and clarity of the submission review and registration process. However, there are still opportunities for further improvements in some areas, including clarifying data requirements and improving the electronic submission process.

PMRA has made progress in initiating and completing cyclical re-evaluations covering pesticides registered since 1995, and re-evaluations covering 401 older pesticides registered prior to 1995. Although the Agency has taken steps to increase efficiencies in the re-evaluation process, there are challenges to completing re-evaluations in a timely manner, and performance standards for their completion have not been formally adopted. Special reviews are initiated if there are reasonable grounds to believe that the health or environmental risks of a product are, or its value is, unacceptable, or when a member country of the OECD prohibits all uses of an active ingredient for health or environmental reasons. As a result, special reviews can arise at any time and, as such, are difficult to account for in planning. Large numbers of special reviews in recent years have contributed to delays in re-evaluations.

Some industry and other stakeholders do not know how PMRA uses the information collected through incident and sales reporting, suggesting opportunities to improve communication to stakeholders about these elements of the Pesticide Program. Similarly, there are opportunities to improve communication on compliance and enforcement policy, activities, and results.

While the Pesticide Program currently conducts some outreach targeting the public, it is unknown whether these activities are reaching and affecting their intended audience. PMRA plans to include public outreach activities in its next strategic plan.

The Pesticide Program collaborates with international, federal, and provincial/territorial partners and consults with industry and non-industry stakeholders through a variety of engagement activities. While partners agree on the value of collaboration, some non-governmental organizations (NGOs) and industry stakeholders are dissatisfied with the Program's efforts at consultation and engagement (for example, in terms of responsiveness, timeliness and transparency).

Achievement of Expected Outcomes (Effectiveness)

PMRA's submission review and registration process is intended to ensure that products registered in Canada do not pose unacceptable risks to health and the environment, and have social and economic value, when used according to label directions. The available data on completed new pesticide submissions suggest that industry is generally meeting regulatory requirements for new pesticides, in large part due to the iterative and collaborative process between PMRA and industry. Of the Category A and B submissions completed between 2009–10 and 2014–15, only 0.03% were rejected and 1.3% were withdrawn.

The re-evaluation program is an important mechanism for helping to ensure that pesticides in the marketplace continue to meet modern scientific standards. However, re-evaluations can take considerable time and effort to complete, and it is unclear how systematically the Program monitors and enforces compliance with those decisions.

There is no evidence to support conclusions on the extent to which outreach activities have contributed to pesticide safety awareness among the public. There is some evidence, albeit limited, that specific outreach and compliance promotion initiatives have contributed to increased pesticide safety awareness among professional audiences and regulated parties.

Overall, although the evaluation findings suggest some areas for improvement, pesticide regulatory activities across the continuum of pre-market and post-market actions contribute to protecting the health and safety of Canadians and the environment. Notable areas where effectiveness could be improved include timeliness of re-evaluations, and outreach and communication to key stakeholders and the public.

Demonstration of Economy and Efficiency

The Program has introduced a variety of measures across program areas to increase efficiencies, such as simplifying and streamlining internal processes and documentation; pursuing modernization of electronic business systems; introducing new tools, technologies, and training; and focusing and targeting re-evaluations. Over the last five years, the planned spending of the Pesticide Program has declined, and funding cuts and the need to re-allocate resources in response to unanticipated issues have presented challenges for some Program activities, particularly progress on re-evaluations.

Program governance is generally seen as effective, and PMRA has plans to develop a logic model and performance measurement strategy (PMS) in the near future. While the Program's approach to performance measurement has historically focused on activities and outputs, a more robust approach should include greater emphasis on outcome measures that speak to its role in protecting the health and safety of Canadians and the environment, relating to the use of pesticides.

RECOMMENDATIONS

Recommendation 1:

PMRA should address the lengthy timelines involved in the re-evaluation process through establishing enhanced work plans that are complete and up-to-date. Progress against these work plans should be published regularly (e.g., annually).

Re-evaluations of registered pesticides take a considerable length of time to complete, and PMRA is facing increasing pressure to conduct cyclical re-evaluations. Although PMRA has taken steps to increase efficiencies in the re-evaluation process and has established internal milestones for completing re-evaluations, establishing enhanced work plans and reporting to the public on its success in implementing them could help to address issues with the current timelines for re-evaluations.

Recommendation 2:

The Pesticide Program should take steps to improve communication to key stakeholders with respect to compliance policy, activities, and outcomes, and with respect to its use of incident and sales reporting data.

Industry and other stakeholders expressed a desire for more information from the Program in several areas, including compliance policy, activities, and outcomes, as well as the Program's use of incident and sales reporting data. Improving communication in these areas should be considered as Health Canada implements the Regulatory Transparency and Openness Framework.

Recommendation 3:

The Pesticide Program should move forward with plans to enhance public outreach activities to increase the awareness and understanding among Canadians of its role and of the risks and safe use of pesticides, and measure the outcomes of related activities.

While the Pesticide Program currently conducts some outreach targeting the public, it is unknown whether these activities are reaching and affecting their intended audience. PMRA plans to include outreach activities in its next strategic plan. As part of this work, it will be important to measure the outcomes of the outreach activities.

Recommendation 4:

As PMRA moves forward with plans to develop a logic model and performance measurement strategy, consideration should be given to reporting on outcomes to a greater extent than has been done in the past.

The Program's approach to performance measurement has, to date, been focused on reporting information on activities, outputs, and performance against service standards. A more robust and meaningful approach to performance measurement could include greater emphasis on outcome measures that speak to the Program's role in protecting the health and safety of Canadians and the environment relating to the use of pesticides.

Management Response and Action Plan
Evaluation of the Pesticide Program - 2010-2011 to 2013-2014

Recommendations	Response	Action Plan	Deliverables	Expected Completion Date	Accountability	Resources
Recommendation 1 *PMRA should address the lengthy timelines involved in the re-evaluation process through establishing enhanced work plans that are complete and up-to-date. Progress against these work plans should be published regularly (e.g. annually).*	**Agree.** Revised work plans will be published in early 2016, and will be updated on a yearly basis. These will include clear expectations for timelines, as well as the expected publication date of the final re-evaluation decision. PMRA's current approach to re-evaluation favours receipt of new information from any and all stakeholders even where this material might arrive very late in the review process. While this approach helps ensure re-evaluations are based on the latest and most complete set of information available, it often delays the final decision as PMRA must then reconsider its assessment. To address this challenge and to meet pre-established timelines, PMRA will consult on and develop a policy with clear rules and criteria for submitting information in order to make timely decisions.	Publish annual work plans for the re-evaluation program (including cyclical re-evaluations and special reviews) to the final decision stage and report on progress in PMRA's annual report to Parliament. Develop a policy to ensure the timely submission of information in support of re-evaluation decisions	Published annual work plan Published consultation document on proposed rules and criteria for submission of information in support of re-evaluations. Publication and implementation of final policy document	February, 2016 March 2016 August 2016	DGs (VRD,HED,EAD) DG,VRD DG,VRD	No additional resources are required

Recommendations	Response	Action Plan	Deliverables	Expected Completion Date	Accountability	Resources
Recommendation 2 *The Pesticide Program should take steps to improve communication to key stakeholders with respect to compliance policy, activities, and outcomes, and with respect to its use of incident and sales reporting data.*	**Agree.** In 2016, PMRA will identify further opportunities to improve communication with stakeholders. Recognizing the importance to promote greater transparency in the regulation of pesticides, PMRA acknowledges that current communication of information can be improved and is constantly striving to find ways to more effectively convey information.	PMRA is in the process of developing a 5 year Strategic Plan, including a strategy for communication and outreach activities. Develop approaches to improve communications regarding compliance policy, activities, and outcomes, and with respect to its use of incident and sales reporting data.	Published PMRA 5 year Strategic Plan, including a strategy for communication and outreach activities. Implementation plan for improving communication in these areas, including measuring the impact of activities	March 2016 July 2016	DG, PCRAD DG's, CLSROD,HED & VRD	No additional resources are required
Recommendation 3 *The Pesticide Program should move forward with plans to enhance public outreach activities to increase the awareness and understanding among Canadians of its role and of the risks and safe use of pesticides, and measure the outcomes of related activities.*	**Agree.** PMRA agrees that outreach to Canadians can improve. In 2016, PMRA will identify further opportunities to enhance communication to Canadians, including on the Agency's regulatory role and the risks and safe use of pesticide products. In addition, the PMRA recognizes the importance of developing a robust method of measuring and monitoring the full extent of its outreach activities and resources used; and addressing the impact of its outreach investments and activities.	The PMRA is in the process of developing a 5 year Strategic Plan, including a strategy for communication and outreach activities. Develop approaches to improve outreach to Canadians that includes the monitoring and measurement of outreach activities, and resources used, and addresses the impact of outreach investments.	Published PMRA 5 Year Strategic Plan, including communication and outreach activities Implementation plan for improving outreach in these areas, including measuring the impact of activities	March 2016 July 2016	DG, PCRAD DG, PCRAD	No additional resources are required

Recommendations	Response	Action Plan	Deliverables	Expected Completion Date	Accountability	Resources
Recommendation 4 *As PMRA moves forward with plans to develop a logic model and performance measurement strategy, consideration should be given to reporting on outcomes to a greater extent than has been done in the past.*	**Agree.** In response to recent audit findings, Treasury Board feedback on Health Canada's PAA/PMF, the departmental performance measurement initiative and the pending implementation of a new cost recovery regime, it is timely for the PMRA to review its performance measurement strategy. A joint PMRA/RAPB Performance Measurement Framework (PMF) has recently been developed for the Pesticide Compliance and Enforcement Program. The PMRA will include more outcome-based and service-related measures in its new Performance Measurement Framework.	PMRA has recently launched an initiative to develop a performance measurement strategy	A Performance Measurement Strategy, including: • A renewed Pesticide Program's Program Activity Architecture (PAA) • A Pesticide Program Logic Model as well as logic models for the business lines of the Pesticide Program. • A Performance Measurement Framework with expected results, key performance indicators, and measures for outcomes, outputs, and efficiency	April 2016	Director, SPFBOD	Existing resources plus a contract of $50 K

1.0 Evaluation Purpose

The purpose of the evaluation was to assess the relevance and performance (effectiveness, efficiency, and economy) of the Pesticide Program for the period of 2010–11 to 2014–15. The Pesticide Program consists of all regulatory activities carried out by the Pest Management Regulatory Agency (PMRA) of Health Canada, as well as pesticide-related activities carried out by the Regions and Programs Bureau (RAPB) of Health Canada. Although previous evaluations have examined aspects of Health Canada's regulatory activities for pesticides, this evaluation was the first time that the Pesticide Program as a whole was evaluated.

The evaluation was conducted in accordance with the Treasury Board Secretariat of Canada's 2009 *Policy on Evaluation* and the *Financial Administration Act*. The evaluation is part of the Five-Year Evaluation Plan of Health Canada and the Public Health Agency of Canada.

2.0 Program Description

2.1 Program Context

The PMRA was established in 1995 as a Branch of Health Canada, and since then has been responsible for the regulation of pest control products under the *Pest Control Products Act* (PCPA). Through administering the Act and its associated regulations, the Minister's primary objective is to prevent unacceptable risks to people and the environment from the use of pest control products imported into, sold, or used in Canada (GoC, 2014, sec. 4(1)). Within Health Canada's Program Alignment Architecture (PAA), the Pesticide Program supports strategic outcome #2: "Health risks and benefits associated with food, products, substances, and environmental factors are appropriately managed and communicated to Canadians" (Health Canada, 2014a).

While the Pesticide Program as a whole has never previously been evaluated, aspects of pesticide regulatory activities have been examined in past evaluations, namely evaluations of Building Public Confidence in Pesticide Regulation and Improving Access to Pest Management Products (2011); the Chemicals Management Plan (CMP) (2011 and 2014); the Consumer Products component of the Food and Consumer Safety Action Plan (FCSAP) (2013); the Evaluation of the Agricultural Regulatory Action Plan under Growing Forward (2014); and the Evaluation of the Food Safety and Nutrition Quality Program (2014).

An external audit by the Commissioner of the Environment and Sustainable Development (CESD), an internal Health Canada audit, and the seven-year statutory review of the PCPA were underway concurrently with this evaluation.

2.2 Program Profile

The Pesticide Program consists of pre-market and post-market activities.

- **Pre-market activities** include the science-based assessment and registration of pesticides to ensure that these products do not pose unacceptable risks to health and the environment, and have social and economic value, when used according to label directions. This process also includes the determination of maximum residue limits (MRLs) for pesticides that are expected to remain on food products.
- **Post-market activities** include re-evaluations and special reviews of registered pesticide products to ensure that they continue to meet modern scientific standards and their risks and value continue to remain acceptable; analysis of incident reports and sales reports; and compliance and enforcement activities, including compliance promotion, verification monitoring, inspections, investigations, and enforcement. In addition, outreach activities are carried out to support awareness building among stakeholders and to facilitate public access to relevant information in relation to pest control products and responsible pesticide use.

The main partners in the Pesticide Program are the PMRA and the RAPB of Health Canada. Within the PMRA, numerous entities have responsibilities for carrying out the activities of the Pesticide Program. These include the Executive Director's Office (EDO); the Registration Directorate (RD); the Health Evaluation Directorate (HED); the Environmental Assessment Directorate (EAD); the Value Assessment and Re-Evaluation Management Directorate (VRD); the Policy, Communications, and Regulatory Affairs Directorate (PCRAD); the Compliance, Laboratory Services, and Regional Operations Directorate (CLSROD); and the Strategic Planning, Financial and Business Operations Division (SPFBOD). A summary of their roles and responsibilities is provided in Table 1 on the following page.

Through offices in five regions, RAPB supports the compliance and enforcement activities of the Pesticide Program by carrying out inspections, undertaking selected compliance promotion activities, and taking enforcement action on violations of the PCPA, as required. RAPB's regional offices are also involved in conducting outreach activities.

Table 1: Roles and responsibilities of PMRA directorates

Directorate	Roles and responsibilities
Executive Director's Office	The EDO takes a leadership role in providing senior level management of the Agency, in pursuit of its mandate, mission, strategic direction, and operational goals and objectives. It also liaises with internal and external partners.
Registration Directorate	The RD screens new pesticide product submissions prior to the evaluation for health, environmental, and value considerations, in order to determine that submissions are complete and meet the format, content, and fee requirements of the Agency. The RD supports integrated scientifically based registration decisions; manages registration issues and determines whether products are subject to registration; manages submission and product information; and coordinates the submission management process, including the coordination of science reviews. In addition, the RD conducts chemistry reviews and is responsible for reviewing Category C submissions. The RD prepares documentation to meet PCPA transparency requirements and develops processes and procedures to facilitate work sharing and the harmonization of pesticide reviews.
Health Evaluation Directorate	The HED evaluates data and other documentation submitted on pesticides (new and older products) to identify possible human health effects, and to establish the levels at which humans can be exposed to the products without any harm. Areas of focus include toxicology, metabolism, occupational exposure, and food residue assessment. The HED also maintains an incident reporting (i.e., surveillance) capability and is responsible for the regulatory process and development of corresponding documents related to the specification of MRLs under the PCPA.
Environmental Assessment Directorate	The EAD evaluates data and other documentation submitted on the environmental toxicology of products, as well as their environmental fate (i.e., what happens to the pesticide once it enters the environment). To address environmental concerns that may arise from the intended use of a product, the EAD also makes recommendations for restrictions on use that would lessen risk. This could include label statements outlining buffer zones, timing, and frequency of applications, and the rate at which the product can be applied, among other restrictions.
Value Assessment and Re-Evaluation Management Directorate	The VRD is composed of the Value Assessment Division (VAD) and the Re-evaluation Management Program. VRD is responsible for two main areas: the assessment of value for new submissions and products undergoing re-evaluation and for the coordination of re-evaluations and special reviews. VRD also coordinates minor use submissions, emergency registrations and research authorizations, and notifications and maintains several databases including the Pesticide Label Database, PMRA Sales Database and the Canadian Grower Priority Database. The VAD determines a pesticide's actual or potential contribution to pest management, which includes an assessment of the product's efficacy, effects on host organisms, health, safety and environmental benefits, and social and economic impacts. The value assessment confirms the use pattern under which a product must be used to provide effective control of pests without being excessive. The value assessment also provides the basis for subsequent human health and environmental risk assessments by other directorates. The Re-evaluation Management Program is comprised of coordinators and evaluators, who plan, coordinate and conduct post-market assessments (re-evaluations and special reviews).
Policy, Communications and Regulatory Affairs Directorate	The PCRAD develops federal policy and regulations for pest control products, and works with other government bodies, grower groups, research facilities, and industry to facilitate information exchange. In this capacity, the PCRAD is responsible for the publication of regulatory decision documents for consultation and for coordinating outreach activities.
Compliance, Laboratory Services, and Regional Operations Directorate	The CLSROD is responsible for planning and coordinating the national compliance program. The PMRA's Laboratory Services supports the Agency's compliance inspections and microcontaminant, guarantee, and misuse inspection programs through conducting approximately 1,500 guarantee, formulation, and residue analyses per year. In addition, laboratory scientists evaluate product chemistry data that companies must provide as part of their submissions for registration.
Strategic Planning, Financial and Business Operations Directorate	The SPFBOD provides business management support services to the PMRA, including strategic planning, financial management (including cost recovery), continuous learning, audit and evaluation, and all facilities-related activities.

2.3 Expected Outcomes

The evaluation measured progress towards the following expected outcomes:

- industry meets Canadian regulatory requirements for new pesticides
- pesticides in the marketplace continue to meet modern scientific standards
- outreach/compliance promotion activities contribute to pesticide safety awareness
- the Program protects the health and safety of Canadians and the environment, relating to the use of pesticides

A formal logic model has not been developed for the Pesticide Program as a whole.

2.4 Program Alignment and Resources

The Pesticide Program contributes to several sub-programs within Health Canada's Program Alignment Architecture (PAA), most notably 2.7 (Pesticides), 2.2 (Food Safety and Nutrition), 2.3 (Environmental Risks to Health), and 2.4 (Consumer Product and Workplace Chemical Safety). It contributes to Health Canada's Strategic Outcome 2: "Health risks and benefits associated with food, products, substances, and environmental factors are appropriately managed and communicated to Canadians" (Health Canada, 2015c).

Financial data for the years 2010–11 through 2014–15 are presented below (Table 2). Overall, the Pesticide Program had a budget of approximately $252.7 million over these five years, which includes $232.9 million in funding for PMRA and $19.7 million in funding for RAPB. Funding includes revenue from cost-recovery initiatives (~$8 million per year).

Table 2: Program resources ($)

Year	Capital	O&M	Salary	Total
Pesticides Program Total				
2010–11	$227,847	$5,129,991	$48,666,140	$54,023,978
2011–12	$200,000	$5,425,621	$47,812,004	$53,437,625
2012–13	$221,642	$3,804,963	$44,884,081	$48,910,686
2013–14	$230,000	$4,175,765	$44,356,141	$48,761,906
2014–15	$286,382	$3,477,111	$43,763,777	$47,527,270
Total	**$1,165,871**	**$22,013,451**	**$229,482,143**	**$252,661,465**
PMRA				
2010–11	$200,000	$4,956,200	$44,946,234	$50,102,434
2011–12	$200,000	$4,937,500	$44,328,000	$49,465,500
2012–13	$200,000	$3,349,000	$41,396,117	$44,945,117
2013–14	$200,000	$3,805,300	$40,855,399	$44,860,699
2014–15	$200,000	$3,147,177	$40,208,262	$43,555,439
Total	**$1,000,000**	**$20,195,177**	**$211,734,012**	**$232,929,189**

Year	Capital	O&M	Salary	Total
RAPB				
2010–11	$27,847	$173,791	$3,719,906	$3,921,544
2011–12	$0	$488,121	$3,484,004	$3,972,125
2012–13	$21,642	$455,963	$3,487,964	$3,965,569
2013–14	$30,000	$370,465	$3,500,742	$3,901,207
2014–15	$86,382	$329,934	$3,555,515	$3,971,831
Total	**$165,871**	**$1,818,274**	**$17,748,131**	**$19,732,276**

Data Source: Financial data provided by Chief Financial Officer Branch.

3.0 Evaluation Description

3.1 Evaluation Scope, Approach, and Design

The evaluation focused on the five-year period ending December 2014, although data outside this timeframe is included as appropriate. The evaluation included all Program regulatory activities.

The evaluation issues were aligned with the Treasury Board of Canada's *Policy on Evaluation* (2009) and considered five core issues under the two themes of relevance and performance. Corresponding to each of the core issues, specific questions were developed based on Program considerations, and these guided the evaluation process. The *Policy on Evaluation* (2009) also guided the evaluation design and the identification of data collection methods, so that the evaluation would meet its objectives and requirements. The evaluation framework detailed the evaluation strategy for this program and provided consistency in the collection of data to support the evaluation.

Data were collected using various methods, including literature review, document and administrative data review, a survey of registrants (n=164), and key informant interviews (n=64). More specific details on the data collection and analysis methods used for the evaluation are provided in Appendix 3. Data were analyzed by triangulating information gathered from the different methods listed above. The use of multiple lines of evidence and triangulation were intended to increase the reliability and credibility of the evaluation findings and conclusions.

3.2 Limitations and Mitigation Strategies

Most evaluations face constraints that may have implications for the validity and reliability of the evaluation findings and conclusions. Table 3 (next page) outlines the limitations encountered during the implementation of the selected methods for this evaluation. In all cases, the limitations were mitigated through triangulating findings from multiple lines of evidence.

Table 3: Limitations and mitigation strategies

Limitation	Impact	Mitigation strategy
The number of survey completions was not sufficient to conduct analyses based on respondent characteristics (e.g., geographic location, type of registrant, experience with specific submission types).	Detailed analysis of the survey results based on respondent characteristics could not be undertaken.	No mitigation strategy was possible and none was undertaken. Reporting on the survey results was limited to the group of respondents as a whole.
External key informants were identified based on purposive sampling. Budget considerations placed constraints on the number of external key informant interviews that could be completed.	External key informant interview findings cannot be interpreted as representing the views of all stakeholders or categories of stakeholders.	Interview findings are used in conjunction with other lines of evidence. No conclusions are drawn solely on the basis of interview data.
Limited quantitative information was available to support the analysis of efficiency and economy. Although some output-based costing information is available (i.e., the cost of submission review outputs as of 2010-11) as evidence to support increased user fees, activity- and output-based costing information for all program activities and over time is not available.	Quantitative analysis of efficiency and economy is limited primarily to comparing planned and actual spending.	Analysis is supplemented by qualitative information from interviews and the literature review.

4.0 Findings

4.1 Relevance: Issue #1 – Continued Need for the Program

Pesticides can pose risks to human health and the environment. New information on the impact of pesticides on human health and the environment is being continually generated, and scientific standards are continually evolving. There is an ongoing need for regulation to manage the risks associated with pesticides.

Use and benefits of pesticides

A recent analysis by Health Canada indicates that 92.9 million kg of active ingredients were sold in the country in 2012, the most recent year for which data are available. Of this, more than three-quarters was used in agriculture, while 17% was employed in non-agricultural uses and the remaining 5% was used in domestic applications.

In the agricultural sector, 81% of active ingredients used by mass are herbicides, while fungicides are responsible for about one-tenth of pesticides sold and all other substances account for the remainder (Health Canada, 2014b). Statistics Canada reports that in 2011, 69% of Canadian crop farms reported applying herbicides, 15% used insecticides and 23% used fungicides (Statistics Canada, 2014). Herbicide application was most common in Saskatchewan and Manitoba, while insecticide application was more common in the Atlantic provinces and British Columbia. Fungicide application was most common in Manitoba and least common in Quebec.

In the non-agricultural sector, antimicrobials are by far the most common product sold, accounting for 85.7% of sales, with herbicides and other substances representing 11.9% and 3.4% of sales, respectively. Many of these products are used in the preservation of wood products or in water treatment (Health Canada, 2014f). Antimicrobials are also the most common type of pesticide sold in the domestic sector, where they account for about three-quarters of active ingredient sold. However, insecticides also represent 18.4% of sales, while herbicides and all other products account for 5.1% and 1.7% of pesticides demanded, respectively (Health Canada, 2014f).

Finally, household use of chemical pesticides for lawns and gardens has declined significantly in Canada over the past two decades. In 2011, 15% of Canadian households with a lawn or garden used these products, compared to 34% in 1994 (Environment Canada, 2014). However, there are large differences in trends in pesticide usage across provinces. For example, whereas 30% of households in Québec and Manitoba used chemical pesticides in 1994, by 2011 it had declined to 5% in the former province while increasing to 53% in the latter province. These differences reflect the establishment of cosmetic pesticide bans in some provinces and municipalities but not others.

Pesticides offer important benefits to people, such as the control of agricultural pests and of organisms that cause disease in crop commodities, as well as the control of pests in sectors such as forestry, industrial settings, structural pest control, and domestic uses.

- By managing agricultural pests, pesticides indirectly increase crop yield and quality. The former benefit is increasingly important, given the pressing need to produce a sufficient volume of food to sustain a growing global population (Carvalho, 2006; Mansour, 2012). Pesticides also contribute to the economic viability and profitability of agricultural activities, and have significant implications for the floriculture and nursery sectors (Parrella, Wagner, & Fujino, 2015).
- Pesticides can manage a variety of organisms, such as mosquitos, cockroaches, houseflies, and rats, which act as vectors for illnesses in humans that cause substantial discomfort, loss of productivity, disability, and loss of life, such as West Nile virus. In addition, a variety of diseases can affect livestock and companion animals.
- Pesticides can manage insects and vegetation that can cause significant damage to infrastructure and buildings, which can significantly affect quality of life and reduce economic productivity (Cooper & Dobson, 2007).
- Pesticides can preserve biodiversity by preventing the spread of invasive species, such as water hyacinth, whether introduced intentionally or accidentally (e.g., in crops exported overseas) (Cooper & Dobson, 2007).
- Pesticides can manage weeds and other pests, in order to improve the appearance of lawns, gardens, and parks, thereby increasing the enjoyment derived from a variety of outdoor recreational and leisure activities (Cooper & Dobson, 2007; Petelle, 2012).

Impacts on human health and the environment

The risks to human health that are associated with pesticides may be either acute or chronic. Acute effects of exposure, which may range in severity from minor to severe, appear well understood for a wide range of pesticides. For example, the symptoms of organophosphate intoxication commonly include diarrhea, urination, miosis, bronchospasm, vomiting, tearing, and salivation. Although mild to moderate cases of exposure usually resolve within days or weeks, severe cases can result in death, usually due to respiratory failure (Britt, 2015). In terms of chronic effects, there are scientific studies that have reported associations between exposure scenarios and a variety of health conditions, such as cancer, neurological disorders, and respiratory disease.

- Several Canadian studies have examined the relationship between cancer and exposure to pesticides, and found associations between specific pesticides and various types of cancer (Kachuri et al., 2013; Schinasi & Leon, 2014; Weichenthal, Moase, & Chan, 2010).
- A number of studies have examined pesticide exposure and Parkinson's disease (PD) and found that although no causal relationship between PD and pesticide exposure has yet been definitively established, there may be an association (Freire & Koifman, 2012; Van Maele-Fabry, Hoet, Vilain, & Lison, 2012).
- Some authors have examined the relationship between respiratory diseases and occupational exposure to pesticides, and found that there is evidence of an association between pesticide exposure and various respiratory issues (Ye, Beach, Martin, & Senthilselvan, 2013, 2014).

Similarly, there is a large amount of literature examining adverse impacts of pesticides on the environment, including both direct and indirect effects on plants, wildlife and ecosystems (Albert, Wilson, Mineau, Trudeau, & Elliott, 2009; Environment Canada, 2010; Gibbons, Morrissey, & Mineau, 2014; National Pesticide Information Center, 2013; Penningroth, 2010; Walker, 2014).

In some instances, exposure scenarios are still being examined (Cutler, Scott-Dupree, & Drexler, 2014, p. 779; Health Canada, 2014c) and the effects of particular pesticides on human health and the environment are still being investigated at the international level (EFSA, 2013; Health Canada, 2014c), and thus, impacts have not been established definitively.

Overall, despite their benefits, pesticides can have detrimental effects on both human health and the environment. New information on the impact of pesticides on human health and the environment is being continually generated, and scientific standards are continually evolving. For these reasons, the ongoing regulation of pesticides is required to ensure that the risks to human health and the environment associated with the use of these products are acceptable and appropriately managed.

4.2 Relevance: Issue #2 – Alignment with Government Priorities

The Pesticide Program is aligned with the priorities of the federal government, as they have been articulated in major federal initiatives in recent years, and with Health Canada's current strategic outcome #2.

Broadly speaking, the objective of the Pesticide Program is to protect people and the environment from risks associated with pesticides. While recent Speeches from the Throne (June 3, 2011 and October 16, 2013) have not specifically mentioned pesticides regulation or protecting Canadians and the environment from risks associated with pesticides, PMRA has been included in several major federal initiatives introduced and/or ongoing during the time period covered by this evaluation. These initiatives include the FCSAP, the CMP, Growing Forward, the Single Window Initiative (SWI), and relevant initiatives under the Canada-United States Regulatory Cooperation Council (RCC). They focussed on addressing federal priorities related to food, health, and consumer product safety; managing risks to human health and the environment associated with toxic chemicals; encouraging innovation, competitiveness, and market development in the agricultural sector; and encouraging regulatory alignment with the United States.

- **FCSAP:** This complex horizontal initiative was funded over five years beginning in fiscal year 2008–09 and ending in 2012–13, with ongoing resources allocated to the partners. The broad objective of the FCSAP was to modernize and strengthen Canada's safety system for food, health, and consumer products (including consumer pesticides) by modernizing regulations and practices in Canada, and using proactive interventions and active oversight to respond as early as possible to potential risks. As part of this initiative, PMRA undertook activities to enhance the understanding of regulatory obligations within the consumer pesticides industry to inform Canadians of the safe use of consumer pesticides, and to monitor and enforce compliance within the consumer pesticides industry (Health Canada & PHAC, 2013).
- **CMP:** Launched in 2006, the CMP is a jointly-managed initiative between Health Canada and Environment Canada with the broad goal of protecting human health and the environment from harmful toxic substances through an integrated approach to chemicals management. As part of this initiative, the PMRA contributes to risk assessments when pest control products are implicated in CMP priorities and, where appropriate, takes action relating to those pesticide active ingredients or formulants as consistent with the requirements of the PCPA. In addition, PMRA received funding to support re-evaluation; to analyze trends and sales data; and to take regulatory action as needed.
- **Growing Forward:** Through the Growing Forward framework, federal and provincial governments are providing funding for investments in innovation, competitiveness, and market development (GoC, n.d.-b). PMRA's Growing Forward funds support the review of new minor uses of pesticides to support the competitiveness of Canadian growers.

- **SWI:** Nine federal departments and agencies, including Health Canada, are participating in this initiative aimed at streamlining the import process and reducing the administrative burden on industry. Through the SWI, commercial traders will be able to provide all required import information electronically to the Canada Border Services Agency (CBSA), which will transmit the information to the appropriate department or agency responsible for regulating the goods. These departments and agencies will assess the information and provide any border-related decisions that are required (CBSA, 2015). In particular, PMRA's access to this commercial trade data is expected to support accurate identification of commercial import/export volumes, enhanced compliance promotion, and the opportunity for detailed data analysis regarding the cross-border movement of goods it regulates.
- **RCC:** Through the RCC, Canada and the United States are undertaking a variety of initiatives to align regulatory requirements across the two countries. With respect to pesticides, PMRA is leading the implementation in Canada of the Crop Protection Products Work Plan. The objectives of the work plan are to identify mechanisms to encourage registrants to submit applications for joint regulatory review in Canada and the United States that include increased numbers of minor uses; develop joint guidelines for residue field trial studies; address obstacles to joint registration; and align data collection processes/procedures for residue trials (GoC, n.d.-a). The objective of this initiative is to facilitate equal access to products and uses in both countries, as well as align MRLs/tolerances where possible.

In addition to aligning with major federal initiatives, the activities and expected outcomes of the Pesticide Program are aligned with the strategic outcomes of Health Canada, as defined in its PAA. These activities align with and support Health Canada's Strategic Outcome 2, that "health risks and benefits associated with food, products, substances, and environmental factors are appropriately managed and communicated to Canadians" (Health Canada, 2015c).

4.3 Relevance: Issue #3 – Alignment with Federal Roles and Responsibilities

The activities carried out under the Pesticide Program are consistent with federal responsibilities under the Pest Control Products Act (PCPA). There is, however, concern among industry that provincial/territorial and municipal activities can sometimes be inconsistent with regulatory decisions made by the PMRA.

The regulation of pesticides in Canada is a shared responsibility of federal, provincial/territorial, and municipal governments. The federal government administers the PCPA and its associated regulations. Federal responsibilities under the Act include assessing new pest control products for registration, specifying pesticide MRLs, re-evaluating registered products, initiating special reviews of registered products when required, and enforcing compliance.

The provinces and territories regulate the transportation, sale, use, and storage/disposal of pesticides in a manner that is consistent with any conditions, directions, and limitations imposed under the PCPA or other federal legislation. For example, a province or territory may prohibit the use of a pesticide in its jurisdiction or may add more restrictive conditions on the use of a product. However, a province or territory may not authorize the use of a product that has not been approved or otherwise authorized under the PCPA.

The provinces and territories also administer a pesticides management program that includes education and training programs; the licensing/certification of applicators, vendors, and growers; and issuing permits for certain pesticide uses. The *Standard for Pesticide Education, Training and Certification in Canada*, which was developed through a collaborative effort of federal and provincial/territorial representatives, outlines the structure and criteria for provincial/territorial certification programs (Health Canada, 2010b). In cooperation with RAPB's regional offices, the provinces and territories are also responsible for enforcement and compliance monitoring, and for responding to spills and accidents.

Municipal governments can pass bylaws for municipal and private/residential lands. For example, in May 2014, Ontario's Prince Edward County became the first Canadian municipality to temporarily prohibit the use of neonicotinoid pesticides on municipal lands (Johnson, 2014).

The evaluation found that the activities carried out under the Pesticide Program are consistent with federal responsibilities under the PCPA. However, only a minority of respondents to the survey of registrants believe that federal and provincial/territorial roles and responsibilities are clear (28%); many were neutral or did not know. Furthermore, some industry stakeholders expressed concerns about federal and provincial/territorial roles and responsibilities in the regulation of pesticides. In particular, they indicated that provincial/territorial activities can sometimes be inconsistent with the PMRA's decisions, citing as examples restrictions on cosmetic pesticide use in several provincial/territorial jurisdictions and Ontario's plans to reduce the use of neonicotinoids in agriculture. In both instances, provinces/territories have taken action to restrict the use of pesticides that have been approved by the PMRA. It is possible that industry concerns in this regard are related to the potential commercial implications of such restrictions.

4.4 Performance: Implementation

4.4.1 Challenges and Emerging Issues

The Pesticide Program addressed several interrelated challenges and issues during the period being evaluated, including the increased complexity and volume of pesticide regulatory activities, increased globalization and international trade, and evolving science. This was accomplished through emphasizing international collaboration and work sharing, developing a proposal for a new cost recovery framework, and initiating efforts to modernize electronic business support systems.

PMRA undertook a number of key initiatives during the evaluation period in order to address emerging issues and changing priorities, such as the increased complexity and volume of pesticide regulatory activities; increased globalization and international trade; and evolving science. These key initiatives include emphasizing international collaboration and work sharing, developing a proposal for a new cost recovery framework, and initiating efforts to modernize electronic business support systems.

Emphasizing international collaboration and work sharing

To respond to increased globalization and trade issues, and to keep pace with evolving science, PMRA has increasingly emphasized international collaboration and work sharing, notably through joint reviews, efforts to align MRLs, joint science policy, and other initiatives. For example, through the RCC, Canada and the United States are undertaking a variety of initiatives under the Crop Protection Products Workplan to align the regulatory requirements across the two countries. Canada, the United States, and Mexico also participate in the North American Free Trade Agreement (NAFTA) Technical Working Group on Pesticides, which was established with the goal of creating "an aligned North American registration system for pesticides and products treated with pesticides and make work sharing a way of doing business" (Health Canada, 2013b). Areas of cooperation include collaborative scientific work, establishing common data requirements, collaborating on risk assessment or compliance methods, carrying out joint reviews, and developing common NAFTA or international standards. Working Group initiatives include NAFTA Joint Reviews and the NAFTA Labelled Products Initiative, under which NAFTA labels on agricultural pesticides allow the cross-border movement of approved products between Canada and the United States.

Canada participates in the Organisation for Economic Co-operation and Development's (OECD) Pesticide Programme through the Working Group on Pesticides. Together with regulatory authorities in the United States, the United Kingdom, Ireland, Italy, Australia, and New Zealand, PMRA participates in the OECD's Global Joint Reviews program. PMRA co-led the development of two OECD's eco-region guidance documents, which were intended to allow for the optimum use of field studies on pesticides conducted in North America and Europe. PMRA also co-leads the OECD's Working Group on Pesticides: Pesticide Effects on Insect Pollinators, in addition to participating in the OECD's Working Group of the National Coordinators on the Test Guidelines Program and the OECD's Network of Officials for Pesticide Compliance and Enforcement. PMRA has provided input into a variety of OECD guidance documents, surveys, and projects related to health evaluation and risk assessment.

In addition to collaborating under the RCC, NAFTA, and the OECD, program partners participate in the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal; Codex Alimentarius; the Commission for Environment Cooperation – Sound Management of Chemicals; the Convention on Long Range Transboundary Air Pollution; the International Pesticide Registration and Residue Limit Database; the Montreal Protocol on Substances that Deplete the Ozone Layer; the Stockholm Convention on Persistent Organic Pollutants; and, Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade.

From PMRA's perspective, international collaboration is a key mechanism by which it stays abreast of and contributes to evolving science. For example, the main benefit of joint reviews is a more robust science review, which results in a higher quality decision. However, external key informants were divided on the extent to which the PMRA has kept pace with evolving science. Those who were critical felt that PMRA has been slow to consider innovations adopted by United States regulators (for example, certain protocols surrounding pharmacokinetics, as well as a mode of action response to carcinogens), and that PMRA has failed to adequately respond to issues related to pollinators and neonicotinoids, in spite of the action being undertaken in other jurisdictions. Some interviewees (both internal and external) suggested resource constraints create challenges in keeping abreast of scientific developments.

Industry key informants supported further international harmonization and collaborative efforts; others, primarily NGOs, were concerned that PMRA's international collaborative work is driven by NAFTA, whereas the Agency has made less of an effort to collaborate and harmonize with Europe, which in their view takes a more protective approach to regulating pesticides. PMRA noted that collaboration with Europe, particularly on joint reviews, is constrained by differences in approach/philosophy (risk-based in Canada and the United States versus hazard-based in Europe) and the existence of legislated timelines in Europe, but not in Canada or the United States, for completing reviews.

Pursuing a new cost recovery framework

The current cost recovery regulations under the PCPA were first introduced in 1997[1] and user fees have not changed since that time, despite an increase in the complexity and volume of pesticide regulatory activities and costs. Currently, one-time application fees are charged in accordance with a prescribed fee schedule for the review of applications for the registration of pesticides; annual fees are charged per registered product for the right to manufacture or sell a product in Canada (PMRA, 2013g). During the evaluation period, PMRA reviewed the cost recovery framework and developed a proposal for a new framework. The modernized system is expected to allow PMRA to continue to meet performance standards for regulatory activities, while supporting re-evaluation and allowing it to direct additional revenue to stakeholder priorities, such as expanding international regulatory cooperation, science policy, electronic infrastructure, and outreach. The formal cost recovery proposal was approved by the Standing Senate Committee on Agriculture and Forestry in April 2015.

Industry key informants were very supportive of enhanced cost recovery, provided that the additional funds are appropriately allocated to PMRA's core regulatory activities of registration and re-evaluation. A few NGO representatives expressed concern about the impact of cost recovery on the independence of the PMRA (i.e., they were concerned that cost recovery may create pressures to make decisions favourable to those paying user fees).

[1] There were fee provisions (albeit minimal) in place before the 1997 Regulations came into existence.

Modernizing electronic business support systems

In 2013, PMRA embarked on an initiative to modernize electronic business support systems. This initiative is driven by a number of factors, including the need to leverage data and processes to support joint reviews and international collaboration; the need for a complete life cycle integration of business support systems; and the need to streamline processes and information in order to increase efficiencies, among other factors (PMRA, 2013c, 2013e). Moving forward, PMRA plans to focus on three major modules: intake (secure electronic submission packages); process (internal life cycle management tools); and outcomes (e-publishing and reporting tools).

Based on the survey of registrants, challenges with electronic submissions are relatively common (see Section 4.4.2). Several external key informants (both industry and others) criticized the current electronic infrastructure that makes information available to stakeholders. They noted that the website is difficult to navigate, that electronic access to data and documents is limited and that it is necessary to contact PMRA directly to obtain certain materials. This can be burdensome and inconvenient, particularly when information is required immediately.

4.4.2 Submission Review and Registration

PMRA has implemented several measures to improve the efficiency and clarity of the submission review and registration process, including revisions to policies, regulatory directives and internal processes. However, there are still opportunities for further improvements in some areas, including clarifying data requirements and improving the electronic submission process.

One of PMRA's main regulatory activities is the review of pesticide submissions. Under section 6 of the PCPA, all pesticides must be registered or otherwise authorized before being sold in Canada. Applicants for registration must provide sufficient data to show that the product does not pose unacceptable risks to health and the environment, and that it has value. There are five categories of submissions (Categories A through E). Products that meet the PMRA's health and environmental requirements, and are shown to have value, are registered for use in Canada under the conditions stated on the label[2].

Between 2009–10 and 2014–15, PMRA completed 18,611 pesticide submissions (Categories A through E) and implemented various measures to improve the efficiency and clarity of the submission review and registration process. This process included implementing the Revised Management of Submissions Policy and various Regulatory Directives (guidance documents), and establishing new internal processes within the PMRA directorates involved in submission review and registration.

[2] Some conditions of registration, such as packaging requirements, may not be on the label.

As already described, PMRA participates in international joint reviews for new active ingredients. Between 2009–10 and 2013–14, there were a total of 46 new active ingredients under joint review and 15 new proposals for joint review (PMRA, 2012a, 2012b, 2012c, 2013a, 2015a). While there are challenges to joint review, including communication, different legislation and policies across participating jurisdictions, and the size and complexity of the submissions,[3] benefits include an increased efficiency and strengthening of the regulatory process and the ability to provide Canadian growers with access to products at the same time as growers in other countries (Stewart, 2012).[4]

As a cost-recovered activity, submission review has established performance standards, which vary based on the submission category and type. As shown in Table 4, performance standards have generally been met for Category A and B submissions in the last three years; prior to that, there was considerable variability from year to year. Conversely, review times have fluctuated for Category C submissions over the last three years, and in 2013–14, only 65% of submissions met the performance standard. Program representatives indicated that this was due to an increase in workload as a result of several re-evaluation decisions from previous years, which were implemented through Category C submissions for label amendments.

PMRA has made changes to its processes for some Category C submissions. As shown in Table 4, in 2014–15, 92% of Category C submissions met the performance standard, a significant improvement over the previous year.

Table 4: Performance against review timelines for Category A, B, and C submissions

Category	2009–10	2010–11	2011–12	2012–13	2013–14	2014–15
Category A	66%	80%	100%	100%	97%	97%
Category B	46%	79%	36%	92%	96%	96%
Category C	81%	74%	92%	90%	65%	92%

Note: Calculations are based on the number of submissions completed, which includes registered, withdrawn, and rejected.
Source: (PMRA, 2012c, 2015a) and data provided by PMRA.

Results from the survey of registrants suggest opportunities to further improve the submission process. About 60% of survey respondents agreed that it was clear what information their organization had to provide, that PMRA provided helpful assistance, that they are satisfied with the electronic submission process, and that the guidance documents were helpful. Fewer (49%) said that PMRA reviewed their submission within published performance standards.[5] More than

[3] For example, according to one source, a recent proposal presented by United States authorities to conduct joint reviews of biocidal product applications was "facing some hesitancy from the EU" due to the complexity of the goal; the proposal has reportedly been revised to focus on shorter term goals (Chemical Watch, 2014).

[4] Information on review times for joint reviews compared to reviews of new active ingredients conducted independently by PMRA was not available. Health Canada reports that the first global joint review in 2008 was completed in 15 months, a "significant improvement to the 21–24 month review standard for reviews conducted independently by these countries" (Health Canada, 2009b) .

[5] This figure is at odds with PMRA's data on review timelines. It is possible that registrants who experienced delays are over-represented among survey respondents.

half of survey respondents (56%) experienced challenges with the submission process, including poorly defined deficiency requests; the need to submit additional data; lengthy delays; and difficulties with the electronic submission process.

In addition to these general challenges identified through the survey, the current approach to registering generic pesticide products is seen as problematic by some industry key informants, who indicated that, despite some recent policy changes, it is almost impossible to obtain generic registrations due to Canada's "cumbersome" data protection system for pesticides. These key informants were of the view that the current rules on negotiation and arbitration for data compensation, set out in the Protection of Test Data regulations made under the Pest Control Product Regulations (PCPR) in June 2010, are onerous and risky so generic companies are unlikely to move forward. They recommended regulatory changes to establish a process similar to the one in the United States. PMRA acknowledged that there may be too many disincentives in the current approach to generics, and indicated that it continues to consider further policy changes. Among survey respondents, a minority (24%) believed that Health Canada effectively supports access to generic pesticide products, while more respondents were neutral (26%), disagreed (15%), or did not know (35%).

4.4.3 Re-evaluations and Special Reviews

PMRA has made progress in initiating and completing re-evaluations under its two re-evaluation streams. However, there are challenges to completing re-evaluations in a timely manner, and performance standards for their completion have not been formally adopted. Special reviews can arise unpredictably and, as such, are difficult to account for in planning and have contributed to delays in re-evaluations.

Through its re-evaluation program, PMRA re-evaluates registered pesticide products to ensure that products on the Canadian market continue to meet modern scientific standards. Re-evaluations involve a review of pesticide active ingredients and their associated end-use products based on current science and data, in order to determine whether, and under what conditions, their continued registration is acceptable. If it is determined that the risks to human health or the environment are no longer acceptable, or that the product is without value for its intended purpose, the registration must be amended or cancelled. Examples of amendments include changes to the use pattern, label statements, or classification of a product.

Re-evaluations are carried out under two distinct streams.

- **Re-evaluation of older pesticides:** In 2001, PMRA launched a re-evaluation program for pesticides registered prior to 1995, which includes registered pesticides as far back as the 1920s. This program involved the review of pesticide active ingredients and their end-use products, based on updated data and information to determine whether, and under what conditions, their continued registration is acceptable. In total, 401 active ingredients are covered under this re-evaluation approach.
- **Cyclical re-evaluations:** The current PCPA outlines the legislative foundation for the current approach to re-evaluation. It requires that the re-evaluation of all pesticides be initiated on a 15-year cycle from the date of the last major registration decision, in order to

ensure that they continue to meet modern scientific requirements. The first pesticides to fall under the current legislated re-evaluation approach were those registered in 1995 (PMRA, 2010, 2012f). This means that the first 15-year cyclical re-evaluations were initiated in 2010. Health Canada released a re-evaluation initiation schedule for 2010–13 which included 27 new active ingredients to be initiated during those years (PMRA, 2011c).

As of 2014, several non-cyclical re-evaluations were also underway. Examples include re-evaluations of three neonicotinoid insecticides (clothianidin, imidacloprid, and thiamethoxam), which were announced in 2012 in response to a large number of incidents of bee mortality from pesticide exposure in Ontario and Quebec during the corn planting season (PMRA, 2013a). These re-evaluations are being undertaken in collaboration with the United States Environmental Protection Agency (EPA). An interim assessment of pollinator risk is expected to be completed in 2015 (PMRA, 2013i).

A number of factors make it challenging to understand the current status of PMRA's re-evaluation activities, including differences over time in PMRA's approach to reporting on re-evaluations and the limitations of its current approach to tracking the status of re-evaluations.[6] The available evidence shows that progress has been achieved in initiating and, particularly under the original re-evaluation program, completing re-evaluations.

- Data provided by the Program show that, as of January 20, 2015, 88% of the 401 older active ingredients have been addressed (including 238 (59%) re-evaluated, 106 (26%) discontinued by the registrant and 10 (3%) no longer registered or no end-use product), and another 5% have had proposed decisions issued. Of the 238 completed assessments, the vast majority (90%) resulted in label changes, 5% were cancelled by the Minister, and 5% were accepted for continued use without any label changes.
- Data provided by the Program show that 53 cyclical re-evaluations have been initiated since 2010. Of these, seven have been completed and eight have been discontinued as a result of registrants withdrawing their products from the market[7]. The remaining 38 are in progress.

The length of time PMRA takes to complete re-evaluations of older pesticides was criticized by the CESD in 2008 (OAG, 2008), and PMRA's timelines for completing re-evaluations continue to be a concern for some key informants and survey respondents. Among the minority (29%) of survey respondents whose products had been subject to re-evaluation by PMRA, for example, only one-third agreed that the process was efficient.[8] Program data show that the 238 re-

6 Information on the status of re-evaluations is maintained using Excel spreadsheets (one for the older re-evaluations and one for the first cyclical re-evaluations). The full functionality of Excel is evidently not being used in these spreadsheets. For example, there are inconsistencies in the way in which data are recorded, as well as missing data, with implications for data reliability and validity. There is also widespread use of text-based string variables to enter data that could be hard-coded or quantified, necessitating time-consuming coding to enable quantification, analysis, and reporting. These challenges could be addressed through relatively low-cost restructuring of the tracking spreadsheets.

7 According to Program representatives, discontinuation can occur at any time since it is voluntary by the registrants. In the context of re-evaluation, it may occur as early as just after the re-evaluation is initiated (announced) right up until the end of re-evaluation.

8 However, 72% agreed that it was clear what information their organization had to provide to support the re-evaluation and 62% agreed that the roles and responsibilities of PMRA and their organization were clear.

evaluations completed under the original re-evaluation approach took, on average, 3.9 years to complete, while the seven cyclical re-evaluations completed took, on average, 2.9 years to complete.

PMRA has taken a number of steps to increase efficiencies in the re-evaluation process. These include a more focused approach where the depth of the review depends on the complexity of the issues and areas of risk assessment that require updates; continued cooperation with international regulatory bodies as well as alignment with the US EPA's re-evaluation schedule, where appropriate; and using a quarterly targets calendar to plan different areas of re-evaluation work.

However, although PMRA has targets for initiating re-evaluations and identifies internal milestones for their completion according to its re-evaluation workplan, it has not implemented a performance standard for their completion. One internal document from March 2012 identifies internal timelines for various categories of re-evaluation (full re-evaluations: 492 days; targeted re-evaluations: 305 days; minimal or no re-evaluation[9]: 204 days), but these have not been formally adopted (PMRA, 2012g).

PMRA key informants acknowledged that re-evaluations can take considerable time to complete, citing challenges such as the timeliness with which required data or information are received from registrants and the inability to predict the timing of special reviews. Program documents identify additional challenges, including (but not limited to) the evolution of assessment methods during the review, the lack of consistency in previous reviews, and the existence of in-house data that was not previously reviewed, as well as a "learning curve to interpreting and selecting study lists provided by registrants" (PMRA, 2013h). Internal interviewees discussed the challenge of knowing when to stop accepting new data so that the review can be completed or "knowing when to close the door on data".

Special reviews may be initiated at any time and, as a result, cannot be predicted. Under section 17 of the PCPA, special reviews must be initiated if there are reasonable grounds to believe that the health or environmental risks of the product are, or its value is, unacceptable. In addition, under s.17(2) special reviews must be initiated when a member country of the OECD prohibits all uses of an active ingredient for health or environmental reasons; this provision legally mandates special reviews regardless of whether there are reasonable grounds to believe the health or environmental risks are acceptable.

According to PMRA, a large number of special review requests in 2013–14 required the Agency to re-allocate resources from re-evaluations to special reviews. Among other factors, this contributed to a decline in the number of re-evaluations initiated that year (only one re-evaluation was initiated in 2013–14, compared to 22 in the previous year) and affected progress in completing them. In total, 27 special reviews have been initiated during the period of the evaluation, including the following:

- one initiated by PMRA in December 2011, following the analysis of a request from the Canadian Wolf Association, and completed in May 2014

[9] Work is required to confirm that no re-evaluation is required. This includes analysis to determine whether science areas are up to current standard and no new risk assessments are needed. Thus, some common elements of re-evaluation work are done within the 204 days, but no time is allotted to completing new reviews of data.

- twenty-three initiated in December 2013, following a request by Ecojustice on behalf of Equiterre and the David Suzuki Foundation, due to prohibitions on all uses in an OECD member country for health or environmental reasons; of the 23, one was completed in November 2014, one was cancelled after it was learned that not all uses of the active ingredient had been prohibited in the OECD member country, and the remainder are targeted for completion in 2018-2019
- three neonicotinoid products initiated in December 2014, following a request by a member of the public, targeted for completion in 2017 (clothianidin, imidacloprid, and thiamethoxam)

External key informants who commented on special reviews had varying opinions. Industry expressed concern that special reviews are being undertaken based on non-scientific criteria and that special reviews have become a significant drain on PMRA's resources, while NGOs were supportive of special reviews and expressed concern that PMRA is not proactively monitoring bans in other countries.

4.4.4 Incident and Sales Reporting

Some industry and other stakeholders do not know how PMRA uses the information collected through incident and sales reporting, suggesting opportunities to improve communication to stakeholders about these elements of the Pesticide Program.

Registrants and applicants are required to report pesticide incident and annual sales information to PMRA under the PCPA and the Pest Control Product Regulations (PCPR).

Under section 13 of the PCPA and the Incident Reporting Regulations, registrants and applicants are required to report to PMRA all incidents of adverse events associated with their products. These reports are intended to provide information on adverse events and potential risks to human health and the environment that become evident when products are used in "real-life" circumstances (Health Canada, 2007). Incidents include effects on humans, domestic animals, or the environment; packaging failure that could result in human exposure or injury; and excessive residues in food. All incident reports are placed in the electronic public registry on Health Canada's website with identifying information removed. PMRA analyzes incident report data to identify potential health and environmental risks, to take action where appropriate[10], and publishes incident evaluation reports on its website.

PMRA data show that between 2009 and 2014, 10,453 pesticide incidents were reported. These include human incidents (14%), domestic animal incidents (74%), environment incidents (6%), food residue incidents (0%), and packaging failure incidents (5%), as well as scientific study incident reports (2%). Although incident evaluation reports have, in the past, been published on Health Canada's website, describing the results of PMRA's evaluation, the reasons for its

[10] Section 14 of the PCPA sets out what is required upon receipt of incident reports – i.e., the Minister (PMRA) has a duty to determine whether a special review should be initiated. If the incident report(s) indicates that there may be a problem with the acceptability of the product, under the PCPA a special review must be initiated.

conclusions, and risk mitigation measures taken, publication has since been discontinued.[11] Instead, a summary of incident report data and completed evaluations is published in PMRA's annual report.

The Pest Control Products Sales Information Reporting Regulations require registrants to report the quantity of every product they make available for sale each year. This information contributes to PMRA's ability to assess health and environmental risks, particularly during the re-evaluation of older pesticides. Health Canada makes pest control product sales information available through the publication of annual reports.

Some stakeholders were uncertain how PMRA uses the information collected through incident and sales reporting. For example, while about 60% of registrants surveyed understood their obligations under the IRP, only 35% understood how PMRA uses the information collected. Furthermore, some NGO key informants believed that the incident evaluation reports posted online do not contain sufficient explanation of the reasons for PMRA's conclusions.

Similar issues emerged with respect to sales reporting. Although about 80% of survey respondents understood their obligations under the Sales Reporting Program, only 43% understood how PMRA uses the information collected. It was also noted that the most recent sales information published online dates to 2012.

4.4.5 Compliance and Enforcement

PMRA and RAPB undertake a wide range of compliance promotion, monitoring, and enforcement activities. There are opportunities to improve communication on compliance and enforcement policy, activities, and results.

Compliance and enforcement activities are designed and administered by PMRA and delivered by regional teams with the Pesticide Compliance Program of the RAPB. These activities are coordinated through the National Pesticide Compliance Program (NPCP), which outlines Health Canada's compliance and enforcement activities on an annual basis (PMRA, 2013b). Annual NPCP activities are planned using a risk-based approach to priority setting, which brings together multiple lines of knowledge and evidence to inform national priority areas. Priorities are informed by examining international commitments, regional "hot issues," common non-compliance patterns, federal-provincial intelligence sharing, and human, environmental, and regulatory integrity risks. Key considerations include whether the problem is national in scope, whether it merits dedicated resources, how success would be measured, and whether there are any potential partners to help address the problems (PMRA, 2011b, 2012d).

[11] The rationale for this decision was that publication is not a legislative requirement and the reports published online received very few views.

Regional offices provide regional perspectives on these national issues and also develop and implement regional-specific priorities to address more localized compliance issues. Together, these approaches are intended to ensure that resources are allocated towards the highest risks to human health and the environment and adequate attention is given to entities that are less likely to comply with regulatory requirements (PMRA, 2012d).

Compliance and enforcement consists of the following three key activities:

- **Compliance promotion**: These activities aim at preventing non-compliance. Activities focus on informing the public, industry, and associations about regulatory requirements, which in turn allow these stakeholders to make better-informed decisions.
- **Compliance monitoring**: This involves regular, planned inspections of activities regulated under the PCPA and the PCPR. Inspections may also be undertaken to characterize areas of concern, determine industry activity in a given area, or as part of an ongoing program to evaluate the safe use of pest control products post registration.
- **Enforcement actions**: These include measures taken to encourage and restore compliance with the PCPA. These may include verbal education, an education/enforcement letter, voluntary removal, denial of product entry into Canada, seizure and detention/forfeiture, amended or cancelled registration, a compliance order, administrative monetary penalties (AMPs), or prosecution (PMRA, 2013b).

PMRA and RAPB representatives indicated that the large size and diversity of the regulated communities and the limited program resources create significant challenges for compliance and enforcement. Particular challenges were noted with respect to unregistered and imported products and users of pesticides. Unlike other products that undergo market approval (i.e. submission review and registration or authorization) by Health Canada, such as pharmaceuticals for human use, biologics, medical devices, and veterinary drugs, PMRA is responsible for compliance promotion and monitoring to ensure that pest control products are used according to the use instructions and safety precautions specified on the product label. Given the range of agricultural, commercial, industrial, and residential pesticide applications, the scope of the Program's compliance and enforcement activities is therefore extremely broad. In 2015–16, for example, the Program planned to undertake compliance promotion projects targeting agricultural and commercial pesticide handlers and post-application workers and municipal inspectors regarding the sanitation of public pools; and to gather details on reported bee mortality incidents to support conclusions regarding any contributing role that neonicotinoid pesticides may have played (PMRA, 2015b). In addition, the Program planned to undertake 14 compliance monitoring projects in that year, including border inspections targeting importers, monitoring to verify compliance with recent re-evaluation decisions for rodenticides and phosphine, and monitoring of pesticide use in aquaculture, among many other projects.

According to PMRA's annual reports, between 2009–10 and 2013–14, PMRA and RAPB:

- undertook over 100 compliance promotion activities targeting a diverse range of stakeholders;
- conducted approximately 4,278 planned inspections and over 200 surveillance inspections of high-risk violators with previous non-conformances; and

- undertook approximately 6,488 enforcement actions in response to detected non-compliances, including approximately 4,428 between 2011–12 and 2013–14. In the latter three years, the most common enforcement actions were written education (n=1,264), verbal education (n=331), and enforcement letters (n=146). Much less commonly, the Program issued Notices of Violation with Penalty (n=38), Compliance Orders (n=8), Compliance Orders with AMPs (n=3), and Notices of Violation with Warning (n=1). It should be noted that the number of enforcement actions is approximate and a complete breakdown of all enforcement actions taken is not provided in the annual reports.

In addition to the information published in its annual reports, PMRA publishes enforcement bulletins describing violations under the *Agriculture and Agri-Food Administrative Monetary Penalties Act* that have resulted in warnings and penalties, and convictions under the PCPA. According to the enforcement bulletins, between calendar years 2010 and 2015, PMRA issued Warnings and Notices of Violation with Penalty to 24 entities (Health Canada, 2015a). The most common violations resulting in warnings and penalties were the use, importation, or distribution of pest control products not registered in Canada; and the use of a pest control product inconsistent with the label directions. Overall, however, the Program publishes relatively limited information on the nature, seriousness, frequency, or prevalence of non-compliances related to pesticides, and instead focusses its reporting on quantifying activities and outputs.

Results from the survey of registrants show that while 70% of respondents believed that their own organization understands what it needs to do to be in compliance, only 43% agreed that the Program communicates effectively with applicants and registrants about the legislative requirements that apply to them. Furthermore, only about one-third believed that compliance and enforcement activities are effective at identifying non-compliances (33%) and that the Program responds effectively to risks posed by non-compliances (31%). In both cases, almost as many respondents were neutral, while about one-fifth did not know. Survey respondents suggested improving compliance and enforcement activities through better communication with and reporting to regulated communities on compliance policy, activities, and results (including how complaints are dealt with); and more focus on unregistered, imported, or counterfeit products and off-label use.

PMRA representatives indicated that the Agency, like other branches within Health Canada, is planning to provide more information to Canadians, including information on compliance and enforcement, under the department's Regulatory Transparency and Openness Framework. Planned activities include making inspection information about pesticides available for the first time and rolling out annual reporting on compliance and enforcement activities across Health Canada, starting with reports for pesticides (Health Canada, 2015d).

4.4.6 Outreach Activities

The Pesticide Program undertakes a variety of outreach activities targeting consumer and professional audiences. PMRA plans to include public outreach activities in its next strategic plan.

PMRA's 2008–13 Strategic Plan identifies, as one of its strategic outcomes, that "Canadians will be better informed about how Health Canada regulates pesticides and how they should be used, and will be confident in the results" (Health Canada, 2009c). Similarly, a 2013 presentation describes the overall goals of the Program's outreach activities as being to increase public awareness of pesticide regulation and the rigours of the risk assessment process; to help the public better understand the science behind the regulation of pesticides; and to explain the contribution of pesticides to food production and pest management (PMRA, 2013c).

In practice, the Program's outreach activities consist of three main functions, targeting professional and user audiences, as well as the public.[12] These functions include the following:

- **Developing and distributing material to professional and consumer audiences**: Activities in this area have included developing a generic outreach package to be used at exhibits and conferences across Canada; translating and updating web-based pest and pest product related factsheets; and creating an educational video on hygiene for seasonal agricultural workers. Target audiences have included consumers, landlords and building managers, and migrant and seasonal agricultural workers. In addition to exhibits and conferences, material was disseminated through PMRA's website and quarterly articles on News Canada (PMRA, 2014b).
- **Managing a 1-800 information line and email service:** PMRA's Pest Management Information Services is intended to respond to questions and requests from the public and other groups (PMRA, 2013c). Between 2011–12 and 2013–14, the service received 5,650 calls or emails (PMRA, 2012c, 2013a, 2015a). Program documents suggest that the largest proportion of calls received has been from registrants (PMRA, 2013d).
- **Provide support and advice for RAPB regional office participation at fairs, exhibits, and other opportunities through the use of displays and printed material:** Between 2011–12 and 2013–14, PMRA conducted approximately 120 booth events.

External key informants had mixed views on the Program's outreach activities. Some perceived the Pesticide Program as having a limited role in this regard, and observed that most outreach is done at the provincial/territorial level. Others remarked that the Program has produced some good outreach materials targeting the public, but were unsure how these materials are being distributed and whether they are reaching the target audience. NGOs believed that there is a need to more clearly communicate to Canadians that pesticide labels are the law (rather than merely a suggestion for use); to release information more quickly to the public; to raise public awareness of pesticide risks; and to encourage the use of safer alternatives to conventional pesticides.

[12] For this reason, the distinction between the Program's outreach activities and its compliance promotion activities is not necessarily clear.

PMRA representatives believed that Canadians do not have a strong understanding of PMRA's role in pesticide safety and indicated that Heath Canada, like other regulatory agencies worldwide, is facing increased pressure to make information available to the public that is easy to understand. PMRA plans to include outreach activities in its next strategic plan, which is expected to be completed by June 2016, and to use some additional funds generated as a result of cost recovery to support public outreach activities.

4.4.7 Collaboration, Consultation, and Engagement

The Pesticide Program collaborates with international, federal, and provincial/territorial partners and consults with industry and non-industry stakeholders through a variety of engagement activities. While partners agree on the value of collaboration, some NGO and industry stakeholders are dissatisfied with the Program's efforts at consultation and engagement.

Collaboration

The Pesticide Program collaborates with a variety of external partners, including international regulatory bodies and organizations, other federal departments and agencies, and the provinces and territories. PMRA's international collaborative activities were described in Section 4.4.1 of this report.

At the federal level, PMRA and Agriculture and Agri-food Canada (AAFC) jointly deliver the Minor Use Pesticide Program (funded through Growing Forward), which is intended to facilitate access to new minor use pesticides for Canadian growers, and the Pesticide Risk Reduction Program, which provides funding and regulatory support for the development and implementation of pesticide risk reduction strategies by growers, grower organizations, pest management stakeholders, and others (AAFC, 2015).

PMRA also collaborates on an ongoing basis with the Canadian Food Inspection Agency (CFIA) in various ways. Canadian MRLs for pesticides established by PMRA are monitored by the CFIA through its national Chemical Residue Sampling Program; the two agencies work together to set priorities and manage exceedences. In addition, the CFIA uses information from PMRA's re-evaluation program to target its monitoring and surveillance activities in areas of highest risk, while PMRA uses the CFIA's monitoring data in its re-evaluations (e.g., to qualify exposure to Canadians). In addition, PMRA is responsible for reviewing the pesticide component of fertilizer-pesticide combination products, which are primarily regulated by the CFIA and do not have to be registered under the PCPA.[13]

PMRA is a participant in the federal government's SWI, involving nine federal departments and agencies, the objective of which is to streamline the import process and reduce the administrative burden on industry.

[13] It is beyond the scope of this evaluation to discuss the complex issues related to the regulation of fertilizer-pesticide combination products, which is currently undergoing regulatory modernization.

There has been little activity over the evaluation period pursuant to Health Canada's Memorandum of Understanding (MOU) with Environment Canada, AAFC, the Department of Fisheries and Oceans Canada (DFO), Natural Resources Canada, and the CFIA pertaining to pesticide research and monitoring (Environment Canada et al., n.d).[14] According to program representatives, although there have been no formal meetings of the 6 Natural Resources Departments Pesticides and Pest Management Working Group (6NR), the working group charged with implementing the MOU, PMRA meets annually with DFO to discuss research priorities through the National Contaminants Advisory Group, and meets with Environment Canada researchers to discuss priorities on an ad hoc basis.

At the provincial/territorial level, the Federal-Provincial-Territorial Committee on Pest Management and Pesticides (FPT-CPMP) is a formal venue for sharing information and expertise and for providing advice and direction to governments on programs, policies, and issues relating to pesticides. The roles of the Committee are to strengthen FPT relationships in the area of pest management and pesticides; promote information exchange; and provide advice and direction to FPT governments on programs, policies, and issues for pesticides, with the aim of enhancing sustainable pest management practices, and seek harmonization where applicable in programs and policies (Health Canada, 2009a). Based on the summary report for the most recent Committee meeting (2014), the Committee is primarily a forum for information-sharing, although two sub-committees (the Pesticide Education, Training and Certification Standing Subcommittee and the Minor Use Standing Subcommittee) have specific mandates and/or work plans (FPT Committee on Pest Management and Pesticides, 2014).

PMRA also collaborates with the provinces and territories on compliance and enforcement issues (including formal MOUs and Memoranda of Agreement),[15] as well as on emergency registrations, education and training for pesticide applicators, and on regional minor use needs through the Canadian Grower Priority Database. In addition, the provinces and territories provide PMRA with monitoring data to support risk assessment (e.g., water monitoring data).

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[14] Under the MOU, the partners agreed to develop an annual integrated work plan for research and monitoring; share priorities for pesticide research and monitoring activities and partake in joint identification of research priorities; provide a platform to share research and monitoring information; and contribute expertise and scientific advice to partners via interdepartmental scientific review committees; among other things. A committee of Senior Managers (the 6NR Working Group) was to be established to monitor progress. An integrated work plan was created in 2009 (6NR Pesticide Research and Monitoring, n.d) and one meeting was held on March 16, 2011 (6NR Pesticide Research and Monitoring, 2011). Representatives of the federal government departments and agencies involved were either unaware of the current status of the 6NR Working Group or indicated that it has not been active.

[15] For example, during fiscal year 2011–12, in cooperation with the province of New Brunswick and Environment Canada, PMRA inspected fish farms to determine compliance in the use of sea lice control products. Several Notices of Violation were issued under the *Agriculture and Agri-Food Administrative Monetary Penalties Act* AAAMPA and several indictable charges were laid under the *Fisheries Act* (PMRA, 2012c). The same year (under FCSAP), PMRA collaborated with the province of Quebec to provide information awareness sessions for 60 pest control operators and worked with the province of British Columbia to manage spray drift issues (PMRA, 2012c).

There was general agreement among international, federal, and provincial/territorial partners who were interviewed, as well as Program representatives, on the value of collaboration and its contribution to more informed pesticide regulatory decisions by the Program and/or their own organizations. Government representatives, in particular, cited specific instances in which they had provided the PMRA with information or expertise that had enabled or was expected to enable the latter to make better decisions than might otherwise be possible. Some interviewees pointed out that collaboration between the PMRA and other federal, provincial, or territorial regulatory bodies is often mutually beneficial.

International key informants also emphasized the importance of and benefits associated with information-sharing. For instance, United States regulators occasionally request the value data collected by the PMRA as part of the pesticide registration process, and information-sharing between the RAPB and its counterpart in another jurisdiction may enable both parties to respond more quickly and effectively to suspected compliance issues.

Consultation and engagement

In addition to the collaborative efforts described above, the Program also engages and consults with industry and non-industry external stakeholders through various mechanisms. Formal mechanisms for industry consultation and engagement include pre-submission meetings; regular meetings with industry associations including CropLife Canada and the Canadian Consumer Specialty Products Association; and the Economic Management Advisory Committee (EMAC), a committee of users and manufacturers of pest control products established in 1997 with a mandate to advise PMRA on “specific ways to improve efficiency and cost effectiveness without compromising health or environmental protection and while maintaining industry competitiveness” (Health Canada, 2011).

Industry and non-industry stakeholders are consulted through the Pest Management Advisory Council (PMAC), a multi-stakeholder group established in 1998 that is intended to foster communication and dialogue among stakeholders and with the PMRA, as well as provide advice to the Minister of Health on policies and issues relating to the federal pest management regulatory system (Health Canada, 2015e). Council members are appointed by the Minister of Health to represent a diverse range of stakeholder interests, including environmental and health groups and individuals with appropriate expertise, and pesticide manufacturers and users. Finally, both industry and non-industry stakeholders may participate in formal public consultation processes.

While industry key informants viewed the Program’s engagement and consultation activities as appropriate and effective, and generally regarded PMRA as open and transparent, industry survey respondents were more ambivalent. Only 40% of survey respondents believed that PMRA consults adequately with applicants and registrants, and only 37% believed that the existing consultation mechanisms are an effective way for them to express their concerns and interests to PMRA. Furthermore, only 35% believed that PMRA has been open and transparent with respect to decision making, while 31% believed that PMRA takes the concerns and interests of applicants and registrants into account in decision making. It is unclear what accounts for these differences between the perceptions of industry key informants and registrants who responded to

the survey. One possible explanation may be that key informants represented major industry associations and large companies, which may be more likely than registrants as a whole who responded to the survey to participate in formal consultation processes, such as those described above.

NGO key informants expressed the least positive views. They perceived relatively little effort by PMRA to consult and engage; criticized PMRA for a lack of responsiveness, timeliness, and transparency; and generally felt that their views are ignored by PMRA. From their perspective, mechanisms such as the PMAC, while welcome, had limitations or did not constitute "true" outreach and engagement. Although key informants did not identify specific examples, the Sierra Club of Canada and the Ontario Beekeepers Association both published criticisms of the Committee process, with respect to the statutory review of the PCPA, arguing that the time allocated to it was excessively short and that they did not receive adequate advance notification that it was taking place (OBA, 2015; SCC, 2015).[16]

In addition, many external stakeholders (industry, NGOs, and others) criticized Health Canada's website for being difficult to navigate and noted that some materials are not available online and have to be requested directly from PMRA.

PMRA representatives acknowledged that its consultation processes are less defined for NGOs and the public than for industry. In its recent report on the statutory review of the PCPA, the Standing Committee on Health recommended that PMRA review the openness and transparency of its processes "with a view to ensuring that Canadians are able to provide meaningful and informed input" (HESA, 2015). In its response to the Committee's report, Health Canada highlighted current opportunities for public participation in the regulatory process, and referred to its commitments under the Regulatory Transparency and Openness Framework, including reviewing how scientific information and decisions are explained, modernizing its electronic public registry, and carrying out a "wide range of outreach and stakeholder engagement initiatives" (Health Canada, 2015b).

[16] In a briefing note dated fall 2013, PMRA recommended allocating two days to the Committee process and identified potential witnesses, including two NGOs, two industry associations, and three user associations (PMRA, 2013f). An additional five NGOs, two innovative pesticide registrants, and three generic pesticide registrants were identified as witnesses who may request to appear before the Committee. Two days were ultimately allocated to the Committee process. Witnesses represented four NGOs, two industry associations, and three grower/producer associations.

4.5 Performance: Issue #4 – Achievement of Expected Outcomes (Effectiveness)

4.5.1 Outcome #1: Industry Meets Canadian Regulatory Requirements for New Pesticides

PMRA assesses progress towards this outcome based on the proportion of completed new submissions that meet regulatory requirements. However, the submission and review process can be an iterative one and modifications made to submissions to address deficiencies or requests for additional information are not accounted for in reporting. Based on completed submissions, industry is generally meeting regulatory requirements for new pesticides.

PMRA assesses progress towards this outcome based on the proportion of completed new submissions that meet regulatory requirements. The Agency offers pre-submission meetings and webinars free of charge to applicants to improve the quality of submissions and to help ensure that submissions comply with regulatory requirements. The available data on completed new pesticide submissions suggest that industry is generally meeting these requirements; of the 3,214 Category A and B submissions completed between 2009–10 and 2014–15, only 0.03% were rejected and 1.3% were withdrawn. It should be noted that the submission and review process can be an iterative one and that these figures do not capture modifications made to submissions to address deficiencies or requests for additional information. New submissions are generally not completed *unless* they meet regulatory requirements[17].

4.5.2 Outcome #2: Pesticides in the Marketplace Continue to Meet Modern Scientific Standards

The re-evaluation program is an important mechanism for helping to ensure that pesticides in the marketplace continue to meet modern scientific standards. However, re-evaluations can take considerable time and effort to complete, and it is unclear how systematically the Program monitors and enforces compliance with those decisions.

The evaluation evidence suggests that the re-evaluation program is an important mechanism for ensuring that pesticides in the marketplace continue to meet modern scientific standards. Re-evaluation data show that in the majority of cases, registration of active ingredients is continued with label modifications, while a minority of active ingredients are phased out; relatively few registrations continue without label modifications.

[17] A pest control product must meet the regulatory requirements in order to be granted a registration. If PMRA determines that the regulatory requirements are not met, then PMRA may either request more data and put the review on hold pending receipt of that data, or the submission must be rejected.

Most key informants and survey respondents agree that the re-evaluation program is an important tool for ensuring that pesticides in the marketplace meet modern scientific standards (70% of survey respondents) and for improving the risk management of pesticides in the marketplace (65% of survey respondents).

That said, it is important to acknowledge that timelines for completing re-evaluations can be lengthy, during which time end-use products remain on the market (although in some cases, PMRA has implemented interim risk mitigation measures prior to completing re-evaluations). Additionally, while the Program monitors implementation of some re-evaluation decisions through its compliance monitoring program, selecting certain decisions for monitoring on the basis of risk criteria,[18] it is unclear how systematically the Program monitors and enforces compliance with re-evaluation decisions such as label changes and phase-outs. In its 2008 audit report, the CESD reported that PMRA had developed and, as of March 2006, had put in place guidelines for determining how quickly a pesticide that does not meet current health or environmental standards for use should be taken off the Canadian market (OAG, 2008). Program representatives reported that the Program does not have a formal policy regarding the timeframe within phase-outs and other re-evaluation decisions must be implemented. They indicated that a 24-month timeframe is the outside limit for label changes with no imminent risk, and this timeframe is outlined in the letter to the registrant; timelines for phase-outs are determined on a case-by-case basis and published in re-evaluation decision documents.

For these reasons, it is challenging to draw a general conclusion about the extent to which products in the marketplace are compliant with re-evaluation decisions, and therefore reflective of modern scientific standards.

4.5.3 Outcome #3: Outreach and Compliance Promotion Activities Contribute to Pesticide Safety Awareness

There is no evidence to support conclusions on the extent to which outreach activities have contributed to pesticide safety awareness among the public, and some evidence, albeit limited, that specific outreach and compliance promotion initiatives have contributed to increased pesticide safety awareness among professional audiences, and applicants, registrants and/or distributors.

With respect to Canadian consumers or the public, there has been no public opinion research (POR) conducted during the evaluation period to assess pesticide safety awareness levels among the public. Previous POR published in 2009 examined stakeholder satisfaction with the federal pesticide regulatory system, but did not measure pesticide safety awareness (EKOS, 2009).

[18] In 2015–16, for example, the Program plans to monitor compliance with re-evaluation decisions for rodenticides and phosphine.

However, a national survey in 2010 measured Canadians' level of concern about pesticides in food.[19] The survey asked Canadians a series of questions about perceived levels of risk and exposure related to pesticides found in food. The findings suggest that pesticides in food are of considerable concern among Canadians and that many Canadians believe the risks of pesticides in food remains unresolved. Over half the respondents (58%) rated pesticides in food as a major risk to their health, and a similar proportion (52%) believed their health had already been affected by pesticides in food. Most respondents (73%) believed that the risk of pesticides in food had either remained the same or generally increased over the five-year period prior to the survey (Phoenix Strategic Perspectives, 2010a, 2010b).

In 2012, PMRA indicated that "negative public perception of chemicals is increasing and it remains a challenge to communicate risk assessment processes to Canadians. In general, Canadians appear to be largely unaware of Health Canada's role in the evaluation and registration of pest control products" (PMRA, 2012e). Similarly, in 2013, PMRA indicated that the "Canadian public and many organizations appear largely unaware of HC/PMRA's role in pesticides and the rigour of its science-based decision-making" and that "stakeholders and PMAC continue to raise the need for improved PMRA communications /outreach" (PMRA, 2013d). Moving forward, PMRA plans to use some additional funds generated as a result of cost recovery for communications and outreach to the public, and to include these activities in its next strategic plan.

With respect to the impact of outreach and compliance promotion activities on pesticide safety awareness among professional audiences, applicants, registrants and/or distributors, there is some evidence, albeit limited, that these activities have contributed to increased awareness among their target audiences.

The following are examples of evidence of increased awareness:

- **Incident reporting – veterinarians**. Beginning in 2011 and continuing in 2012, PMRA collaborated with the Canadian Veterinary Medical Association (CVMA) to disseminate information about the importance of incident reporting to provincial veterinary associations. PMRA indicates that reports from veterinarians increased by 47% in 2012, which it attributed to its outreach efforts (Health Canada, 2013a).
- **Incident reporting – commercial class pesticide companies**. In 2012, PMRA conducted an education outreach initiative with 41 commercial class pesticide companies that had never reported a pesticide incident, to gauge their understanding of the incident reporting requirements. Most companies had high levels of awareness and understanding, but had never reported because they had not been informed of any adverse reactions or concerns relating to any of their pesticides. However, a few lacked understanding of the reporting requirements or did not have a reporting process in place. PMRA undertook additional efforts to educate these companies about pesticide incidence reporting requirements (Health Canada, 2013a).

[19] This research was conducted as part of an assessment of the effectiveness of the *HazardCheck* environmental health guide, which was published in 2010 and aimed to raise Canadians' awareness of preventable health risks associated with their lived environment and inform them of ways to reduce these risks (Phoenix Strategic Perspectives, 2010a). The guide focused generally on hazardous substances in the household and includes a single information box specifically on using pesticides (Health Canada, 2010a).

- **Structural pest control obligations of rental property associations.** During 2011–12, PMRA undertook a three-phase initiative targeting rental property associations to increase their understanding of the legislation governing pest control use in buildings and other structures. The initiative involved identification of knowledge gaps; development and dissemination of an information piece to address these gaps; and follow-up interviews and presentations with rental property associations and their membership. PMRA's report on the initiative indicates that most participants in presentations and interviews found the information to be very or mostly useful, and concluded that the Program "raised awareness of pesticide regulation to the rental property sector" (PMRA, 2014a).

The evaluation also found some evidence of Program activities that have not, so far, led to increased awareness. In particular, a recent compliance planning document reports that failure to adhere with label requirements for personal protective equipment (PPE) is one of the most common forms of non-compliance, occurring across Canada in every inspected user community (agricultural, commercial applicators, industrial users, etc.) (PMRA, 2015b). The document notes further that "traditional active prevention activities have not produced the desired results (increased compliance with PPE requirements)." The Compliance, Laboratory Services, and Regional Operations Directorate (CLSROD) and RAPB intend to consider and possibly pilot new compliance strategies to increase PPE use in user communities during 2015–16.

Overall, the Program has not systematically tracked the effect of its outreach and compliance promotion activities on awareness. The implementation of the new Compliance and Enforcement Performance Measurement Framework is expected to generate relevant data to enable assessment of outcomes for its compliance promotion activities moving forward.

4.5.4 Outcome #4: The Program Protects the Health and Safety of Canadians and the Environment Relating to the Use of Pesticides

Although there are areas for improvement, pesticide regulatory activities across the continuum of pre-market and post-market actions contribute to protecting the health and safety of Canadians and the environment.

The Pesticide Program contributes to protecting the health of Canadians and the environment relating to the use of pesticides through its actions and decisions at various stages of the regulatory process and throughout the product lifecycle.

At the pre-market stage, all pesticides must undergo a science-based review prior to being approved for sale in Canada. Products that meet the PMRA's health and environmental requirements, and are shown to have value, are registered for use in Canada under the conditions stated on the label. That said, the Program's use of conditional registrations was identified as a concern by the CESD in its March 2008 Status Report (OAG, 2008), and the safety of products subject to conditional registrations continues to be a concern for some stakeholders.[20] Under section 12 of the PCPA (2006), registrants may, as a condition of registration, be required to "compile information, conduct tests and monitor experience with the pest control product for the purpose of obtaining additional information with respect to its effects on human health and safety or the environment or with respect to its value" and report this information to PMRA. Conditional registrations may be granted for up to three years[21]. If the required data is not submitted during this time, the expiry date may be extended to allow the applicant to provide it, or the registration may be cancelled.

Program data shows that the number of conditional registrations has declined. As of September 2014, only 1% (n=88) of 7,000 registered products on the market were conditional, although seven have been conditional for over five years.[22] Recently the Standing Committee on Health recommended that PMRA "review the use of conditions of registration to ensure that they are being used in a manner that protects the health of Canadians and their environment" (HESA, 2015). In its response, PMRA indicated that it is currently conducting such a review (Health Canada, 2015b).

At the post-market stage, PMRA conducts re-evaluations and special reviews to ensure that pesticides on the market continue to meet modern scientific standards and their risks and value continue to remain acceptable. The available data on completed re-evaluations shows that the majority of re-evaluations result in changes to the conditions of use, while a large minority are voluntarily discontinued by the manufacturer, and a small minority are phased out. Relatively few are accepted for continued use without any label changes. However, re-evaluations can take a significant length of time to complete, during which time affected end-use products remain on the market, and it is unclear how systematically the Program monitors implementation of re-

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20 For example, the Canadian Environmental Law Association (CELA), on behalf of four environmental groups, objected to PMRA's 2013 decision to renew the conditional registration of Clutch 50 WDG, Arena 50 WDG, and clothianidin insecticides, stating that "clothianidin products…have been allowed in Canadian commerce…for many years without having valid studies otherwise necessary for registration" (CELA, 2014). More recently, Environmental Defence issued a media release after appearing as an expert witness before the federal Standing Committee on Health with respect to its ongoing review of the PCPA. The media release outlined the organization's substantive position against conditional registrations, with specific reference to clothianidin (Environmental Defence, 2015).

21 A decision made under section 8 of the PCPA to grant a registration or amend a registration automatically becomes a "conditional registration" by virtue of section 14 of the PCPRs if a notice under section 12 of the PCPA accompanies the registration decision. That this type of registration decision becomes a "conditional registration" with a shorter prescribed validity period is a function of the Regulations, not section 12 the PCPA.

22 By comparison, in 2008, the CESD reported that 13% of pesticides registered in 2006–07 were conditional. Although these indicators are not directly comparable (one refers to the percentage of all registered products on the market at a given point in time that are conditional, while the other refers to the percentage of products registered in a particular year that are conditional), these data support the conclusion that conditional registrations have declined.

evaluation decisions. Furthermore, levels of compliance with re-evaluation decisions are not well understood due to the Program's risk-based approach to monitoring compliance, since this means that statistically valid conclusions cannot be drawn. In other words, high-risk areas are targeted for inspections, which means that the sample is not representative and, as a result, compliance rates cannot be extrapolated to the industry as a whole.

PMRA conducts compliance promotion and compliance monitoring using a risk-based approach targeting the highest risk sectors, and takes enforcement action where necessary. While PMRA's annual reports include some output data related to compliance and enforcement activities (i.e., number of inspections conducted, number of enforcement actions taken), other information that is important to understanding compliance with the PCPA and its regulations, such as compliance rates among inspected entities and sectors, is not routinely reported.

Finally, PMRA assesses accumulated data from pesticide incident reports[23], and according to Program representatives, once a risk is established, may take action to mitigate the risk. Examples of mitigation actions include amending the conditions of product registration, modifying product packaging, referring the incident to the compliance section, or providing educational outreach. For example, in 2010, an American incident involving the death of two children following exposure to phosphine gas was evaluated and resulted in PMRA prohibiting use of phosphine rodenticides within 500 metres of any residential area. All registered Canadian phosphine-based products were subject to the changes (PMRA, 2011a). As another example, a major environmental incident involving hundreds of weakened or dead lobsters in New Brunswick was identified through analysis of incident reports. An investigation identified a probable connection to cypermethrin, which is not registered in Canada for aquaculture. Further investigation by Environment Canada led to charges under the *Fisheries Act* (PMRA, 2011a).

4.6 Performance: Issue #5 – Demonstration of Economy and Efficiency

Over the last five years, the planned spending of the Pesticide Program has declined. Funding cuts and the need to re-allocate resources in response to unanticipated issues have presented challenges for some program activities, particularly progress on re-evaluations.

Program governance is generally seen as effective and PMRA has plans to develop a logic model and performance measurement strategy in the near future. While the Program's approach to performance measurement has historically focused on activities and outputs, a more robust and meaningful approach could include greater emphasis on outcome measures that speak to the Program's role in protecting the health and safety of Canadians and the environment relating to the use of pesticides.

[23] Section 14 of the PCPA requires the Minister (PMRA) to determine whether a special review should be initiated after receiving information under s. 13 (incident reports) of the PCPA. A special review must be initiated if there are reasonable grounds to believe that the health or environmental risks of the product are, or its value is, unacceptable.

The Treasury Board of Canada's *Policy on Evaluation* (2009) and guidance document, *Assessing Program Resource Utilization When Evaluating Federal Programs* (2013), defines the demonstration of economy and efficiency as an assessment of resource utilization in relation to the production of outputs and progress toward expected outcomes. This assessment is based on the assumption that departments have standardized performance measurement systems and that financial systems link information about program costs to specific inputs, activities, outputs and expected results. Since the Pesticide Program does not take this approach to financial tracking and reporting, the evaluation provided observations on economy and efficiency based on findings from the key informant interviews and relevant financial data. In addition, the findings below provide observations on the adequacy and use of performance measurement information to support economical and efficient program delivery and evaluation.

Observations on Economy and Efficiency

As shown in Table 5, the planned spending of the Pesticide Program declined 13% over the period covered by the evaluation, from $54 million in 2010–11 to $47 million in 2014–15. Over this period, both PMRA and RAPB spent close to their planned expenditures. PMRA directorates generally spent within a few percentage points of their planned budgets in most years covered by the evaluation.[24] The Program as a whole had a small surplus (ranging from 0.6% to 3.5%) in the first four years covered by the evaluation and small deficit (1%) in the fifth year, with an overall surplus of $4.86 million over the five-year period.

Table 5: Variance between planned spending vs. expenditures, program overview

Year	Planned spending ($ millions)	Expenditures ($ millions)	Variance ($ millions)	% Planned budget spent
Pesticides Program Total				
2010–2011	$54.02	$53.70	$.33	99.4%
2011–2012	$53.44	$51.55	$1.89	96.5%
2012–2013	$48.91	$47.37	$1.54	96.8%
2013–2014	$48.76	$47.16	$1.61	96.7%
2014–2015	$47.53	$48.04	-$.51	101.0%
Total	**$252.66**	**$247.81**	**$4.86**	**98.1%**
PMRA				
2010–2011	$50.10	$50.02	$.08	99.8%
2011–2012	$49.47	$47.77	$1.69	96.6%
2012–2013	$44.95	$43.50	$1.45	96.8%
2013–2014	$44.86	$42.99	$1.87	95.8%
2014–2015	$43.56	$44.04	-$.48	101.1%
Total	**$232.93**	**$228.32**	**$4.61**	**98.0%**
RAPB				
2010–2011	$3.92	$3.68	$.25	93.7%
2011–2012	$3.97	$3.78	$.19	95.1%
2012–2013	$3.97	$3.87	$.10	97.5%

[24] One notable exception is the EDO, where the ratio of actual to planned spending ranged from 83% to 142% over the five-year period, although with more stability in the last two years (99% in both years).

Year	Planned spending ($ millions)	Expenditures ($ millions)	Variance ($ millions)	% Planned budget spent
2013–2014	$3.90	$4.16	-$.26	106.7%
2014–2015	$3.97	$4.00	-$.03	100.7%
Total	**$19.73**	**$19.49**	**$.25**	**98.8%**

Data Source: Financial data provided by Chief Financial Officer Branch.

Program representatives indicated that while funding cuts have been challenging, the Program has responded by implementing efficiency measures such as (but not limited to) the following:

- simplifying and streamlining internal processes and associated documentation, such as standard operating procedures
- pursuing modernization of electronic business systems
- introducing new tools, technologies, and training (e.g., databases for internal use, mobile technology tools such as tablets and core training for compliance and enforcement officers)
- simplifying and streamlining processes related to data protection for generics, product renewals, and applications involving minor changes
- revising and creating new guidance documents and templates for applicants
- conducting focused and targeted re-evaluations
- simplifying planning processes for compliance and enforcement activities, and reducing the number of compliance and enforcement programs
- developing and working to implement a new cost recovery regime that will allow increased revenues to be directed to Program priorities
- placing increased emphasis on collaboration, work sharing, and alignment with international regulatory agencies, particularly in terms of new chemistry, science policy, submission requirements, joint reviews, and re-evaluations[25]

Program representatives indicated that, in addition to budget reductions, the need to re-allocate resources to unplanned-for-activities and emerging issues has presented challenges, and has had consequences for some Program activities, particularly re-evaluations. They noted that resources dedicated to re-evaluation have not been stable or dedicated over the years, despite increased pressure as a result of the statutory requirement to do more cyclical re-evaluations. Staff reported that the large number of special reviews initiated in 2013–14, and the need to respond to a large number of pollinator incidents in 2012, required resource re-allocations and contributed to a decline in the number of re-evaluations initiated in 2013–14 relative to the previous year, and also affected progress in completing re-evaluations. It is unclear if, over the longer term, the Program's re-evaluation work will be impacted by these or similar occurrences.

Finally, some external key informants believe that Program resources are insufficient to keep abreast of evolving science, a concern that was also raised in consultations on possible changes to the cost recovery regulations. PMRA representatives acknowledged that it can be challenging to balance its regulatory activities with the need to keep up-to-date on scientific developments.

[25] However, although program representatives expected that efficiencies may eventually be gained through such collaborative work, they also observed that the main benefit of international collaboration is better quality regulatory decisions, rather than efficiency gains.

Science policy is one of the areas to which PMRA intends to direct additional funds generated as a result of cost recovery.

Program and external key informants identified relatively few additional measures and alternatives that could further enhance efficiencies. At the pre-market stage, suggestions included conducting group assessments of pesticides similar to the approach to risk assessment being taken by the CMP, and mutual recognition of other countries' decisions. At the post-market stage, key informants suggested exploring the use of social media and other new technologies to promote compliance, and introducing multi-year programs for compliance and enforcement consisting of stakeholder education and engagement in the first year, followed in later years by monitoring, inspection, and enforcement.

Observations on Program Governance and the Adequacy and Use of Performance Measurement Data

Within PMRA, the Pest Management Regulatory Agency Management Committee (AMC) is the most senior committee, responsible for establishing and fulfilling the mission and vision of the PMRA and supporting the strategic management of the Agency's substantive and corporate responsibilities. The AMC is chaired by the Executive Director (ED) of PMRA, and consists of the ED, the Directors General (DG) and any Director reporting directly to the ED. The AMC is supported by the Science Management Committee (SMC) and the Operations Sub-Committee (OSC). In addition, the Science Operations Sub-committee reports to the SMC. Terms of Reference exist for all of these committees, outlining their respective roles and responsibilities.

The relationship between PMRA and RAPB is governed by a "Strategic Partnership Structure between PMRA and RAPB" document, which describes how these organizations work together in the area of compliance and enforcement and to deliver specific aspects of the FCSAP. The document describes a three-tiered decision-making structure, supported by a variety of non-decisional/delivery-level structures and networks.

While some Program key informants noted that it can be occasionally challenging to coordinate the timing of the interdependent activities of the various directorates involved in Program activities, on balance the existing governance structure is seen by all Program partners as effective, and no changes were suggested.

With respect to performance measurement, a joint PMRA/RAPB Performance Measurement Framework (PMF) has been developed for the Pesticide Compliance and Enforcement Program. The strategic plan, which is expected to be completed by June 2016, will include commitments to improve performance information and develop a logic model and Performance Measurement Strategy for PMRA and the Program as a whole.

Based on internal performance reports (such as monthly dashboards), as well as external reports (such as PMRA's annual reports and Health Canada's DPR), the Program's approach to performance measurement has, to date, been heavily focused on reporting information on activities, outputs, and performance against service standards. Collecting data and reporting on operational indicators is important for informing effective Program management. However, a

more robust and meaningful approach to performance measurement could include greater emphasis on outcome measures that speak to the Program's role in protecting the health and safety of Canadians and the environment relating to the use of pesticides.

5.0 Conclusions

5.1 Relevance Conclusions

5.1.1 Continued Need

Pesticides can pose risks to human health and the environment. New information on the impact of pesticides on human health and the environment is being continually generated, and scientific standards are continually evolving. There is an ongoing need for regulation to manage the risks associated with pesticides.

Pesticides offer important benefits to people, such as the control of agricultural pests and of organisms that cause disease in crop commodities, as well as control of pests in sectors such as forestry, industrial settings, structural pest control, and domestic uses. However, despite their benefits, pesticides can have detrimental effects on both human health and the environment if not used properly. New information on the impact of pesticides on human health and the environment is being continually generated, and scientific standards continually evolve. For these reasons, the ongoing regulation of pesticides is required to ensure that the risks to human health and the environment, as associated with the use of these products, remain acceptable and are appropriately managed.

5.1.2 Alignment with Government Priorities

The Pesticide Program is aligned with the priorities of the federal government, as they have been articulated in major federal initiatives in recent years, and with Health Canada's current strategic outcome #2.

While recent Speeches from the Throne have not specifically mentioned pesticides regulation or protecting Canadians and the environment from risks associated with pesticides, PMRA has been included in several major federal initiatives introduced and/or ongoing during the time period covered by this evaluation. These initiatives focussed on addressing federal priorities related to food, health, and consumer product safety; managing risks to human health and the environment associated with toxic chemicals; encouraging innovation, competitiveness, and market development in the agricultural sector; and encouraging regulatory alignment with the US. These initiatives include the FCSAP, the CMP, Growing Forward, the SWI, and relevant initiatives under the RCC.

The activities and expected outcomes of the Pesticide Program align with and support Health Canada's Strategic Outcome 2, that "Health risks and benefits associated with food, products, substances, and environmental factors are appropriately managed and communicated to Canadians."

5.1.3 Alignment with Federal Roles and Responsibilities

The activities carried out under the Pesticide Program are consistent with federal responsibilities under the Pest Control Products Act (PCPA). There is, however, concern among industry that provincial/territorial and municipal activities can sometimes be inconsistent with regulatory decisions made by the PMRA.

There is some concern among industry that provincial/territorial and municipal activities such as restrictions on pesticide use and Ontario's plans to reduce the use of neonicotinoids in agriculture are inconsistent with regulatory decisions made by the PMRA. Despite these concerns, the activities carried out under the Pesticide Program are consistent with federal responsibilities under the PCPA.

5.2 Performance Conclusions

5.2.1 Response to Challenges and Emerging Issues

The Pesticide Program addressed several interrelated challenges and issues during the period being evaluated, including increased complexity and volume of pesticide regulatory activities, increased globalization and international trade, and evolving science. This was accomplished through emphasizing international collaboration and work sharing, developing a proposal for a new cost recovery framework, and initiating efforts to modernize electronic business support systems.

PMRA undertook a number of initiatives during the evaluation period to address challenges, emerging issues, and changing priorities, such as increased complexity and volume of pesticide regulatory activities, increased globalization and international trade, and evolving science. To respond to increased globalization and trade issues and keep pace with evolving science, PMRA has increasingly emphasized international collaboration and work sharing, notably through joint reviews, efforts to harmonize MRLs, joint science policy, and other initiatives. While international collaboration is a key mechanism by which PMRA stays abreast of and contributes to evolving science, both internal and external key informants indicated that resource constraints create challenges in keeping abreast of scientific developments.

PMRA also developed a proposal for a new cost recovery framework, which is expected to allow it to continue to meet performance standards for regulatory activities, while also allowing it to direct additional revenue to stakeholder priorities, such as expanding international regulatory cooperation, science policy, electronic infrastructure, and outreach. Finally, PMRA has embarked on an initiative to modernize its electronic business systems to support international collaboration and increase efficiencies.

5.2.2 Submission Review and Registration

PMRA has implemented several measures to improve the efficiency and clarity of the submission review and registration process, including revisions to policies, regulatory directives and internal processes. However, there are still opportunities for further improvements in some areas, including clarifying data requirements and improving the electronic submission process.

PMRA implemented various measures to improve the efficiency and clarity of the submission review and registration process, for example implementing the Revised Management of Submissions Policy and various Regulatory Directives, and establishing new internal processes within the PMRA directorates involved in submission review and registration. Performance standards for submission review have generally been met for Category A and B submissions in recent years.

Nevertheless, more than half of survey respondents experienced challenges with the submission process, citing unclear data requirements, delays, and difficulties with the electronic submission process. PMRA's current approach to registering generic pesticide products is seen as problematic by some industry key informants, who recommended implementing a more streamlined process similar to the one in the US.

5.2.3 Re-evaluations and Special Reviews

PMRA has made progress in initiating and completing re-evaluations under its two re-evaluation streams. However, there are challenges to completing re-evaluations in a timely manner, and performance standards for their completion have not been formally adopted. Special reviews can arise unpredictably and, as such, are difficult to account for in planning and have contributed to delays in re-evaluations.

Limitations of PMRA's approach to tracking and reporting on re-evaluation activity make it challenging to understand the current status of this activity. The available evidence suggests that PMRA has made progress in initiating and completing cyclical re-evaluations and original re-evaluations. To date, the majority of the completions were initiated as part of the original re-evaluations.

The length of time PMRA takes to complete re-evaluations was criticized by the CESD in 2008, and continues to be a concern for some key informants. Data analysis indicates that older re-evaluations required, on average, 3.9 years from initiation to completion (based on 238 re-evaluations), while the small number of cyclical re-evaluations completed to date (7) required an average of 2.9 years to complete. PMRA acknowledged that re-evaluations can take a considerable length of time to complete, citing challenges in receiving required information in a timely manner and inability to predict the timing of special reviews, which have necessitated resource re-allocations and contributed to delays. Although the Agency has taken steps to increase efficiencies in the re-evaluation process, and has established internal timelines for re-evaluations, it has not implemented a formal performance standard for their completion.

5.2.4 Incident and Sales Reporting

Some industry and other stakeholders do not know how PMRA uses the information collected through incident and sales reporting, suggesting opportunities to improve communication to stakeholders about these elements of the Pesticide Program.

Registrants and applicants are required to report pesticide incident and annual sales information to PMRA under the PCPA and the PCPR. While the survey of registrants found that about 60% of registrants understand their obligations under the IRP, only 35% understand how PMRA uses the information collected. Similarly, although about 80% of survey respondents understand their obligations under the Sales Reporting Program, only 43% understand how PMRA uses the information collected. Key informants representing industry and NGOs also expressed uncertainty about PMRA's use of incident and sales reporting data, or were critical of the nature or timeliness of the information published by PMRA with respect to these Program elements.

5.2.5 Compliance and Enforcement

PMRA and RAPB undertake a wide range of compliance promotion, monitoring, and enforcement activities. There are opportunities to improve communication on compliance and enforcement policy, activities, and results.

Compliance promotion, monitoring, and enforcement activities are designed and administered by PMRA and delivered by regional teams with the Pesticide Compliance Program of the RAPB. The scope of these activities is broad due to the range of agricultural, commercial, industrial, and residential pesticide applications, and particular challenges exist with respect to unregistered and imported products and pesticide users. Given limited resources, a risk-based approach to annual planning and priority setting is taken. To date, the Program's reporting on compliance and enforcement has focused primarily on activities and outputs.

Results from the survey of registrants suggest opportunities to improve communication on compliance and enforcement policy, activities, and results. While 70% of respondents believe their own organization understands what it needs to do to be in compliance, only 43% agree that the Program communicates effectively with applicants and registrants about the legislative and regulatory requirements that apply to them. Only about one-third believe that compliance and enforcement activities are effective at identifying non-compliances and that the Program responds effectively to risks posed by non-compliance; areas of particular concern were imported, unregistered, and counterfeit products and off-label use. PMRA plans to provide more information to Canadians on pesticide compliance and enforcement under Health Canada's Regulatory Transparency and Openness Framework.

5.2.6 Outreach Activities

The Pesticide Program undertakes a variety of outreach activities targeting consumer and professional audiences. PMRA plans to include public outreach activities in its next strategic plan.

The Program's outreach activities target professional and user audiences, as well as the public, and include developing and distributing educational materials; managing a 1-800 information line and email service; and providing support and advice for RAPB regional office participation at fairs,

exhibits, and other opportunities through the use of displays and printed materials. External key informants had mixed views on the extent to which these outreach activities are reaching and affecting their intended audiences, and NGOs in particular perceive a need to more clearly communicate to Canadians that pesticide labels are the law (rather than merely a suggestion for use); to release information more quickly to the public; to raise public awareness of pesticide risks; and to encourage safer alternatives to conventional pesticides. PMRA plans to include outreach activities in its next strategic plan.

5.2.7 Collaboration, Consultation and Engagement

The Pesticide Program collaborates with international, federal, and provincial/territorial partners and consults with industry and non-industry stakeholders through a variety of engagement activities. While partners agree on the value of collaboration, some NGO and industry stakeholders are dissatisfied with the Program's efforts at consultation and engagement.

The Pesticide Program collaborates with a variety of external partners, including international regulatory bodies and organizations, other federal departments and agencies, and the provinces and territories. There was general agreement among international, federal, and provincial/territorial partners who were interviewed, as well as Program representatives, on the value of collaboration and its contribution to more informed pesticide regulatory decisions by the Program and/or their own organizations.

The Program engages and consults with industry and non-industry external stakeholders through various mechanisms. Overall, industry stakeholders have more opportunities for consultation than other external stakeholders such as NGOs, which may in part account for generally less positive views of these activities among the latter. Recently, the Standing Committee on Health recommended that PMRA review the openness and transparency of its processes in order to ensure that Canadians are able to provide meaningful and informed input, and PMRA has made related commitments under the Regulatory Transparency and Openness Framework.

5.3 Achievement of Expected Outcomes (Effectiveness)

5.3.1 Outcome #1: Industry Meets Canadian Regulatory Requirements for New Pesticides

PMRA assesses progress towards this outcome based on the proportion of completed new submissions that meet regulatory requirements. However, the submission and review process can be an iterative one and modifications made to submissions to address deficiencies or requests for additional information are not accounted for in reporting. Based on completed submissions, industry is generally meeting regulatory requirements for new pesticides.

PMRA's submission review and registration process is intended to ensure that products registered in Canada do not pose unacceptable risks to health and the environment, and that they have value. The available data on completed new pesticide submissions suggest that industry is generally meeting regulatory requirements for new pesticides, in large part due to the iterative

and collaborative process between PMRA and industry. Of the Category A and B submissions completed between 2009–10 and 2014–15, only 0.03% were rejected and 1.3% were withdrawn.

5.3.2 Outcome #2: Pesticides in the Marketplace Continue to Meet Modern Scientific Standards

The re-evaluation program is an important mechanism for helping to ensure that pesticides in the marketplace continue to meet modern scientific standards. However, re-evaluations take considerable time to complete, and it is unclear how systematically PMRA monitors and enforces compliance with re-evaluation decisions.

The re-evaluation program is an important mechanism for ensuring that pesticides in the market place continue to meet modern scientific standards. Re-evaluation data show that in the majority of cases, registration of active ingredients is continued with label modifications, while a minority of active ingredients are phased out; relatively few registrations continue without label modifications. However, timelines for completing re-evaluations can be lengthy, and while the Program monitors compliance with some re-evaluation decisions through its compliance monitoring program, it is unclear how systematically the Program monitors and enforces compliance with re-evaluation decisions.

5.3.3 Outcome #3: Outreach and Compliance Promotion Activities Contribute to Pesticide Safety Awareness

There is no evidence to support conclusions on the extent to which outreach activities have contributed to pesticide safety awareness among the public, and some evidence, albeit limited, that specific outreach and compliance promotion initiatives have contributed to increased pesticide safety awareness among professional audiences and regulated parties.

There has been no POR conducted during the evaluation period to assess pesticide safety awareness levels among the public, and therefore no evidence to support conclusions on the extent to which the Program's outreach activities have contributed to increased awareness. PMRA has acknowledged the need to improve communications and outreach to the public, and plans to use some additional funds generated as a result of cost recovery for this purpose.

There is some evidence, albeit limited, that outreach and compliance promotion activities have contributed to increased awareness among professional audiences and regulated parties. Overall, the Program has not systematically tracked the effect of its outreach and compliance promotion activities on awareness. The implementation of a new Compliance and Enforcement Performance Measurement Framework is expected to generate relevant data to enable assessment of outcomes for its compliance promotion activities moving forward.

5.3.4 Outcome #4: The Program protects the health and safety of Canadians and the environment relating to the use of pesticides

Although there are areas for improvement, pesticide regulatory activities across the continuum of pre-market and post-market actions contribute to protecting the health and safety of Canadians and the environment.

The Pesticide Program contributes to protecting the health of Canadians and the environment relating to the use of pesticides through its actions and decisions at various stages of the regulatory process and throughout the product lifecycle.

At the pre-market stage, all pesticides must undergo a science-based review prior to being approved for sale in Canada. Products that meet the PMRA's health and environmental requirements, and are shown to have value, are registered for use in Canada under the conditions stated on the label. The use of conditional registrations, which has been an area of concern for the CESD and other stakeholders, has declined, and PMRA is currently reviewing their use in response to recommendations recently made by the HESA Committee in its statutory review of the PCPA.

At the post-market stage, PMRA conducts re-evaluations and special reviews to ensure that pesticides on the market continue to meet modern scientific standards and their risks and value continue to remain acceptable; conducts compliance promotion, monitoring, and enforcement activities using a risk-based approach targeting the highest risk sectors; and analyzes pesticide incident report data and takes action to mitigate established risks. Although PMRA has taken steps to improve efficiencies in the re-evaluation process, there are opportunities to address the lengthy timelines involved in completing re-evaluations, and for more systematic monitoring and enforcement of re-evaluation decisions (for example, label changes and product removal).

5.4 Demonstration of Economy and Efficiency

Over the last five years, the planned spending of the Pesticide Program has declined, and funding cuts and the need to re-allocate resources in response to unanticipated issues have presented challenges for some Program activities, particularly re-evaluations.

The current approach to program governance is generally seen as effective and PMRA has plans to develop a logic model and performance measurement strategy in the near future. While the Program's approach to performance measurement has historically focused on activities and outputs, a more robust approach could include greater emphasis on outcome measures that speak to its role in protecting the health and safety of Canadians and the environment relating to the use of pesticides.

The planned spending of the Pesticide Program declined 13% over the period covered by the evaluation, from a high of $54 million in 2010–11 to $47 million in 2014–15, and the need to re-allocate resources to unplanned-for-activities and emerging issues has had consequences for some activities, and in particular has delayed progress on initiating and completing re-evaluations. The Program has responded to budget cuts by implementing efficiency measures, such as simplifying and streamlining internal processes and documentation; pursuing modernization of electronic business systems; introducing new tools, technologies, and training; and focusing and targeting re-evaluations, among many others. Some stakeholders raised both the Program's ability to

manage its re-evaluation workload and its ability to keep abreast of evolving science as areas of concern, given its current resources.

The current approach to governance is generally seen as effective, despite occasional challenges in coordinating the interdependent activities of the various directorates involved in Program activities. With respect to performance measurement, a joint PMRA/RAPB PMF has been developed for the Pesticide Compliance and Enforcement Program, and PMRA has plans to develop a Program-wide logic model and performance measurement strategy in the near future. The Program's approach to performance measurement has, to date, been heavily focused on reporting information on activities, outputs, and performance against service standards. While collecting data and reporting on operational indicators is important for informing effective program management, a more robust and meaningful approach to performance measurement could include greater emphasis on outcome measures that speak to the Program's role in protecting the health and safety of Canadians and the environment relating to the use of pesticides.

6.0 Recommendations

Recommendation 1:

PMRA should address the lengthy timelines involved in the re-evaluation process through establishing enhanced work plans that are complete and up-to-date. Progress against these work plans should be published regularly (e.g., annually).

Re-evaluations of registered pesticides take a considerable length of time to complete, and PMRA is facing increasing pressure as a result of the statutory requirement to conduct cyclical re-evaluations. Although PMRA has taken steps to increase efficiencies in the re-evaluation process and has established internal milestones for completing re-evaluations, establishing enhanced work plans and reporting to the public on its success in implementing them could help to address issues with the current timelines for re-evaluations.

Recommendation 2:

The Pesticide Program should take steps to improve communication to key stakeholders with respect to compliance policy, activities, and outcomes, and with respect to its use of incident and sales reporting data.

Industry and other stakeholders expressed a desire for more information from the Program in several areas, including compliance policy, activities, and outcomes, as well as the Program's use of incident and sales reporting data. Improving communication in these areas should be considered as Health Canada implements the Regulatory Transparency and Openness Framework.

Recommendation 3:

The Pesticide Program should move forward with plans to enhance public outreach activities to increase the awareness and understanding among Canadians of its role and of the risks and safe use of pesticides, and measure the outcomes of related activities.

While the Pesticide Program currently conducts some outreach targeting the public, it is unknown whether these activities are reaching and affecting their intended audience. PMRA plans to include outreach activities in its next strategic plan.

Recommendation 4:

As PMRA moves forward with plans to develop a logic model and performance measurement strategy, consideration should be given to reporting on outcomes to a greater extent than has been done in the past.

The Program's approach to performance measurement has, to date, been focused on reporting information on activities, outputs, and performance against service standards. A more robust and meaningful approach to performance measurement could include greater emphasis on outcome measures that speak to the Program's role in protecting the health and safety of Canadians and the environment relating to the use of pesticides.

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Appendix 2 – Summary of Findings

Rating of Findings
Ratings have been provided to indicate the degree to which each evaluation issue and question has been addressed.

Relevance Rating Symbols and Significance:
A summary of Relevance Ratings is presented in Table 1 below. A description of the Relevance Ratings Symbols and Significance can be found in the Legend.

Table 1: Relevance Rating Symbols and Significance

Issues	Indicators	Overall Rating	Summary
Continued need for the Program			
Does the Pesticide Program continue to address a demonstrable need?	• Evidence of current/emerging health and/or environmental impacts related to pesticide use • Presence/absence of other programs addressing Program objectives • Expert/stakeholder assessment of ongoing need	**High**	Pesticides offer important benefits to people, such as control of agricultural pests and of organisms that cause disease in crop commodities, as well as control of pests that are inconvenient to or threaten human activities. However, despite their benefits, pesticides can have detrimental effects on both human health and the environment. Moreover, the nature of some of these effects, depending on the substance, remains controversial and is being actively investigated by researchers. New information on the impact of pesticides on human health and the environment is being continually generated, and scientific standards are continually evolving. For these reasons, ongoing regulation of pesticides is required to ensure that the risks to human health and the environment associated with the use of these products are acceptable.
Alignment with Government Priorities			
Do the objectives of the Pesticide Program align with federal government priorities? Do the objectives of the Program align with Health Canada strategic outcomes?	• Correspondence of Pesticide Program objectives with federal government priorities • Correspondence of objectives with strategic outcomes of Health Canada	**High**	While recent Speeches from the Throne have not specifically mentioned pesticide regulation or protecting Canadians and the environment from risks associated with pesticides, PMRA has been included in several major federal initiatives introduced and/or ongoing during the time period covered by this evaluation. These initiatives focussed on addressing federal priorities related to food, health, and consumer product safety; managing risks to human health and the environment associated with toxic chemicals; encouraging innovation, competitiveness and market development in the agricultural sector; and encouraging regulatory alignment with the US.

Legend - Relevance Rating Symbols and Significance:

High	There is a demonstrable need for program activities; there is a demonstrated link between program objectives and (i) federal government priorities and (ii) departmental strategic outcomes; role and responsibilities for the federal government in delivering the program are clear.
Partial	There is a partial need for program activities; there is some direct or indirect link between program objectives and (i) federal government priorities and (ii) departmental strategic outcomes; role and responsibilities for the federal government in delivering the program are partially clear.
Low	There is no demonstrable need for program activities; there is no clear link between program objectives and (i) federal government priorities and (ii) departmental strategic outcomes; role and responsibilities for the federal government in delivering the program have not clearly been articulated.

Issues	Indicators	Overall Rating	Summary
			The activities and expected outcomes of the Pesticide Program align with and support Health Canada's Strategic Outcome 2, that "Health risks and benefits associated with food, products, substances, and environmental factors are appropriately managed and communicated to Canadians."
Alignment with Federal Roles and Responsibilities			
Do Pesticide Program activities align with federal government roles and responsibilities? Do any federal roles/activities duplicate those of other stakeholders?	• Correspondence of Pesticide Program activities with federal government/Health Canada roles and responsibilities • Evidence of duplication or overlap of roles or activities with other stakeholders/jurisdictions • Related federal and provincial/territorial programs related to pesticide safety • Perceptions related to duplication of roles/activities • Perspectives on appropriateness of federal involvement	**High**	The activities carried out under the Pesticide Program are consistent with federal responsibilities under the Pest Control Products Act (PCPA). There is, however, concern among industry that provincial/territorial and municipal activities can sometimes be inconsistent with regulatory decisions made by the PMRA, for example, restrictions on pesticide use and Ontario's plans to reduce the use of neonicotinoids in agriculture.

Legend - Relevance Rating Symbols and Significance:

High There is a demonstrable need for program activities; there is a demonstrated link between program objectives and (i) federal government priorities and (ii) departmental strategic outcomes; role and responsibilities for the federal government in delivering the program are clear.

Partial There is a partial need for program activities; there is some direct or indirect link between program objectives and (i) federal government priorities and (ii) departmental strategic outcomes; role and responsibilities for the federal government in delivering the program are partially clear.

Low There is no demonstrable need for program activities; there is no clear link between program objectives and (i) federal government priorities and (ii) departmental strategic outcomes; role and responsibilities for the federal government in delivering the program have not clearly been articulated.

Performance Rating Symbols and Significance:

A summary of Performance Ratings is presented in Table 2 below. A description of the Performance Ratings Symbols and Significance can be found in the Legend.

Table 2: Performance Rating Symbols and Significance

Issues	Indicators	Overall Rating	Summary
Achievement of Expected Outcomes (Effectiveness)			
To what extent does industry meet Canadian regulatory requirements for new pesticides?	• Number and percentage of submissions that meet/do not meet regulatory requirements • Perspectives on extent to which industry meets regulatory requirements for new pesticides	**Achieved**	PMRA assesses progress towards this outcome based on the proportion of completed new submissions that meet regulatory requirements. However, the submission and review process can be an iterative one and modifications made to submissions to address deficiencies or requests for additional information are not accounted for in reporting. That having been said, the available data on completed new pesticide submissions suggest that industry is generally meeting regulatory requirements for new pesticides. Of the Category A and B submissions completed between 2009–10 and 2014–15, only 0.03% were rejected and 1.3% were withdrawn.
To what extent do pesticides in the marketplace continue to meet modern scientific standards?	• Number of re-evaluations initiated and completed (original and cyclical) • Number and percentage of products or uses subject to continued registration with label modifications as a result of an unacceptable health and/or environmental risk finding following re-evaluation • Number and percentage of products or uses phased out as a result of an unacceptable health and/or environmental risk finding following re-evaluation • Timelines for completing re-evaluations • Compliance rates for re-evaluations • Perspectives on extent to which pesticides continue to meet modern scientific standards	**Progress Made; Further Work Warranted**	The re-evaluation program is an important mechanism for ensuring that pesticides in the marketplace continue to meet modern scientific standards. Re-evaluation data show that in the majority of cases, registration of active ingredients is continued with label modifications, while a minority of active ingredients are phased out; relatively few registrations continue without label modifications. However, timelines for completing re-evaluations can be lengthy, and while the Program monitors compliance with some re-evaluation decisions through its compliance monitoring program, it is unclear how systematically the Program monitors and enforces compliance with re-evaluation decisions.

Legend - Performance Rating Symbols and Significance:

Achieved	The intended outcomes or goals have been achieved or met.
Progress Made; Further Work Warranted	Considerable progress has been made to meet the intended outcomes or goals, but attention is still needed.
Little Progress; Priority for Attention	Little progress has been made to meet the intended outcomes or goals and attention is needed on a priority basis.

Issues	Indicators	Overall Rating	Summary
To what extent have outreach/compliance promotion activities contributed to pesticide safety awareness?	• Number and type of outreach activities (including compliance promotion) • Pesticide safety awareness levels among target audiences • Perspectives on effectiveness of outreach activities	**Progress Made; Further Work Warranted**	PMRA and RAPB conduct a variety of outreach and compliance promotion activities targeting professional and consumer audiences. There has been no POR conducted during the evaluation period to assess pesticide safety awareness levels among the public, and therefore no evidence to support conclusions on the extent to which the Program's outreach activities have contributed to increased awareness. PMRA has acknowledged the need to improve communications and outreach to the public, and plans to use some additional funds generated as a result of cost recovery for this purpose. There is some evidence, albeit limited, that outreach and compliance promotion activities have contributed to increased awareness among professional audiences and regulated parties. Overall, the Program has not systematically tracked the effect of its outreach and compliance promotion activities on awareness. The implementation of a new Compliance and Enforcement Performance Measurement Framework is expected to generate relevant data to enable assessment of outcomes for its compliance promotion activities moving forward.
To what extent has the Program protected the health and safety of Canadians and the environment relating to the use of pesticides?	• Number and percentage of submissions that meet/do not meet regulatory requirements • Number and percentage of conditional registration • Number of re-evaluations initiated and completed (original and cyclical) • Number and percentage of products or uses subject to continued registration with label modifications as a result of an unacceptable health and/or environmental risk finding following re-evaluation • Number and percentage of products or uses phased out as a result of an unacceptable health and/or environmental risk finding following re-evaluation • Timelines for completing re-evaluations • Compliance rates for re-evaluations • Compliance rates among inspected entities and sectors • PMRA response to incident reports (i.e., actions taken) • Perspectives on extent to which the Program has protected the health and safety of Canadians and the environment	**Progress Made; Further Work Warranted**	The Pesticide Program contributes to protecting the health of Canadians and the environment relating to the use of pesticides through its actions and decisions at various stages of the regulatory process and throughout the product lifecycle. At the pre-market stage, all pesticides must undergo a science-based review prior to being approved for sale in Canada. Products that meet the PMRA's health and environmental requirements, and are shown to have value, are registered for use in Canada under the conditions stated on the label. Program data indicate that the vast majority of submissions meet regulatory requirements and result in product registration. The use of conditional registrations, which has been an area of concern for the CESD and other stakeholders, has declined, and PMRA is currently reviewing their use in response to recommendations recently made by the HESA Committee in its statutory review of the PCPA. At the post-market stage, PMRA conducts re-evaluations and special reviews to ensure that pesticides on the market continue to meet modern scientific standards and their risks and value continue to remain acceptable; conducts compliance promotion, monitoring, and enforcement activities using a risk-based approach targeting the highest risk sectors; and analyzes pesticide incident report data and takes action to mitigate established risks. Although PMRA has taken steps to improve efficiencies in the re-evaluation process, there are opportunities to address the lengthy timelines involved in completing re-evaluations.

Legend - Performance Rating Symbols and Significance:

Achieved	The intended outcomes or goals have been achieved or met.
Progress Made; Further Work Warranted	Considerable progress has been made to meet the intended outcomes or goals, but attention is still needed.
Little Progress; Priority for Attention	Little progress has been made to meet the intended outcomes or goals and attention is needed on a priority basis.

Issues	Indicators	Overall Rating	Summary
Demonstration of Economy and Efficiency			
To what extent are the governance and working relationships clear, effective and efficient for achieving expected results (e.g., between directorates, and between RAPB and PMRA)? How is achievement of results measured and reported? How is this information used in decision-making?	• Evidence of a functioning governance structure, clearly defined roles and responsibilities, and effective working relationships among partners and within PMRA • Perceived clarity and effectiveness of governance and working relationships • Evidence of implementation of a performance measurement system with baseline data and targets • Availability of timely and reliable performance data for measuring outcomes • Evidence that performance data is used in decision making • Extent to which performance data is reported Perceived utility of performance data for decision making	**Progress Made; Further Work Warranted**	The current approach to governance is generally seen as effective, despite occasional challenges in coordinating the interdependent activities of the various directorates involved in Program activities. With respect to performance measurement, a joint PMRA/RAPB PMF has been developed for the Pesticide Compliance and Enforcement Program, and PMRA has plans to develop a Program-wide logic model and performance measurement strategy in the near future. The Program's approach to performance measurement has, to date, been heavily focused on reporting information on activities, outputs, and performance against service standards. While collecting data and reporting on operational indicators is important for informing effective program management, a more robust and meaningful approach to performance measurement could include greater emphasis on outcome measures that speak to the Program's role in protecting the health and safety of Canadians and the environment relating to the use of pesticides.
Are Program resources/capacity aligned appropriately across key activities? Has the Program undertaken its activities in the most economical and efficient manner? Are there alternative ways to achieve similar results at a lower cost?	• Analysis of resource allocations and outputs relative to targets/commitments including the extent to which failure to meet targets or commitments was due to misalignment of resources • Allocation of resources based on risks or other factors • Perspectives on appropriateness of resource allocations • Evidence of/views on efficiencies or inefficiencies • Comparison of Program budget allocation vs. expenditures • Potential efficiencies/cost savings identified by key informants • Approaches taken in other jurisdictions implementing similar activities • Progress responding to previous evaluations/audits • Potential alternatives identified by Pesticide Program representatives and stakeholders • Approaches taken by other jurisdictions to achieve similar results	**Progress Made; Further Work Warranted**	The planned spending of the Pesticide Program declined 13% over the period covered by the evaluation, from $54 million in 2010–11 to $47 million in 2014–15, and the need to re-allocate resources to unplanned-for-activities and emerging issues has had consequences for some activities. The Program has responded to budget cuts by implementing efficiency measures, such as simplifying and streamlining internal processes and documentation; pursuing modernization of electronic business systems; introducing new tools, technologies, and training; and focusing and targeting re-evaluations, among many others. Some stakeholders raised both the Program's ability to manage its re-evaluation workload and its ability to keep abreast of evolving science as areas of concern, given its current resources.

Legend - Performance Rating Symbols and Significance:

Achieved	The intended outcomes or goals have been achieved or met.
Progress Made; Further Work Warranted	Considerable progress has been made to meet the intended outcomes or goals, but attention is still needed.
Little Progress; Priority for Attention	Little progress has been made to meet the intended outcomes or goals and attention is needed on a priority basis.

Appendix 3 – Evaluation Description

Evaluation Scope

The evaluation focused on the five-year period ending December 2014, although data outside this timeframe is included as appropriate, and included all Pesticide Program regulatory activities.

Evaluation Issues

The specific evaluation questions used in this evaluation were based on the five core issues prescribed in the Treasury Board of Canada's *Policy on Evaluation* (2009). These are noted in the table below. Corresponding to each of the core issues, evaluation questions were tailored to the Program and guided the evaluation process.

Table 1: Core Evaluation Issues and Questions

Core Issues		Evaluation Questions
Relevance		
Issue #1:	Continued Need for Program	Assessment of the extent to which the Program continues to address a demonstrable need and is responsive to the needs of Canadians • Does the Pesticide Program continue to address a demonstrable need?
Issue #2:	Alignment with Government Priorities	Assessment of the linkages between Program objectives and (i) federal government priorities and (ii) departmental strategic outcomes • Do the objectives of the Pesticide Program align with federal government priorities? • Do the objectives of the Program align with Health Canada strategic outcomes?
Issue #3:	Alignment with Federal Roles and Responsibilities	Assessment of the role and responsibilities for the federal government in delivering the Program • Do Pesticide Program activities align with federal government roles and responsibilities? • Do any federal roles/activities duplicate those of other stakeholders?
Performance (effectiveness, economy and efficiency)		

Issue #4:	Achievement of Expected Outcomes (Effectiveness)	Assessment of progress toward expected outcomes (incl. immediate, intermediate and ultimate outcomes) with reference to performance targets and program reach, program design, including the linkage and contribution of outputs to outcomes
		• Have the activities produced the expected outputs?
		  ◦ To what extent are regulatory activities/decisions delivered in a timely manner?
		  ◦ To what extent have collaborations (both internally and externally) contributed to more informed pesticides regulatory decisions?
		  ◦ How effective has PMRA's approach to international collaboration, including harmonizing processes and scientific approaches for joint reviews been?
		• Has the Program effectively addressed challenges, emerging issues and changing priorities (e.g., evolving science, increased globalization, trade issues, cost recovery, changing regulations, electronic infrastructure)?
		• To what extent has the Program achieved its expected outcomes?
		  ◦ To what extent does industry meet Canadian regulatory requirements for new pesticides?
		  ◦ To what extent do pesticides in the marketplace continue to meet modern scientific standards?
		  ◦ To what extent have outreach/compliance promotion activities contributed to pesticide safety awareness?
		  ◦ To what extent has the Program protected the health and safety of Canadians and the environment relating to the use of pesticides?

Core Issues		Evaluation Questions
Issue #5:	Demonstration of Economy and Efficiency	Assessment of resource utilization in relation to the production of outputs and progress toward expected outcomes • How is achievement of results measured and reported? How is this information used in decision-making? • To what extent are the governance and working relationships clear, effective and efficient for achieving expected results (e.g., between directorates, and between RAPB and PMRA)? • Are Program resources/capacity aligned appropriately across key activities? • Has the Program undertaken its activities in the most economical and efficient manner? • Are there alternative ways to achieve similar results at a lower cost?

Data Collection and Analysis Methods

Evaluators collected and analyzed data from multiple sources. Sources of information included literature review, document and data review, a survey of registrants, and key informant interviews.

Literature review — The literature review gathered information from both peer-reviewed (scientific and other academic) journals and grey literature, such as industry journals, newspapers, magazines, and websites. The scope of the literature review was limited to a small number of evaluation questions related to relevance and efficiency and economy (alternatives). With respect to relevance, the literature review provides evidence of the extent to which the Pesticide Program is meeting the needs of Canadians, the extent to which there is an ongoing need for the Program, and any areas of duplication. The literature review also compared Canada's regulatory approach to pesticides against approaches taken in other jurisdictions to provide information about possible alternative approaches.

Document and data review — The document/data review provided historical and contextual information for the Pesticide Program, assisted in developing the data collection instruments, and responded directly to virtually all of the evaluation questions. The majority of documents and data were provided by the Program and/or retrieved from Health Canada's website. To complement these sources of information, requests for specific administrative data were made by the evaluation to PMRA.

Survey of registrants — A bilingual, web-based survey of registrants was conducted. PMRA was responsible for supplying the survey sample in the form of an Excel file containing all current registrants. In some cases, the file included two contacts for each registrant (e.g., the main representative of the registrant and the Canadian representative). Both were retained for the purpose of the survey.

The original sample provided by PMRA consisted of 2,682 email addresses. After cleaning (i.e., removal of duplicate email addresses), the final loaded sample consisted of 1,329 distinct email addresses. Prior to the survey launch, the Office of Evaluation sent potential respondents an email describing the survey and advising them that they would receive an invitation to complete the survey in the near future. An email including the link to the survey was sent two days later.
The survey launched on May 11, 2015 and closed on June 1, 2015. After accounting for bounce-backs (n=148), the total valid sample was 1,181. Three reminders were issued to increase the response rate. Overall, the survey achieved 164 completions, representing a completion rate of 14%. The survey results were analyzed using SPSS.

Key informant interviews – In-depth key informant interviews were conducted with representatives of the Pesticide Program (n=28) and external stakeholders (n=36). The latter included federal government departments and agencies (n=9), provincial/territorial governments (n=3), industry representatives (manufacturer and grower associations) (n=12), non-governmental organizations (n=7), international regulatory agencies and organizations (n=4), and one academic. Interviews were recorded with the permission of key informants, and interview notes were returned to them for review and sign-off.

Data were analyzed by triangulating information gathered from the different sources and methods listed above, which included the following:

- systematic compilation, review and summarization of data to illustrate key findings
- quantitative analysis of administrative data, including trend analysis over time
- thematic analysis of qualitative data
- comparative analysis of data from disparate sources to validate findings