

Pest Management Regulatory Agency Annual Report 2015–2016

YOUR HEALTH AND SAFETY... OUR PRIORITY.



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Message from the Executive Director

Health Canada's Pest Management Regulatory Agency (PMRA) is pleased to present the 2015–2016 Annual Report to Parliament, which details PMRA's accomplishments and activities over the last fiscal year.

PMRA continues to be committed to upholding high standards of health and environmental protection, and to meeting work performance expectations for its core pesticide regulatory activities. It is also important to keep pace with change, and PMRA relies on stakeholder feedback to assess our priorities against the needs and expectations of Canadians. In 2015–2016, PMRA received significant input through a number of committees, consultations and audits.

The Commissioner of the Environment and Sustainable Development, under the authority of the Auditor General, conducted an audit of the pesticide regulatory program and published its report in January 2016. Many of the recommendations have already been addressed through measures such as eliminating the future use of conditional registrations, and publishing a multi-year re-evaluation work plan. Work is ongoing to address other audit recommendations.

A statutory review of the *Pest Control Products Act* was completed by the Standing Committee on Health with input from various stakeholders, and a report was published in April of 2015. Key recommendations supported ongoing work by PMRA to address openness and transparency of our regulatory approach, elimination of conditional registrations, cost-recovery modernization, and reduction of trade barriers related to Maximum Residue Limits.

The development of a new cost recovery framework involved a high level of stakeholder engagement to ensure that the proposed new fee structure is modern, fair, and allows PMRA to address Canadian priorities. This proposal was approved by Parliament in May of 2015, and work continued through much of this year on development of regulations and an implementation plan.

In an era of instant access to information, PMRA must work to improve communication with Canadians. A new Communications and Outreach Strategy is being developed to identify the needs of various stakeholder groups, and to tailor how we engage them. We've consulted with Canadians and stakeholders throughout this process. The overall objective of this Strategy is to support our goal of enhancing the confidence of all Canadians in our modern, effective, science-based pesticide regulatory system.

About PMRA

PMRA is a branch of Health Canada and is responsible for regulating pest control products under the federal authority of the *Pest Control Products Act*. Our mandate is to prevent unacceptable risks to people and the environment from the use of these products. We also encourage the development and application of sustainable pest management strategies and facilitate access to lower risk pest control products. We use modern scientific assessment techniques to assess human and environmental health risks when evaluating and re-evaluating pest control products. PMRA endeavours to address public and stakeholder concerns, as well as to develop mechanisms to facilitate access to newer and safer products.

New PMRA Vision and Mission Statements

As part of a new 5-year strategic plan, PMRA created new vision and mission statements, to reflect the importance of public confidence in our science-based regulatory approach. The new plan was published in the summer of 2016.

Vision

Canadians are confident that Canada's pesticide regulatory system protects their health and the environment.

Mission

To protect the health and environment of Canadians by using modern evidence-based scientific approaches to pesticide regulation, in an open and transparent manner.

New Pesticide Registrations

Pesticides are regulated in Canada by Health Canada, reflecting the importance placed on human health and environmental protection in the regulation of these products. The *Pest Control Products Act* governs how pesticides are risk-assessed and risk-managed, before and after they are registered for use.

Before a pesticide can be sold in Canada, pesticide registrants are required to provide PMRA with large volumes of data to show that their product does not pose unacceptable risks to health and the environment, and that the product has value. These data are reviewed by PMRA scientists to determine whether a product is acceptable for registration in Canada.

PMRA's science-based risk assessment includes the following:

- an examination of all sources and routes (oral, dermal, inhalation) of potential exposure to a given pesticide, including exposure through diet, from drinking water and from contact with treated areas like lawns and gardens;
- an estimation of the amount of pesticides that people, including children, may come in contact with, both during and after a pesticide application;
- a human health risk assessment with a particular focus on vulnerable populations, including children; this considers the potential for a pesticide to cause adverse health effects such as cancer, birth defects and endocrine disruption, and allows registration only for those pesticides with exposures well below levels that cause adverse effects;
- an assessment of the movement, persistence and transformation (fate) of a pesticide in the environment;
- an environmental risk assessment that considers risks to plants, birds, mammals, beneficial insects, aquatic organisms as well as fate in the environment; and,
- a value assessment that considers the contribution of the product to pest management, as well as its health, safety and environmental benefits, and social and economic impact.

The studies required to be submitted by applicants for registration depends on various factors such as the nature of the product, the intended use, and the type of registration (for an overview of product submission types, please see Appendix Table 1). PMRA follows timelines and standards for these evaluations as outlined in the “Revised Management of Submissions Policy” (Regulatory Directive DIR2013-01). The number and type of submissions reviewed by PMRA can vary significantly by year, as shown in Appendix Figure 1. Despite these shifts, PMRA continues to work to meet review timelines consistently across all submission categories (Appendix Figure 2).

All categories of pre-market submissions have a performance standard of 90% against the established review timelines for Category A, B, and C submissions. With a focus on workload management, the PMRA is making progress in balancing the performance across these three submission categories.

NEW ACTIVE INGREDIENTS REGISTERED IN 2015–2016

In 2015–2016, 18 new active ingredients (the substance with the pesticidal effect) were registered for use in Canada, resulting in the registration of 38 new end-use products (different formulations of products containing the active ingredient). Of the 18 new active ingredients, nine were biopesticides and nine were conventional (in other words, chemical) pesticides (Appendix Figure 3).

All of the new active ingredients registered in 2015–2016 were granted full registration. As of March 31, 2016 there were 75 conditionally registered products representing approximately 1% of all registered products. In addition, in January 2016 Health Canada published a Notice of Intent proposing to discontinue the granting of new conditional registrations under the Pest Control Products Regulations effective June 1, 2016.

Please see Appendix Table 2 for a full list of new active ingredients registered, and their uses.

JOINT REVIEWS

Joint reviews are pesticide assessments conducted in cooperation with other jurisdictions. In the last two decades, Canada has progressed from developing pilot pesticide joint review approaches with the United States, to conducting international joint reviews as a primary course of business. As of March 31, 2016, 10 new active ingredients were under joint review, including two conventional chemicals under global joint review.

MINOR USES

PMRA regularly meets with Agriculture and Agri-Food Canada's Pest Management Centre to provide regulatory advice that supports growers and grower associations in a collaborative process to identify priorities for new minor uses in Canada. PMRA also works directly with the provinces to assist in addressing the regional minor use needs. The Canadian Grower Priority Database enables stakeholders to communicate their pest control product priorities while providing PMRA with a vehicle for monitoring progress in bridging the technology gap. In 2015–2016, PMRA reviewed minor use submissions from Agriculture and Agri-Food Canada and the provinces and made 114 regulatory decisions resulting in the registration of 745 new minor uses of which nine were joint reviews or workshares.

EMERGENCY REGISTRATIONS

A pest control product can be registered for up to one year for the emergency control of pest infestations for which no other effective method of control exists. The product must be already registered for another use, must be effective, and the human health and environmental risks must be acceptable.

Emergency registrations are not intended as a solution to an ongoing pest-management problem. However, they may be considered again if the emergency situation exists in subsequent years and there is evidence that users and the sponsoring agencies are actively working towards satisfying the data requirements for registration. The number of emergency requests that PMRA receives can vary from year to year, depending on pest outbreaks, environmental conditions and the availability of alternative products and methods. In 2015–2016, PMRA granted 22 emergency registrations.

GENERIC REGISTRATIONS

Regulatory provisions for the protection of test data are intended to encourage the introduction of new pesticides by protecting the innovator's substantial investment in a supporting database. At the same time, established limits on the data protection period allow for timely introduction of equivalent products by generic manufacturers, thus enhancing market competition to the benefit of users, including growers. These regulations are important to innovators, generic companies, and to growers. PMRA is continually seeking ways to improve the efficiency, effectiveness and predictability of generic applications for applicants/registrants and PMRA.

In 2015–2016, 44 generic products were registered, including 27 technical or manufacturing products and 17 end-use products. Some examples of generic active ingredients registered for agricultural use include sulphur, cypermethrin, S-metolachlor and R-enantiomer, fenoxaprop-P-ethyl, and chlorothalonil.

GROWER REQUESTED OWN USE

Grower Requested Own Use (GROU) is an initiative that aims to make it easier for Canadian growers to import less expensive, equivalent pest control products available in foreign jurisdictions. Prior to 2014 this program was based on policy; however, in August 2014, GROU was formalized in the Pest Control Products Regulations. Through continued support from not-for-profit national grower associations, growers are able to request product nominations for the program. Growers with an approved import certificate can legally obtain an equivalent version of a Canadian-registered product from outside Canada. Please see Appendix Table 3 for a list of approved GROU products for 2015–2016.

Regulation of Pesticides on the Market

Once a pesticide has been granted registration status, it becomes subject to a system of post-market risk management controls under the *Pest Control Products Act*. This includes re-evaluations and special reviews of registered pesticides, compliance and enforcement activities, and response to health and environmental incidents. This section will also describe activities addressing pollinator impacts, efforts to help growers transition from obsolete products to different pest management approaches, and outreach activities targeted at users.

RE-EVALUATION / SPECIAL REVIEW PROGRAMS

Under the *Pest Control Products Act*, post-market reviews are conducted on registered pesticides currently available on the market. These reviews may be conducted as re-evaluations, which are initiated every 15 years at the latest. Under this program, new methodologies, data, and scientific approaches are incorporated into the assessments to ensure that registered pesticides continue to meet modern standards for health and environmental protection and have value. In addition to re-evaluation, special reviews are another mechanism used under the *Pest Control Products Act* to determine the continued acceptability of registered pesticides where the review is focussed on addressing a specific aspect(s) of concern (for example, concerns raised by an Organisation of Economic Cooperation and Development (OECD) member country decision to prohibit all uses of an active ingredient).

Five-year Re-evaluation and Special Review Work Plan

As part of our commitment to improve transparency, PMRA published a work plan for the re-evaluation and special review programs over a five-year period from April 2015 to March 2020. This work plan includes the target timelines to publish proposed and final decisions for re-evaluations and special reviews.

In 2015–2016, PMRA met all re-evaluation and special review targets as outlined in the published work plan. Final decisions were published for six re-evaluations and three special reviews. This corresponds to 76 end-use products for which improved product use conditions were required to further protect human health and the environment. Public consultations on 21 proposed re-evaluation decisions and six proposed special review decisions were conducted during this fiscal year. Appendix Table 4 provides a list of re-evaluation and special review proposed and final decision documents published in 2015–2016.

An additional 43 re-evaluations and 5 special reviews were initiated in accordance with the *Pest Control Products Act*.

Outreach and Stakeholder Engagement in Re-evaluation and Special Review Programs

In 2015–2016, PMRA increased outreach and stakeholder engagement activities with respect to re-evaluations and special reviews. Where proposed decisions indicated further information was required to refine risk assessments, or risk management actions were proposed, PMRA engaged specific stakeholder sectors near the publication date of the consultation document in order to facilitate and maximize their participation.

Final decision documents have been improved to clearly indicate the time frame to implement decisions, and now provide a list of products that are involved, so that the public can be better informed of which products are impacted and when changes will take effect. In certain cases, PMRA also engages user and stakeholder groups to better inform their members of required changes to products as a result of re-evaluation, such as new use directions, or removal of products from the marketplace. This collaborative approach promotes user awareness and timely implementation of product changes.

PMRA continues to work with stakeholders on the development of transition strategies. The cancellation of an active ingredient or specific uses following re-evaluation or special review may present a number of complicating issues, such as lack of viable alternatives to replace the cancelled uses, loss of uses with a high value to public health or the economy, or a significant impact on a specific sector. As part of the risk management approach, and in order to ensure smooth phase-out of these actives/critical uses, PMRA organizes and facilitates a forum for growers, registrants, provincial coordinators and other stakeholders to discuss and develop transition strategies. Through this forum, working groups identify alternate lower risk pest management tools as solutions to uses lost as a result of cancellation. During 2015–2016, 27 crop/pest/product combinations were registered, as prioritized by transition strategy working groups. Two transition strategies relating to phorate and terbufos were completed in January 2016.

In March 2016, PMRA published Regulatory Proposal (PRO2016-02), *Management of the Pesticide Re-evaluation Process*, to invite the public to provide feedback for the development of an enhanced re-evaluation process. Proposed improvements include increased transparency and stakeholder engagement at the onset of the process, and timelines for specific steps of the re-evaluation process from initiation to the publication of a final decision.

PEST CONTROL PRODUCT SALES INFORMATION REPORTING

PMRA's Pest Control Product Sales Information Reporting Program has been collecting sales information in the form of total volume since 2007, for all registered products available for sale. These data are reported by calendar year (January 1 to December 31). The purpose of the sales information reporting program is to collect sales data to be used by PMRA to better understand pesticide use in Canada.

Sales data are considered in risk assessments of pesticides, in policy decisions, in identifying trends in pesticide use, and in providing guidance for risk-reduction strategies. For example, sales data are used in the re-evaluation of older pesticides to help understand the presence and value of the pesticide in the Canadian marketplace, as well as the potential impacts if changes are made to the registration status of the pesticide. Sales data are also used to inform the Pesticide Incident Reporting Program on the market share of particular pesticides to help identify potential risks that may require attention.

In 2015–2016, PMRA published annual sales reports for the 2012 and 2013 calendar years. Implementation of program efficiencies allowed for the publication of these two reports within the same fiscal year, and have allowed for a reduction in the amount of time required to publish future annual sales reports.

PESTICIDE COMPLIANCE AND ENFORCEMENT PROGRAM

The National Pesticide Compliance Program is responsible for promoting, monitoring and enforcing compliance with the *Pest Control Products Act* and its Regulations. The program is administered jointly by PMRA and the Regulatory Operations and Regions Branch (RORB). PMRA sets the strategic direction, program priorities and policies, and determines how those priorities are implemented nationally. RORB is responsible for the delivery of compliance and enforcement activities and for maintaining valuable relationships with regional partners and stakeholders.

In 2015–2016, compliance and enforcement activities were organized under the four main areas that follow.

Active Prevention

Active prevention involves providing regulatory guidance to pesticide registrants, manufacturers, users and the public, while identifying safety concerns at an early stage to encourage compliance with the *Pest Control Products Act* and its associated Regulations. Priority areas in 2015–2016 were pollinator protection, safe use of pesticides by commercial and agricultural users, and municipal pool chemical sanitation. In 2015–2016, 199 outreach activities were completed, including presentations to associations, meetings and exhibit booths at trade shows, and distribution of fact sheets with topics such as Personal Protective Equipment and Incident Reporting.

Targeted Oversight

Targeted oversight is conducted for early detection of health, safety and environmental concerns at any stage of the pest control product life cycle. In 2015–2016, most of the detected instances of non-compliance involved sale, import, or use of unregistered products; or use contrary to the label. Most violations were among retailers, importers, and distributors. Surveillance inspections of previously non-compliant regulatees at high risk of re-offending showed a 78% return to compliance. Interviews focusing on 14 key priority areas were conducted, as well as 1286 monitoring and surveillance inspections.

Complaints, incidents and inquiries led to 488 compliance verifications. PMRA's laboratory analysed 436 soil, plant, tissue and other samples to verify compliance, with an additional 900 samples collected and analysed for bee-related incidents and bee health issues.

Rapid Response

Rapid response involves timely interventions when unacceptable risks of non-compliance are identified during inspections, or during responses to complaints and incidents reported from the public. In 2015–2016, inspections resulted in 1775 enforcement responses, including education and enforcement letters (612), verbal education (67), issuance of Compliance Orders (3), issuance of notices of violations (NOVs) under the *Agriculture and Agri-Food Administrative Monetary Penalties (AMPs) Act* with warnings or penalties (27), requests to stop the sale or dispose of a pest control product (718), requests to return or recall a pest control product (80), requests for relabelling (29), orders to cease sale or dispose products (20), collection of investigative samples (15), denials of entry at the border (165), and other actions (39).

Border and International Activities

Border monitoring processes are implemented with Canada Border Services Agency (CBSA) to reduce risks posed by imported pesticides, and to bolster the international cooperation that facilitates the resolution of global pesticide compliance and enforcement issues. In 2015–2016, border data was used to plan subsequent follow-up inspections and blitzes, and set targets for suspected pesticide imports. Non-compliance was found in 48% of 203 targeted inspections. Responses included verbal education (16), written education (64), enforcement letters (17), and one compliance order. Referrals from various border points resulted in 165 denials of pesticide entry into Canada.

PMRA strengthened working relationships with international regulatory partners through the OECD's Network of Illegal Trade of Pesticides, and continued monitoring unsafe shipments of pesticides using the OECD Rapid Alert System database.

A more detailed report of compliance and enforcement activities in 2015–2016 is available on the Health Canada website: <http://healthycanadians.gc.ca/product-safety-securite-produits/pest-control-products-produits-antiparasitaires/index-eng.php>.

INCIDENT REPORTING

PMRA's Pesticide Incident Reporting Program has been collecting incident reports since April 2007. Incident reports are vital for detecting adverse effects, including those that are not evident during the initial registration of a pesticide.

PMRA uses incident report data to identify and characterize potential risk to humans, domestic animals and the environment from the use of pesticides. Incident report assessments are prioritized based on the type of incident. Serious adverse effects (such as death) are evaluated immediately and mitigation measures are put into place if warranted. If a potential risk is identified, it is investigated and protective action may be taken, such as changes to how a pesticide is manufactured, packaged, labelled, or used. Incident report data also informs risk assessments for new registrations and re-evaluations. Monitoring incidents for unanticipated effects is an ongoing process that includes re-assessing previous conclusions, as necessary. In cases where mitigation strategies have been adopted, PMRA also monitors incident report data to determine if the actions were effective in managing the identified risk.

In 2015–2016, 2623 incident reports were filed, 1831 of which occurred in Canada. Details of these reports and other information about the incident reporting program can be found on the Health Canada website at <http://pr-rp.hc-sc.gc.ca/pi-ip/disclaimer-avertissement-eng.php>. PMRA takes appropriate action following evaluation of incident reports. For example, in 2015–2016:

- Changes were made to the labels for diquat products to strengthen warning and first aid statements for eye, skin, inhalation and oral exposure.
- Labels for new commercial products containing beta-cyfluthrin will include an extended restricted-entry interval, and will list potential adverse effects based on incident information. Additionally, new requirements were introduced for commercial applicators to provide information sheets when they treat homes or structures.

OUTREACH ACTIVITIES

PMRA's outreach program has three main functions: to develop and distribute material to professional and consumer audiences on all aspects of responsible pesticide use; manage a 1-800 information line and e-mail service to respond to enquiries on pesticides and pest management; and provide support and advice for the participation of regional pesticide managers and officers at fairs, exhibits and other opportunities through the use of displays, didactic tools and printed material.

In 2015–2016, working closely with PMRA scientific teams, the outreach team produced and disseminated a variety of materials in response to current and emerging needs. The Pest Management Information Service responded to over 2500 calls and e-mails from the public on a broad range of questions relevant to pest management and responsible pesticide use. PMRA staff and regional compliance officials were able to attend over 50 outreach events, including exhibits at fairs, various meetings and presentations. These activities allowed PMRA to engage the public, grower groups and provincial partners in discussions about pesticide products and safety. PMRA also engaged more Canadians through the use of social media, with news and updates about pesticide issues.

In 2014–2015, PMRA produced an animated multilingual video (English, French, Spanish, Vietnamese, Cantonese, Mandarin, Punjabi and Low German) as an extension of a poster on pesticide safety for seasonal and migrant workers. This short video conveyed the importance of hygiene with respect to pesticide safety. A second video was added to the series, also in eight languages, educating workers on the need to wait a period of time before entering areas treated by some pesticides. These videos have been well received, each earning a media points rating of over 11 million—an industry standard that measures the effectiveness of communications strategies.

Keeping Pace with Change

Globalization, rapid technological advances, evolving science and economic pressures and various other challenges and opportunities require a pesticide regulatory system that is flexible and responsive to change. PMRA is continuously modernizing risk assessment and risk management approaches, refining business practices to ensure the needs of all stakeholders are met, and responding to major scientific and environmental developments, in Canada and abroad, with the goal of improving health and environmental protection.

Pollinator Mortality Reports

Following the increased reporting of honey bee incidents in 2012, Health Canada initiated a program to investigate the potential causes of the increased number of incident reports. It was determined that pesticide-containing dust generated during planting of neonicotinoid-treated corn and soybean seed contributed to the mortalities. Mandatory measures to reduce exposure to pesticide-containing dust during planting of neonicotinoid treated seed were put in place prior to the 2014 planting season. Following implementation of these measures, an 80% decrease in the number of incidents was realized during the planting periods in 2014 and 2015 as compared to 2013. Health Canada continues to monitor and receive information regarding honey bee mortality incidents. Health Canada is currently analysing the honey bee mortality incident data available across all years (2012–2015) to investigate potential trends and factors that may be contributing to bee incidents.

Hive Monitoring Project

To gain a better understanding of the potential factors leading to incident reports throughout the season, with the assistance of provinces across Canada, PMRA monitored selected bee yards to gather information surrounding various factors including pesticide exposure and regional agricultural practices. A more intensive program was completed in Ontario where, with the assistance of the Ontario Ministry of the Environment, Energy and Climate Change and the Ontario Ministry of Agriculture, Food and Rural Affairs, 12 bee yards were monitored over two years (2014 and 2015) to examine pesticide exposure, presence and levels of various pathogens and the surrounding agriculture practices. Results of the hive monitoring project are being analyzed.

Working with Stakeholders in Canada and Internationally

PMRA continued to work with stakeholders to address concerns regarding bee health. In addition to working collaboratively with the provinces to investigate incidents, PMRA, the Regulatory Operations and Regions Branch, and the provinces of Ontario and Quebec continued the hive monitoring project throughout the 2015 corn and soybean growing season as a continuation of the monitoring work completed in 2014.

PMRA continued to be an active participant at Agriculture and Agri-food Canada's Bee Health Roundtable, and international working groups such as the OECD working group on pesticides: Pesticide Effects on Insect Pollinators (co-led by Canada, the United States and Germany); and the International Commission for Plant-Pollinator Relationships Bee Protection Group.

Support for Research

PMRA continued to actively support efforts to generate new research and monitoring information. This research aims to, among other things, gain additional monitoring data in soil, surface waters and other environment compartments; further characterise potential effects of neonicotinoids on pollinators and other organisms (such as aquatic organisms and birds); and better understand the state of bee health in Canada.

Re-evaluation

PMRA, the United States Environmental Protection Agency (USEPA) and the California Department of Pesticide Regulation have published the preliminary pollinator risk assessment for imidacloprid and public comments have been received on this document. The three agencies continue to work together on finalizing the imidacloprid pollinator re-evaluation and the preliminary pollinator risk assessments for thiamethoxam and clothianidin.

SCIENCE POLICY DEVELOPMENT

In 2015–2016, PMRA published two value guideline documents: Value Guidelines for New Plant Protection Products and Label Amendments, and Value Guidelines for New Antimicrobial Pest Control Products and Label Amendments.

These documents reflect the value approach that PMRA has implemented as described in Regulatory Directive DIR2013-03, and outline the general principles of value assessment in Canada for plant protection products and antimicrobial products respectively. The documents describe the types of information that could be provided to register new products and to support label amendments, and provide guidance on summarizing value information prior to submission to PMRA.

These two documents replace DIR2003-04, *Efficacy Guidelines for Plant Protection Products* (issued in 2003), and T-1-215: *Efficacy Data for Antimicrobial Products* (issued in 1980).

WORK ON ENDOCRINE DISRUPTORS

PMRA continued to integrate results from the USEPA endocrine screening program into relevant assessments. PMRA also worked with Government of Canada partners towards minimizing potential domestic implications of changes to the European Plant Protection Products Regulations, by providing technical input on scientific risk-based approaches to managing endocrine disrupting substances.

MAXIMUM RESIDUE LIMITS

A Maximum Residue Limit (MRL) is the maximum amount of residue that is expected to remain on food products when a pesticide is used according to label directions, and these are set at levels well below the amount that could pose a health concern. MRLs are established around the world for each combination of pesticide and treated agricultural product. International differences in MRLs are due to many variables, such as risk assessment and MRL-setting methodologies, and data available to regulators at the time of MRL establishment. Though MRL differences rarely reflect a difference in risk, these discrepancies can cause barriers to the movement of treated agricultural products around the world.

The demand for better global alignment on MRLs is an increasingly important issue around the world. Work includes ensuring that all MRLs are protective of health and the environment, establishing MRLs for incoming and outgoing commodities that are lacking them, and identifying and resolving international discrepancies that can result in barriers to trade. Horizontal and international collaboration is critical in resolving these issues, which are of high importance to registrants, growers, and the Canadian economy.

In 2015–2016, PMRA continued to work with its international partners in North American Free Trade Agreement (NAFTA), OECD and the Codex Alimentarius Commission to better collaborate on science policy and establishing MRLs internationally. PMRA supported Agriculture and Agri-Food Canada by providing specialized, scientific knowledge and expertise to assist in resolving market access irritants related to MRLs. The PMRA also addressed pesticide MRL-related inquiries from the World Trade Organization's Sanitary and Phytosanitary Committee, and was an active participant on Canada's Interdepartmental and Industry-Government Working Group on Pesticide MRLs.

Through its involvement in the Regulatory Cooperation Council initiative, PMRA analyzed new scientific methods and process improvement strategies to further streamline data requirements for establishing

MRLs between jurisdictions. The recommendations stemming from this work were shared with OECD and Codex, in support of further alignment of MRLs for major and minor uses of pesticides. The outcome of these efforts has resulted in the successful incorporation of the methods developed through the Regulatory Cooperation Council initiative into the second edition of the OECD Guidance on Crop Field Trials, which was published on September 7, 2016.

CUMULATIVE RISK ASSESSMENTS

This is an emerging area in the science used to regulate pesticides, and in 2015–2016 PMRA actively worked with international partners to understand how to best apply these principles to protect the health and safety of Canadians. Most countries, including Canada, are working on a cumulative risk assessment methodology for pesticides. However, the international scientific community has not yet reached a consensus on how to best assess the cumulative effects of pesticides.

In response to the Commissioner of the Environment and Sustainable Development 2015 Audit on Pesticide Safety, PMRA continued to work towards finalizing a methodology document for public consultation related to conducting cumulative risk assessments. In January of 2016, PMRA published a document outlining the agency's approach to assessing cumulative effects of pesticides.

INTEGRATED APPROACHES TO TESTING AND ASSESSMENT / 21ST CENTURY ALTERNATIVE TESTING METHODS

The goal of Integrated Approaches to Testing and Assessment (IATA) is to develop common approaches to the application of testing to the human health and ecological risk assessment of pesticides. IATA combines data from existing laboratory animal studies, in vitro high throughput screening assays, predictive models, mechanistic studies and other data to refine, reduce or even replace standard targeted laboratory animal studies for risk assessments, without compromising health and environmental protection.

In 2015–2016, PMRA co-led the development of an OECD Guidance for Waiving or Bridging Mammalian Acute Toxicity Tests based on PMRA guidance document on the same topic, with the goal of applying IATA to the human health and ecological risk assessment of pesticides. The OECD guidance document on Considerations for Waiving or Bridging of Mammalian Acute Toxicity Test was published on August 2, 2016. Use of this guidance will reduce animal testing while still providing a scientifically valid approach to hazard assessment.

On March 3, 2016, PMRA also updated its Guidance for Developing a Database for Conventional Pest Control Products. This update included changes to the toxicology data requirements section, such as the removal of the 1-year dog study (Part 4). The removal of the routine requirement for the 1-year dog study for food uses reflects Health Canada's commitment to reducing the need for animal testing wherever possible, and was based on a scientific review conducted by PMRA.

The PMRA continued to support and collaborate on a number of other initiatives related to the investigation and application of updated conventional testing protocols such as the OECD Extended One-Generation Reproductive Toxicity Study, (Q)SAR predictions, genomics, and other alternative methods, such as using IATA for skin sensitization.

OILFIELD BIOCIDES

In 2015–2016, PMRA initiated the development of a risk assessment framework and guidance for the assessment of oilfield biocides. This work is meant to address some uncertainties around how these products are used, the potential for environmental exposure and what other federal and provincial acts and regulations may also apply to these types of uses.

COST RECOVERY

The current pesticide regulatory fees were established in 1997 and have not changed since that time. However, the work being supported by these fees has become more complex and global in nature. Stakeholders have recognized that PMRA may not be able to meet their future needs and expectations without additional resources.

Consultations on updating the current fee structure have been ongoing since 2010 culminating in a public consultation on a proposal in March 2014, and a formal consultation “Pre-Proposal Notice” as required by the *User Fees Act* in December 2014.

Comments on the Pre-Proposal Notice were received from approximately seven stakeholder groups. In accordance with the *User Fees Act*, PMRA addressed comments and concerns in bilateral discussions with stakeholders as well as official response letters at the end of February 2015.

The Pesticide Cost Recovery Official Notice of Fee Proposal was tabled for consideration before each house of Parliament on April 2, 2015. In the Senate, the Proposal was referred to the Standing Senate Committee on Agriculture and Forestry. Both houses of Parliament have approved the proposal without amendment.

PMRA is taking steps to prepare the proposed regulations for consultation.

PESTICIDE LABELS MOBILE APP

On January 25, 2016, PMRA launched a new mobile app that allows users to access pesticide labels that have been registered for use in Canada. This app allows stakeholders, including registrants, growers, and the public, to search and download labels for pest control products on their mobile devices. This app was developed in order to have labels available to stakeholders whether they are at their home, office, retailer, warehouse, or field. The app provides updated and on-demand information on the product, its uses, how to apply and most importantly, how to use the product safely. The ability for the user to download the label to their mobile device also allows them to have access to the label even if they don’t have Internet access. The up-to-date information on a product can supplement, or even replace the printed label on the product, the latter of which may be outdated by the time the user applies the product.

INTERNATIONAL SCIENTIFIC AND REGULATORY COOPERATION

Canada’s internationally respected regulatory model has allowed Canada to form strong partnerships, and to play a significant role in developing collaborative approaches to joint pesticide reviews, promoting international regulatory alignment, and addressing barriers to agricultural innovation and trade. This

leadership role has also afforded Canada the capacity to ensure that terms of trade are compatible with Canada's unique market conditions, and our commitment to health and environmental protection.

Stockholm Convention

The Stockholm Convention is a legally binding international treaty that addresses international management of chemicals with the focus on production and use of persistent organic pollutants.

PMRA collaborated with other federal partners in the development of Canadian positions and submissions to the Persistent Organic Pollutants Review Committee and the Conference of the Parties of the Stockholm Convention and by providing the Canadian technical expert to the POPRC. PMRA is the responsible federal authority for meeting the obligations and for ongoing participation at the Stockholm Convention as it pertains to pesticides. In 2015–2016, PMRA contributed to the drafting of the risk profile for dicofol, an agricultural pesticide that is no longer registered for use in Canada, and supported federal partners in the assessment of industrial substances.

Rotterdam Convention

The Rotterdam Convention promotes information exchange and informed consent in the international trade of chemicals, with the aim of protecting human health and the environment. Canada is a party to this Convention. In collaboration with Environment Canada, PMRA participated in the development of Canadian positions and submissions to the Convention.

In 2015–2016, PMRA participated in the Convention's annual technical committee meeting where the committee recommended adding two new pesticides (carbofuran and carbosulfan) to the Convention's prior informed consent list. PMRA also administers Canada's obligations concerning import and export of all other pesticides subject to the Convention.

OECD

PMRA is involved in several OECD task force and subcommittee Expert Group projects and initiatives. PMRA continues to provide advice to the Expert Group on Minor Uses and supports ongoing projects on an as-needed basis.

As described in other parts of this report, in 2015–2016, PMRA continued to participate in Science-Policy work through OECD. In addition to the IATA and MRL-related activities, PMRA was also actively involved with the OECD ad hoc Expert Group on Novel Technologies and their Use as Pesticides. The initial focus of this group was on Ribonucleic acid interference (RNAi), a novel pesticide technology currently at the research and development stage.

Finally, PMRA participated in and is co-chair of the Expert Group on the Electronic Exchange of Pesticide Data. In 2014, this group completed the Globally Harmonised Submission Transport Standard (GHSTS), which is intended to be an OECD standard for the submission of pesticide product applications, or dossiers. This expert group is now working on an implementation strategy, part of which is the development of an eDossier Builder, which helps companies and regulatory authorities prepare and receive dossiers based on the GHSTS.

Regulatory Cooperation Council

In 2015, the pollinator risk assessment of the neonicotinoids was identified as an initiative under the Regulatory Cooperation Council. PMRA has been working with the USEPA to conduct the risk assessments. These assessments are being conducted in accordance with the improved, harmonized pollinator risk assessment guidance that was jointly developed. In January 2016, the first of these pollinator risk assessments was published for public consultation in Canada and the United States. In

addition, a joint update was published by both countries. PMRA is currently continuing its work with the USEPA to publish the remaining neonicotinoid pollinator risk assessments for consultation in late 2016.

NAFTA

Since its inaugural meeting in 1996, the NAFTA Technical Working Group on Pesticides has served as the focal point for addressing pesticide-related issues arising in the context of liberalized trade between Canada, Mexico, and the United States. Our multilateral collaboration has resulted in success in aligning pesticide regulation in North America to create and maintain high standards of protection for human health and the environment.

In 2015–2016, the Technical Working Group on Pesticides published its Accomplishment Report for 2008–2013 and, with the support of stakeholders in all three countries, launched a new five-year strategy for 2016–2021. The new strategy focusses on three objectives: i) working cooperatively on priority science and regulatory issues and practices including data requirements, science approaches and policies for data interpretation, and risk assessment and communications of regulatory decisions; ii) encouraging cooperation on joint reviews of new pesticides and uses, and the re-evaluation/re-registration review of pesticides to increase efficiency and quality of decision making; and, iii) identifying trade barriers and approaches to promote equal access and simultaneous introduction for pest management tools. The strategy reflects the maturing of the Working Group's work on issues to support the NAFTA mission and goal, and its significant accomplishments with the pest management sector. It also looks to the future to improve the alignment of the North American registration and maximum residue limit (MRLs) systems for pesticides and for products treated with pesticides.

Financial Profile

A-Base	\$27.4 million
Revenue	\$7.9 million
Growing Forward	\$3.7 million
Chemicals Management Plan	\$5.0 million
Total	\$44.0 million

PMRA received \$3.7M through the Growing Forward initiative to support the registration of minor use products. As a result, newer, more environmentally sustainable, and more modern products have been made available to Canadian producers, which helps sustain Canada's competitive position globally.

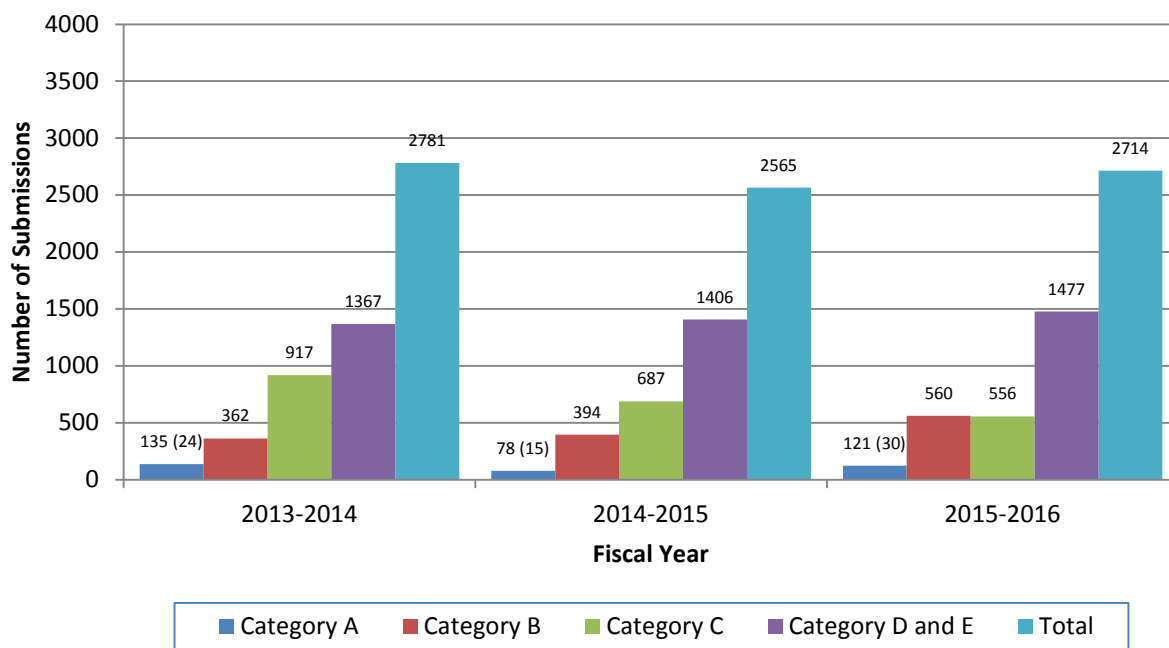
Through Canada's Chemicals Management Plan, PMRA received \$5M to re-evaluate older pesticides, improve risk-management approaches through Incident Reporting and Sales Reporting regulations, and contribute to the development of scientific and regulatory approaches with other jurisdictions on high-priority issues. For more information, please consult the Chemicals Management Plan webpage at: <http://www.chemicalsubstanceschimiques.gc.ca/plan/index-eng.php>.

Appendices

TABLE 1 PRODUCT SUBMISSION CATEGORIES

Category A	Submissions to register new active ingredients and their companion end-use product(s); applications to add a major new use to a registered pesticide; submissions to establish a maximum residue limit for a previously non-assessed active ingredient; and submissions for user requested minor use registrations. Category A submissions require a full, supporting data package.
Category B	Submissions to amend a product label (for example, changes in application rates, timing of applications, new pests, changes to precautionary statements) or to change the product chemistry. Supporting data must be provided.
Category C	Submissions to register or amend a product label (add pest, use or change application rate) or change a formulation based on previously established precedents.
Category D	Submissions to register or amend products within particular programs such as the Import for Manufacture and Export, Own-Use Import, Grower Requested Own Use program, Master Copy, Private Label, User Requested Minor Use Label Expansion and renewal of registration.
Category E	Submissions for research authorizations and research notifications, when the research is carried out in Canada.

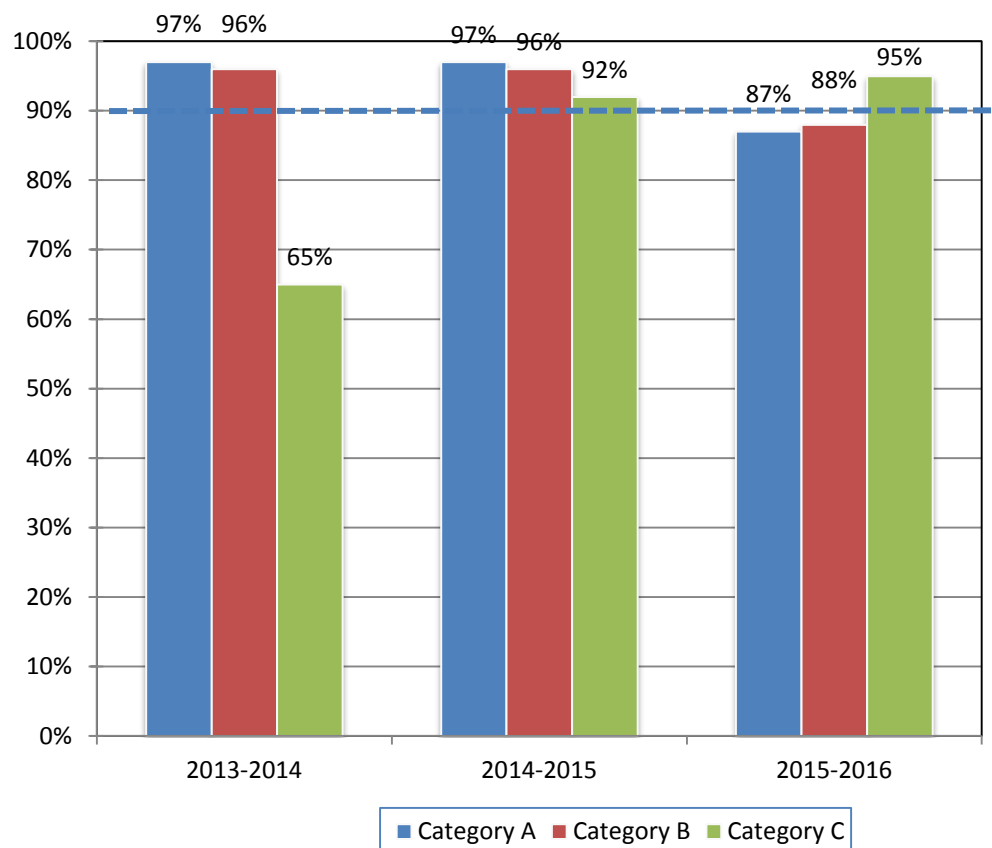
FIGURE 1 Number of Submissions Completed by PMRA from April 1, 2013 to March 31, 2016



Trends and Limitations:

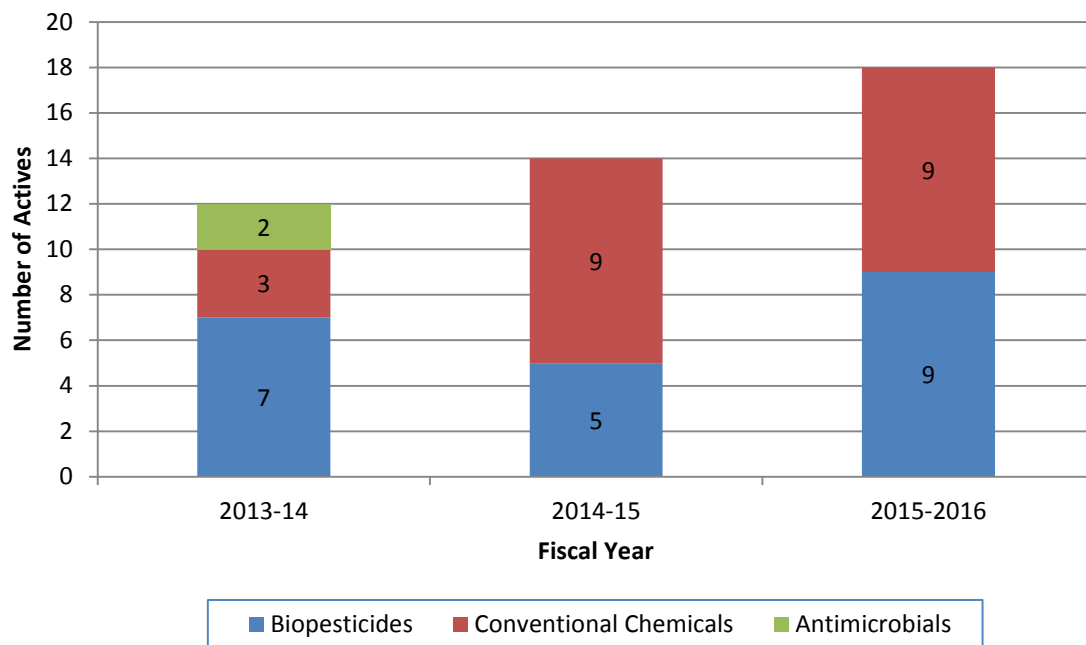
- Represents 12-month period
- Most Category A and many Category B submissions have a review timeline greater than 12 months, therefore work on many of the submissions reported as being completed in 2015-2016 was conducted in previous years.
- The reduction in the number of Category C and increase in Category B submissions since 2013-2014 are due in part to revisions to the submission categories. Following the implementation of the revised Notification / Non-Notification directive in 2013, certain minor changes to registered products can now be made through a simplified notification process, rather than through a Category C submission. A small subset of Category C submissions were also reclassified to Category B submissions with shorter timelines. Furthermore, a large number of Category C submissions completed in 2013-2014 were required updates to labels as a result of re-evaluation decisions.
- For Category A submissions, the number in parentheses reflects the number of new active ingredients completed and includes any new active ingredient for which only a maximum residue limit on imported food was established.
- The number of submissions completed does not include pre-submission consultations, and includes Registered, Withdrawn and Rejected submissions.

FIGURE 2 Performance Against Review Timelines for Category A, B and C Submissions Completed from April 1, 2013 to March 31, 2016



- All categories of pre-market submissions have a performance standard of 90% against the established review timelines for Category A, B, and C submissions.
- Performance against review timelines for Category C submissions has increased since 2013-2014. Several policy changes (see Figure 1) contributed to improved performance in this submission category, which is now surpassing the published standard.
- Performance against timelines for Category A and B submissions are slightly below the performance standard of 90%. This can be explained, in part, by an increase in the number of Category A submissions and the number of new active ingredients that were completed during the year (30 in 2015-2016 compared to 15 in 2014-2015). Since Category A and B submissions both require a detailed scientific assessment, performance in the category B submissions is often influenced by the Category A submission workload.

FIGURE 3 Number of New Active Ingredients Registered by PMRA from April 1, 2013 to March 31, 2016



- This figure provides the number of new active ingredients registered over the course of the last three fiscal years. It represents active ingredients that have been registered for use in Canada and excludes any new active ingredients for which only a maximum residue limit on imported food was established.

TABLE 2 NEW ACTIVE INGREDIENTS REGISTERED IN 2015–2016

	Active Ingredient	End-Use Product (s)	Product Type	Registration Status	Product Category	Uses/Sites
1	3-Ketopetromyzono 1-24-Sulfate, Ammonium Salt	Male Sea Lamprey Mating Pheromone	Pheromone	Full	Biopesticide	Sea lamprey attractant in tributaries of the Great Lakes basin and Lake Champlain
2	(9Z,12E)-9,12-tetradecadien-1-yl acetate	CIDETRAK IMM	Pheromone	Full	Biopesticide	A mating disruptant for certain moth species for indoor use only in storage and manufacturing facilities such as but not limited to raw, intermediate/in process goods and finished facilities, mills, bakeries, drying areas, tarped or otherwise enclosed commodities or susceptible packaged goods.
3	<i>Bacillus amyloliquefaciens</i> , strain D747	DOUBLE NICKEL LC	Fungicide, Bactericide	Full	Biopesticide	Agricultural crops grown outdoors or in greenhouses, shadehouses, or other covered structures: Cucurbits cucumbers, squash (all types), cantaloupes, muskmelons, watermelons, and other melons (including cucurbits grown for seed production), Fruiting vegetables tomatoes, peppers, eggplant, tomatillo, and okra (including those grown for seed production), Lettuce (Head and leaf varieties, including those grown for seed production), Pome fruits apple, pear, crabapple, quince,
		DOUBLE NICKEL 55	Fungicide, Bactericide	Full	Biopesticide	

						Grapes, Potato, Soybean, Strawberry.
4	Baculovirus: Nucleopolyhedrovirus <i>Autographa californica</i> (ACMNPV)	LOOPEX	Insecticide	Full	Biopesticide	Greenhouse Food Crops: cucumber, peppers and tomatoes
5	Benzovindiflupyr	A15457TO Fungicide	Fungicide	Full	Conventional Chemical	Turf, outdoor ornamentals, greenhouse ornamentals.
		A15457 FUNGICIDE	Fungicide	Full	Conventional Chemical	<p>Potatoes, sweet potatoes, soybeans, blueberries (low bush), wheat, barley, rye, oats, triticale, corn (Field, sweet, popcorn and specialty Including all cultivars and/or hybrids of these),</p> <p>Dried shelled pea and beans (Crop Subgroup 6C): Any dried cultivar of bean (<i>Phaseolus</i> spp.); and dried cultivar of pea (<i>Pisum</i> spp.): dried cultivars of bean (<i>Lupinus</i> spp.) (includes grain lupin, sweet lupin, white lupin, and sweet white lupin); (<i>Vigna</i> spp.) (includes adzuki beans); (<i>Phaseolus</i> spp.) (includes field bean, kidney bean, lima bean (dry), navy bean, pinto bean, tepary bean, mung bean, rice bean, southern bean, urd bean); broad bean (dry); chickpea; guar; lablab bean; lentil; pea (<i>Pisum</i> spp.) (includes field pea); and pigeon pea</p> <p>Fruiting vegetables (Crop Group 8-09) Eggplant; Groundcherry; Okra ;</p>

						<p>Pepino; Pepper (includes bell pepper, chili pepper, cooking pepper, pimento, sweet pepper); Tomatillo; Tomato;</p> <p>Cucurbit vegetables (Crop Group 9) Chinese waxgourd; Citron melon; Cucumber (field); Gerkin; Gourd, edible; Momordica spp.; Muskmelons (includes cantaloupe); Pumpkin; Squash, summer (includes zucchini); Squash, winter; Watermelon. Including cultivars and/or hybrids of these.</p> <p>Pome fruit (Crop Group 11-09) Apples, Crabapples, Pear, Pear (Asian), Quince, and Cultivars, varieties and/or hybrids of these commodities</p> <p>Small Fruit Vine Climbing Subgroup (Crop Subgroup 13-07F) Gooseberry, Grape, Maypop, Schisandra berry and cultivars, varieties and/or hybrids of these</p> <p>Rapeseed (Crop Subgroup 20A) Crambe, Gold of pleasure, Hare's ear mustard, Lesquerella, Lunaria, Mustard seed, Oil radish, Rapeseed (canola), Sweet rocket and Cultivars and/or hybrids of these.</p>
		MURAL Fungicide	Fungicide	Full	Conventional Chemical	Outdoor ornamentals, greenhouse ornamentals

		Elatus	Fungicide	Full	Conventional Chemical	<p>Potatoes, sweet potatoes, soybeans, corn (Field, sweet, popcorn and specialty Including all cultivars and/or hybrids of these),</p> <p>Dried shelled pea and beans (Crop Subgroup 6C): Any dried cultivar of bean (<i>Phaseolus</i> spp.); and dried cultivar of pea (<i>Pisum</i> spp.); dried cultivars of bean (<i>Lupinus</i> spp.) (includes grain lupin, sweet lupin, white lupin, and sweet white lupin); (<i>Vigna</i> spp.) (includes adzuki beans); (<i>Phaseolus</i> spp.) (includes field bean, kidney bean, lima bean (dry), navy bean, pinto bean, tepary bean, mung bean, rice bean, southern bean, urd bean); broad bean (dry); chickpea; guar; lablab bean; lentil; pea (<i>Pisum</i> spp.) (includes field pea); and pigeon pea</p> <p>Fruiting vegetables (Crop Group 8-09) Eggplant; Groundcherry; Okra ; Pepino; Pepper (includes bell pepper, chili pepper, cooking pepper, pimento, sweet pepper); Tomatillo; Tomato;</p> <p>Cucurbit vegetables (Crop Group 9) Chinese waxgourd; Citron melon; Cucumber (field); Gerkin; Gourd, edible; Momordica spp.; Muskmelons (includes cantaloupe); Pumpkin; Squash, summer (includes</p>
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						zucchini); Squash, winter; Watermelon. Including cultivars and/or hybrids of these.
		A18993 Fungicide	Fungicide	Full	Conventional Chemical	Soybeans, wheat, barley, rye, oats, triticale, corn (Field, sweet, popcorn and specialty Including all cultivars and/or hybrids of these), Dried shelled pea and beans (Crop Subgroup 6C): Any dried cultivar of bean (<i>Phaseolus</i> spp.); and dried cultivar of pea (<i>Pisum</i> spp.): dried cultivars of bean (<i>Lupinus</i> spp.) (includes grain lupin, sweet lupin, white lupin, and sweet white lupin); (<i>Vigna</i> spp.) (includes adzuki beans); (<i>Phaseolus</i> spp.) (includes field bean, kidney bean, lima bean (dry), navy bean, pinto bean, tepary bean, mung bean, rice bean, southern bean, urd bean); broad bean (dry); chickpea; guar; lablab bean; lentil; pea (<i>Pisum</i> spp.) (includes field pea); and pigeon pea Rapeseed (Crop Subgroup 20A) Borage, Crambe, Cuphea, Echium, Flax seed, Gold of pleasure, Hare's ear mustard, Lesquerella, Lunaria, Meadowfoam, Milkweed, Mustard see, Oil radish, Poppy seed, Rapeseed (Canola), Sesame, Sweet rocket and Cultivars and/or hybrids of these.

		APROVIA TOP	Fungicide	Full	Conventional Chemical	<p>Tuberous and Corm Vegetables (Crop Subgroup 1C): Arrowroot; Artichoke, Chinese; Artichoke, Jerusalem, Canna, edible; Chufa; Dasheen; Ginger; Potato; Sweet potato</p> <p>Fruiting vegetables (Crop Group 8-09): Eggplant; Groundcherry; Pepino; Pepper (includes bell pepper, chili pepper, cooking pepper, pimento, sweet pepper); Tomatillo; Tomato; Okra;</p> <p>Cucurbit vegetables (Crop Group 9): Chinese waxgourd; Citron melon; Cucumber (field); Gerkin; Gourd, edible; Momordica spp.; Muskmelons (includes cantaloupe); Pumpkin; Squash, summer (includes zucchini); Squash, winter; Watermelon. Including cultivars and/or hybrids of these.</p> <p>Pome fruit (Crop Group 11-09): Apples. Crabapples, Loquat, Mayhaw, Pears and Quince</p> <p>Small Fruit Vine Climbing Subgroup (Crop Subgroup 13-07F): Gooseberry, Grape, Schisandra chinensis and cultivars, varieties and/or hybrids of these</p> <p>Rapeseed (Crop Subgroup 20A): Borage, Canola, Crambe, Cuphea, Echium, Flax seed, Gold of pleasure, Hare's ear mustard, Lesquerella, Lunaria,</p>
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						Meadowfoam, Milkweed, Mustard seed, Oil radish, Poppy seed, Rapeseed (canola), Sesame, Sweet rocket and Cultivars and/or hybrids of these.
		ASCERNIT Y Fungicide	Fungicide	Full	Conventional Chemical	Turf (golf courses).
		INSTRATA II A FUNGICID E (A COMPONE NT OF THE INSTRATA II FUNGICID E TANK-MIX)	Fungicide	Full	Conventional Chemical	Golf course turf.
6	Bicyclopyrone	SYNA16003 Herbicide	Herbicide	Full	Conventional Chemical	Corn (field, seed and sweet) for sale and use in Eastern Canada only
		ACURON Herbicide	Herbicide	Full	Conventional Chemical	Corn (field, seed and sweet) for sale and use in Eastern Canada only
7	BLAD polypeptide	PROBLAD PLUS FUNGICID E	Fungicide	Full	Biopesticide	Grape, Strawberry, Tomato, Stone Fruit and Almond (Almond, Apricot, Cherry, Nectarine, Peach, Plum, Prune), Ornamentals grown outdoors
8	Codlure	Semios CM Plus	Insecticide	Full	Biopesticide	Pome fruits and stone fruits.
9	Copper (present as copper octanoate)	CUEVA COMMERC IAL	Fungicide	Full	Biopesticide	Turf (lawns, golf course turf, lawn bowling greens) Greenhouse and outdoor ornamental shrubs and flowering plants (such as rose, hollyhock, hydrangea, crape myrtle) Agricultural Crops: Crop Group 1: Root and Tuber Vegetables (Garden beet, Celeriac, Potato,

						<p>Sugar beet)</p> <p>Crop Group 3: Bulb Vegetables (Chives, Garlic, Leek, Onion, Shallot)</p> <p>Celery</p> <p>Crop Group 5: Brassica Leafy Vegetables (Bok choy, Broccoli, Brussels sprouts, Cabbage, Cauliflower, Kale, Kohlrabi, Mustard, Pak-choi)</p> <p>Crop Group 6: Legumes (Bean, Pea, Soybean)</p> <p>Crop Group 8: Fruiting Vegetables (Eggplant, Pepper, Tomatoes)</p> <p>Crop Group 9: Cucurbits (Cucumbers, Cantaloupe, Melon, Squash, Pumpkin, Zucchini)</p> <p>Crop Group 11: Pome Fruit Trees (Apple, Pear, Quince)</p> <p>Crop Group 12: Stone Fruit Trees (Apricot, Cherry, Nectarine, Peach, Plum and Necta-plum)</p> <p>Crop Group 13: Small Fruits (Blackberry, Blueberry, Currant, Gooseberry, Grape, Raspberry, Strawberry)</p> <p>Filbert, Hazelnut, Walnut, Parsley, Cranberry</p>
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						<u>Greenhouse Food Crops:</u> Celery Crop Group 6: Legumes (Bean, Pea, Soybean) Crop Group 8: Fruiting Vegetables (Eggplant, Pepper, Tomatoes) Crop Group 9: Cucurbits (Cucumbers, Cantaloupe, Melon, Squash, Pumpkin, Zucchini)
		CUEVA CONCENT RATE	Fungicide	Full	Biopesticide	Turf (lawns) Greenhouse and outdoor ornamental shrubs and flowering plants (such as rose, hollyhock, hydrangea, crape myrtle) <u>Vegetable, Fruits, Nuts and Berries</u> Root and Tuber Vegetables (Garden beet, Celeriac, Potatoes, Sugar beet) Bulb Vegetables (Chives, Garlic, Leek, Onion, Shallot) Celery Brassica Leafy Vegetables (Bok choy, Broccoli, Brussels sprouts, Cabbage, Cauliflower, Kale, Kohlrabi, Mustard, Pak-choi) Legumes (Bean, Pea, Soybean) Fruiting Vegetables (Eggplant, Peppers, Tomatoes)

						<p>Cucurbits (Cucumbers, Cantaloupe, Melon, Squash, Pumpkin, Zucchini)</p> <p>Pome Fruit Trees (Apple, Pear, Quince)</p> <p>Stone Fruit Trees (Apricot, Cherry, Nectarine, Peach, Plum)</p> <p>Small Fruits (Blackberry, Blueberry, Currant, Gooseberry, Grape, Raspberry, Strawberry)</p> <p>Filbert, Hazelnut, Walnut, Parsley</p> <p><u>Greenhouse Food Crops:</u> Celery</p> <p>Crop Group 6: Legumes (Bean, Pea, Soybean)</p> <p>Crop Group 8: Fruiting Vegetables (Eggplant, Pepper, Tomatoes)</p> <p>Crop Group 9: Cucurbits (Cucumbers, Cantaloupe, Melon, Squash, Pumpkin, Zucchini)</p>
		CUEVA READY- TO-SPRAY	Fungicide	Full	Biopesticide	Turf (lawns)
		CUEVA RTU	Fungicide	Full	Biopesticide	Greenhouse and outdoor ornamental shrubs and flowering plants (such as rose, hollyhock, hydrangea,
		CUEVA	Fungicide	Full	Biopesticide	

		RTU WITH PULL'N SPRAY APPLICATOR				crape myrtle)
		CUEVA RTU WITH QUICKPUMP APPLICATOR	Fungicide	Full	Biopesticide	<u>Vegetables, Fruit, Nuts and Berries:</u> Root and Tuber Vegetables (Garden beet, Celeriac, Potatoes, Sugar Beet) Bulb Vegetables (Chives, Garlic, Leek, Onion, Shallot)
		CUEVA RTU WITH WAND APPLICATOR	Fungicide	Full	Biopesticide	Celery Brassica Leafy Vegetables (Bok choy, Broccoli, Brussels sprouts, Cabbage, Cauliflower, Kale, Kohlrabi, Mustard, Pak-choi)
		CUEVA RTU WITH QUICK CONNECT SPRAYER	Fungicide	Full	Biopesticide	Legumes (Bean, Pea, Soybean) Fruiting Vegetables (Eggplant, Peppers, Tomatoes) Cucurbits (Cucumbers, Cantaloupe, Melon, Squash, Pumpkin, Zucchini) Pome Fruit Trees (Apple, Pear, Quince) Stone Fruit Trees (Apricot, Cherry, Nectarine, Peach, Plum, Necta-plum) Small Fruits (Blackberry, Blueberry, Currant, Gooseberry, Grape, Raspberry, Strawberry) Filbert, Hazelnut, Walnut, Parsley

						<u>Greenhouse Food Crops:</u> Celery Legumes (Bean, Pea, Soybean) Fruiting Vegetables (Eggplant, Pepper, Tomatoes) Cucurbits (Cucumbers, Cantaloupe, Melon, Squash, Pumpkin, Zucchini)
10	Etoxazole	TetraSan 5 WDG Miticide	Miticide	Full	Conventional Chemical	Greenhouse Tomatoes, Greenhouse Ornamental Plants Including: Bedding Plants, Flowering Plants, Foliage Plants, Ground Covers, Non-Bearing Fruit Trees, Non-Bearing Nut Trees, Ornamentals, Ornamental Trees, Shrubs, and cut flowers,
11	Fenpyroximate	Fenpyroximate 5SC Miticide/Insecticide	Miticide, Insecticide	Full	Conventional Chemical	Indoor ornamentals grown in greenhouses and interiorscapes, greenhouse tomatoes, greenhouse peppers, greenhouse eggplants and greenhouse cucumbers.
12	Flupyradifurone	BYI 02960 480 FS	Insecticide	Full	Conventional Chemical	Soybeans
		Sivanto Prime Insecticide	Insecticide	Full	Conventional Chemical	Crop Subgroup 1-B: Root and tuber vegetables - root vegetables (except sugarbeet): garden beet, edible burdock, carrot, celeriac (celery root), turnip-rooted chervil, chicory,

					<p>ginseng, horseradish, turnip-rooted parsley, parsnip, radish, oriental radish (daikon), rutabaga, salsify, black salsify, Spanish salsify, skirret, turnip.</p> <p>Crop Subgroup 1-C: Root and tuber vegetables - tuberous and corm vegetables: arrowroot, Chinese artichoke, Jerusalem artichoke, edible canna, chufa, dasheen (taro), potato. sweet potato, true yam.</p> <p>Crop Group 4-13: Leafy vegetables: Chinese amaranth, leafy amaranth, arugula, Indian aster, blackjack, broccoli raab, Chinese broccoli, Abyssinian cabbage, seakale cabbage, cat's whiskers, cham-chwi, cham-na-mul, fresh chervil leaves, bok choy (Chinese cabbage), chipilin, garland chrysanthemum, fresh cilantro leaves, collards, corn salad, cosmos, garden cress, upland cress, dandelion leaves, dang-gwi, fresh dillweed leaves, dock, dol-nam-mul, ebolo, endive, escarole, fameflower, feather cockscomb, Good King Henry, Hanover salad, huauzontle, jute leaves, kale, bitter lettuce, head lettuce, leaf lettuce, maca, mizuna, mustard greens, orach, fresh parsley leaves,</p>
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					<p>buckhorn plantain, English primrose, garden purslane, winter purslane, radicchio (red chicory), radish leaves, rape greens, wild rocket, shepherd's purse, spinach, Malabar spinach, New Zealand spinach, tree spinach (giant lambsquater), Swiss chard, tanier spinach, turnip greens, Chinese violet, watercress.</p> <p>Crop Group 22-B: Leaf petiole vegetables: cardoon, celery, Chinese celery, fuki, rhubarb, udo, zuiki.</p> <p>Crop Group 5-13: Brassica head and stem vegetables: broccoli, Brussels sprouts, cabbage, Chinese cabbage (napa), cauliflower.</p> <p>Crop Group 6: Legume vegetables (succulent or dried): bean (includes grain lupin, sweet lupin, white lupin and white sweet lupin), bean (includes field bean, kidney bean, lima bean, navy bean, pinto bean, runner bean, snap bean, tepary bean and wax bean), bean (includes adzuki bean, asparagus bean, blackeyed pea, catjang, Chinese longbean, cowpea, Crowder pea, moth bean, mung bean, rice bean, southern pea, yardlong bean), broad bean (fava</p>
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						<p>bean), chickpea (garbanzo bean), guar, jackbean, lablab bean (hyacinth bean), lentil, pea (includes dwarf pea, edible-pod pea, English pea, field pea, garden pea, green pea, snow pea, sugar snap pea), pigeon pea, soybean (includes immature seed), sword bean.</p> <p>Crop Group 8-09: Fruiting vegetables: eggplant, African eggplant, pea eggplant, scarlet eggplant, garden huckleberries, goji berry, groundcherry, martynia, okra, pepino, bell pepper, non-bell pepper, sunberry, tomatillo, tomato, currant tomato, and cultivars, varieties and/or hybrids of these.</p> <p>Crop Group 9: Cucurbit vegetables: Chinese waxgourd (Chinese preserving melon), citron melon, cucumber, gherkin, edible gourd (includes hyotan, cucuzza, hechima, Chinese okra), Momordica (includes balsam apple, balsam pear, bitter melon, Chinese cucumber), muskmelon (includes true cantaloupe, cantaloupe, casaba, crenshaw melon, golden pershaw melon, honeydew melon, honey balls, mango melon, Persian melon, pineapple melon, Santa Claus melon, snake</p>
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					<p>melon and excludes cantaloupes) (soil application only), pumpkin, summer squash (includes crookneck squash, scallop squash, straightneck squash, vegetable marrow, zucchini), winter squash (includes butternut squash, calabaza, hubbard squash, <i>C. mixta</i>, <i>C. pepo</i>, acorn squash, spaghetti squash), watermelon.</p> <p>Crop Group 11-09: Pome Fruits: apple, azarole, crabapple, mayhaw, medlar, pear, Asian pear, quince, Chinese quince, Japanese quince, tejocote, and cultivars, varieties and/or hybrids of these.</p> <p>Crop Subgroup 13-07B: Berry and small fruit - bushberry (except highbush cranberry): aronia berry, highbush blueberry, lowbush blueberry, buffalo currant, Chilean guava, black currant, red currant, elderberry, European barberry, gooseberry, edible honeysuckle, huckleberry, jostaberry, Saskatoon berry (Juneberry), lingonberry, native currant, salal, sea buckthorn.</p> <p>Crop Subgroup 13-07F: Berry and small fruit - small fruit vine climbing, except</p>
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						<p>fuzzy kiwifruit: Amur river grape, gooseberry, grape, hardy kiwifruit, maypop, schisandra berry.</p> <p>Crop Subgroup 13-07G: Berry and small fruit - low growing berry (except cranberry and lowbush blueberry): bearberry, bilberry, cloudberry, lingonberry, muntries, partridgeberry, strawberry.</p> <p>Crop Group 14-11: Tree nuts: almond, beech nut, black walnuts, bur oak nuts, butternuts, chestnuts, chinquapin nuts, English walnuts, ginkgo nuts, hazel nuts (filberts), heartnuts, hickory nuts, Japanese horse-chestnuts, monkey puzzle nuts, pecan, pine nuts, yellowhorn nuts.</p> <p>Corn (field, sweet, pop, seed),</p> <p>Alfalfa (forage, silage and hay production only),</p> <p>Peanut, Hops</p>
13	Noviflumuron	Recruit HD Termite Bait	Insecticide	Full	Conventional Chemical	For use in an integrated management program for the protection of structures against subterranean termites, e.g., buildings, fences, utility poles, decking, landscape plantings and trees, or other features that could be damaged by termite

						feeding and foraging activity.
14	Oxathiapiprolin	Orondis Fungicide	Fungicide	Full	Conventional Chemical	HEAD AND STEM BRASSICA VEGETABLES – Crop Subgroup 5A: Broccoli, Broccoli, Chinese (gailon), Brussels sprouts Cabbage, Cabbage, Chinese (napa), Cabbage, Chinese, mustard (gai choy), Cauliflower Cavolo broccolo, Kohlrabi BULB VEGETABLES – Crop Group 3: Chive, fresh leaves; chive, Chinese,fresh leaves;garlic, bulb;garlic, great-headed, bulb; garlic, serpent, bulb; kurrat; lady's leek; leek; leek, wild; onion, Beltsville bunching; onion, bulb; onion, Chinese, bulb; onion, fresh; onion, green; onion, macrostem; onion, pearl; onion, potato, bulb; onion, tree, tops; onion, Welsh, tops; shallot, bulb; shallot, fresh leaves; cultivars, varieties, and/or hybrids of these. CUCURBIT VEGETABLES – Crop Group 9: Chinese waxgourd (Chinese preserving melon); citron melon; cucumber (field + greenhouse foliar only); gherkin; gourd, edible (includes hyotan, cucuzza, hechima, Chinese okra); Momordica spp (includes balsam apple, balsam pear, bittermelon, Chinese
		DuPont Zorvec Enicade Fungicide	Fungicide	Full	Conventional Chemical	

					<p>cucumber); muskmelon (includes cantaloupe); pumpkin; squash, summer; squash, winter (includes butternut squash, calabaza, hubbard squash, acorn squash, spaghetti squash); watermelon</p> <p>LEAFY VEGETABLES – Crop Group 4: Amaranth leafy, Arugula, Cardoon, Celery, Celery (Chinese), Celtuce, Chevril, Chrysanthemum (edible leaved), Chrysanthemum (garland), Corn Salad, Cress (garland), Cress (upland), Dandelion leaves, Dock, Endive, Florence Fennel, Lettuce (head & leaf), Orach, Parsley leaves, Purslane (garden), Purslane (winter), Radicchio, Rhubarb, Spinach, Spinach (vine), Spinach (New Zealand), Swiss Chard,</p> <p>Tomato (field, greenhouse); Pepper, bell, non-bell (field, greenhouse); Eggplant (field)</p> <p>Potato</p> <p>Tobacco</p> <p>Peas, succulent <i>Pisum</i> spp., includes dwarf pea, edible-pod pea, snow pea, sugar snap pea, English pea, garden pea, green pea.</p> <p>Ginseng (<i>Panax quinquefolius</i>)</p>
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		DuPont Zorvec Epicaltrin Fungicide	Fungicide	Full	Conventional Chemical	CUCURBIT VEGETABLES – CROP GROUP 9: Chinese waxgourd (Chinese preserving melon); citron melon; cucumber ; gherkin; gourd, edible (includes hyotan, cucuzza, hechima, Chinese okra); Momordica spp (includes balsam apple, balsam pear, bittermelon, Chinese cucumber); muskmelon includes cantaloupe); pumpkin; squash, summer; squash, winter (includes butternut squash, calabaza, hubbard squash, acorn squash, spaghetti squash); watermelon Eggplant, Pepper (bell, non-bell), Tomato
		Orondis 200SC Fungicide	Fungicide	Full	Conventional Chemical	
15	<i>Pasteuria nishizawae</i> Pn1	CLARIVA pn	Nematicide	Full	Biopesticide	Soybeans
16	Prohydrojasmon	BLUSH Plant Growth Regulator Solution	Plant Growth Regulator	Full	Biopesticide	Apples
17	Propoxycarbazon e-Sodium	MKH 6561 70WG Herbicide	Herbicide	Full	Conventional Chemical	Winter wheat in Manitoba, Saskatchewan, Alberta and Peace River, Okanagan And Creston Flats Regions Of British Columbia
18	Spiroxamine	Priwen 500 EC Fungicide	Fungicide	Full	Conventional Chemical	Wine grapes

TABLE 3 APPROVED GROU PRODUCTS 2016

In 2015–2016, 19 products were available under the Grower Requested Own Use (GROU) Program:

- FirstRate Herbicide (Registration Number 26697) (expires December 31, 2016)
- Quadris Flowable Fungicide (Registration Number 26153) (expires December 31, 2016)
- Reglone Desiccant (Registration Number 26396) (expires December 31, 2016)
- SUMAGIC Plant Growth Regulator (Registration Number 25781) (expires December 31, 2016)
- Tattoo Fungicide (Registration Number 29554) (expires December 31, 2016)
- Assail 70 WP Insecticide (Registration Number 27128) (expires December 31, 2017)
- Assure II Herbicide (Registration Number 25462) (expires December 31, 2017)
- Bonzi Plant Growth Regulator (Registration Number 25453) (expires December 31, 2017)
- Elevate 50 WDG Fungicide (Registration Number 25900) (expires December 31, 2017)
- Ridomil Gold 480SL Fungicide (Registration Number 28474) (expires December 31, 2017)
- SePRO A-Rest Solution (Registration Number 16393) (expires December 31, 2017)
- Agri-Mek SC Formulation (Registration Number 31607) (expires December 31, 2018)
- Basagran Liquid Herbicide (Registration Number 12221) (expires December 31, 2018)
- B-Nine WSG Plant Growth Regulator (Registration Number 17465) (expires December 31, 2018)
- Pursuit 240 (Registration Number 23844) (expires December 31, 2018)
- Pursuit Herbicide (Registration Number 21537) (expires December 31, 2018)
- Reflex Liquid Herbicide (Registration Number 24779) (expires December 31, 2018)
- Roundup WeatherMax with Transorb 2 Technology Liquid Herbicide (Registration Number 27487) (expires December 31, 2018)
- Upbeet Herbicide Dry Flowable 50% (Registration Number 25813) (expires December 31, 2018)

TABLE 4 RE-EVALUATION/SPECIAL REVIEW DOCUMENTS PUBLISHED IN 2015–2016

Active Ingredient	Document Number	Summary of Decision or Proposed Decision
Final Decisions – Re-evaluations		
Triflurosulfuron-methyl	RVD2015-02	Acceptable for continued registration. Mitigation includes new/revised label statements to further protect human health and the environment.
<u>Phosphine:</u> - Aluminum phosphide - Magnesium phosphide - Phosphine gas	RVD2015-03	Acceptable for continued registration. Mitigation includes new/revised label statements to further protect human health.
Dimethoate	RVD2015-04	Acceptable for continued registration for certain uses only. Mitigation includes removal of some uses and new/revised label statements to further protect human health and the environment.
Prosulfuron	RVD2015-05	Acceptable for continued registration for certain uses only. Mitigation includes new/revised label statements to further protect the environment.
Carbaryl	RVD2016-02	Acceptable for continued registration for certain uses only. Mitigation includes removal of some uses and new/revised label statements to further protect human health and the environment.
Propamocarb	RVD2016-03	Acceptable for continued registration for certain uses only. Mitigation includes removal of certain uses and new/revised label statements to further protect human health and the environment.
Final Decisions – Special Reviews		
Paraquat	REV2015-14	Acceptable for continued registration. Mitigation includes new/revised label statements to further protect human health and the environment.
Quintozene	REV2016-01	Acceptable for continued registration.
Imazapyr	REV2016-02	Acceptable for continued registration. Mitigation includes new/revised label statements to further protect the environment.
Proposed Decisions for Public Consultation – Re-evaluations		
<u>Glyphosate:</u> - Glyphosate (present as isopropylamine salt or ethanolamine salt) - Glyphosate (present as mono-ammonium salt or diammonium salt) - Glyphosate - Glyphosate (present as potassium salt) - Glyphosate (present as dimethylamine salt)	PRVD2015-01	Proposed for continued registration with implementation of new/revised mitigation measures to further protect human health and the environment.
Prosulfuron	PRVD2015-02	Proposed for continued registration with implementation of new/revised mitigation measures to further protect the environment.
Propamocarb	PRVD2015-03	Proposed for continued registration.
Imazamox	PRVD2015-04	Proposed for continued registration with implementation of new/revised mitigation measures to further protect human health and the environment.

d-Phenothrin	PRVD2015-05	Proposed for continued registration with implementation of new/revised mitigation measures to further protect human health and the environment.
Deltamethrin	PRVD2015-07	Proposed for continued registration with implementation of new/revised mitigation measures to further protect human health and the environment.
Octhilinone	PRVD2015-11	Proposed for continued registration for certain uses with implementation of new/revised mitigation measures to further protect human health and the environment. Proposed cancellation of other uses due to health risk concerns.
Acephate	PRVD2016-01	Proposed for continued registration for certain uses with implementation of new/revised mitigation measures to further protect human health and the environment. Proposed cancellation of other uses due to health risk concerns.
Methomyl	PRVD2016-02	Proposed for continued registration for certain uses with implementation of new/revised mitigation measures to further protect human health and the environment. Proposed cancellation of other uses due to health risk concerns.
Fludioxonil	PRVD2016-03	Proposed for continued registration with implementation of new/revised mitigation measures to further protect the environment.
Pyridaben	PRVD2016-04	Proposed for continued registration for certain uses with implementation of new/revised mitigation measures to further protect human health and the environment. Proposed cancellation of other uses due to health risk concerns.
Ferbam	PRVD2016-05	Proposed cancellation of all uses due to health and environmental risk concerns.
Ziram	PRVD2016-06	Proposed cancellation of all uses due to health and environmental risk concerns.
Thiram	PRVD2016-07	Proposed cancellation of all uses due to health and environmental risk concerns.
4-Aminopyridine	PRVD2016-08	Proposed for continued registration with implementation of new/revised mitigation measures to further protect human health and the environment.
Iprodione	PRVD2016-09	Proposed cancellation of all uses due to health risk concerns.
Tetramethrin	PRVD2016-10	Proposed for continued registration for certain uses with implementation of new/revised mitigation measures to further protect human health and the environment. Proposed cancellation of other uses due to health risk concerns.
Clethodim	PRVD2016-11	Proposed for continued registration with implementation of new/revised mitigation measures to further protect human health and the environment.
Sodium Omadine	PRVD2016-12	Proposed for continued registration for certain uses with implementation of new/revised mitigation measures to further protect human health. Proposed cancellation of other uses due to health risk concerns.
Captan	PRVD2016-13	Proposed for continued registration for certain uses with implementation of new/revised mitigation measures to further protect human health and the environment. Proposed cancellation of other uses due to health risk concerns.
Chlorothalonil (amendment)	REV2016-06	Proposed for continued registration for certain uses with implementation of new/revised mitigation measures to further protect human health and the environment. Proposed cancellation of other uses due to health risk concerns.

Proposed Decisions for Public Consultation – Special Reviews		
Fluazinam	REV2015-08	Proposed for continued registration.
Fluazifop-P-butyl	REV2015-09	Proposed for continued registration.
Paraquat	REV2015-10	Proposed for continued registration for certain uses with implementation of new/revised mitigation measures to further protect human health and the environment.
Atrazine	REV2015-11	Proposed for continued registration.
Trifluralin	REV2015-12	Proposed for continued registration.
<u>2,4-D:</u> - 2,4-D (present as acid) - 2,4-D (present as amine salts: dimethylamine salt, diethanolamine salt, or other amine salts) - 2,4-D (present as low volatile esters) - 2,4-D (present as choline salt)	REV2016-08	Proposed for continued registration.