Health Canada Santé Canada

Canada

Pest Management Regulatory Agency

2018–2019 Annual Report

Protecting the health and environment of Canadians

Protéger la santé des Canadiens et l'environnement

Également offert en français sous le titre : Agence de réglementation de la lutte antiparasitaire Rapport annuel 2018–2019

This publication is also available on the Internet at Canada.ca/pesticides.

This publication can also be made available in alternate format(s) upon request.

The Pest Management Regulatory Agency publications team was responsible for the translation, formatting and publication of this document.

For additional copies, please contact: Publications Pest Management Regulatory Agency
2720 Riverside Drive Ottawa ON K1A 0K9

Telephone: 1-800-267-6315 Facsimile: 1-613-736-3758

ISSN: 1719-2358 (PDF version) Catalogue Number: H110-2019E-PDF

Table of Contents

Message from the Executive Director 1
About the Pest Management Regulatory Agency 2
- Vision 2
- Mission 2
- Our People 2

What Are Pesticides 3
New Pesticide Registrations 4
- New Active Ingredients and Products Registered in 2018–2019 5
- Joint Reviews 6
- Generic Registrations 6
- Minor Uses 6
- Protecting Species at Risk 7
- Emergency Registrations and Invasives Species 7
- Maximum Residue Limits 7

Regulation of Pesticides on the Market 9
- Re-evaluation/Special Review Programs 10
- Neonicotinoids Imidacloprid, Clothianidin and Thiamethoxam – Environmental Assessments 11
- Pest Control Product Sales Information Reporting 12
- Glyphosate 12
- Incident Reporting 14

Compliance and Enforcement 16
- 2018–2019 Key Statistics 17

Keeping Page with Change 18
- Cumulative Risk Assessment 18
- Evaluating New Technologies 18
- Water Monitoring 20
- Vegetative Filter Strips 20

International Scientific and Regulatory Cooperation 21
- Stockholm Convention 21
- Rotterdam Convention 21
- Organisation for Economic Co-operation and Development 22
- Codex 22

Regulatory Modernization 23
- Regulation of in-Transit Pesticides 23
- Targeted Regulatory Review of the Agri-Food and Aquaculture Sector 23
- Pest Control Product Regulations Review 24

Communications and Outreach 25
- Educational Videos about PMRA 25
- Public Engagement Portal 25
- Stakeholder Webinars 25
- New Pest Management Advisory Council 25

Financial Profile 26
- Service Fees Act 27

Appendix 28

Message from the Executive Director

Health Canada's Pest Management Regulatory Agency (PMRA) is pleased to present the 2018–2019 Annual Report to Parliament, which details PMRA's accomplishments and activities over the last fiscal year.

PMRA's mission is to protect the health and environment of Canadians by using current, evidence-based, scientific approaches to pesticide regulation, in an open and transparent manner.

As the former Chief Registrar and new Executive Director, I am committed to seeing that PMRA continues to adapt to constantly evolving pressures and opportunities such as new science, new technologies, and a growing global marketplace. This requires a workforce that is flexible, capable and innovative.

PMRA's re-evaluation of older pesticides program continues to be a significant and increasing pressure. PMRA updated the re-evaluation workplan for 2018–2023, and the need for a new approach to this key activity became clear. We have established a team dedicated to examining various potential regulatory, resource and process options to develop a more sustainable re-evaluation program. This includes a comparative analysis of international approaches to re-evaluation, broad stakeholder consultation, and development of recommendations for the anticipated 2020 statutory review of the *Pest Control Products Act*.

In 2018–2019, PMRA continued to develop new science and business approaches to improve efficiency, transparency, and health and environmental protection. New procedures were implemented for emergency registrations, and a new policy on cancellation and phasing out of pesticides came into effect. New science was incorporated into pollinator protection, and health and environmental risk assessments.

Collaboration with our international counterparts is an ongoing and increasing necessity. In 2018–2019, PMRA continued its strong emphasis on joint scientific reviews with the United States Environmental Protection Agency and other global partners, and increased its outreach with international regulators.

In addition to joint reviews, Canada participated in international activities aimed at aligning policies and approaches where appropriate. These activities involved work with Codex Alimentarius, the Organisation for Economic Co-operation and Development and the Canada-United States Regulatory Cooperation Council, as well as trilateral United States/Mexico/Canada meetings.

I would like to take this opportunity to thank Dr. Richard Aucoin for more than 20 years of service at PMRA, including 12 years as Executive Director. Dr. Aucoin's contribution to pesticide regulation has been significant, not only in Canada but also globally through strong advocacy for Canadian participation in international fora such as the Organisation for Economic Co-operation and Codex.

The accomplishments highlighted in this report reflect the strength of Dr. Aucoin's leadership, and the dedication of our highly trained workforce, whose focus remains upholding the highest standards of health and environmental protection for Canadians.

Peter Brander

Executive Director

Pest Management Regulatory Agency

About the Pest Management Regulatory Agency

The Pest Management Regulatory Agency (PMRA) is the branch of Health Canada responsible for regulating pesticides under the authority of the *Pest Control Products Act*. PMRA's primary mandate is to prevent unacceptable risks to Canadians and the environment from the use of these products.

PMRA applies current, evidence-based scientific approaches to assess whether the health and environmental risks of pesticides proposed for registration are acceptable, and if the products have value.

This same approach is used to regularly and systematically review whether pesticides already on the Canadian market continue to meet modern scientific standards.

In collaboration with Health Canada's Regulatory Operations and Enforcement Branch (ROEB), PMRA also promotes, monitors and enforces compliance with the *Pest Control Products Act* across Canada. PMRA is committed to doing this in a collaborative, open and transparent manner.

This work is carried out by a highly skilled workforce, the majority of whom are scientists, with additional expertise in areas such as regulatory and policy development, stakeholder engagement and international collaboration and information management.

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.

OUR PEOPLE

Effective pesticide regulation requires an experienced workforce with a diversity of expertise. Of the 450 employees at PMRA, 73% are scientists, including biologists, toxicologists, epidemiologists and chemists. PMRA has a highly diverse and experienced workforce; 80% of PMRA employees have more than 10 years of federal government experience.

WHAT ARE PESTICIDES?

- Pesticides are toxic chemicals intentionally released into the environment to control pests on crops, in homes and workplaces, and in industrial processes.
- There are 665 registered active ingredients in almost 8000 pesticide products in Canada.

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 registered for sale in Canada, pesticide applicants are required to provide PMRA with extensive scientific 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 or 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 pregnant women, infants, children, women and seniors; 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 environmental risk assessment that considers the fate (movement, persistence and transformation), toxicity, and risks to plants, birds, mammals, beneficial insects and aquatic organisms; 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.

For some currently registered pesticides, registrants may request changes to the use pattern. For these types of registrations, PMRA may also assess:

- additional environmental data, such as levels of pesticides detected through monitoring of pesticide concentrations in water across Canada or the United States;
- any incident reports from Canada or other jurisdictions where the pesticide is already registered; and,
- any other information needed to evaluate the health and environmental risks and the value of the pest control product.

Various factors determine which studies are required to be submitted by applicants for registration, such as the nature of the product, the intended use, and the type of registration (for an overview of product submission types, see Appendix Table 1). PMRA follows established service standards, or defined timelines, for these evaluations as outlined in the Management of Submissions Policy (Regulatory Directive DIR2017-01). 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).

NEW ACTIVE INGREDIENTS AND PRODUCTS REGISTERED IN 2018–2019

In 2018–2019, 12 new active ingredients (the substance with the pesticidal effect) were registered for use in Canada, resulting in the registration of 23 new related end-use products (different formulations of products containing the active ingredient). Of the 12 new active ingredients, eight were biopesticides (derived from natural sources such as bacteria, fungi, viruses, plants, animals and minerals), three were conventional (in other words, chemical) pesticides and one was an antimicrobial.

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

Some examples of end-use products registered in 2018–2019 include:

- products to protect greenhouse and field food crops, and products to extend the shelf life of flowering and ornamental crops
- products to preserve industrial polymers such as rubber and PVC
- slimicides to be used in industrial sites such as oil fields
- biopesticides for use on cannabis
- a new insecticide to defend against Hemlock woolly adelgid, an invasive insect responsible for attacking and killing hemlock trees in Canada

The total number of active ingredients registered for use in Canada has increased from approximately 560 in 2007 to 658 towards the end of 2018. The overall number of registered products increased from approximately 5505 to 7707 between 2007 and March 2019, despite the removal of many older products.

PMRA continued to largely meet its performance targets on pre-market evaluations despite an increasingly complex workload (please see Appendix Figure 2). PMRA also responded to a high number of requests for pre-submission consultations or Subject to Registration enquiries, including those for use of pesticides with drones and products for use on cannabis.

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 joint reviews as a primary course of business. Registrants must apply to register their product in each participating jurisdiction at the same time for a joint review to be conducted.

In 2018–2019, of the 12 active ingredients registered, two were joint reviews. PMRA is currently piloting a new joint review approach with the United States Environmental Protection Agency to increase efficiencies on the review process. The pilot approach has been shared with international partners with the aim of increasing international interest in joint reviews, potentially leading to more global joint reviews in the future.

GENERIC REGISTRATIONS

When a new pesticide is developed, the innovator invests substantial funds into the studies required to show that the product works as intended, and the health and environmental risks are acceptable. The data supporting a new innovation to Canada (in other words, a new active ingredient) receives exclusive use protection for a period of time, to prevent it from being used for the benefit of a competitor without the innovator's approval. Data subsequently used to amend or maintain a registration or register a new product are given compensable protection.

This practice allows the innovator the opportunity to recover their investment, but also encourages further innovation by allowing competition on the market after a period of time. Allowing timely introduction of equivalent products by generic manufacturers following the exclusive period can enhance market competition to the benefit of users, including growers. These regulations are important to innovators, generic companies and to growers.

In 2018–2019, PMRA received 167 applications to register generic products. The number of generic applications received has remained higher than previously anticipated by PMRA. Recently implemented process changes are continuing to help PMRA meet its performance targets. There were 59 generic products (32 technical and 27 end-use products) registered in 2018–2019. PMRA continues to seek ways to improve the data protection program for innovator registrants, generic companies and PMRA.

MINOR USES

A minor use is a use of a pest control product for which the anticipated volume of sales is not sufficient to persuade a manufacturer to register and sell the product in Canada. The definition emphasizes that it is the projected sales of the pest control product that is minor and not necessarily the size of the crop. A minor use may be registered on a major crop because the use may be needed only occasionally or is limited to a small percentage of the total area of the crop.

To help resolve these pesticide access issues for Canadian growers, PMRA works with Agriculture and Agri-Food Canada's Pest Management Centre to provide regulatory advice that supports growers and grower associations in identifying priorities for new minor use registrations in Canada. PMRA also works directly with the provinces to assist in addressing regional minor use needs.

In 2018–2019, PMRA reviewed minor use submissions from Agriculture and Agri-Food Canada and the provinces, and made 77 regulatory decisions, of which nine were joint reviews or workshares with the United States Environmental Protection Agency. Final label reviews resulted in the registration of 435 new minor uses.

PROTECTING SPECIES AT RISK

An emergency registration request from Parks Canada was granted for control of rats for the protection of globally significant breeding seabird colonies and endangered bats, and their habitat islands in Gwaii Haanas National Park Reserve in British Columbia. Hotsprings and House Islands and associated islets are breeding habitat for over 2000 pairs of Ancient Murrelets (Species-At-Risk: Threatened), and is the only known maternity roost location for the Little Brown Myotis bat (Species-At-Risk: Endangered) on federal lands in western Canada. Rats are not native to the islands and are known to be voracious predators of burrow-nesting seabird adults and eggs, and are thought to prey upon the bats. The encroachment of the rats could lead to the potential decimation of the seabird breeding colonies and the bat maternity colony on Hotspring Island, which may affect the ability of the Little Brown Myotis bat population to persist in North America given its endangered status.

Ancient Murrelet

Little Brown Myotis Bat

EMERGENCY REGISTRATIONS AND INVASIVE SPECIES

A pest control product can be registered for up to one year for the emergency control of seriously detrimental pest infestations, such as during the spread of invasive species. The product must be effective, and the human health and environmental risks must be acceptable.

The number of emergency registration submissions that PMRA receives can vary from year to year, depending on pest outbreaks, environmental conditions and the availability of alternative products and methods. In 2018–2019, PMRA granted nine emergency registrations.

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. These are set at levels well below the amount that could pose a health concern, and are established for each combination of pesticide and treated agricultural product.

Health Canada sets science-based MRLs to ensure the food Canadians eat is safe. As of 2018, Canada had approximately 22 000 pesticide MRLs set (Figure 1). Typically, an MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it. If it is determined that an unacceptable risk exists, the product will not be permitted for sale or use in Canada.

The Canadian Food Inspection Agency is responsible for monitoring MRL compliance in foods in the Canadian marketplace. In their most recent reports from 2014–2015 and 2015–2016, the overall compliance rates for pesticide MRLs were 93.2% for imported fresh fruits and vegetables, indicating that the vast majority of fresh food on the market meets Canadian pesticide standards.

Differences in MRLs between countries can lead to trade barriers. If an importing country's MRL for a given commodity is set lower

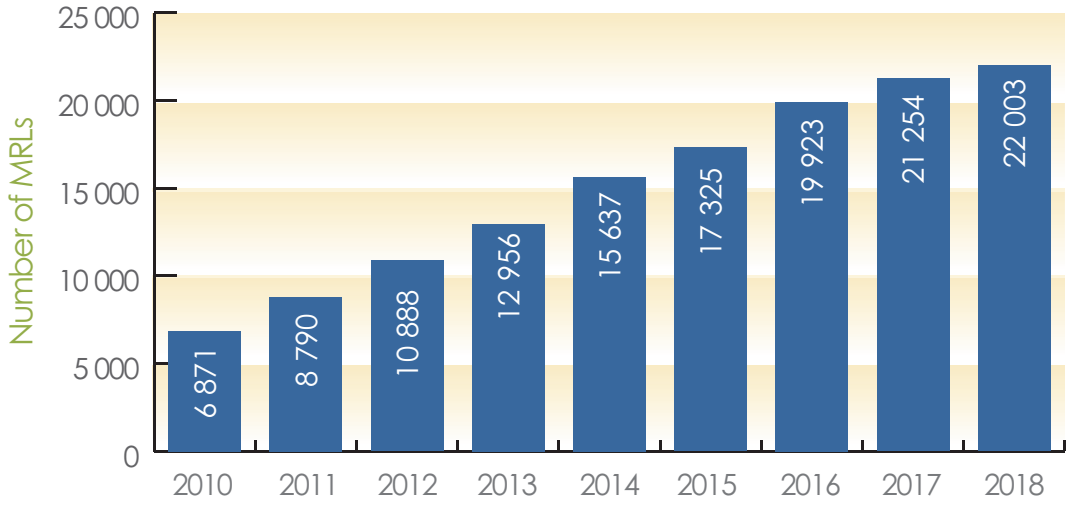
than Canada's, this can lead to the importing country refusing entry to the Canadian commodity, despite the fact that the difference does not reflect a health risk.

International differences in MRLs can occur as a result of differences in both methods and data available to regulators at the time of MRL establishment, as well as other factors. Aligning MRLs globally has become increasingly important to reduce barriers to the movement of treated agricultural products around the world. Domestic and international collaboration is critical in resolving these issues, which are of high importance to registrants, growers, and the Canadian economy.

PMRA continued work with its international partners under the North American Free Trade Agreement, the Organisation for Economic Co-operation and Development (OECD) and Codex, on science policies relevant to establishing MRLs internationally.

The absence of an MRL for a particular pesticide-crop combination in an export market (sometimes called a "missing MRL") can also be a challenge for agricultural exporters. PMRA supports Agriculture and Agrifood Canada in the latter's efforts to address this challenge.

Figure 1. Total Number of Canadian MRLs over time



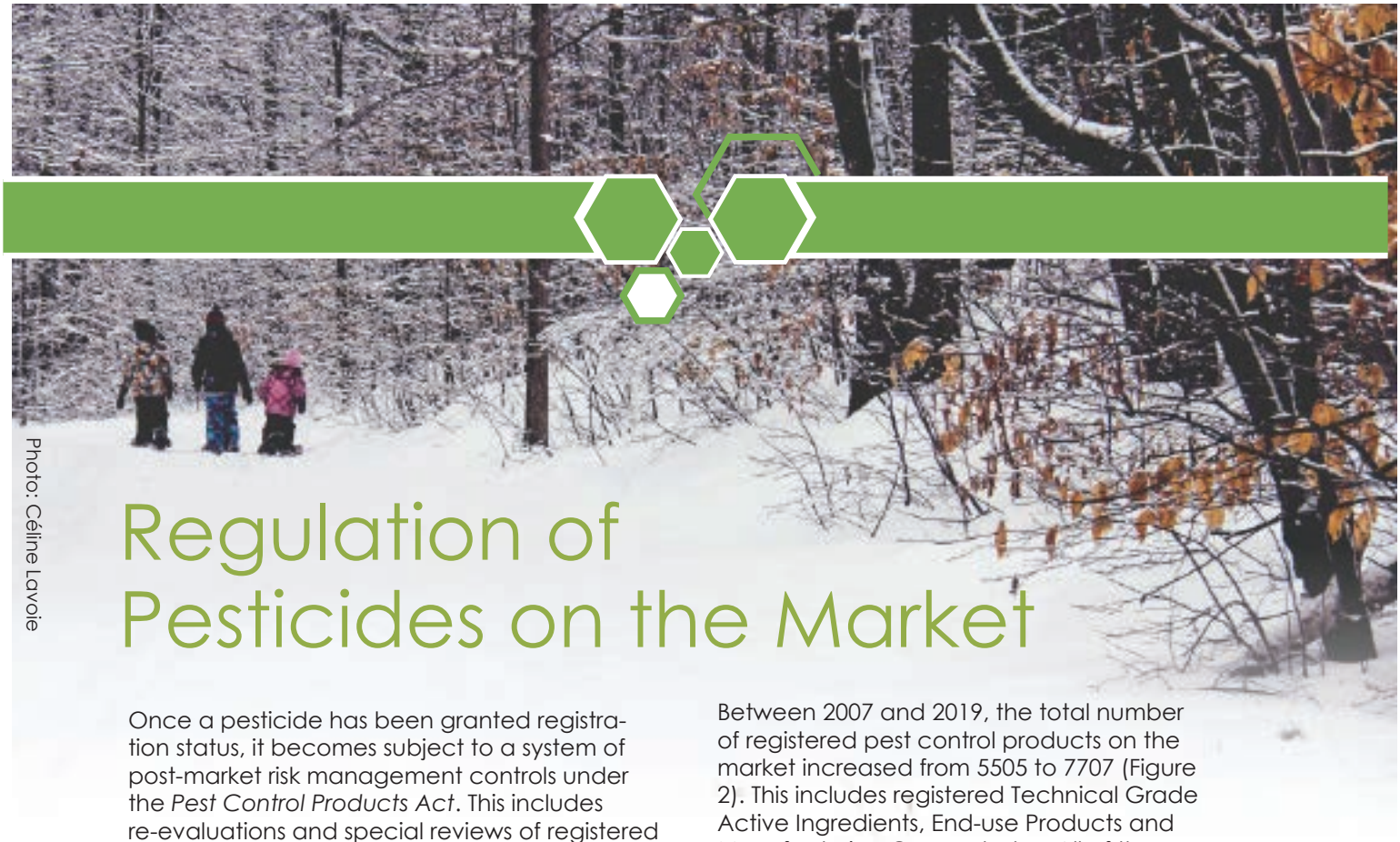


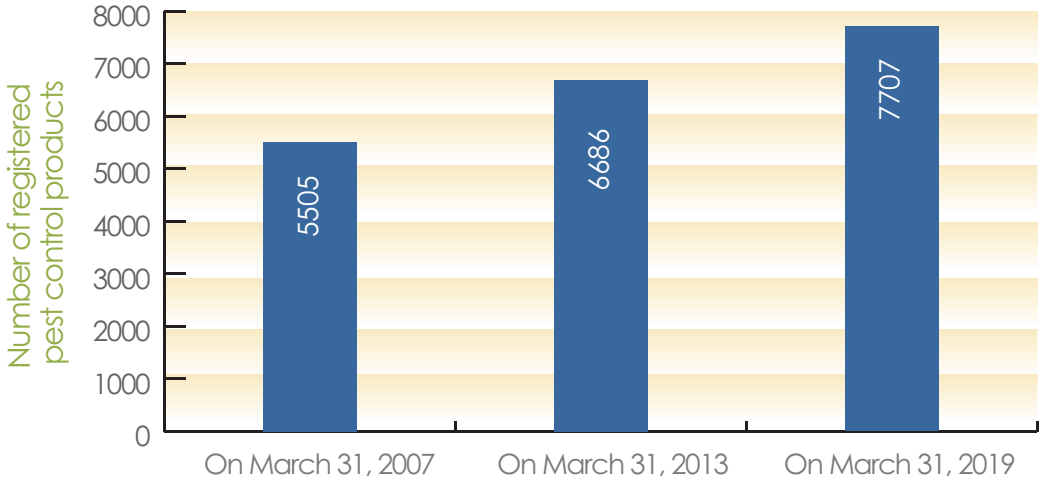
Photo: Céline Lavoie

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.

Between 2007 and 2019, the total number of registered pest control products on the market increased from 5505 to 7707 (Figure 2). This includes registered Technical Grade Active Ingredients, End-use Products and Manufacturing Concentrates. All of these products are subject to PMRA's post-market regulatory activities, and represent a significant increase in workload in these areas.

Figure 2. Increase in the number of registered pesticides over time



RE-EVALUATION/SPECIAL REVIEW PROGRAMS

Under the *Pest Control Products Act*, registered pesticides currently available on the market are subject to re-evaluations, which are initiated 15 years after the most recent registration decision, at the latest. Pesticides registered after 1995 are referred to in the re-evaluation context as 'cyclical pesticides'.

Pesticides registered prior to 1995 are referred to as 'older pesticides', and when the re-evaluation program was established, there were 401 of these older pesticides. As of March 31, 2019, there remained only 17 re-evaluations to complete of the original 401. PMRA is targetting completion of re-evaluations of older pesticides by the end of 2020. In general, these remaining older pesticides are complex re-evaluations based on their large use patterns, and require large volumes of scientific data that may be complex to generate.

Under the re-evaluation 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.

Special reviews are another mechanism used under the *Pest Control Products Act* to determine the continued acceptability of registered pesticides. These reviews focus on addressing specific aspects of concern, such as the basis of an OECD-member country decision to prohibit all uses of an active ingredient, or when there are reasonable grounds to believe that the health or environmental risks of the product are, or its value is, unacceptable.

Five-year Re-evaluation and Special Review Work Plan

As part of our commitment to improve transparency, PMRA updated the five-year Pest Management Regulatory Agency Re-evaluation and Special Review Work Plan 2018–2023 (Re-evaluation Note REV2018-06). This work plan includes the target timelines to publish proposed and final decisions for re-evaluations and special reviews from April 2018 to March 2023, as well as the list of anticipated re-evaluation initiations in the next five years.

In 2018–2019, PMRA saw an increase the number of re-evaluation and special review decisions, closing a high number of straightforward re-evaluations while also making good progress on the re-evaluation of "older pesticides" supported by additional temporary resources. Completing these large and complex re-evaluations will continue to be a priority, acknowledging that workload continues to increase as new re-evaluations and special reviews are initiated every year. As of March 31, 2019, 97 re-evaluations and special reviews are underway with a requirement to initiate 35 new re-evaluations later in 2019–2020.

Overall Workload for Re-evaluations and Special Reviews

Over the past five years, PMRA has completed an average of 24 final decisions per year for re-evaluations and special reviews. Though this is an improvement over previous years, workload continues to increase significantly as new re-evaluations and special reviews are initiated. As of March 31, 2019, 97 re-evaluations and special reviews are underway with a plan to initiate 35 additional re-evaluations in 2019–2020. Based on the projected number of re-evaluation initiations for the next five years and an average of 24 final decisions per year, work on hand will build significantly. Refer to Figure 3 for details.

Transformation project and progress

PMRA is committed to continuous improvement and conducts periodic examination of its programs. Specific to the re-evaluation program, PMRA previously conducted a review that evaluated the functionality of processes to maximize efficiencies, leading to improvements being implemented to the post-market program in 2016.

PMRA is now completing a review of its post-market pesticide program with the goal of achieving a more modern, efficient and sustainable re-evaluation program by considering broader, transformative changes. This review is exploring alternative pesticide re-evaluation models and assessing whether they are more efficient, timely and flexible than the current model. It is also looking closely at approaches taken by other regulators internationally as well as perspectives from stakeholders gathered through extensive consultations across Canada.

In coming years, the number of statutory re-evaluations needing to be initiated will increase to as many as 49 per year. PMRA is developing options and approaches to keep pace with re-evaluations and make timely decisions to protect health and environment. With the goal of re-establishing the sustainability of Canada's re-evaluation program, PMRA is also considering how to best respond to stakeholder expectations and maintain Canada's place among leading regulators internationally.

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

PMRA has increased outreach efforts with global regulators such as the United States Environmental Protection Agency, the Australian Pesticides and Veterinary Medicines Authority and the European Food Safety Authority, to build awareness and potential opportunities for post-market collaboration.

PMRA also increased its commitment to stakeholder outreach with the establishment of the Agricultural Stakeholder Engagement Unit. This pilot initiative is meant to provide agricultural stakeholders with an opportunity for improved collaboration during re-evaluations. The unit has been working with growers to increase understanding of PMRA's re-evaluation process and risk assessments, as well as to address specific concerns raised over proposed re-evaluation decisions.

NEONICOTINOIDS IMIDACLOPRID, CLOTHIANIDIN AND THIAMETHOXAM – ENVIRONMENTAL ASSESSMENTS

On November 23, 2016, PMRA initiated special reviews for clothianidin and thiamethoxam (Re-evaluation Note REV2016-17) at the same time as the publication of the proposed cyclical re-evaluation decision of imidacloprid (Proposed Re-evaluation Decision PRVD2016-20).

The aquatic risk assessment for imidacloprid identified risks of concern to aquatic invertebrates, and as a result, PMRA proposed to phase out all agricultural uses and a majority of the outdoor uses of imidacloprid over 3–5 years.

Clothianidin and thiamethoxam share the same mode of action as imidacloprid, and available monitoring data indicated that these pesticides were being detected at concentrations and frequencies in aquatic environments that may pose a risk to aquatic invertebrates. The aspect of concern for the special reviews was to assess potential risks to aquatic invertebrates exposed to clothianidin and thiamethoxam applied as a seed, foliar or soil treatment.

After considering data and published literature available at the time, PMRA was unable to conclude that the risks to aquatic invertebrates are acceptable from uses of clothianidin and thiamethoxam. These invertebrates are an important part of the ecosystem, including as a food source for fish, birds and other animals.

As a result, on August 15, 2018, PMRA proposed to phase out all the outdoor agricultural and turf uses of clothianidin (PSRD2018-01) and all outdoor agricultural and ornamental uses of thiamethoxam (Proposed Special Review Decision PSRD2018-02) over 3–5 years.

In advance of the final decisions, PMRA continues to analyze an extensive body of additional information received in the fall of 2018, including aquatic toxicity studies and monitoring data on imidacloprid, clothianidin and thiamethoxam in water bodies across Canada.

Pollinator Assessments

PMRA published proposed pollinator re-evaluation decisions in 2017 and 2018 for imidacloprid (Proposed Re-evaluation Decision PRVD2018-12), clothianidin (PRVD2017-13) and thiamethoxam (PRVD2017-14). The risk assessments were updated based on comments received during the consultation periods. Final pollinator re-evaluation decisions were published on April 11, 2019, for the three neonicotinoids: imidacloprid (Re-evaluation Decision RVD2019-06), clothianidin (RVD2019-05) and thiamethoxam (RVD2019-04). To protect bees and other pollinators, some uses of these pesticides will be cancelled, and other uses will have changes to the conditions of use, such as restricting the timing of application.

PEST CONTROL PRODUCT SALES INFORMATION REPORTING

Since 2007, PMRA's Pest Control Product Sales Information Reporting Program has been collecting sales information, in the form of total quantity (by volume or mass), for all registered products available for sale. These data are reported by calendar year (January 1 to December 31). The purpose of the 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 scale of use of the pesticide in the Canadian marketplace, as well as the potential impacts if changes are made to the registration status of the pesticide.

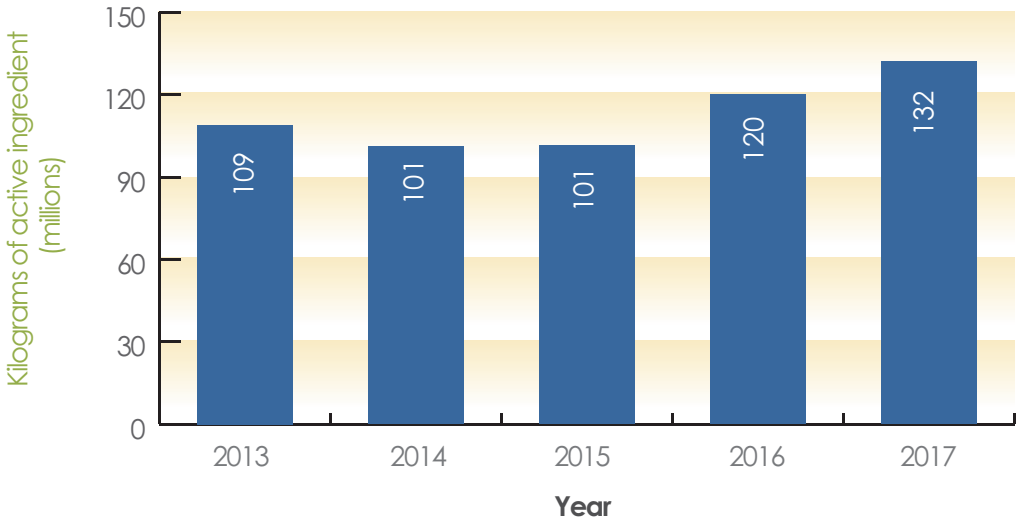
GLYPHOSATE

Glyphosate is a widely used herbicide that has attracted considerable public interest around the world. PMRA has responded to hundreds of letters, petitions, calls, and interview requests about glyphosate in recent years.

In 2017, PMRA completed an extensive re-evaluation of all available information and data, not only from manufacturers, but also from a large body of published independent scientific studies, and from other internationally recognized regulatory agencies. Over 1300 studies were reviewed, totalling more than 89 000 pages. This re-evaluation confirmed that, under the conditions of use specified on the label, glyphosate did not pose unacceptable risks to humans or the environment.

Following the publication of the final decision in 2017, PMRA received a number of objections to this decision. A full scientific review was undertaken by a new team of scientists, who had access to all relevant data and information from federal and provincial governments, international regulatory agencies, published scientific reports and multiple pesticide manufacturers. After a thorough scientific review, it was concluded that the concerns raised by the objectors could not be scientifically supported when considering the entire body of relevant data. Therefore, in January 2019, PMRA re-affirmed its decision that the original decision of 2017 was valid.

Figure 3. Quantity of pesticides sold in Canada over five years



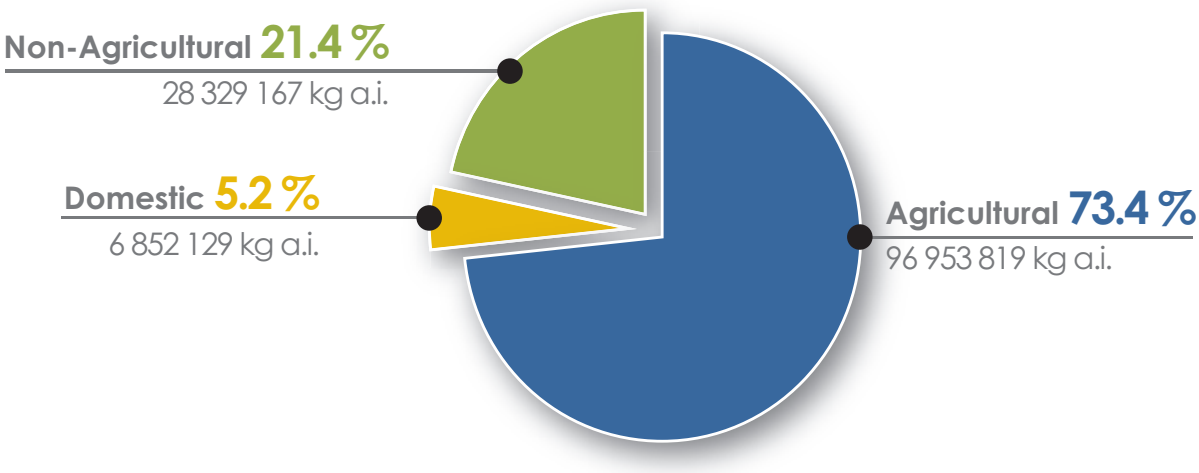
Sales data are also used to inform the Pesticide Incident Reporting Program on the market share of particular pesticides to help identify potential risks that may require attention.

The overall pesticide sales in Canada in 2017 were 132 million kg a.i. (kilograms of active ingredient), which is a 10% increase from the 120 million kg a.i. sold in 2016 (Figure 3).

In 2017, 73.4% of pesticide sales in Canada were commercial products for use in the agricultural sector (Figure 4), and 21.4% were commercial products for use in the non-agricultural sector. Domestic products for use by the public in and around the home accounted for 5.2% of sales.

In 2017, there were 175 active ingredients identified as biopesticides, which accounted for 1002 registered products. Biopesticides include microbial pesticides (which contain a bacterium, fungus, virus, protozoan, or alga as the active ingredient), pheromones and other semiochemical pesticides, and other non-conventional (formerly biochemical) pesticides.

Figure 4. Pesticides sold in Canada in 2017 by sector



INCIDENT REPORTING

PMRA uses incident reports to identify and characterize potential risks to humans, domestic animals and the environment from the use of pesticides, which were not evident during the initial registration of a pesticide. Incident report assessments are prioritized based on the type of incident. Serious adverse effects such as death or life-threatening effects 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 to be manufactured, packaged, labelled, or used.

Incident reports also inform risk assessments for new registrations and re-evaluations. New scientific studies must also be submitted as an incident report to PMRA by registrants of a registered pesticide if the study demonstrates any new hazard, any risk that may be greater than the risk determined at the time of registration, or the presence of a previously undetected component or derivative of a pest control product.

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 reports to determine if the actions were effective in managing the identified risk.

In the 2018–2019 fiscal year, 2265 pesticide incident reports and 87 scientific studies were submitted to PMRA. Details of these reports can be found through the Pesticide Incident Reporting Database, by visiting Canada.ca/pesticides and clicking on ‘Report a Pesticide Incident’.

- Domestic animal incidents were reported most frequently, followed by human and environment incidents.
    - The majority of reported domestic animal incidents involved spot-on pesticides used for flea, tick and mosquito control, and the reported health effects were mostly minor in nature.
- 1524 incidents occurred in Canada, and 741 incidents relevant to Canadian products occurred in the United States.
- Overall, Canadian incidents involved over 254 different pesticide products.
- The majority of products in reported incidents were domestic class pesticides, followed by commercial class pesticides.

The most significant actions taken in 2018–2019 by PMRA following evaluation of incident reports involved more restrictive/informative instructions, including label changes, and improvements to scientific assessment approaches:

- To improve the safety of spot-on products, PMRA proposed changes including new label statements for spot-on products, and updated data requirements for future registrations of companion animal products such as spot-ons, shampoos and impregnated collars. The goal of these regulatory changes is to better inform consumers of the possible effects that may be expected in their pets following spot-on product use and to improve the current animal safety testing strategy for pesticide products used on companion animals.
- Other label improvements were implemented to reduce the likelihood of exposure of pets to certain products used in and around the home.
- To further protect workers and bystanders, mitigation measures were implemented for two pesticide products containing cyfluthrin and beta-cyfluthrin. These included a lengthened restricted-entry interval, ventilation requirements and provision of additional information for building occupants. Additional label statements were also added to domestic class labels for these products, directing users to ventilate treated areas, and describing the potential adverse effects and what to do if users or occupants experience these effects.

Compliance and Enforcement

The National Pesticide Compliance Program (NPCP) is responsible for promoting, monitoring and enforcing compliance with the *Pest Control Products Act* and its Regulations. The primary objective of this legislation is to prevent unacceptable risks to the health of Canadians and the environment from the use of pest control products.

The scope of the NPCP covers a range of parties regulated by the *Pest Control Products Act*, including pesticide registrants, manufacturers, importers, retailers and users. To align activities with these regulated parties and to better capture work conducted, the NPCP adopted a new framework beginning in 2017–2018. The NPCP is divided into seven sectors: registrants, importation, marketplace, users, re-evaluation, surveillance, and inquiries and complaints.

To account for regional variation, the NPCP includes both national and regional activities. The diversity of these activities allows the NPCP to assess a sample of users from a variety of subsectors and provides Health Canada with information about compliance issues or potential trends.

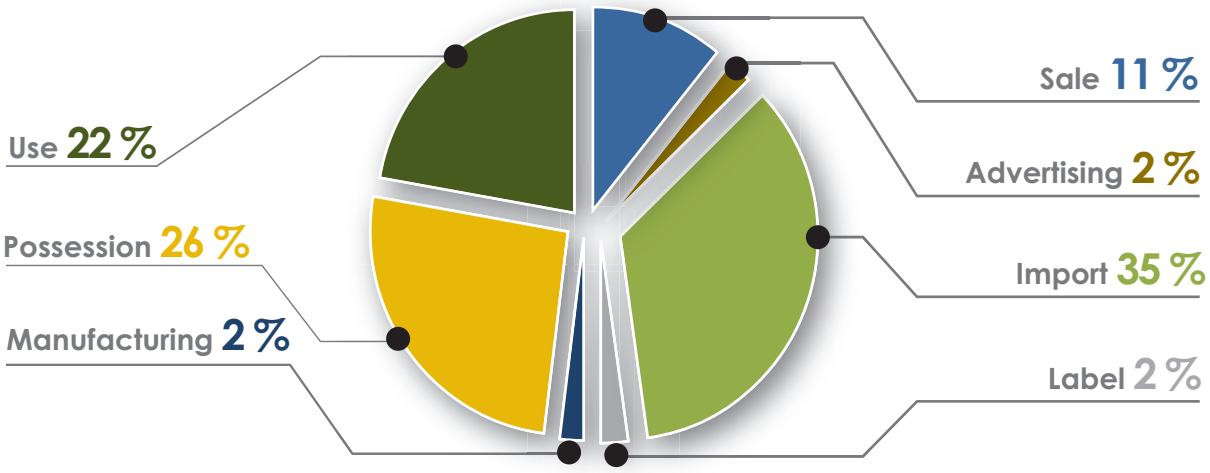
Compliance activities are prioritized based on risk to human health, the environment and regulatory integrity. In some situations, random inspections are undertaken. In other instances, when non-compliance in a sector is suspected, a targeted approach is used. For example, the NPCP collaborates with the Canadian Border Services Agency (CBSA) and other federal agencies at border points nationwide to identify, inspect and intercept non-compliant shipments at the border. In 2018–2019, CBSA referred 464 shipments of pest control products intercepted at various Canadian border points of entry to Health Canada for decisions on admissibility. Only 8% of these were allowed entry into Canada. The vast majority of these products were purchased online by Canadian consumers. Online purchasing of pest control products is a growing trend.

Compliance rates presented below reflect the regulated parties inspected. NPCP highlights are noted below, with details provided in the 2018–2019 Compliance and Enforcement Annual Report.

2018–2019 KEY STATISTICS

- 217 compliance outreach activities were conducted to promote compliance with the *Pest Control Products Act*. These activities included presentations, exhibit booths at trade shows, and other activities such as attending meetings, providing publications for mail-outs and contributing to association newsletters.
- 780 inspections were conducted as part of planned NPCP activities.
- 404 samples were analyzed by Health Canada's pesticide laboratory: 300 in support of NPCP activities and 104 compliance verification samples in response to complaints.
- The rate of compliance varied by subsector, ranging from 8% (see imported pesticides example above) to 100%.
- The most common violation types (Figure 5) noted for all inspections were import (35%), possession (26%) and use (22%). This includes violations noted during planned activities (955) and compliance verifications (550).
- 990 enforcement responses were issued to non-compliant parties: 463 from planned inspections, 100 as a result of complaints and 427 decisions regarding the admissibility into Canada of imported products. Enforcement responses included warning letters (989) and Compliance Orders (1).
- 6 Notices of Violation (NOV) with penalty and 1 NOV with warning were issued under the *Agriculture and Agri-Food Administrative Monetary Penalties Act*.

Figure 5. Violations by type (as a percentage of total violations) for 2018–2019 NPCP activities



Keeping Pace with Change

Globalization, rapid technological advances, evolving science, 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 help 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.

CUMULATIVE RISK ASSESSMENT

A pesticide cumulative risk assessment determines whether low-level exposure to similar pesticides could lead to the same or increased health risk relative to a higher level of exposure to any of these pesticides individually. Since 2015, each major decision by PMRA includes a cumulative assessment, or an evaluation of whether or not a cumulative assessment is required.

For larger clusters of pesticides within a cumulative assessment group, a separate evaluation is undertaken once individual pesticides within the group have been re-evaluated. This is the case for the N-methyl carbamate cluster, for which a cumulative health risk assessment was initiated in November 2018 (Re-evaluation Note REV2018-17). This assessment will be based on the methodology outlined in the 2018 Science Policy Note on the Cumulative Health Risk Assessment Framework for pesticides (Science Policy Note SPN2018-02).

As an emerging area in regulatory science, PMRA continues to work with international partners to develop approaches for applying the principles of cumulative risk assessment in protecting the health and safety of Canadians.

EVALUATING NEW TECHNOLOGIES

In addition to assessing the potential health and environmental risks of chemical and biological pesticides, PMRA keeps abreast of new technologies such as robotics and drones. Many show potential benefits (for example, for precision agriculture) but all must be assessed to ensure they do not pose unknown risks to health (for example, worker exposure) or the environment. PMRA is working with manufacturers to understand and assess new technologies and equipment that support modern agricultural practice.

PMRA also continues to seek opportunities to reduce the need for animal testing wherever possible, while continuing to ensure scientifically robust approaches are in place for assessing risk. Integrated Approaches to Testing and Assessment or New Approach Methods involve using data from existing laboratory animal studies, in vitro high-throughput screening

assays, predictive models, mechanistic studies and other data in order to refine, reduce and in some cases even replace laboratory animal studies for human health and environmental assessment of pesticides.

PMRA continues to collaborate with North American and OECD partners in examining new approaches to current study types (for example, acute eye irritation or skin sensitization), as well as new pesticide technologies including ribonucleic acid interference.

Protecting Agricultural Workers

In an effort to further reduce pesticide exposures, PMRA has established a stakeholder working group tasked with exploring measures to both refine and reduce post application exposure to pesticides, from both a risk assessment and risk mitigation perspective.

Areas being explored include determining the level of protection that personal protective equipment may provide as a post-application risk mitigation measure, generating data to provide new and/or revised exposure inputs for risk assessments, and obtaining updated information on post application activities that occur in agricultural crops.

Unmanned Aerial Vehicles (drones) for Pesticide Application

PMRA has received a number of inquiries related to the application of pesticides by Unmanned Aerial Vehicles (UAVs, or "drones"). UAVs are increasingly used internationally in agriculture for scouting-related activities (for example, sensing, mapping and tracking) as well as for vehicles for the delivery of agrochemicals.

The use of UAVs for agrochemical spraying is established in some jurisdictions including China and Japan, and is at the initial stages in others, such as the United States, Switzerland, New Zealand and Australia. In each jurisdiction, both the aviation and the pesticide regulatory authorities have specific criteria that must be met to allow for the application of pesticides by UAVs.

There can be no use of unmanned aircraft until there are specific instructions, including any limitations for use of these kinds of aircraft on pesticide labels (Information Notice Regarding the Use of Drones when Applying Pesticides; published on May 8, 2018). Parties interested in adding the use of UAVs are encouraged to work with registrants using PMRA Pre-Submission process to determine the kinds of data necessary to assess this new application technology.

PMRA is currently working with Transport Canada regarding operating regulations, as well as industry stakeholders (for example, CropLife Canada) and international regulators (for example, the OECD) to obtain information on the health and environmental safety of this new application method.

Due to the variety of UAV delivery systems on the market and a lack of equipment standards internationally, there is a need to coordinate the review of available data for assessing the safety of these aircraft.

WATER MONITORING

As the regulator of pesticides in Canada, it is the responsibility of PMRA to understand the potential risk to humans and aquatic life to levels of pesticides that may be present in Canadian waters. PMRA currently uses both water modelling and monitoring data to estimate the potential exposure in water to aquatic organisms and humans.

Water models are used to estimate residue levels in drinking and ambient water sources for both new registrations and re-evaluations. Monitoring data are usually only available for a small number of pesticides that have been on the market for a number of years. A strong monitoring dataset provides a real world picture of potential pesticide exposure to inform the regulatory decision. PMRA relies solely on other federal, provincial and municipal departments and agencies as well as researchers to provide this information.

PMRA is working with other federal departments, provinces, stakeholder associations and users to address challenges with the current available monitoring datasets, including lack of on-going targeted data, high analytical limits of detection and a lack of agriculture use information in the sampled areas.

Communicating priorities for water monitoring of pesticides

PMRA has developed a list of pesticides for which water monitoring data is needed most, and has shared it with relevant federal and provincial authorities for consideration in water monitoring programs across the country. The intent is that with a proactive approach in communicating PMRA's priorities, there will be an increased probability that water monitoring data will be available when the pesticides undergo re-evaluation.

Aquatic Life Reference Values and Human Health Reference Values

Many stakeholders including the public, and provincial and federal departments desire to have reference values to interpret the levels of pesticides detected in water and to identify and prioritize sites and pesticides that may require further investigation. Environment and Climate Change Canada and Health Canada currently set water quality guidelines for aquatic life and human health, respectively. There are currently only a small number of aquatic life and human health guidelines for pesticides. PMRA has developed Aquatic Life Reference Values and Human Health Reference Values for approximately 250 pesticides that have the potential to reach surface, ground and drinking water.

VEGETATIVE FILTER STRIPS

A vegetative filter strip (VFS) is a permanent strip of dense, perennial vegetation situated on the downslope border of the treated area (such as an agricultural field, plantation or woodlot), along the edge of the water body into which the area drains. The vegetation within a VFS contains grasses, but may also contain other vegetation, such as shrubs and trees. The VFS reduces the velocity of water runoff to allow soil and pollutants, such as pesticides, to settle out before entering the water.

The use of a VFS is recommended on all product labels as a best practice. More recently (since 2017), PMRA has required a mandatory 10-metre wide VFS for certain pesticides when a risk to aquatic non-target organisms from runoff has been identified and there is supporting information to demonstrate that a VFS would effectively mitigate risks. At this time, the requirement for a VFS has focused on pesticides that bind strongly to soil particles, which in the absence of VFS, may otherwise be transported offsite to water bodies.

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.

STOCKHOLM CONVENTION

The Stockholm Convention is a legally binding international treaty that addresses international management of chemicals with the focus on the production and use of persistent organic pollutants. PMRA is the responsible federal authority for meeting the obligations and for ongoing participation at the Stockholm Convention as it pertains to pesticides.

PMRA collaborated with other federal partners by providing scientific experts to work with the Persistent Organic Pollutants Review Committee (POPRC) and the Conference of the Parties (COP) of the Stockholm Convention, and in the development of Canadian positions and submissions. At POPRC, PMRA actively participates in the review of the scientific justification for identifying a substance as a persistent organic pollutant (POP) and making recommendations on how these substances can be managed globally. At the COP, PMRA provides experts to negotiate international decisions on the restrictions and ultimately the elimination of each POP at the global level.

This year, POPRC recommended that the COP list a formulant formerly in pesticides, pentadecafluorooctanoic acid (PFOA plus its salts and PFOA-related compounds) to Annex A to the Convention, with certain specific exemptions. POPRC also recommended the removal of specific exemptions and acceptable purposes of another chemical with industrial and pesticidal uses – perfluorooctane sulfonic acid (PFOS), its salts and perfluorooctane sulfonyl fluoride – banning most remaining uses of PFOS. POPRC also reviewed effective participation measures for the committee, and adopted the workplan for the intersessional period between the fourteenth and fifteenth meetings.

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. The Convention is a multilateral treaty to promote shared responsibilities in relation to importation of hazardous chemicals. The Convention promotes open exchange of information and calls on exporters of hazardous chemicals to use proper labelling, include directions on safe handling, and inform purchasers of any known restrictions or bans.

In collaboration with Environment and Climate Change Canada, PMRA participates in the development of Canadian positions and

submissions to the Convention. PMRA actively reviews the justification for adding a substance to the Rotterdam Convention and ensures the justification meets the Canadian and international standards. At the COP, PMRA provides experts to negotiate international decisions for each substance at the global level.

This year the Convention's Chemical Review Committee adopted draft decision guidance documents for the flame retardant hexabromocyclododecane, as well as pesticides acetochlor and phorate, to support a recommendation that the COP list these chemicals in Annex III to the Convention. The Chemical Review Committee also reviewed notifications of final regulatory action for hexabromocyclododecane, PFOA and the organophosphate insecticide methyl-parathion. Of these, PFOA was recommended for inclusion Annex III to the Convention. A draft decision guidance document for PFOA will be developed in the intersessional period.

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

PMRA is involved with several OECD initiatives, including various OECD task forces and expert group projects. PMRA participated in meetings of both the OECD Working Group on Pesticides (WGP) as well as the OECD Working Group on Biocides. The WGP functions as a vehicle for global cooperation and facilitates information exchange and alignment of approaches with respect to pesticides assessment as well as development of strategies to assess evolving digital and mechanical technologies for pesticides.

PMRA routinely provides experts to participate in the OECD WGP Expert Groups on Residue Chemistry, Pollinator Safety and Bio-pesticides. In addition, PMRA continues to contribute to the facilitation of data sharing with OECD partners through its participation in the Expert Group on the Electronic Exchange of Pesticide Data, contribution to the OECD Dossier Guidance update, and playing a lead role in the use of the OECD Pesticide Information Notification System – a mechanism for sharing pesticide-related information within the regulatory community.

In 2018–2019 PMRA continued to participate with OECD members in collaborative science policy work including the use of novel technologies as pesticides, such as ribonucleic acid interference.

In addition, PMRA led discussions with global manufacturers of pesticides regarding new chemistries in order to broaden collaboration and promote global joint reviews and alignment between international regulatory partners.

CODEX

PMRA plays an active role in the WHO/FAO Codex Committee on Pesticide Residues, which is responsible for setting international food standards. Codex participation enables PMRA to:

- Enhance Canada's influence on Codex deliberations and outcomes;
- Promote the development of science-based standards that will result in fair practices in food trade (for example, establishment of MRLs);
- Promote more effective work-planning by the committee (help ensure priorities include Canadian Stakeholders' interests); and
- Promote the timely development of standards (for example, continue to support joint reviews through the Joint Meeting on Pesticide Residues).

Regulatory Modernization

In 2018–2019, PMRA continued to take steps to modernize is legislative framework.

REGULATION OF IN-TRANSIT PESTICIDES

In December 2018, PMRA amended the Pest Control Products Regulations and the Agriculture and Agri-food Administrative Monetary Penalties Regulations Respecting the *Pest Control Products Act* and Regulations to support Canada's implementation of the World Trade Organization Agreement on Trade Facilitation. These amendments permit in-transit shipments of unregistered pest control products through Canada, while ensuring that health and safety information is available to individuals handling these products while they transit through Canada.

TARGETED REGULATORY REVIEW OF THE AGRI-FOOD AND AQUACULTURE SECTOR

The Government of Canada announced in Budget 2018 that it would fund over three years "targeted reviews of regulatory requirements and practices that are bottlenecks to economic growth and innovation."

As part of this initiative, in 2018, PMRA participated in the targeted regulatory review of the agri-food and aquaculture sector. A central feature of the review was to invite input from businesses, Canadians, academia and other stakeholders, on ways to make regulations more agile, transparent, and responsive.

Work on the review included the development of an Agri-food and Aquaculture Regulatory Review Roadmap, which will lay out a regulatory modernization plan in support of innovation and economic growth in the agri-food and aquaculture sector. This roadmap is set to be released in 2019–2020.

In 2018–2019, PMRA consulted Canadians on proposed amendments to the Pest Control Products Incident Reporting Regulations, which involve reducing regulatory and administrative burden without impacting health and environmental protection.

In 2018–2019, PMRA also worked on other PMRA regulatory modernization initiatives (for example, related to the post-market review process, labelling, data protection, and the authorization of pesticides not requiring registration) for possible inclusion in the Roadmap.

PEST CONTROL PRODUCT REGULATIONS REVIEW

Prior to the launch of the Regulatory Reviews, the departments and agencies responsible for regulating the agri-food and aquaculture sector, including PMRA, each had an ambitious regulatory modernization agenda that extended over several years.

In 2018–2019, PMRA continued its comprehensive review of the Pest Control Products Regulations, the first such review since they were established in 2006. The review is aimed at ensuring the regulations continue to meet program objectives (for example, of health and environmental protection) in an effective and efficient manner, while attempting to minimize regulatory burden on regulatory parties.

In 2018–2019, the review included public and industry engagement on issues such as data protection, pest control devices and product exemptions.

Communications and Outreach

PMRA recognizes that the transparency and openness of our work is critical to strengthening trust in our regulatory decisions. Canadians deserve to understand how the health and environmental risks of pesticides are evaluated, and to participate in and be aware of decisions that affect them. In 2018–2019, PMRA launched several new initiatives aimed at improving the way we communicate with Canadians.

EDUCATIONAL VIDEOS ABOUT PMRA

A two-minute animated video called "Pesticides: What do Health Canada Scientists Do?" was posted on the Healthy Canadians YouTube channel in April 2019. The video outlines the pesticide evaluation process, and reinforces the importance of reading the label before using a pesticide.

In 2018–2019, a further two videos were developed to show Canadians how PMRA assesses health and environmental risks of pesticides, for posting in 2019–2020.

PUBLIC ENGAGEMENT PORTAL

The Public Engagement Portal is designed to help engage Canadians in the pesticide regulation process. There are currently six electronic forms available for Canadians to submit any question, provide comments on any proposed decisions or policies, report incidents caused by registered pest control products, submit complaints on any violations regarding pest control products, request to view data used to support proposed decisions, and object to decisions.

STAKEHOLDER WEBINARS

In December of 2018, PMRA hosted the second of what will be a regular series of webinars aimed at providing a diverse group of stakeholders with live updates on pesticide regulation, as well as an opportunity to ask questions.

NEW PEST MANAGEMENT ADVISORY COUNCIL

In March 2019, the new membership of the Pest Management Advisory Council (PMAC) was appointed with representatives of pesticide manufacturers, user groups, health and environment non-government organizations, and members from academia/research institutes.

Financial Profile

2018–2019 FUNDING AND REVENUE (IN MILLIONS OF DOLLARS)	TOTAL
A-Base	29.6
Revenue	
Application Fees $5.4	14.8
Annual Charge $9.4	
Growing Forward	3.3
Chemicals Management Plan	5.0
Comprehensive Review	4.7
Total PMRA FY 2018–2019:	**57.4**

A portion of revenues paid by regulated parties is allocated to support employee benefits plans (non-respendable revenue) and internal services.

Comprehensive review funding of $4.7M was not included in PMRA main estimates. (Funding received as in-year funding.)

PMRA received $3.3M 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.

SERVICE FEES ACT

Since enactment of the *Service Fees Act* in 2017, PMRA has been working with departmental partners and the Treasury Board of Canada Secretariat to realign its performance reporting methodology with the requirements of the *Service Fees Act*. In 2018–2019, PMRA also began developing a fee remission policy framework. This framework describes the scenarios under which a portion of pre-market application fees will be returned to the applicant when service standards are not met. The full policy document will be drafted during 2019–2020 and will come into effect on April 1, 2020. See Appendix Table 1 for a list of service standards that are subject to the *Service Fees Act*.

Appendix

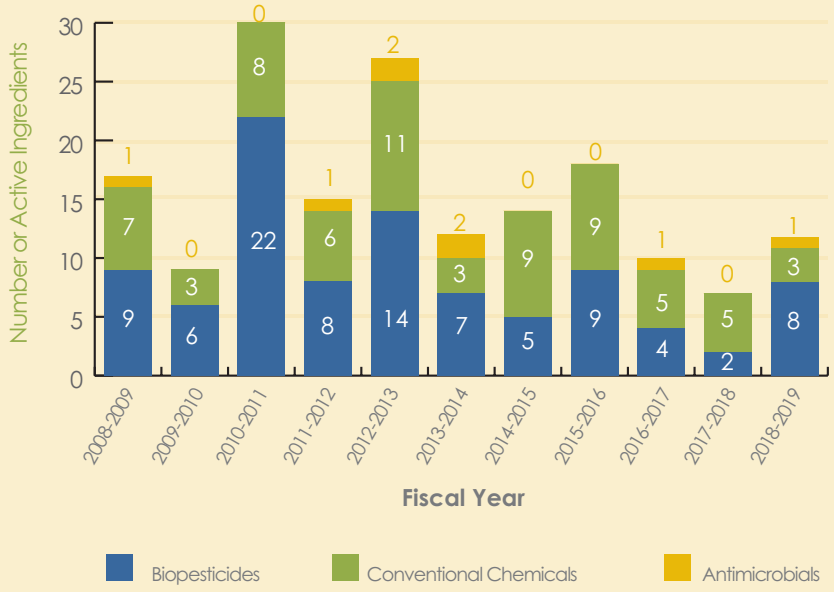
APPENDIX TABLE I PRODUCT SUBMISSION CATEGORIES AND SERVICE STANDARDS FOR PRE-MARKET APPLICATIONS

SUBMISSION CATEGORY	SERVICE STANDARD IN DAYS
Category A New Active ingredients or integrated system products, their related end-use products and manufacturing-use products; major new use of registered pest control products; maximum residue limits for an unregistered active ingredient; and user requested minor use registrations (URMUR).	
Conventional Chemicals and import MRLs for an unregistered active ingredient	665
Reduced risk, other biopesticides, non-conventionals, non-straight chain lepidopteran pheromone (NSCLP)	555
Microbials, and URMUR for all pesticide types (conventional chemical, reduced risk, microbial, other biopesticides, non-conventionals, NSCLP)	470
Straight Chain Lepidopteran Pheromone (SCLP), including URMUR	285
Applications with atypical timelines (joint reviews, tailgaiters, renegotiated timelines, synchronized timelines, coordination with Re-evaluation	Variable
Category B New pest control products containing registered active ingredients; an amendment to existing pest control products (for example, product chemistry, labelling); Emergency Registration; the addition of import MRLs for previously assessed active ingredients.	
Conventional Chemicals (including emergency use) and new import MRL for previously assessed active ingredient	425
Reduced risk, other biopesticides, non-conventionals, NSCLP (including emergency use)	360
Microbials and SCLP (including emergency use)	240
Streamlined applications (application rate changes, tank mixes, new pests, or changes to level of control)	158
Applications with atypical timelines (joint reviews, tailgaiters, renegotiated timelines, synchronized timelines, coordination with re-evaluation)	Variable
Category C Product registrations and amendments with no data requirements. These applications involve minor label or formulation reviews, such as product registration based on registered precedent products.	
New / changes to product labels; addition of approved minor use; similar product	240
New / changes to TGAI, ISP, MA or EP chemistry; administrative changes; administrative re-instatement	180
Applications with atypical timelines (tailgaters, renegotiated/ synchronized timelines, coordination with re-evaluation)	Variable
Category D Submissions within particular programs.	
Registration renewal	246

SUBMISSION CATEGORY	SERVICE STANDARD IN DAYS
Registration/ amendment to registration of active ingredient to be used in pest control product manufactured for export only	46
Master copies	42
Private labels	10
Own Use Import Equivalency and Permits*	70 (Equivalency)
	30 (Permits)
Grower Requested Own Use Equivalency and Permits*	TBD (Equivalency)
	30 (Permits)
Discontinuations*	45
Category E Authorizations and notifications for research in Canada.	
Research authorization for new technical grade active ingredients	159
Research authorization for new uses of registered active ingredients	69
Research notification for research carried out in Canada	30
Category F Notification	
Registration and amendments to registered pest control products via notification	45
Category L Submissions to register or amend products where the applicant wishes to use or rely upon data provided by another registrant.	
Equivalency and data compensation assessment of end-use product and manufacturing concentrate with partial data package (conventional chemical)	425
Equivalency and data compensation assessment of active ingredient, end-use product and manufacturing concentrate with no data (all product types)	365
Equivalency and data compensation assessment of end-use product and manufacturing concentrate with partial data package (reduced risk, other biopesticide, non-conventional, NSCLP)	360
Equivalency and data compensation assessment of end-use product and manufacturing concentrate with partial data package (microbial and SCLP)	240
Applications with atypical timelines (tailgaters, renegotiated/ synchronized timelines, coordination with re-evaluation)	Variable
Regulatory Decision*	45
Requests to extend the exclusive use protection period based upon minor uses*	240
Category P Pre-submission Consultations	
Pre-submission Consultations excluding those for Joint Reviews and Subject to Registration inquiries*	80

*Submissions not subject to the *Service Fees Act* (in other words, no fees)

APPENDIX FIGURE 1 NUMBER OF NEW ACTIVE INGREDIENTS REGISTERED BY PMRA FROM APRIL 1, 2008 TO MARCH 31, 2019

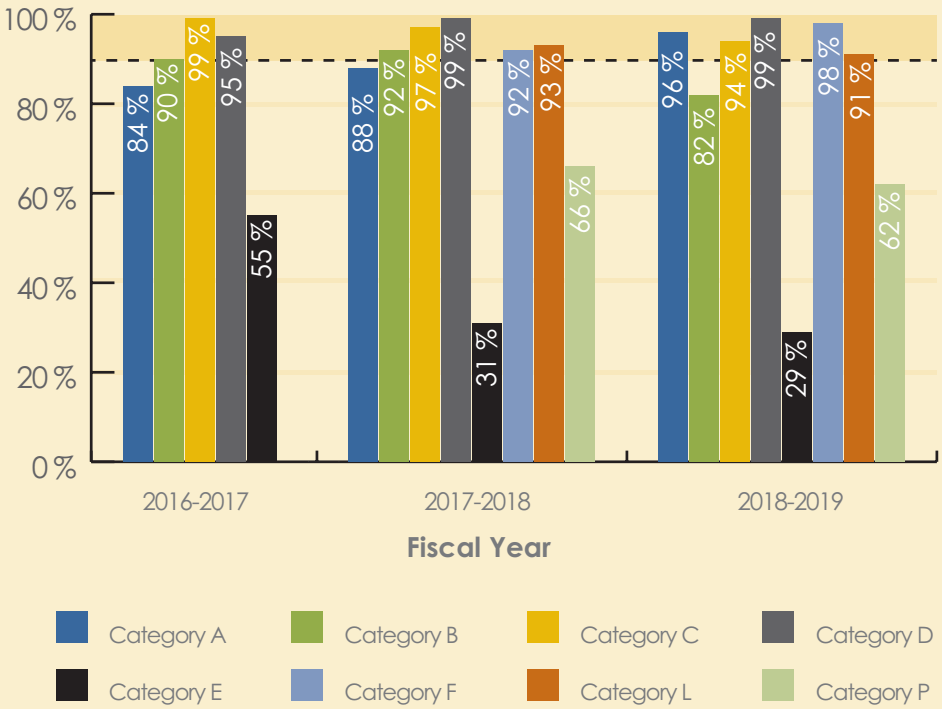


This figure provides the number of new active ingredients registered over the course of the last eleven fiscal years. It represents active ingredients that have been registered for use in Canada and excludes any new active ingredients for which only a maximum residue limit on imported food was established.

APPENDIX TABLE 2 NEW ACTIVE INGREDIENTS REGISTERED IN 2018–2019

	New Active Ingredient	End-Use	Product Type	Product Category
1	2,6-Diisopropylnaphthalene	Aceto Amplify II	Plant Growth Regulator	Biopesticide
2	Afidopyropen	Sefina Insecticide	Insecticide	Conventional Chemical
		Versys Insecticide	Insecticide	Conventional Chemical
3	Bacillus amyloliquefaciens strain F727	Stargus Biofungicide	Fungicide	Biopesticide
4	Bacillus licheniformis strain FMCH001	F4018-4	Fungicide Nematicide	Biopesticide
5	Bacillus subtilis strain FMCH002	F4018-4	Fungicide Nematicide	Biopesticide
6	Bacillus subtilis (strain BU 1814)	Velondis Extra	Fungicide	Biopesticide
		BAS 154 U ST	Fungicide	Biopesticide
		BAS 100 U ST	Fungicide	Biopesticide
		Velondis Flex	Fungicide	Biopesticide
		Velondis Plus	Fungicide	Biopesticide
7	Bacillus thuringiensis subsp. galleriae, strain SDS-502	Grubhalt!	Insecticide	Biopesticide
		Beetlegone!	Insecticide	Biopesticide
		Grubgone! G	Insecticide	Biopesticide
		Beetlejus!	Insecticide	Biopesticide
8	Flazasulfuron	Flazasulfuron 25WG Herbicide	Herbicide	Conventional Chemical
9	Helicoverpa armigera Nucleopolyhedrovirus BV-0003	Helicovex	Insecticide	Biopesticide
10	Pepino mosaic virus, strain CH2, isolate 1906	PMV-01	Non-Parasitic Plant Disease Control	Biopesticide
11	Pydiflumetofen	A19649 Fungicide	Fungicide	Conventional Chemical
		Posterity Fungicide	Fungicide	Conventional Chemical
		A20259 Fungicide	Fungicide	Conventional Chemical
		A20560 Fungicide	Fungicide	Conventional Chemical
		Miravis Neo Fungicide	Fungicide	Conventional Chemical
12	Tributyl Tetradecyl Phosphonium Chloride	Bellacide 350	Slimicide	Antimicrobial

APPENDIX FIGURE 2 PERFORMANCE AGAINST REVIEW TIMELINES FOR CATEGORY A, B, C, D, E, F, L AND P SUBMISSIONS COMPLETED FROM APRIL 1, 2016 TO MARCH 31, 2019



- Effective April 1, 2017 categories F, L and P were added to the Management of Submissions Policy.
- This figure shows the percentages of submissions by submission category that met the applicable review timelines outlined in the Management of Submissions Policy over the last three fiscal years.
- All categories of pre-market submissions have a performance standard of 90% against the established review timelines for the different submission categories.
- Performance was largely met for pre-market reviews but fell short on category B, E and P submissions. Pre-submission consultations (Category P) are not cost recovered.

APPENDIX TABLE 3 RE-EVALUATION/SPECIAL REVIEW DOCUMENTS PUBLISHED IN 2018–2019

Active Ingredient	Document Number	Summary of Decision or Proposed Decision
Final Decisions – Re-evaluations		
Diflufenzopyr (sodium salt)	RVD2018-08	Acceptable for continued registration. Mitigation includes new/revised label statements to further protect human health and the environment.
Hydrogen peroxide	RVD2018-09	Acceptable for continued registration. Mitigation includes new/revised label statements to further protect human health and the environment.
Peroxyacetic acid	RVD2018-10	Acceptable for continued registration. Mitigation includes new/revised label statements to further protect the environment.
Chlorothalonil (Agricultural and Turf Uses)	RVD2018-11	Acceptable for continued registration for certain uses. Mitigation includes new/revised label statements to further protect human health and the environment. Cancellation of other uses due to health risk concerns.
Captan	RVD2018-12	Acceptable for continued registration for certain uses. Mitigation includes new/revised label statements to further protect human health and the environment. Cancellation of other uses due to health risk concerns.
Acetic acid	RVD2018-13	Acceptable for continued registration. Mitigation includes new/revised label statements to further protect human health and the environment.
Isopropyl alcohol	RVD2018-14	Acceptable for continued registration. No additional mitigation measures or label updates are required.
Aminoethoxyvinylglycine hydrochloride	RVD2018-15	Acceptable for continued registration. Mitigation includes new/revised label statements to further protect the environment.
Iprodione	RVD2018-16	Acceptable for continued registration for certain uses. Mitigation includes new/revised label statements to further protect human health and the environment. Cancellation of other uses due to health risk concerns.
Piperine and Oil of black pepper	RVD2018-17	Acceptable for continued registration. Mitigation includes new/revised label statements to further protect human health and the environment.
Zinc oxide (Swimming Pool and Spa Uses)	RVD2018-18	Acceptable for continued registration. Mitigation includes new/revised label statements to further protect human health and the environment.
Trichoderma harzianum rifai strain KRL-AG2	RVD2018-19	Acceptable for continued registration. Mitigation includes new/revised label statements to further protect human health and the environment.
Metiram	RVD2018-20	Acceptable for continued registration for potatoes (foliar) only. Mitigation includes new/revised label statements to further protect human health and the environment. Cancellation of all other uses due to health risk concerns.
Cypermethrin	RVD2018-22	Acceptable for continued registration. Mitigation includes new/revised label statements to further protect human health and the environment.
Iron (ferric phosphate)	RVD2018-23	Acceptable for continued registration. Mitigation includes new/revised label statements to further protect human health and the environment.

Active Ingredient	Document Number	Summary of Decision or Proposed Decision
Soybean oil	RVD2018-24	Acceptable for continued registration. Mitigation includes new/revised label statements to further protect human health and the environment.
Ethyl alcohol	RVD2018-25	Acceptable for continued registration. Mitigation includes new/revised label statements to further protect the environment.
Essential Oils: Camphor Oil Eucalyptus Oil Lemon Oil Oil of Geranium Pine Needle Oil	RVD2018-26	Acceptable for continued registration. Mitigation includes new/revised label statements to further protect human health and the environment.
Deltamethrin	RVD2018-27	Acceptable for continued registration. Mitigation includes new/revised label statements to further protect human health and the environment.
(Z,Z)-3,13-Octadecadienyl acetate	RVD2018-28	Acceptable for continued registration. No additional mitigation measures or label updates are required.
Methyl anthranilate	RVD2018-29	Acceptable for continued registration. Mitigation includes new/revised label statements to further protect human health and the environment.
Chloropicrin	RVD2018-30	Acceptable for continued registration. Mitigation includes new/revised label statements to further protect human health and the environment.
Cydia pomonella granulovirus (strain CMGv4)	RVD2018-31	Acceptable for continued registration. Mitigation includes new/revised label statements to further protect human health and the environment.
Azadirachtin	RVD2018-32	Acceptable for continued registration. No additional mitigation measures or label updates are required.
Metam Sodium and Metam Potassium	RVD2018-33	Acceptable for continued registration. Mitigation includes new/revised label statements to further protect human health and the environment.
Dazomet	RVD2018-34	Acceptable for continued registration. Mitigation includes new/revised label statements to further protect human health and the environment.
Cyfluthrin	RVD2018-35	Acceptable for continued registration. Mitigation includes new/revised label statements to further protect human health and the environment.
Sodium bromide	RVD2018-36	Acceptable for continued registration for certain uses. Mitigation includes new/revised label statements to further protect human health and the environment. Cancellation of other uses due to health risk concerns.
Ferbam	RVD2018-37	Cancellation of all uses/products.
Thiram	RVD2018-38	Acceptable for continued registration for certain uses. Mitigation includes new/revised label statements to further protect human health and the environment. Cancellation of other uses due to health risk concerns.
Ziram (Agricultural Uses)	RVD2018-39	Cancellation of all agricultural uses/prodcuts.

Active Ingredient	Document Number	Summary of Decision or Proposed Decision
Pyridaben	RVD2018-40	Acceptable for continued registration. Mitigation includes new/revised label statements to further protect human health and the environment.
2,4-DB	RVD2019-01	Acceptable for continued registration. Mitigation includes new/revised label statements to further protect human health and the environment.
Chlorimuron-ethyl	RVD2019-02	Acceptable for continued registration. Mitigation includes new/revised label statements to further protect human health and the environment.
Fluroxypyr	RVD2019-03	Acceptable for continued registration. Mitigation includes new/revised label statements to further protect human health and the environment.
Final Decisions – Special Reviews		
Fluopicolide	SRD2018-01	Acceptable for continued registration. Label updates are required.
Hexazinone	SRD2019-01	Acceptable for continued registration. Mitigation includes new/revised label statements to further protect the environment.
Proposed Decisions for Public Consultation – Re-evaluations		
Imidacloprid (Pollinator)	PRVD2018-12	Proposed for continued registration with implementation of new/revised mitigation measures to further protect pollinators.
Strychnine (Ground squirrel use)	PRVD2018-13	Proposed for cancellation.
Chlorimuron-ethyl	PRVD2018-14	Proposed for continued registration with implementation of new/revised mitigation measures to further protect human health and the environment.
Fomesafen	PRVD2018-15	Proposed for continued registration with implementation of new/revised mitigation measures to further protect human health and the environment.
Clodinafop-propargyl	PRVD2018-16	Proposed for continued registration with implementation of new/revised mitigation measures to further protect human health and the environment.
Mancozeb (re-issue)	PRVD2018-17	Proposed for continued registration for greenhouse tobacco and proposed cancellation of all other uses due to risk to human health and the environment. Implementation of new/revised mitigation measures may be required during the phase-out period to protect human health and the environment.
Copper (cuprous thiocyanate)	PRVD2018-18	Proposed for continued registration with implementation of new/revised mitigation measures to further protect human health and the environment.
Iron (ferrous sulfate and ferrous sulfate heptahydrate)	PRVD2019-01	Proposed for continued registration.
Triforine	PRVD2019-02	Proposed for continued registration with implementation of new/revised mitigation measures to further protect human health and the environment.

Active Ingredient	Document Number	Summary of Decision or Proposed Decision
Proposed Decisions for Public Consultation – Special Reviews		
Clothianidin (Aquatic invertebrates)	PSRD2018-01	Proposed for cancellation all outdoor uses of food and feed crops, including seed treatments, and turf. Additional mitigation measures may be required during the phase-out period.
Thiamethoxam (Aquatic invertebrates)	PSRD2018-02	Proposed continued registration for greenhouse uses with implementation of wastewater mitigation measures. Proposed for cancellation all outdoor uses of food and feed crops, including seed treatments, and outdoor ornamentals over 3-5 years. Additional mitigation measures may be required during the phase-out period.
Bromoxynil	PSRD2019-01	Proposed for continued registration.