

Health Canada's Pest Management Regulatory Agency / Regulatory Operations and Regions Branch Compliance and Enforcement Report 2015-2016

NATIONAL PESTICIDE COMPLIANCE PROGRAM

ANNUAL REPORT

2015 - 2016



YOUR HEALTH AND SAFETY ... OUR PRIORITY.

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This document does not constitute part of the Pest Control Products Act (Act) or its associated Regulations and in the event of any inconsistency or conflict between that Act or Regulations and this document, the Act or the Regulations take precedence. This document is not intended to provide legal advice regarding the interpretation of the Act or Regulations. If a regulated party has questions about their legal obligations or responsibilities under the Act or Regulations, they should seek the advice of legal counsel.

Mission and Vision

OUR MISSION

The mission of Health Canada's National Pesticide Compliance Program is to help protect the health and environment of Canadians by promoting, monitoring and enforcing compliance with the *Pest Control Products Act* and its Regulations.

OUR VISION

The vision is to strive for Excellence in Pesticide Compliance.

Executive Summary

This report outlines activities and results for Health Canada's National Pesticide Compliance Program (NPCP) in Fiscal Year (FY) 2015-2016.

The NPCP is responsible for promoting, monitoring and enforcing compliance with the *Pest Control Products Act* (PCPA) and its Regulations. The program is administered jointly by Health Canada's Pest Management Regulatory Agency (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.

2015-2016 STATISTICS - HIGHLIGHTS

This report outlines compliance and enforcement activities conducted by PMRA in partnership with RORB in FY 2015-2016. In planning the activities for the NPCP, a risk-based approach is utilised. In some instances, when non-compliance is known or suspected, a targeted approach may be used, while in other situations, a randomly selected inspection is preferred. The results presented in this report include summary findings of all compliance observations.

The NPCP activities fall into the following main areas: Active Prevention, Targeted Oversight, Rapid Response, and Border and International Activities. Highlights from each of those areas are noted below, with details provided in later chapters.

Active Prevention:

The objective is to provide regulatory guidance to industry and the public while identifying safety concerns at an early stage to encourage compliance with the PCPA and its associated Regulations.

- The key priority was to continue to educate stakeholders in priority areas of their
 obligations under the PCPA, for example, promotion of pollinator protection, safe use of
 pesticides by following label directions and use of proper personal protective equipment
 (PPE) by commercial and agricultural users and municipal pool chemical sanitation
 product users.
- A total of 199 outreach activities were completed, including presentations to associations, meetings or exhibit booths at trade shows. Communication materials were distributed on risk mitigation measures to be taken during the use of pesticides, for example fact sheets on PPE and Incident Reporting.
- Outreach elements such as the provision of verbal or written regulatory requirements were included during the delivery of many targeted oversight activities.

Targeted Oversight:

The objective is to identify health, safety and environmental concerns at the appropriate stage of the pest control product life cycle.

In 2015-2016, levels of compliance with the PCPA for inspected entities varied depending on the sector of activity. Most of the detected instances of non-compliance involved the sale of an unregistered product, as well as the import and use of unregistered products, or use contrary to the label approved by PMRA. Most violations were among retailers, importers, and distributors.

Surveillance inspections verified whether compliance had been restored in sectors of concern. Regulated parties who were previously non-compliant with the regulations, and for whom the risks to re-offend were significant, were inspected -78% were found to have returned to compliance.

- The key priority was to monitor compliance with the PCPA among pest control products users, registrants, manufacturers and vendors.
- A total of 1286 monitoring and surveillance inspections and 117 interviews focusing on 14 priority areas were conducted. In addition, 488 compliance verifications stemming from complaints, incidents and inquiries were also conducted.
- A total of 486 soil, plants, tissues or other samples were analysed by PMRA's laboratory to verify compliance, with an additional 900 samples collected and analysed for beerelated incidents and bee health issues.

Rapid Response:

The objective is to conduct timely interventions when unacceptable risks of non-compliance are identified.

- The key priority was risk-based action in response to non-compliant situations noted during inspections, as well as responses to publicly-reported complaints and incidents.
- In 2015-2016, inspections resulted in a total of 1775 enforcement responses. Enforcement responses included education and enforcement letters (614), verbal education (65), 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 relabeling (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

The objective is to implement border monitoring processes with Canada Border Services Agency (CBSA) to reduce risks posed by imported pesticides, and to bolster the international cooperation that facilitates the management of global pesticide compliance and enforcement issues.

- Following the analysis of CBSA importation data, 203 targeted inspections were conducted, and 48% of these inspections found non-compliance. The enforcement responses to non-compliant importations were verbal education (14), written education (63), enforcement letters (20), and one compliance order. Referrals from various border points resulted in 165 denials of pesticide entry into Canada.
- The pesticide program strengthened working relationships with international regulatory
 partners through the Organisation of Economic Cooperation and Development's (OECD)
 Network of Illegal Trade of Pesticides (ONIP) and continued using the OECD Rapid
 Alert System database for targeting unsafe shipments of pesticides.

Summary of Key Observation

In 2015-2016, levels of compliance with the PCPA for inspected entities varied depending on the sector of activity. Most of the instances of non-compliance involved the sale of an unregistered product, as well as the import and use of unregistered products, or use contrary to the PMRA approved label. Most violations were among retailers, importers, distributors, and users.

Surveillance inspections verified whether compliance had been restored in sectors of concern. Inspections of regulated parties who were previously non-compliant found that 78% had returned to compliance. The NPCP took active steps, including application of escalated enforcement measures, to induce the non-compliant regulated parties to fully comply with the PCPA and its associated Regulations.

Chapter 1- Overview of the NPCP

The NPCP is coordinated from Ottawa and is delivered by regional inspectors located in Burnaby, Kelowna, Edmonton, Calgary, Lethbridge, Regina, Saskatoon, Winnipeg, London, Guelph, Toronto, Montreal, Quebec City, Ottawa, Moncton, Charlottetown, and Kentville. In Newfoundland and Labrador, the NPCP is implemented by the Provincial inspectors located in St. John's, Corner Brook, and Gander. The NPCP is supported by a laboratory located in Ottawa.



Figure 1. Map of Regional Offices and Headquarters (Ottawa)

NPCP Planning

Annual compliance promotion and inspection priorities are determined after consultation with PMRA science directorates, RORB staff and their provincial and territorial partners. Results from previous inspection programs, stakeholder concerns and changes in product registration status or use patterns are also considered. NPCP activities cover specific sectors periodically in order to remain aware of challenges faced by stakeholders, changes in compliance levels, and to maintain a presence in the regulated community.

Every fall, all relevant information is assessed on a risk basis, from which priority sectors and activities are selected for inspection during the upcoming fiscal year. These risk-based work plans include activities in each of the three pillars of Health Canada's compliance and enforcement framework. Figure 2 represents the activities which fall under each pillar of compliance and enforcement.

Active Prevention

Targeted Oversight

Rapid Response

- Education and outreach
 - Workshops
 - Presentations
 - Consultations
 - · Booths at trade shows
- Interviews
 - Inspections
 - Sampling
 - Surveillance
- Enforcement responses
 - Investigations

Figure 2. PMRA Compliance and Enforcement Continuum

Implementation

The following is a description of current national pesticide program measures used in the delivery of compliance promotion, inspection, and enforcement activities under the PCPA and its Regulations.

Identifying Compliance

Compliance issues may be identified to PMRA and RORB through the following avenues:

- ongoing NPCP activities;
- voluntary reporting of suspected infractions; and/or
- information reported from other government agencies.

When a situation of non-compliance has been recognized, a compliance risk analysis is performed to determine an appropriate response.

ACTIVE PREVENTION - ENCOURAGING AND PROMOTING COMPLIANCE

There are a number of activities conducted by regional and headquarters officers that encourage and promote compliance. These activities support the collection, distribution and exchange of information and include the following:

- compliance education and outreach;
- working agreements, partnerships and consultations with other regulators of pesticides;
- sector consultations with the regulated community.

TARGETED OVERSIGHT - INSPECTING FOR COMPLIANCE

Inspections are conducted to assess or verify compliance by registrants, distributors or pesticide users. The types of inspections include the following:

- monitoring inspections;
- surveillance inspections; and
- compliance verification inspections.

During an inspection, the inspector assesses activities conducted by the regulated party and records all deviations from regulatory requirements in accordance with the PCPA and Regulations. When required, samples are taken and submitted to PMRA's ISO 17025 accredited laboratory in Ottawa for chemical analysis.

RAPID RESPONSE - MANAGING THE RISK RESULTING FROM SITUATIONS OF NON-COMPLIANCE

A compliance risk management approach is taken when there is a known or suspected non-compliance that would result in an unacceptable risk. All violations are assessed to determine if there is knowledge, intent, and/or lack of the ability to comply with regulatory requirements. The following factors are also considered:

- the history of compliance, including corrective action already taken;
- the degree of actual or potential risk (human health and the environment) as a result of non-compliance; and
- the level of response necessary to achieve and maintain continuing compliance by the violator and others in the regulated community.

Since the majority of the regulated community will generally comply if they understand the requirements, many violations are addressed through education. Education is typically used when the resulting infraction has limited health or environmental impact, the offender clearly does not understand or know of their obligations, or in some circumstances, it is not clear that they were responsible. Other enforcement options could include: enforcement letters, NOVs with warning or penalty, prosecution, suspension or cancelation of registration, recall, seizure and detention or forfeiture, and denial of product entry into Canada.

Chapter 2- Active Prevention

In 2015–2016, Health Canada delivered three national compliance promotion programs to promote awareness about requirements under the PCPA and its Regulations, including several activities focused on agricultural communities. A total of 199 compliance promotion activities were conducted (Table 1).

Table 1. Type of Compliance Promotion Activity by Program

Active Prevention	Type of activity		
	Booths	Presentations	Meetings
Pollinator protection	0	4	0
Agricultural and commercial users	21	25	3
Municipal pool outreach	0	0	20
Inspection programs	1	18	5
Other compliance promotion activities	7	31	64
Total	29	78	92

National Program: Responding to Bee Mortality Incidents and Hive Monitoring

This program responded to ongoing concerns about the potential impact of pesticides on bees in Canada. Activities delivered included collecting information on reported bee mortality incidents to aid Health Canada in making decisions about the potential contributing role of neonicotinoid pesticides. Details were also gathered around pre-determined bee yards with and without a history of incidents, to help Health Canada understand whether there are differences in neonicotinoid exposure between these areas. Over 900 samples of bees, pollen, nectar, soil, vegetation and water were collected for laboratory analysis, and over 100 interviews were conducted with beekeepers and growers. Four presentations included information on the pollinator protection best management practices. More information can be found on Health Canada's pollinator protection web page.

National Program: Agricultural and Commercial Users

This outreach program provided pesticide handlers and post-application workers with information on the importance of complying with the label directions, wearing required PPE, following Restricted Entry Intervals (REIs) and proper sanitation procedures. The information on proper pesticide use was displayed and presented to diverse audiences including: the general public, farm employees, migrant workers, farm service providers, federal and provincial regulators, gardeners, arborists, landscape companies, aerial applicators, pesticide retailers, vegetation management technicians, veterinarians, and town administrators. Forty-nine presentations were delivered to students in agricultural schools and to grower groups and associations.

Multi-language fact sheets on topics such as PPE, Incident Reporting, Protecting Pollinators, Label Search Database, Pesticides and Food, and Healthy Lawn Tips were distributed. Pest Notes on common pests were also distributed and covered the following topics:

- ants
- aphids
- bats
- bed bugs
- ladybugs
- moles and voles
- mosquitoes
- pigeons
- rats and mice
- slugs and snails
- spiders
- tent caterpillars
- wasps

The distribution of items such as nitrile gloves and magnets was found to be an effective way to encourage participants to learn more about PPE. PPE posters were also provided to a variety of stakeholders including agricultural retailers, farmers, rural municipalities and businesses to remind their staff to wear the necessary PPE. In total, several thousand handouts were distributed.

Regional Program: Municipal Pool Outreach

Quebec Region piloted an outreach program targeting 20 municipalities (with populations greater than 15,000). In this program, the Region met with municipal representatives responsible for the maintenance of municipal pools to ensure that only registered products were purchased and used according to label instructions. Two instances of non-compliance were identified and enforcement letters were issued.

Other Compliance Promotion Activities

Health Canada participated in 102 compliance promotion activities across Canada that were not part of the planned compliance promotion programs. These activities consisted primarily of presentations at trade shows, annual general meetings of associations, and conferences. Additionally, every inspection included outreach elements through the provision of relevant <u>fact</u> sheets and other resources.

SUMMARY

A total of 199 compliance promotion activities involving over 25 unique communication materials were distributed in 2015-2016. Through these activities, the NPCP increased awareness among targeted regulated groups of their regulatory obligations under the PCPA. Health Canada will continue to prioritize communicating regulatory requirements with all affected stakeholders to achieve voluntary compliance.

Chapter 3- Targeted Oversight

In 2015–2016, inspections targeting pesticide distributors and users were conducted across Canada. These included 1286 planned inspections and 488 compliance verification inspections in response to complaints and incidents of suspected non-compliance. Surveillance inspections were also conducted to assess the return to compliance.

USER INSPECTION PROGRAMS

Eight monitoring inspection programs to determine compliance of users with the PCPA were delivered and 690 inspections were conducted:

- phosphine fumigation (27)
- pest control operators (83)
- rodenticide commercial (217)
- aquaculture (62)
- fruit and nut bearing trees, bush and vines (172)
- soil fumigants (35)
- antifouling and marine paint (30)
- diazinon (64)

Phosphine Fumigation Inspection Program

Over the course of the re-evaluation of phosphine, a number of new risk mitigation measures were required. Due to the high acute toxicity of phosphine and reported incidents, a compliance program targeting phosphine applicators was initiated. The program began in 2013 with promotion of risk mitigation requirements associated with the use of the product, and continued with inspections in 2014-2015, and again in 2015-2016 based on the high level of noncompliance.

The program delivered 27 inspections and 7 presentations were made to applicators as part of provincial licensing training. As well, 7 interviews were conducted to educate retailers on the regulatory requirements.

Twenty-three of twenty-seven (85%) user inspections were found to have elements of non-compliance with respect to label requirements. The violations observed were essentially related to worker protection and not to public safety. The most common non-compliant situations involved incomplete PPE when phosphine levels were above 0.1 ppm, followed by incomplete fumigation management plan and incomplete signage. All non-compliant applicators were educated verbally on-site and received letters detailing the non-compliance noted and corrective measures required. A frequently observed issue among individual growers and small Pest Control Operators is a lack of knowledge of the current regulatory requirements. Some users have used the product for years and were unaware of the new risk mitigation measures that had been added to the label and some on-farm applicators used the product infrequently and relied on

out-of-date training manuals. Additional work to reinforce the understanding of risk mitigation measures will continue in 2016-2017.

Pest Control Operators (PCO) Inspection Program

PCOs are specialized commercial users who provide structural and landscaping extermination services for a wide range of clients in residential, commercial, institutional, and industrial settings. PCOs apply pest control products to control a vast array of indoor and outdoor pests. The NPCP has been conducting outreach and inspection activities targeting this user group since 2013-2014. These activities focused on PMRA's regulatory role, new risk mitigation measures following the re-evaluation of specific pest control products used by PCOs, and safe use of the PPE.

In 2015-2016, 83 PCOs were inspected across the country to verify compliance with the various labels of pest control products used by the PCOs. Key elements verified during the inspections included:

- safe use of products, e.g., use of proper PPE, proper handling of products and precautionary notifications;
- product use according to label specifications, e.g., pest controlled, use site and rate; and
- use of Canadian registered products.

Overall, 54% of PCOs inspected were compliant. The most frequent violations included the use of pest control products contrary to label directions (use not included on the label, incorrect use sites and incorrect rates), use or possession of unregistered pest control products, and inadequate use of the PPE. Enforcement responses included verbal education, provision of outreach materials to all inspected PCOs, education letters (9), enforcement letters (16), and NOVs with penalty (11).

During the delivery of this program, additional outreach activities were undertaken targeting PCOs and their staff. This included 11 presentations and participation in one trade show. This inspection program remains a high priority for the 2016-2017 NPCP activities.

Rodenticide Commercial Inspection Program

In 2010, as part of an overall risk-reduction strategy for rodenticides in Canada, PMRA required additional risk mitigation measures to prevent accidental exposure of children and wild animals. As of January 1, 2013, use restrictions for several commercial and domestic class rodenticides came into effect on product labels (re-evaluation decision on rodenticide). Bait must either be placed in tamper-resistant bait stations or in locations not accessible to children, pets, livestock or non-target wildlife. In 2014-2015, commercial rodenticide vendors and users were inspected with a high rate of non-compliance among users. Given these inspection results, it was decided to continue this activity in 2015-2016.

In 2015-2016, 55 vendors were inspected with 41 (75%) being compliant and 162 users were inspected with 152 (93%) being compliant. The main violations included the possession of expired products, the use of pest control products contrary to label directions, as well as the possession of unregistered products. Vendors found to be non-compliant received an education letter. A marketplace inspection program targeting vendors of domestic class rodenticides is a priority for 2016-2017 NPCP activities.

Aquaculture Inspection Program

Over the last several years, this industry has used pest control products to control sea lice, a marine pest which attaches itself to salmon. These products are potentially harmful to the marine environment if not used according to the label directions.

The 2015-2016 aquaculture inspection program delivered 62 inspections on fish and shellfish farms. There were 52 salmon farms inspected in New Brunswick, Newfoundland and Labrador; 6 fish farms inspected in British Columbia, and 4 lake fish farm inspections in Ontario. Additionally, 5 interviews were conducted. On the Pacific coast, there was no indication of pesticide use in the aquaculture industry. Of the 52 inspections in the Atlantic Region, 54 salmon samples were submitted to PMRA's laboratory for analysis of cyfluthrin, cypermethrin, deltamethrin and permethrin. Two samples had cypermethrin and 2 NOVs were issued. A compliance rate of 96% was observed in the Atlantic Region. Overall, there is a high level of compliance in the aquaculture industry.

Fruit and Nut Bearing Trees, Bush and Vine Growers Inspection Program

In 2015-2016, 172 growers of trees, vines, and bushes that produce edible fruits and nuts were inspected and 278 samples were collected across Canada.

Ninety-one growers (53%) were found fully compliant. The majority of the violations involved worker protection violations related to not following the label directions, such as not wearing the proper PPE (73 growers), not respecting the re-entry interval (REI) (32 growers) and the pre-harvest interval (PHI) (21 growers). Additionally, 95% of pest control products found in storage were in compliance. Twenty-three enforcement letters, 60 educational letters, and 4 verbal education responses were issued for non-compliant situations.

Soil Fumigant Inspection Program

The PMRA re-evaluation of soil fumigants required manufacturers to make improvements to their product labels to further limit human exposure during applications, as well as to further protect bystanders and the environment. A Fumigation Management Plan (FMP) was also required for all applications. This program was implemented to verify compliance with the new risk mitigation measures introduced from the re-evaluation.

Thirty-five inspections were conducted nationally and 23% of fumigants applicators were fully compliant. The level of non-compliance varied greatly among fumigant applicators from no awareness of the requirements, to strong compliance with only very minor infractions (i.e., missing small section of the FMP). In Eastern Canada, the majority of applicators inspected were aware that the label requirements had changed for soil fumigants and had implemented (or partially implemented) many of the required practices. However, in British Columbia many of the applicators inspected were in possession of the old product label and were unaware of the new requirements. As such, in 2016-2017, this activity is a high priority for the NPCP in British Columbia. All inspections of applicators included an educational component promoting the understanding of label directions and the completion of a FMP.

Distributors and Users of Antifouling, Marine Paint Products Inspection Program

Antifouling marine paints are used to provide a protective coating on boat hulls against algae, barnacles and other marine fouling organisms. Like many pesticides, antifouling marine paints can be dangerous to human health and the environment. Interviews were conducted with 2 major antifouling paint distributors and inspections were conducted at 30 marine product distributors and vendors in Ontario and Atlantic regions. An additional follow-up inspection with the Canadian agent of a US registrant was conducted as a result of finding products with expired registration in the marketplace. Verification was conducted to determine whether the antifouling paint products were being used according to label directions with a focus on PPE. Many retail vendors inspected did not apply these products themselves and they often contracted out this work to a third party. The few vendors inspected that did apply these products were either unaware of the label PPE requirements or used only some of the PPE listed on the product label. Fifteen out of 30 (50%) users inspected were not compliant, which resulted in 2 verbal education. 9 written education and 4 enforcement letters.

Diazinon Inspection Program

The 2009 PMRA <u>re-evaluation decision on diazinon</u> required the phase-out of most uses due to health and environmental risk concerns. Some product uses were identified for short-term phase-out (March 2012). Critical uses, with no registered alternative pest control products, were identified for longer-term phase-out and managed under a <u>risk management plan</u> (RMP). These uses were targeted for inspection in 2015-2016.

The inspection program verified compliance with the PMRA's diazinon RMP and phase-out requirements among distributors/retailers and growers. Thirty-three growers and 31 retailers were inspected. Five interviews were also conducted. Results indicated that 19 of 31 inspected retailers sold diazinon products in 2015. Inspections of 33 growers found that 17 (52%) were compliant. In all non-compliant cases, education letters were issued and the non-compliant parties were advised to respect the RMP and phase-out requirements. Inspections of 31 retailers found that 25 (81%) were compliant. Verbal education or education letters were issued to non-compliant retailers.

Summary Compliance Rates for User programs

Across all monitoring inspection programs directed toward users of pest control products, varying levels of compliance were observed. Violations observed were primarily related to worker protection and not to consumer or public safety. In 2015-2016, levels of non-compliance were highest among phosphine fumigation users, soil fumigants users and pest control operators. These three areas are of high priority for the 2016-2017 NPCP activities. In all instances of non-compliance, immediate enforcement actions were taken.

DISTRIBUTION INSPECTION PROGRAMS

Three monitoring inspection programs were conducted to determine compliance of stakeholders along the distribution chain. Two hundred and fifty-three inspections were completed through these programs:

- registrants (51)
- research authorizations (59)
- marketplace pet products (143)

Registrant Inspection Program

In 2015-2016, the program objectives were to verify compliance of international registrants with the requirements of the PCPA and its Regulations, and to provide information on these requirements to international registrants.

There are 300 registrants outside of Canada with approximately 1800 products registered with the PMRA. A total of 51 inspections were conducted. Information was collected and verified from the international registrants and/or their Canadian agents. Twenty-seven registrants were compliant and 24 were non-compliant. Common issues of non-compliance included label violation, unapproved formulating sites and Technical Grade Active Ingredient (TGAI), as well as non-compliant websites. Verbal education was given to 2 registrants and written educations or enforcement letters were issued to 22 registrants.

Research Authorization Inspection Program

The Pest Control Products Regulations allow the use of unregistered pest control products for research purposes if specified conditions are met. This program monitored compliance with the requirements associated with using pest control products for research. Fifty-nine research sites were inspected across the country, and 51 (86%) were found fully compliant. There were three instances of improper signage and improper product disposal, two instances of not wearing PPE as required, as well as one instance of research being done in the unapproved location using an unapproved tank mix. The majority of violations detected were related to use of products that was inconsistent with the directions on the experimental label. All researchers and co-operators were informed of regulatory requirements.

Marketplace Pet Products Inspection Program

Every year, the NPCP monitors pesticide retailers for sale of unregistered pest control products. In 2015-2016, the program focussed on inspections of retailers selling pet products to consumers. Of 143 inspections, 94 had one or more unregistered products for sale, and their distributors were identified. Two thousand two hundred ninety (91%) of the 2517 inspected products were compliant, and the non-compliant products were removed from store shelves. Education and enforcement letters were issued to the non-compliant vendors. Non-compliance typically resulted from a lack of knowledge of the regulatory requirements. Fifty-seven percent of vendors were unaware that a pesticide can only be sold if it has a registration number. Follow-up inspections in 2016-2017 will determine if non-compliant retailers have returned to compliance.

Summary Compliance Rates for Distribution Programs

Across all targeted oversight programs directed toward distributors of pest control products, varying levels of compliance were observed. The most frequent violation was the distribution of unregistered products. The highest level of compliance was observed during the research authorizations inspections.

RE-EVALUATION RELATED PROGRAMS

Thimet 15-G Inspection Program

Following a re-evaluation decision in 2012, the registration for the pest control product Thimet 15-G (active ingredient, phorate) became subject to cancellation and the phase-out period was extended as per the following schedule:

- Last date of sale by registrant June 1, 2015
- Last date of sale by retailers and distributors June 1, 2015
- Last date of use by growers and users August 1, 2015

Stakeholders were informed of the upcoming cancellation of Thimet 15-G in 2012. In addition, PMRA requested that the registrant of this product be responsible for the disposal of any product remaining in the marketplace after the registration expired.

In August 2015, a scan of the marketplace was conducted to determine whether Thimet 15-G continued to be available for sale. Forty-two inspections of retail (40) and distribution centres (2) were conducted. Four interviews were also conducted. None of these retailers were selling the product. However, 4 retailers still had Thimet 15-G in storage. These retailers were advised to return the product to the distributor for disposal by the registrant.

SURVEILLANCE INSPECTION PROGRAMS

In 2015-2016, the surveillance program verified whether there was a return to compliance in sectors of concern. Regulated parties and individuals were targeted in 68 surveillance inspections based on previous non-compliance with the regulations, and likelihood to re-offend. Seventy-eight percent of these inspections found a return to compliance (15 non-compliant findings). In addition, 30 inspections were selected from previous violators from the 2010-2012 Unregistered International Marketplace program in Ontario. The international surveillance program verified whether compliance had been restored in sectors of concern. Sixty-seven percent of these inspections found a return to compliance (10 non-compliant inspections).

NPCP is taking active steps, including application of escalated enforcement measures, to induce the remaining regulated parties and individuals to fully comply with the PCPA and its associated Regulations.

SUMMARY

Targeted Oversight activities in 2015-2016 included inspections, presentations, meetings and interviews with growers, pest control operators, retailers, registrants and distributors. Non-compliance was detected across several sectors. The most frequent violations were possession of an unregistered product; sale, import, and use of unregistered products; and use contrary to the label approved by PMRA. Lack of awareness of regulatory obligations and decisions were the primary reasons for non-compliance.

Chapter 4- Rapid Response

In 2015-2016, 1775 enforcement actions were taken as a result of non-compliance, 942 from planned inspections and 833 as a result of complaints.

There were 1066 violations with respect to non-compliant pest control products not meeting regulatory requirements. Enforcement actions taken included denial of entry (165), stop sale and disposal (718), return to vendor (74), recall (6), order of disposal (20), relabel of products (29), and others (39).

As well, another 709 enforcement actions were taken such as written education (458), verbal education (65), enforcement letters (156), compliance orders (3) and administrative monetary penalties (27).

In support of the program, 486 samples of soil, plants, animal tissues, liquid and surface wipes were submitted to PMRA's laboratory to verify compliance with the PCPA. Among these samples, 196 were collected during compliance verification inspections to ascertain compliance with the PCPA.

Response to Incidents and Complaints

In 2015-2016, the pesticide program responded to 488 reported incidents of suspected non-compliance and complaints received from the public and regulated parties. When instances of non-compliance with the PCPA were detected, measures were taken appropriate to the circumstances and risks involved.

One example of a higher risk incident is summarized below:

Agricultural products sold to homeowners

Health Canada became aware of a company selling repackaged agricultural class products for domestic class use. Chemical analysis confirmed that the products were agricultural insecticides and herbicides not registered for domestic class use. The repackaged products did not indicate the nature and concentration of the active ingredients nor the protective measures to be followed during handling. Non-compliant products were seized and disposed of. Compliance Orders were issued to stop the non-compliant repackaging and sales activities, and 6 NOVs were issued.

SUMMARY

Compliance verification of 488 complaints and suspected incidents of non-compliance resulted in 833 enforcement responses. Enforcement actions for products were mainly requests to stop the sale. Written education, enforcement letters and AMPs were the main enforcement tools used against the PCPA offenders.

Chapter 5- Border Activities

Internet commerce has led to a dramatic increase in the number of pest control products being shipped into Canada via international mail and private courier services. Many of these products are domestic class pest control products purchased online by Canadian residents from out of country distributors, a practice that can be illegal depending on the type, quantity and monetary value of the pest control product. Pest control products purchased online and shipped by mail or private courier may not have been subjected to the safety and quality checks that Health Canada places on legally imported products, and may pose health risks to consumers. Working with other federal agencies, including Canada Border Services Agency (CBSA), Health Canada deploys risk-based strategies, including blitzes at border points nationwide to identify, examine, and intercept these shipments.

Import Data

CBSA's Pathfinder import data have been used by Health Canada's pesticide compliance program since 2012 to identify trends in pesticide imports and to gather evidence to respond to non-compliant importations. An inspection program targeted at importers was delivered in 2015-2016 to address non-compliance and to educate importers on the PCPA. More than 80% of the pest control products used in Canada are imported. Unregistered products offered for sale constitute the most common violation of the PCPA found in the marketplace.

Of the 203 targeted import inspections, there was a 48% rate of non-compliance, primarily with retailers importing unregistered pest control products, followed by importation of unregistered pest control products for personal use. Commercial (growers and industrial facilities) and distribution violations were the next most frequent area of non-compliance. In response, 63 written education, 20 enforcement letters, 14 verbal education and one compliance order were issued.

Admissibility referrals from CBSA at various border points resulted in 165 denials of entry into Canada. In addition, 11 presentations as well as one meeting were provided to border officers to inform them of the regulatory requirements related to the importation of pesticides.

Target pilot and CBSA Admissibility Referrals

In September 2015, the Ontario region targeted a courier point of entry. As a result, Health Canada received 108 referrals from CBSA. Health Canada made 105 admissibility decisions with an 82% refusal rate. Based on this initiative, approximately 454 kg of unregistered pest control products were refused entry into Canada. The majority of these referrals (91%) were personal imports. All of the refusals were followed up with education letters outlining the requirements of the PCPA and the reason for the refusal.

SUMMARY

Since 2012, the importation data from the CBSA enables the NPCP to develop and implement a compliance program focussed on the verification of suspect imports and removal of unregistered pest control products from the Canadian market.

Chapter 6 - National and International Partnerships to Further Reduce Risk for Canadians

National Collaboration

There are a number of collaborative initiatives with Health Canada regional offices and provincial, territorial and municipal partners. A few examples:

- Sprayer calibration workshop
- Education Credit program for pesticide applicators
- Pest Management Regulatory Agency policy and regulatory updates

Sprayer calibration workshop

In March 2016, a sprayer calibration workshop was delivered in conjunction with an equipment manufacturer in British Columbia. Workshop attendees included Non-Government Organizations, provincial personnel and pesticide program staff. The workshop was designed to increase knowledge of sprayer maintenance, provide an understanding of issues applicators face and provide participants with potential solutions to allow them to mitigate risk associated with the wrong equipment calibration.

Education Credit program for pesticide applicators

Agricultural producers in Prince Edward Island require a Class A Pesticide Applicator License in order to apply pesticides on agricultural crop, agricultural land, seed grain, or potato seed pieces. First time applicants must write an exam and certification is valid for five years. As an alternative to writing the exam for licence renewals, a method of re-certification was developed to promote continuing education for pesticide applicators. Two different sessions are held and applicators must take both sessions over the five-year period before their license expires.

The pesticide compliance program participated in delivering the 2015-2016 Continuing Education Credit program. Topics covered included pesticide registration, re-evaluation and the importance of complying with label directions, re-entry intervals (REIs), pre-harvest intervals (PHIs), buffer zones (aquatic and terrestrial), and ways to reduce spray drift. The program was attended by 200 pesticide applicators.

Pest Management Regulatory Agency policy and regulatory updates

In support of continuing efforts to inform provincial partners, Quebec Region staff produced a list of changes to the registration of pesticides and transmitted the list to their provincial colleagues each month. The list detailed any additions on use or removals from use on the labels, new products, and phase-outs of products. The information is relayed to growers and their advisors, and is used to update the provincial database, SAgE-Pesticides. The NPCP is considering the expansion of this activity across Canada.

International Collaboration

With world commerce growing larger, more complex, and even more interconnected, surveillance is increasingly essential to protect the health of Canadians. The NPCP engages with a wide variety of organizations, including other government agencies and international organizations, to leverage information. Through effective engagement with selected partners, the NPCP expands its reach to protect health and the environment with finite resources.

During 2015-2016, the NPCP strengthened working relationships with its international regulatory partners through the OECD Network of Illegal Trade of Pesticides (ONIP).

The access to the OECD Rapid Alert System facilitated quick sharing of information when illegal or unsafe shipment of pest control products was identified by one of its member countries. The NPCP participated in ONIP meetings that discussed the elements to be included in the Best Practice Guidance Document. The goal of the document is to provide an overview of best practices in detecting and stopping illegal trade of pesticides, primarily to assist regulators in OECD countries that are developing this capacity.

SUMMARY

By collaborating with our international partners and working with other federal and provincial/territorial ministries, Health Canada has rapid access to compliance information for promoting and verifying compliance with the PCPA and to educate individuals, local officials and grower groups on regulatory requirements.

Chapter 7- Compliance Overview

Compliance Trends

Activities carried out by the NPCP in 2015-2016 indicated that compliance exists to varying degrees depending on the sectors of activity. Violations related to sale, unregistered use and importation of unauthorised products were the major types of non-compliance encountered during the inspections (Figure 3).

Selected regulated parties who were previously non-compliant with the regulations in 2014-2015 and were likely to re-offend showed a 78% return to compliance. In 2015-2016, 1775 enforcement responses were delivered to induce non-compliant regulated parties to fully comply with the PCPA and its associated Regulations.

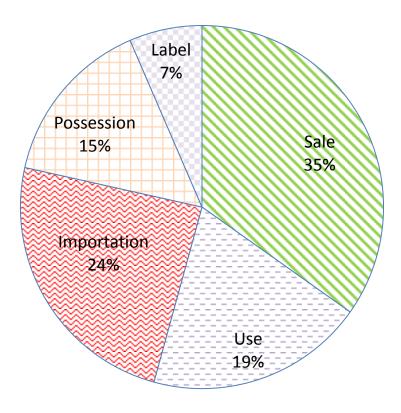


Figure 3. Types of violations in 2015-2016

Chapter 8- Forward Planning

Several priorities were identified by the NPCP for the 2016-2017 fiscal year:

- Delivering the 2016-2017 NPCP commitments in the areas of manufacture and reevaluation, import, marketplace, agriculture use, commercial and industrial use, as well continuing the delivery of surveillance inspections targeting regulated parties who were previously non-compliant;
- Delivering on-going compliance promotion activities to encourage and promote compliance, for example by providing education and outreach materials;
- Delivering the Regulatory Transparency and Openness commitments, including web
 posting the 2015-2016 Compliance and Enforcement report, and the registrant inspection
 information; and consulting with industry and OECD member countries in the further
 development and refinement of an initiative that would look at sharing of global risk
 information;
- Improving information sharing with regulatory partners, and strengthening compliance and enforcement relationships with governments and organizations such as information sharing Memorandum of Understanding with the United States Environmental Protection Agency, information sharing with the OECD ONIP and working closer with CBSA and other government departments.

Glossary

<u>Active Prevention</u>: Promotion of appropriate import, manufacture, distribution, sale, and use of pest control products. See also the definition of compliance promotion.

Administrative Monetary Penalties (AMPs): The Agriculture and Agri-Food Administrative Monetary Penalties Act provides a system of penalties and warnings for violations of several federal Acts including the Pest Control Products Act. The Agriculture and Agri-Food Administrative Monetary Penalties Act allows Canadian pesticide regulatory officials to impose penalties without having to pursue formal prosecution.

<u>Candidate:</u> The person or business reported or suspected of being in contravention of the *Pest Control Products Act* or its associated Regulations.

<u>Compliance</u>: The full implementation of legal requirements. It is the state of conformity of a regulated party (including a corporation, institution, individual or other legal entity) or a pest control product with the *Pest Control Products Act* and its associated Regulations.

<u>Compliance Monitoring</u>: Collecting and analysing information on compliance status of a pest control product or a facility (place or operation where pest control products are manufactured, held, stored, marketed, sold, distributed, transported, used or disposed or where records relating to such activities are maintained) or of an industry or use sector. Compliance monitoring involves interviews, inspections and sampling.

<u>Compliance Orders</u>: A tool to inform the regulated party of a violation of the *Pest Control Products Act* and its associated Regulations which requires timely action to prevent risk to health and safety.

<u>Compliance Promotion</u>: Action taken to assist regulated enterprises, individuals and other legal entities to comply with the *Pest Control Products Act* and its associated Regulations. These actions include educational activities and the provision of information on legislation and policies.

<u>Compliance Verification</u>: Inspections that are not part of a planned program that are in response to specific violations, suspected violations, or complaints. They can be surveillance inspections which are planned to target specific individuals or groups for follow-up on previous findings or concerns.

<u>Contravention</u>: The act of coming into conflict with a provision of legislation. Under the *Pest Control Products Act* and its associated Regulations, a contravention can lead to either a violation or an offence.

<u>Co-operator</u>: Any individual, corporation or institution not engaged in pesticide research who has agreed to use or allows the use of a pesticide for research purposes on a site owned or operated by that individual, corporation or institution.

<u>Detention</u>: The act of holding a pest control product in the custody of the Pest Management Regulatory Agency, which nullifies the rights of the owner over this product, until the provisions of the *Pest Control Products Act* and its associated Regulations are complied with.

<u>Education Letters</u>: Primarily provides an individual or company with information about their regulatory obligations.

<u>Emergency Registration</u>: Registration of a pest control product, for a period not exceeding one year, for the emergency control of seriously detrimental pest infestations.

<u>Enforcement Letters</u>: In addition to informing stakeholders of their regulatory obligations, enforcement letters require that action be taken to restore compliance.

<u>Enforcement Responses</u>: Actions that may be taken by Health Canada's pesticide program to induce, encourage or compel compliance by the regulated party with the *Pest Control Products Act* and its Regulations or to cause a contravention to cease, to prevent future contravention or to impose sanctions for non-compliance. Enforcement responses include education letters, enforcement letters, compliance orders, Administrative Monetary Penalties, and Prosecution.

<u>Forfeiture</u>: The loss or surrendering of an item to the Crown as part of the enforcement response to a contravention, where an item has been seized and detained and subsequently forfeited using either section 55 of the *Pest Control Products Act* or section 22 of the *Agriculture and Agri-Food Administrative Monetary Penalties Act*.

<u>Guarantee Limits</u>: The active ingredient(s) levels in the pest control product must be in compliance with its declared guarantee statement and product specifications.

<u>Inspection</u>: The review and examination of the compliance status of a pest control product or any place or operation where pest control products are manufactured, held, stored, marketed, sold, distributed, transported, used or disposed, or where records relating to such activities are maintained.

<u>Interview</u>: A compliance monitoring activity that is part of the National Pesticide Compliance Program and involves a questionnaire. Health Canada's pesticide program officer gathers information to determine risk of non-compliance. The consideration of this risk determines the nature, type and frequency of oversight in a given situation.

<u>Investigation</u>: Actions taken to gather evidence to support a case referral for potential judicial determination regarding specific violations of the *Pest Control Products Act* and its associated Regulations. This includes taking statements and activities carried out under the *Criminal Code*, i.e., executing search warrants.

Monitoring inspection: A planned inspection

<u>Phase-Out</u>: The gradual elimination of registered product uses, product formulations, or product registrations, through the Pest Management Regulatory Agency's <u>Re-evaluation Program</u>.

<u>Pre-Harvest Interval (PHI)</u>: The time between the last application of the pesticide and harvest.

<u>Rapid Response</u>: Enforcement responses to non-compliance, which can vary depending on a number of factors, such as the harm or potential harm caused by the infraction, compliance history, whether the regulated party acted with indifference or premeditation, the likelihood that the problem will reoccur, and the probable and likely outcome of each enforcement action.

Registrant: A person in whose name a pest control product is registered.

<u>Restricted Entry Interval (REI)</u>: A restricted-entry time after the application of a pest control product.

<u>Seizure</u>: The act of taking possession of a product under the authority of the *Pest Control Products Act* without the person's consent for the purposes of placing the product under detention. Seizure deprives the owner of the item from freely doing anything with the item, but unlike forfeiture, he/she retains ownership of the item.

Surveillance: Follow-up inspections conducted to verify the effectiveness of previous programs.

<u>Targeted Oversight</u>: Early detection of health, safety and environmental concerns at the appropriate stage of a pest control product's life cycle. This is achieved by undertaking a variety of activities including inspections, sampling and surveillance to identify risks.

<u>Violation</u>: A contravention of the Act or the Regulations that may be proceeded with in accordance with the *Agriculture and Agri-Food Administrative Monetary Penalties Act* see subsection 2(2) of the *Pest Control Products Act*.