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Executive Summary

Canadian pesticide manufacturers are required by law to submit pesticide incident reports to Health Canada's Pest Management Regulatory Agency (PMRA). These incident reports are used to help identify and characterize potential risk to humans, domestic animals and the environment from the use of pesticides.

In 2013, 2139 incident reports were received by the PMRA. Most were categorized as domestic animal incidents, followed by human, environment and packaging failure incidents, and scientific study reports. Most incidents were minor in nature (for example, incidents that involved effects such as headaches or skin irritation). Pesticide incident data are monitored by the PMRA and evaluated when a potential risk is identified.

Several activities were undertaken by the PMRA in response to 2013 incident data. These include modifying certain product labels to warn against the exposure of children to treated seed, ongoing development of mitigation measures to reduce the likelihood of accidental paraquat ingestion, and conducting compliance activities aimed at improving pesticide manufacturer knowledge of incident reporting.

Of note is the ongoing evaluation of honeybee mortality incidents. Initial analysis of 2013 information continues to suggest a link between dust generated during the planting of treated corn seed and many of the acute mortalities reported during the spring season. Additional measures are being developed to reduce the exposure of bees to dust generated during planting of treated seeds.

Additionally, the PMRA obtained pesticide poisoning case data from the Ontario Poison Centre (OPC), which provides information and advice by telephone to callers concerned about potential or real exposures to poisonous substances. From this data, the PMRA could determine whether there were additional or unforeseen health incident patterns that were identifiable in another source of poisoning data. Overall, the patterns noted in the OPC data mimic incident trends observed in the PMRA database. The most frequently reported active ingredients are in both databases, and have been previously evaluated by the PMRA.





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1.0 Introduction

Health Canada regulates pesticides under the *Pest Control Products Act*, which is administered by the Pest Management Regulatory Agency (PMRA). Under the Act, the PMRA determines which pesticides can be registered for use in Canada through a series of detailed, science-based evaluations that assess a pesticide's potential risk to human health and the environment, and its value in relation to the intended use. Pesticides are registered by Health Canada if the risks to human health and the environment are determined to be acceptable and the product has value. Following the registration of pesticides, the PMRA continues to monitor their safety by collecting and evaluating reports of incidents that may be related to these products.

As of the end of 2013, more than 10 500 incident reports have been submitted to the PMRA since the Incident Reporting Program began in April 2007. This review summarizes the incident reports received from 1 January to 31 December 2013, and provides key details of the PMRA evaluations.

1.1 Pesticide Incidents

A pesticide incident is any unintended effect to human health, domestic animal health or the environment resulting from exposure to a pesticide. A pesticide incident may also be a packaging failure that could result in human exposure or injury, excessive residues in food, or a scientific study that indicates a new hazard or increased risk.

Incidents are further classified by severity based on the criteria outlined in the Pest Control Products Incident Reporting Regulations. Human and domestic animal incidents are categorized as one of four severity levels: death, major, moderate and minor. Minor incidents include symptoms that are minimally bothersome and resolve rapidly without medical treatment (for example, nausea). Moderate incidents include symptoms that are more pronounced or prolonged than minor symptoms, and that may require some form of medical treatment. Major incidents include symptoms that could be life-threatening or result in chronic disability (for example, respiratory failure). For environment incidents, there are three severity classifications: major, moderate and minor. These severity classifications are determined based on the type and number of organisms affected.

1.2 Reporting a Pesticide Incident

While manufacturers of pesticide products have a legal obligation to report all information that they receive about an incident that relates to their product(s), anyone can report a suspected pesticide incident to the PMRA, including the general public, farmers or medical professionals. The PMRA encourages the reporting of all pesticide incidents, including incidents resulting when instructions for use were not correctly followed, or when the adverse effects that occurred are already indicated on the product label.

Pesticide manufacturers are required to report all incidents that occur in Canada and a subset of incidents that occur in the United States. This subset includes incidents classified as human death, human major and domestic animal death. As such, the number of American incidents reported to the PMRA does not reflect the total number of incidents that are reported to authorities in the United States.



Submitted pesticide incident reports are made available through the Health Canada website on the PMRA public registry's Pesticide Incident Reporting Database.

The Use of Pesticide Incident Data 1.3

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Health Canada's PMRA uses incident report data to identify the hazard and characterize potential risks from the use of pesticides to humans, domestic animals and the environment. Evaluations can vary in scope, depending on a variety of factors, such as the amount of information that is available and the complexity of the issue. There are limitations associated with reported incidents that must be taken into consideration. For example, the information provided in reports is usually unsubstantiated and often incomplete. The adverse effects that are reported may be related to non-pesticide factors and the reporting of a particular effect does not necessarily mean that it was caused by the pesticide. Conversely, it is likely that not all pesticide incidents are reported, and assumptions about the absence of incident reports cannot be made. For example, the absence of incident reports cannot be used to validate the safety of a pesticide.

Monitoring incidents for unanticipated effects or changes in a pesticide's risk profile is an ongoing process at the PMRA that may include re-assessing previous conclusions. In cases where mitigation strategies were adopted, the PMRA monitors the incident report data to determine if the actions were effective in managing the identified risk.

2.0 **Incident Reports Received in 2013**

2.1 **General Analysis**

In 2013, the PMRA received 2139 incident reports. There were 1302 incidents that occurred in Canada (61% of all incidents received). Incidents that occurred in the United States represented 36% of all reports received. The remainder were scientific studies, for which a location is not specified. As with previous years, domestic animal incidents were the most frequently reported type of incident, followed by human incidents, environment incidents, packaging failure incidents, and scientific studies. Most of the incidents that occurred in Canada involved products that can be purchased and used by the general public, such as Domestic Class products.

2.2 **Summary of 2013 Human Incident Reports**

In 2013, the PMRA received 266 human incident reports involving 336 individuals (note that some incidents involved more than one person). Exposure was often reported as being related to the application of a product inside or outside the home, or for personal use (such as the use of an insect repellent). Most incidents involved adults. The primary route of exposure was dermal, followed closely by inhalation.

For incidents that occurred in Canada, symptoms were generally minor or moderate in nature (87% of the incidents were categorized as minor in severity). Common symptoms included headache, shortness of breath, rash, eye irritation or respiratory tract irritation. In 2013, there was one Canadian report in which serious symptoms were listed. In this case the individual suffered from a stroke during the application of a pesticide product, but the incident was not considered related to the product.



There were an additional 27 serious incidents reported, all of which occurred in the United States. Twenty of these incidents were not considered to be related to the reported pesticide exposure. In the other seven cases, the PMRA determined that there was some association of the symptoms with the reported exposure to the pesticide. Two of the serious human incidents involved the accidental ingestion of paraquat. The PMRA conducted an evaluation of all paraquat incidents, the details of which are in Section 2.2.4. Of the remaining serious human incidents, three were due to the intentional ingestion of a pesticide. There was another incident that was the result of the pesticide being accidentally sprayed in the subject's eye. In the last incident, a young child had access to an open bag of herbicide. The PMRA evaluated the circumstances of the incidents as well as the safety precautions and use directions on the product labels. With the exception of the paraquat incidents, the PMRA concluded that additional regulatory actions, such as label changes, were not warranted at the time. However, the database of incident reports is continually monitored and these conclusions will be re-assessed, as required.

The evaluations of human incidents that led to actions being taken by the PMRA are summarized below.

2.2.1 **Incidents Involving Multiple People**

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There were two incidents reported to the PMRA in 2013 in which several people experienced symptoms after their office was treated with a pesticide. In the first incident, a call centre was reportedly treated with the product Ecosense Bug-B-Gon Insecticide Concentrate (Reg. No. 28404) containing the active ingredient pyrethrins. The diluted product was applied to the carpet, chairs and fabric cubicle dividers. Some employees were present at the time of treatment and sat on chairs that were still saturated with the product. During the next four days, 23 individuals experienced minor effects such as dizziness, headache, shortness of breath and irritated skin.

In the second incident, the product *Tempo 20 WP Insecticide* (Reg. No. 25673) containing cyfluthrin was applied by a pest control operator to an office. The employees were out of the office for 12 hours following the application of the product. It was reported that when they returned, they could see pesticide residue on the desks. There were 20 individuals affected with symptoms such as blurred vision and respiratory irritation. In both cases, it appears that the pesticide was applied by a pest control operator in a manner that was contrary to the product label.

2.2.2 **Fludioxonil**

Fludioxonil is currently under re-evaluation. An evaluation of human incidents was conducted in support of this review. At the time of the evaluation, the PMRA had received 17 human incident reports involving fludioxonil. Exposure mainly occurred when individuals handled seeds that had been treated with a product containing fludioxonil. Minor effects, such as itchy skin and rash were frequently reported in these incidents.

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There were two minor incidents involving children aged 6-12 years old that occurred as a result of contact with treated seeds or seed dust and several incidents involving domestic animals. As part of the re-evaluation process, the product label will be modified to include the requirement that tags on all bags of fludioxonil-treated seed, which are intended for sale or use in Canada, have the statement: "Keep out of reach of children and animals".

2.2.3 Chloropicrin

There were three incident reports received in 2013 that involved the restricted class product Pic Plus Fumigant (Reg. No. 28715), which contains the active ingredient chloropicrin. The incidents occurred at approximately the same time and within the same town. In all three incidents, the product was applied as a soil treatment by tobacco growers. Five individuals experienced effects such as eye irritation and breathing difficulties.

The Ontario Ministry of Environment investigated all three incidents. In two incidents, the release of the fumigant vapours may have occurred as a result of ineffective sealing of the soil following the injection of the product. In the third incident, the grower may have cultivated the treated field shortly after application of the soil fumigant, thereby causing the vapour to be released from the treated field.

The PMRA made extensive amendments to all chloropicrin soil fumigation product labels (REV2012-09, Label Amendments for Soil Fumigants Products Containing Chloropicrin) with changes that were designed to reduce the potential for human exposure to the products. The updated chloropicrin soil fumigant labels were implemented in September 2014.

2.2.4 **Paraquat**

There have been 31 human incident reports involving paraquat submitted to the PMRA. Two serious incidents were received in 2013. During the review of these incidents, two potential human health hazards were identified; paraquat is corrosive and can cause skin burns, and the accidental ingestion of a paraquat product can result in life-threatening effects or death.

In the incident reports reviewed, dermal and ocular exposure resulted in serious effects in most people who were exposed to paraquat. It is known to be corrosive to the skin and if decontamination is delayed, third degree burns can result.

In all of the accidental ingestion incidents, it was reported that the product was transferred into an unmarked container, such as a water bottle, and later mistakenly ingested. All cases reported ingestion of very small amounts of paraquat.

The PMRA is developing risk mitigation measures to help prevent dermal and ocular injury, as well as the accidental ingestion of paraquat.

2.3 **Summary of 2013 Domestic Animal Incident Reports**

There were 1611 domestic animal incidents reported to the PMRA in 2013. As in previous years, dermally applied spot-on type products for the control of fleas and ticks remain the most frequent type of product reported in the domestic animal incidents. In 2010, pesticide companies were required to modify their product labels to include additional warnings to protect smaller animals

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and to prevent the use of dog products containing permethrin on cats. Despite these actions, there has been an increase in the volume of domestic animal incident reports received by the PMRA relating to products applied for the control of fleas and ticks, possibly due to increased public awareness of the issue. The PMRA has initiated an evaluation of these incidents in order to determine whether the new risk mitigation measures adequately minimize the risks associated with the use of these products. Further risk reduction measures will be implemented if the review supports such an action.

Other than incidents involving spot-on type products, the PMRA received 450 domestic animal incident reports (affecting 827 animals). Dogs and cats were most frequently reported, followed by fish and cows (other animals included goats, poultry or birds). Just over 50% of the incidents occurred in Canada, most of which were minor or moderate in severity. Of the deaths reported, 90% of them occurred in the United States.

For those incidents that were not related to spot-on type products, the majority of the domestic animal incident reports involved products that are used in and around the home. Animals were often treated directly with the product, had contact with a treated area, were exposed via spray drift or accidentally ingested the product. Symptoms reported were often gastrointestinal (for example, vomiting), general (such as lethargy) or related to nervous and muscular systems (for example, tremors).

2.4 **Summary of 2013 Environment Incident Reports**

In 2013, the PMRA continued to receive reports of honeybee mortalities from corn and soy growing regions of Ontario, Quebec and Manitoba (see Section 2.4.1 for a summary of honeybee incidents). Overall, of the non-honeybee environmental incidents, the reported effects were minor in nature (97%). These effects were usually plant damage that occurred as a result of the application of a pesticide to lawns or grass.

2.4.1 **Honeybees**

The PMRA conducted an extensive evaluation of the reports of honeybee mortalities that were received in the spring and summer of 2013. Information considered during this evaluation included reports from beekeepers and follow-up investigations conducted by Health Canada, the Ontario Ministry of the Environment, and the Ontario Ministry of Agriculture and Rural Affairs. Factors considered included timing of pesticide application, presence or absence of pesticide residues in the bees, bee colony health and agriculture practices surrounding the bee yards. The PMRA continues to analyze the vast amount of data and information collected, with initial analysis continuing to demonstrate a link between dust generated during the planting of treated corn seed and many of the acute mortalities reported during the spring season.

Additional measures to further reduce bee exposure to neonicotinoid pesticides during the planting of treated corn and soybean seeds were implemented for the 2014 planting season. These measures included the requirement to use a safer dust-reducing seed flow lubricant, safer seed planting practices, new pesticide and seed labels with enhanced warnings and a request for additional information to support the continued need for neonicotinoid treatment on up to 100% of corn and 50% of soybean seed (*Update on Actions to Protect Bees from Exposure to* Neonicotinoid Pesticides, Notice of Intent, NOI2013-01). These new requirements and Best



Management Practices were promoted and communicated to both growers and beekeepers through cooperation among the PMRA and many other stakeholders. These stakeholders include provincial departments, grower groups, pesticide manufacturers, CropLife Canada and the Canadian Seed Trade Association.

The PMRA is continuing to work with stakeholders to develop and implement additional measures to reduce the exposure of bees to dust generated during the planting of treated seeds, including developments in the areas of seed coat quality and modifications to improve planting equipment. Additional information is available in the PMRA document *Pollinator Protection* and Responsible Use of Insecticide Treated Seed – Best Management Practices.

The evaluation of bee mortalities in Canada continues to be a priority for the PMRA.

2.5 **Summary of 2013 Packaging Failure Incident Reports**

There were 59 packaging failure incidents reported to the PMRA in 2013. The most frequently reported packaging type in these incidents was pressurized products, followed by plastic bottles and plastic jugs. One incident also involved a minor human injury. Assessment of the packaging failure incidents did not identify any significant issues to warrant changes at this time.

3.0 **Other Reviews Conducted**

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3.1 Rodenticides – an Update

The PMRA recently required that new safety measures be implemented for rodenticide products. In 2012, following this regulatory change, there was a decrease in rodenticide-related incidents compared with previous years. This 2012 decrease was mainly noted in domestic animal incidents involving second-generation anti-coagulant rodenticides. The rodenticide incident reports received in 2013 continue to be fewer relative to the period prior to the regulatory change, and are similar in number to those reported in 2012.

3.2 **Ontario Poison Centre**

The Ontario Poison Centre (OPC) provides information and advice by telephone to callers concerned about potential or real exposures to poisonous substances. The PMRA obtained pesticide poisoning case data from the OPC in order to help identify any unforeseen health risks related to pesticide use. Any important incident patterns observed in the OPC database were checked against incident data in the PMRA incident reporting database.

A total of 2479 exposures related to pesticide products were logged at the OPC for the years 2010 and 2011. Most calls were about potential pesticide exposures, and did not include any adverse effects. A portion of the pesticide-related calls to the OPC involved adverse effects following a pesticide exposure (33%). Cases involving adverse effects are summarized below.

The majority of the cases involved adults, whereas a quarter of the cases involved children aged 12 years or less. Products that were reported in pesticide-related calls included insecticides used to control flying and crawling insects or fleas and ticks, personal insect repellents or herbicides. Gastrointestinal effects were the most commonly reported type of adverse effect, followed by eye effects, nervous and muscular effects, and skin effects. Less than 1% of exposures resulted in

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serious symptoms. There was one case in which the individual died after intentionally ingesting a product containing paraquat. This case was not in the PMRA database as an incident. See Section 2.2.4 of this report for a summary of the PMRA's evaluation of paraguat incidents.

It was noted that there were more cases involving mothballs, which contain naphthalene, in the OPC data than in the PMRA database. In light of this, the PMRA reached out to all naphthalene registrants to ensure that these companies are aware of their requirement to report incidents to Health Canada.

Generally, the patterns noted in the OPC data were similar to those observed in the PMRA database. Most cases involved pesticides containing pyrethrins, pyrethroids, or N, N-diethyl-mtoluamide (DEET). Incidents involving these active ingredients have previously been evaluated by the PMRA. The OPC data helped to identify one pesticide manufacturer of DEET products that had not been reporting incidents to the PMRA. After being contacted by the PMRA, the company submitted the incident reports and is now compliant with the Pest Control Products Incident Reporting Regulations.

4.0 **Conclusions**

As with previous years, Canadian pesticide incident reports received in 2013 were predominantly minor in nature and involved products that are used by the general public. Most incidents occurred during the application of a product to an animal, or in or around the home.

Pesticide incident reports are used to identify unforeseen health risks to humans, domestic animals or to the environment. Actions may be taken in response to incident data and incident information may be included in regulatory work (for example, ongoing re-evaluations) being done by the PMRA.

Reviews of the 2013 pesticide incident data resulted in several actions being taken by the PMRA. Dermal and ocular injury and the accidental ingestion of paraquat were identified as a potential risk to human health. Mitigation measures are currently being developed to address this risk. Label improvements are being made to address the potential that children and domestic animals could be accidentally exposed to seed treated with fludioxonil. Additionally, initial analysis of 2013 honeybee mortality data confirmed that there was a link between dust generated during the planting of treated corn and some bee mortalities. For all of these situations, the PMRA is continuing to work on developing mitigation strategies to help prevent future incidents from occurring.

Two years of additional pesticide adverse effect data were obtained from the OPC to assess whether the incident report information received by the PMRA reflects the potential risks to Canadians from the use of pesticide products. The majority of incidents in both the OPC and PMRA data involved the same three active ingredients. The PMRA has previously evaluated all incident reports involving these three ingredients. A discrepancy in the number of cases reported to the OPC versus the PMRA prompted the PMRA to conduct targeted education efforts with manufacturers of mothballs to ensure that they knew of the legislated requirement manufacturers have to report such incidents to the PMRA.



The PMRA will continue to collect and analyze pesticide incident reports in order to better inform the risk assessment process for new registrations and re-evaluations by identifying and characterizing potential risk to humans, domestic animals and the environment from the use of pesticides.

5.0 **How to Report Pesticide Incidents**

There are two ways to report pesticide incidents:

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- 1. Contact the pesticide company using the information on the product label. They are required by law to report all incidents related to their products to Health Canada.
- 2. Go to the Report a Pesticide Incident webpage and fill out one of the forms under the section "How do I report a pesticide incident?". If you have any questions about the forms, or need help filling them out, please call Health Canada at 1-800-267-6315 (within Canada) or 1-613-736-3799 (outside of Canada), or send an email to PMRA-incident-ARLA@hc-sc.gc.ca.
- 3. More information is available on the Report a Pesticide Incident webpage.