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Canada

2015 Report of Pesticide Incidents

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Contents

Introduction

Health Canada's Pest Management Regulatory Agency (PMRA) is pleased to present the 2015 Report of Pesticide Incidents, which provides a general overview of the incident reports received in 2015, as well as PMRA's assessment of the more serious Canadian incident reports. These incident reports were received from pesticide registrants and voluntary sources.

The PMRA has been collecting pesticide incident reports since 2007. Between 2007 and 2015, 15,000 incidents were reported to the PMRA. In 2015, the Agency received 2288 incidents. Domestic animal incidents were reported most frequently, followed by human and environment incidents. Most incidents involved minor effects.

About incidents and the incident reporting program

A pesticide incident is any unintended effect on 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 may indicate a new hazard or increased risk.

In accordance with the Pest Control Products Incident Reporting Regulations, Canadian pesticide registrants are required to report to Health Canada's Pest Management Regulatory Agency (PMRA) all incidents that they receive that are associated with their registered Canadian products. In some cases, Canadian registrants are also registrants of a similar product in the United States (US). In these cases, the registrant is also required to report serious incidents that occur in the US with those products (human death, human major and domestic animal death). This subset of US data is used to support the post-market review of pesticides conducted at the PMRA. Medical professionals, other government departments, and members of the public can report either to the registrant or directly to Health Canada by using a form available on the PMRA website (Report a Pesticide Incident).

The PMRA Incident Reporting Program reviews all incidents to ensure that there are no unanticipated effects from the use of registered pesticides. Priority for in-depth reviews is given to incidents that are serious in nature, that involve multiple people or animals, or that indicate a recurring problem. In addition, when the PMRA reviews new active ingredients or conducts re-evaluations of older pesticides, a complete analysis of all incidents involving that pesticide is integrated into the risk assessment.

Potential risks are identified by searching the information provided in incident reports for trends (such as repeated effects or multiple incidents for a particular pesticide), serious effects, and unanticipated effects not currently mitigated through product label statements. This identification is not, by itself, proof of an association between a pesticide and a health or environmental risk, but it triggers the need to further investigate a potential association. The PMRA evaluates the information in conjunction with available scientific information, using a weight-of-evidence approach. That is, many different sources of information, such as available scientific studies and poisoning data, are considered and integrated into assessments of pesticide incident information. Thus, the evaluation of risk is based on extensive data analysis in order to determine whether improved label language or additional mitigation measures should be put in place to further reduce pesticide exposure and prevent adverse effects. Further details on the analysis of incidents can be found in Appendix I.

Monitoring incidents for unanticipated effects or changes in a pesticide's risk profile is an ongoing process within 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.

Overall findings in 2015

The PMRA received 2288 incident reports in 2015. Of the reported incidents, 65% occurred in Canada while the remaining incidents occurred in the United States (serious incidents that registrants must report as part of the Incident Reporting Regulations). The most frequently reported incidents involved domestic animals (78%), followed by humans (13%), the environment (3%), packaging failure (3%), and scientific studies (3%). Most of the incidents that occurred in Canada reported minor effects and involved domestic products that can be purchased by the general public for use on their pets, followed by products used in and around the home. Commercial class products, such as those used in agriculture or applied in urban settings by professional applicators, were also reported in some incidents.

Human Incidents

The PMRA received 291 human incidents in 2015, involving 346 people. Overall, people reported that they were exposed via inhalation or when the product came in contact with their skin. Exposure to domestic class products usually occurred during application of the product or contact with an area that had been treated with the product, while exposure to commercial class products was mainly the result of the product drifting on to adjacent areas during application or contact with a treated area.

Following pesticide exposure, symptoms like coughing, headache, nausea, rash, eye or respiratory irritation were common across all age groups. The more minor symptoms generally lasted less than a day. In most people, the symptoms were observed within 24 hours of exposure.

In approximately two-thirds of cases, it was not known how long the person was exposed to the pesticide; when it was known, exposure usually lasted for less than 15 minutes.

The majority of cases involved adults aged 19 to 64 years of age. For adults, handling insecticides around the home was the most frequently reported exposure. For incidents involving commercial products, insecticides and herbicides were most common. In cases involving children (24 incidents) most exposures occurred when they were in areas where the product was used, either in or outside of the home – in almost all of these cases, the children experienced minor effects such as cough, stuffy nose, or vomiting. In a few cases, children were exposed when they had access to the product container, which resulted in either accidental ingestion or a splash of product into the eye; the reported symptoms were minor and included mostly eye irritation and vomiting.

A small number of serious incidents were reported to the PMRA. Almost all of these incidents occurred in the US and are summarized below.

Review of Serious Human cases

The Incident Reporting Program conducts a thorough review of all serious incidents as they are received to ensure that there are no unanticipated serious effects from the use of registered pesticides. In 2015, the PMRA received 40 serious incident reports. The review of these serious incidents found that in 26 cases, the reported effects were considered unrelated to pesticide exposure.

In the remaining 14 cases, there was some degree of association between the reported symptoms and the exposure to the pesticide. In two fatal cases, individuals accidentally ingested paraquat from unmarked containers; one of these incidents occurred in Canada. The concern of accidental ingestion of paraquat was addressed in a special review - Re-evaluation Note REV2015-14, Special Review Decision: Paraquat [Health Canada, Pest Management Regulatory Agency]. Additional details can also be found in the ‘Follow-up Activities’ section below.

Of the remaining serious cases, 3 individuals in the US died in separate incidents when they entered tarp-covered residential properties that had recently been fumigated with sulfuryl fluoride. The active ingredient sulfuryl fluoride is not registered for use in residences in Canada, and no regulatory action was required. Another individual died in Canada after intentionally ingesting a pesticide. Serious effects were reported in one case each of pesticide spill, contact with a pet collar, and pesticide drift. Finally, there were 5 cases (one of which occurred in Canada), where homes were treated with various insecticides and individuals were exposed during product application activities or after entering treated areas. One of these incidents, which occurred in the US, resulted in serious neurological effects in a child when an agricultural insecticide was used in the home, including on the mattresses. In all of these cases, the strength of the information was not considered sufficient to warrant regulatory action.

Human Incident Trend: *Bacillus Thuringiensis*

In 2015, a cluster of 45 incidents was reported following the aerial application of an insecticide (*Bacillus thuringiensis*) in British Columbia for the control of gypsy moth. The incidents were mostly minor. The most frequently reported symptoms were coughing and nasal congestion. While the incident data indicates that the pesticide may have a mild, irritating effect, the evidence is inconclusive. For example, it was often difficult to determine definitively whether exposure had occurred, or by how much. However, the reports did highlight residents' concerns regarding aerial applications. Following these incidents, the BC government began work on improved communication plans to ensure that information about future spray programs are better disseminated to residents. This plan should help to address residents' concerns regarding notification and unintentional exposure. No further action is proposed by the PMRA at this time.

Domestic Animal Incidents

The PMRA received 1789 domestic animal incident reports in 2015, and more than half of these reported minor or moderate effects. For those incidents classified as death, almost all occurred in the US.

Most incidents involved products that are applied as a spot on a dog's or cat's back to control fleas and ticks. Spot-on incidents commonly included symptoms such as pruritus, abnormal behaviour, or lethargy.

Other types of flea and tick control products, such as collars and shampoos, were also frequently reported in animal incidents. There was a five-fold increase in reported incidents involving flea and tick collars in 2015 when compared to 2014. This marked increase was because of the receipt of incidents occurred in the United States and involved a flea collar containing the active ingredients flumethrin and imidacloprid. No similar product is registered in Canada for pets. There was no increase in incidents for any Canadian registered flea control collars.

In the remaining incidents, rodenticides, herbicides and insecticides were often ingested by farm animals such as horses, cows, or poultry. In all of these incidents, the typical symptoms included gastrointestinal effects such as vomiting or anorexia, as well as more general symptoms such as lethargy.

Domestic Animal Incident Trend: Spot-on Flea and Tick Control Products

Historically there have been a significant number of incidents with the use of flea and tick control products on companion animals, particularly spot-on products. Label amendments implemented in 2011 to warn users of the consequences of using dog products that contain permethrin on cats resulted in a 46% decrease in this type of mis-use.

Although there has been a decrease in the misuse of permethrin products, incidents related to spot-on flea and tick products are still frequently reported and continue to be of concern. In 2015, approximately 900 Canadian incidents were reported. Adverse reactions include effects such as skin irritation to more serious effects such as seizures. Overall, 58% of animals experienced minor effects which resolve rapidly; 35% experienced effects which generally require medical treatment; 5% of animals experienced life-threatening effects; and 2% of the animals died.

Given the number of incidents and nature of the reports received, an in-depth review was again conducted in 2014-2016. Based on the results of this review, the Agency is considering a proposal to develop mitigation options with the aim of decreasing the number of incidents that occur with spot-on products.

Environmental Incidents

In 2015, almost all environmental incidents occurred as a result of herbicide application. Herbaceous plant damage, with effects to lawn or grass in particular, was most common. There were also some incidents involving fish, birds and honey bees.

In two of the environment incidents, significant effects were reported. In one incident, drift and runoff of a dicamba product resulted in plant damage and the loss of 50 acres of soybeans planted nearby. Failure to follow label instructions (nozzle was not recommended size and application made within hours of a predicted rainfall) contributed to these adverse effects. The incident was sent to the PMRA's Compliance, Laboratory Services and Regional Operations Directorate. In the other incident, the accidental spill of 50L of glyphosate (diluted in 2100L water) from an agricultural sprayer resulted in the death of approximately 100 fish (Pike, Catfish, Chub, minnow) in a creek. In this case, the registrant provided assistance to the provincial ministry to ensure proper cleanup.

The number of bee incidents reported to the PMRA in 2015 has decreased relative to reports from 2012-2014. Investigation into bee mortality incidents is ongoing. The PMRA has worked in collaboration with Health Canada's Regulatory Operations and Regions Branch (RORB) and the provinces as part of the investigation. More details on the progress of the investigations can be found in the "Follow-up Activities" section below.

Packing Failure Incident Reports

Both packaging failure incidents and scientific studies made up a small percentage of the incident reports received in 2015 (3% each).

Packaging failure incidents most frequently occurred with either storage or use of the product. Pressurized containers were the packaging type that failed most frequently. In five cases, this resulted in human exposure to the pesticide and minor skin or eye effects. Assessment of the packaging failure incidents did not identify any significant issues. These incidents occurred with a variety of products, and no one particular product stood out that would require mitigation on the part of the registrant or the PMRA.

Scientific Study Incident Reports

Scientific study incident reports are received when new studies sponsored by the registrant indicate that there may be an increased risk or new hazard compared to what was known at the time of registration. As with all other incidents, these are triaged as they are received, and reviewed. In addition, relevant studies are integrated into the re-evaluation of older pesticides or in the review of a new use for a registered pesticide.

Actions Taken by PMRA

When the PMRA reviews new active ingredients or conducts re-evaluations of older pesticides, a complete analysis of all incidents involving that pesticide is integrated into the risk assessment. In doing so, the Agency can determine whether improved label language or additional mitigation measures should be put in place to further avoid pesticide exposure and prevent adverse effects.

Beta-Cyfluthrin and Cyfluthrin

A review of all incidents containing cyfluthrin or beta-cyfluthrin was conducted for support of the registration of two commercial class products containing beta-cyfluthrin, and for the re-evaluation of cyfluthrin. The review of data in the PMRA and US databases highlighted the potential for respiratory effects in individuals re-entering homes or workplaces up to 24 hours after the product had been applied. Given the concern that similar incidents could occur in Canada with the proposed new products containing beta-cyfluthrin, as well as currently registered products containing cyfluthrin, a number of mitigation measures were included in the respective proposed regulatory decision documents for consultation: increasing the re-entry interval; listing potential adverse effects on the product label (as per other pyrethroid products); and requiring an information sheet be left at points of entry or with the occupants of each treated home/structure, so that people are aware of the re-entry interval, the need to ventilate, and what to do if they experience adverse effects (since commercial applicators may not always interact with occupants). These same measures have been proposed for the product Tempo 20WP as part of the re-evaluation of cyfluthrin.

Further details regarding this mitigation measure can be found on the Health Canada website Beta-Cyfluthrin - Proposed Registration Decision PRD2016-21 - Health Canada Consultation Notice and Proposed Re-evaluation Decision PRVD2016-17, Cyfluthrin - Health Canada Consultation Notice. Both documents are subject to public consultation and comments received will be considered prior to making a final decision.

Boron
A review of boron incidents was conducted as part of a re-evaluation. Domestic animals experienced adverse effects after ingesting boron products that had been placed in or around the home. Minor symptoms such as vomiting were most frequently reported. Updated label statements regarding the placement of boron products in and around the home were required as a result of this review. Further details regarding this mitigation measure can be found on the Health Canada website (Re-evaluation Decision RVD2016-01, Boric Acid and its Salts (Boron))

Fludioxonil
A review of human incidents was conducted in support of the re-evaluation of fludioxonil. Most incidents involved individuals handling seeds that had been treated with a product containing fludioxonil, with effects such as itchy skin and rash frequently reported. There were also incidents involving children, which occurred as a result of contact with treated seeds or seed dust. It was recommended in the proposed re-evaluation decision document that the product label be modified to include a requirement that tags for all bags of fludioxonil-treated seed intended for sale or use in Canada have the statement: "Keep out of reach of children and animals". (Fludioxonil - Proposed Re-evaluation Decision PRVD2016-03 - Health Canada Consultation Notice).

Abamectin
Incident reporting information was incorporated into the evaluation of a submission proposing a new product size for ant bait products containing abamectin. In the incidents reviewed, domestic animals generally ingested, or were suspected to have ingested, an abamectin product. Most were domestic class products that had been placed inside or outside the home. As a result, a statement was added to the new product labels warning users to keep the products out of reach of pets.

Follow-Up Activities

In some instances, Compliance and Enforcement staff follow up on issues identified by the Incident Reporting Program – for example, when there is an indication that a violation took place or targeted oversight is required. In 2016, this group conducted inspections of vendors to ensure that registrants were compliant with mitigation proposed for the 2016 growing season for two active ingredients: paraquat and diquat. In addition, notices of violation and a monetary penalty were filed against NOD Apiary Products Ltd. for failing to provide information concerning bee incidents. Finally, the Regulatory Operations and Regions Branch in conjunction with Provincial Authorities continued to track and investigate bee mortality incidents.

PARAQUAT

The review of incidents associated with the accidental ingestion of paraquat was part of a Special Review that brought about significant amendments to the registration of the product. Mitigation was required to be in place by April 1, 2016 and included additional warnings regarding acute

oral, dermal, and eye hazards; toxicological information related to the seriousness of health effects; and revised first aid and treatment advice. As well, the registrant was required to implement a stewardship/outreach program for applicators and vendors, which included education on changes to the product, and information cards to distribute to users. Finally, the product Gramoxone was to be reclassified as Restricted. For more details on the special review decision, please refer to Re-evaluation Note REV2015-14, Special Review Decision: Paraquat [Health Canada, Pest Management Regulatory Agency].

To comply with the additional mitigation that was required by April, 2016, the registrant ensured that new production stock had revised label statements. For stock already in the supply chain, the registrant contacted distributors and vendors across the country to identify the location and volume of inventory. Because the hazards of paraquat are so serious, the registrant recalled this existing stock and had it transported to centralized locations to affix stickers and new labels, and place information cards into cases and totes. Customers, retailers, and account managers were all updated on these changes. The Canadian Horticultural Council was also updated so that they could communicate the changes to their members. Additionally, both the company website and the emergency contact line for paraquat poisonings were updated with the new hazard warnings, toxicological information, and treatment advice. Health Canada inspected 37 vendors nationally to monitor compliance.

Overall, the work done by the registrant to communicate the new label changes was extensive. For stock already in the supply chain, Health Canada identified issues at 10 of the retail outlets inspected. These included vendors with old product in stock that lacked stickers or new labels, vendors not informed of why label changes were occurring, and outreach materials not made available to vendors for distribution. In these cases, the PMRA worked with the registrant to address the issues.

The inspection process did serve to highlight some of the difficulties that arise when mitigation is required in a short time frame. Lessons learned were discussed with the registrant; one of the biggest challenges appeared to be ensuring that all products in the supply chain carry the most up-to-date product label. The registrant met with PMRA to discuss these challenges and lessons learned, and discussed improvements for future scenarios.

DIQUAT

The review of diquat incidents also required that labels of all products be modified by April 1, 2016 to improve clarity regarding the potential seriousness of ocular or dermal contact, the potential for delayed onset of symptoms, as well as the addition of a statement that oxygen supplementation is contraindicated unless the patient develops severe hypoxemia. Because of the volume of diquat in the marketplace, and because the hazards were not as serious as those of paraquat, the registrants communicated the required changes to all known retailers and vendors of diquat. Stewardship leaflets and stickers were couriered to all retail and channel partners across the country with instructions and electronic copies of the new label. Management of the large volume of diquat in the marketplace did take time. Health Canada inspected 58 vendors across the country, and, in approximately half of these inspections, at least one issue was

identified. Problems included product with old labels on site, vendors not informed of label changes, and outreach materials not made available for distribution. As with paraquat, the PMRA worked with the registrants to address the issues. Again, the inspections highlighted the challenges faced when mitigation must be implemented in a short time frame. The registrant met with PMRA to discuss these challenges and lessons learned, and discussed improvements. For more details on the review of diquat incidents, refer to the Report on Pesticide Incidents for 2014.

Honeybee Incidents

Over the past few years, there have been a significant number of reports of bee mortality as well as considerable challenges in maintaining healthy bee colonies both in Canada and abroad. Health Canada's PMRA, in collaboration with Health Canada's Regulatory Operations and Regions Branch (RORB) and the provinces, conducted detailed inspections of the bee mortality incidents reported in 2012, 2013 and 2014. Analysis of the data in 2012 and 2013 suggested that exposure to neonicotinoids in dust generated during the planting of treated corn or soybean seed with vacuum planters contributed to the mortalities observed. Before the 2014 planting season began, the PMRA, in collaboration with many stakeholders, worked to help ensure risk mitigation measures were communicated to growers across Canada and that a dust-reducing lubricant was readily available. This outreach campaign was successful. The number and severity of incidents reported in 2014 during planting were lower, with a 70% reduction in incidents during planting in 2014 compared to 2013.

Health Canada’s PMRA and RORB continued to track and investigate bee mortality incidents with the support of the appropriate provincial ministry. In 2015, with mitigation measures still in place and more typical planting weather, the number of reported incidents during the planting period decreased further, with the number of incidents reported being ~80% less than in 2013. (Update on Bee Incident Reports 2012-2016).

Conclusions

The majority of Canadian pesticide incident reports received in 2015 were minor in nature. Most incidents involved products that can be used by the general public, although some serious incidents were associated with products that are commercial or restricted class only (i.e., not for use by the general public). As with previous years, most incidents occurred during the application of a pesticide product to an animal, or in or around the home.

Pesticide incident reports are used to identify unforeseen risks to humans, domestic animals or the environment. Such risks are sometimes identified from a single incident report, but are more often identified during the evaluation of a group of incidents. Some risks may require significant mitigation, while others may require minor changes to a product registration. In 2015, there were several measures taken by the PMRA as a consequence of evaluations of pesticide incident data. In particular, the PMRA worked with paraquat and diquat registrants to help them develop a

stewardship/outreach program within a short time period, and also developed an outreach strategy for occupants of buildings where beta-cyfluthrin or cyfluthrin are sprayed, so that they can then take steps to minimize their exposure and avoid adverse effects.

Incident reports are an essential element of post-market monitoring. Under the Incident Reporting Regulations, the PMRA will continue to collect and analyse incident report information to identify and characterize potential risk to humans, domestic animals, and the environment from the use of pesticides.

How to Report Pesticide Incidents

There are two ways to report pesticide incidents:

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 http://www.healthcanada.gc.ca/pesticideincident and fill out one of the forms under the section called "How to 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.

More information is available at: www.healthcanada.gc.ca/pesticideincident.

Appendix I How Incident Reports are Evaluated

Pesticide incidents are prioritized for evaluation, with a focus placed on reports of serious effects or signals that indicate a possible risk. A signal is indicated when similar incidents occur repeatedly, such as a high number of incidents occurring with the same product.

Evaluations vary greatly in scope, depending on the amount of information that is available and the complexity of the issue. The information provided in pesticide incident reports is unsubstantiated and often incomplete. Many effects reported in pesticide incidents may be caused by non-pesticide related factors. Furthermore, the reporting of a particular effect does not necessarily mean that it was caused by the pesticide. These limitations in the data must be taken into account when incidents are being published and evaluated.

The objective of an incident evaluation is to determine if there is a possible risk to health or the environment. The first step in the evaluation is to determine if the pesticide product caused the reported effect. This is known as the causality level (see Appendix II for definitions), and is assessed based on information such as biological plausibility or the amount of exposure. Several questions are asked when determining the level of causality. How likely is it that exposure to the pesticide occurred? Are the symptoms consistent with the toxicology data and available poisoning data? Are there multiple incidents with the same or similar effects? Also considered is whether there was any physical evidence of exposure (such as blood tests), and whether the timing of the effects was consistent with the reported exposure. The level of causality, therefore, depends on the amount of supporting information that is available; generally, the more information provided in the incident, the more definitive the causality level.

A weight of evidence approach is used to evaluate pesticide incident data. That is, many different sources of information, such as available scientific studies and poisoning data, are considered and integrated into assessments of pesticide incident information. Thus, the evaluation of risk is based on extensive data and also takes into consideration the opinions of in-house experts.

If a risk from the use of a pesticide is identified, the next step involves determining whether mitigation is required. Considerations include whether the incident was related to the use of the product (versus a spill, for example), the possibility of the event re-occurring, and whether the risk can be mitigated. If warranted, mitigation is developed and implemented, and could include such actions as amending the pesticide product label or focusing outreach on a particular issue.

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.

Appendix II Definitions for the Levels of Causality

Insufficient Information: Information regarding the reported exposure or effect is lacking or conflicting such that a determination as to whether the effects were related to a pesticide exposure cannot be made.

Unrelated: Evidence demonstrates the effect was caused by factors other than the pesticide, or the effect occurred before exposure to the pesticide.

Unlikely: The likelihood that exposure to the pesticide occurred is low or the effect reported is not typical for the pesticide; however, the possibility that exposure to the pesticide caused the effect cannot be completely ruled out.

Criteria: low likelihood of exposure

OR

some likelihood of exposure *AND* low degree of plausibility

Possible: Information may be ambiguous, although there is some correlation between the pesticide and the effect. The pesticide could have caused the effect, but there are other explanations that are at least as plausible.

Criteria: some likelihood of exposure *AND* some degree of plausibility

Probable or higher*: The circumstances of the incident and properties of the pesticide or history of previous incidents give strong support that this pesticide was the cause.

Criteria: some likelihood of exposure *AND* high degree of plausibility

NOTE: It is not necessary to characterize the causality level beyond 'probable' for risk characterization purposes. Further optional classification:

Highly probable: The incident meets the criteria for a causality level of 'Probable' and there is confirmatory evidence, such as residue analysis or medical testing, indicating that exposure to the pesticide definitely occurred.

Criteria: confirmation of exposure AND high degree of plausibility