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Report on Pesticide Incidents for 2016

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Contents

Executive Summary

Health Canada's Pest Management Regulatory Agency (PMRA) is pleased to present the 2016 Report of Pesticide Incidents for 2016, which provides a general overview of the incident reports received in 2016, as well as the 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 2016, almost 18,000 incidents were reported to the PMRA. In 2016, the Agency received 2724 incident reports. Domestic animal incidents were reported most frequently, followed by human and environmental incidents. Most incidents involved minor effects.

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. 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 analysis in order to determine whether improved label language or additional mitigation measures is warranted to further reduce pesticide exposure and reduce the occurrence adverse effects.

The Incident Reporting Program's review of incidents related to flea and tick spot-on products has led to the PMRA's development of options to mitigate incidents occurring in dogs and cats with these products. This mitigation includes listing adverse effects on product labels to inform consumers, as well as the proposal of additional data requirements to better predict potential effects that may occur with the use of spot-on products; this proposal will be subject to public consultation in 2018.

The PMRA proposed several risk reduction measures as a result of evaluations of incident report data in 2016. Most notably, certain product labels were modified (for example, deltamethrin), or are proposed to be modified (for example, dichlorvos) to clarify warnings for users. The proposal to modify labels of domestic class products containing dichlorvos to warn users that the products could not be used in any areas occupied by people was published in PRVD2017-16, and the label of a new deltamethrin-containing product was amended to reduce the potential of pets being accidentally exposed during and following the use of the product.

Follow-up activities also took place in 2016 to ensure ongoing compliance by the registrants with the mitigation requirements implemented by the PMRA, following the review of pesticide incidents. These included inspections following the implementation of risk mitigation measures from the special review of paraquat. As well, inspections were conducted to confirm adherence with the required label amendments for products containing the active ingredient diquat.

The PMRA worked collaboratively with the registrant of beta-cyfluthrin and cyfluthrin products in order to ensure that an information sheet for occupants of treated areas was made available by the pest control operators. The PMRA also provided input to registrants in their development of an appropriate stewardship program to require that all distributors of beta-cyfluthrin and cyfluthrin products be educated on product use, including safe handling, application and post-treatment requirements.

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 risks to humans, domestic animals, and the environment from the use of pesticides.

Introduction

This document summarizes the pesticide incident reports that were received in 2016 by Health Canada's Pest Management Regulatory Agency (PMRA). These incident reports were received from pesticide registrants and voluntary sources. The PMRA's assessment of the more serious Canadian incident reports are discussed, as are summaries of additional steps that the PMRA took to reduce potential health risks to Canadians and/or the environment.

The PMRA has been collecting pesticide incident reports since 2007. Between 2007 and 2016, 17 757 incidents have been reported to the PMRA. In 2016, the Agency received 2724 reports.

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. 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, coughing). 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, seizure). 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. A pesticide incident may also be a packaging failure, excessive residues in food, or a scientific study that indicates a new hazard or increased risk that may be greater than

the risk determined at the time of registration. Effects do not need to be substantiated in order for them to be reported to the PMRA.

In accordance with the Pest Control Products Incident Reporting Regulations, Canadian pesticide registrants are required to report to the PMRA all incidents that they receive that are associated with their registered Canadian products. In some cases, Canadian registrants are also registrants of similar products 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 (i.e., 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, as well as any new active ingredient proposed for Canadian registration, when applicable. Medical professionals, other government departments, and members of the public can contact the registrant to report an incident, or they can report directly to Health Canada by using a form available on Canada.ca (Report a Pesticide Incident).

The PMRA uses incident report data to identify hazards and characterize potential risks to humans, domestic animals and the environment from the use of 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 incident data 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 scientific 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 reduce the 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 2016

The PMRA received 2724 pesticide incidents in 2016. The majority of these were domestic animal incidents (84%), followed by human incidents (9%), environment (3%), and packaging failure and scientific study incident reports (2% each). Most incidents were minor in nature, and involved domestic class products that can be purchased by the 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/residential settings by professional applicators, were also reported in some incidents, and these incidents also resulted in mostly minor effects.

Human Incidents

In 2016, 257 human incident reports were submitted to the PMRA, in which 281 people were affected. Generally, exposure occurred to products that had been used in or around the home by an occupant. These exposures usually occurred during application of the product or through contact with an area that had been treated with the product. When exposures to commercial class products occurred, they were mainly the result of the product drifting onto adjacent areas during application or through contact with a treated area. People were most often exposed to products via inhalation or when the product came into contact with their skin. The length of exposure was most often unknown, but when reported usually lasted for less than 15 minutes.

Most people experienced minor effects, such as throat or eye irritation, nausea, or tingling skin. The length of time that the symptoms lasted was usually unknown (86%), but when known, most people had symptoms that lasted for less than 24 hours. Symptoms were most frequently observed within 24 hours of exposure.

Adults were most frequently involved in human incidents; 70% of individuals involved in incidents that had an age recorded were older than 19 years of age. There were 27 cases involving individuals younger than 19 years old. Most of these children and adolescents experienced minor symptoms after being exposed to areas that had been treated with a pesticide product, although three cases of accidental ingestion and two cases involving direct application of insect repellants were also reported. Dermal, oral, and respiratory exposures were most frequently reported. Skin, gastrointestinal, and eye symptoms were common.

Overall, a small number of serious incidents (classified as major or death) were reported to the PMRA in 2016; two of these cases occurred in Canada, while the remaining 89 occurred in the US (including three cases in which a child experienced serious symptoms). These are described more fully below.

Review of Serious Human Cases

The Incident Reporting Program conducts an in-depth review of all serious incidents as they are received to ensure that there are no unanticipated serious effects from the use of the implicated registered pesticides. In 2016, the PMRA received 91 serious incident reports involving humans (two human death that occurred in the US, and 89 human major). Three incidents that had been

reported as major were reclassified by the PMRA as moderate (two incidents) or minor (one incident). There were another two incidents that were reported to the PMRA as moderate in severity that were reclassified as major. Therefore, the summary below includes the 90 serious human incidents that the PMRA evaluated in 2016.

The review of eight incidents classified as major (2 Canadian incidents and 6 US incidents) found that there was some degree of association between the reported symptoms and the exposure to the pesticide. Two of the US cases involved a child. In one case, a baby had seizures after entering a home that had been treated with a pyrethrin product by a commercial applicator three days prior. This incident was incorporated into the ongoing risk assessment for pyrethrins, which are currently under re-evaluation. In the second case, a child accidentally ingested a small quantity of an insecticide containing bifenthrin. The child had stomach pain, muscle tremors and tingling in legs, was admitted to hospital, and when the signs worsened, was sedated, intubated, and placed on a ventilator. The symptoms gradually diminished and the child was discharged seven days later. Since the only registered Canadian product containing bifenthrin must be stored under lock and key, it was determined that the circumstances of the incident were already addressed in the Canadian context. The six serious incident in adults involved different products with different active ingredients. Two of these cases occurred in Canada. In the first incident, a man was repairing a sprayer when it malfunctioned, resulting in dermal and respiratory exposure to glufosinate ammonium. He experienced delirium and a blood disorder, and was hospitalized for 10 days. This case was the result of an unfortunate accident, and so no regulatory action was proposed. In the second Canadian incident, a woman re-entered a home treated with cyfluthrin and developed wheezing and respiratory irritation, aggravating her pre-existing chronic obstructive pulmonary disease. She was treated in hospital for 6 days. Mitigation has been proposed for products containing cyfluthrin (see ‘Actions Taken by PMRA’ below). In the remaining cases that occurred in the US the exposure occurred during product use; symptoms were different for each individual, but included effects such as respiratory distress, convulsion, and skin burns. In these cases, although it was considered possible that the effects were caused by exposure to the pesticide, there was no clear evidence of a trend or exposure pattern for these products that would warrant any regulatory action.

In 14 incidents, the reported effects were considered unrelated to pesticide exposure, or there was too little information supplied with which to review the incident. In addition to these cases, a cluster of 68 serious incidents were submitted to the PMRA following the initiation of several class action lawsuits involving glyphosate in the United States. The complainants alleged that they had developed cancer because of their exposure to glyphosate. In most of these incidents, there was little to no detail provided in the report, and as such there was insufficient information to assess the incidents.

The PMRA also reviews all incidents where multiple people or a cluster of people in nearby areas are affected following a single pesticide event. In 2016, two such incidents involved multiple people. In the first incident, seven people were working outside when a crop-dusting plane sprayed the nearby area with a fungicide. They all reported a chemical smell and taste in their mouths, and one developed chest tightness. In the second incident, six people were exposed when an aerial application of an insecticide was made to an adjacent property. Symptoms

included malaise, respiratory irritation, and headaches. The degree of exposure due to spray drift from an application conducted nearby is dependent on environmental conditions such as wind speed, wind direction, as well as the distance of the individuals from the application site and how long they remained at their location. This level of detail was not available in these incident reports, and so although the minor signs reported are possible following exposure, there was not sufficient information available to warrant any regulatory action.

Domestic Animal Incidents

The PMRA received 2297 domestic animal incident reports in 2016. Three-quarters of the domestic animal incident reports were minor or moderate in severity. Of the 453 incidents classified as death, 437 occurred in the United States.

Most incidents involved 'spot-on' products that are applied to a dog's or cat's back to control fleas and ticks. The volume of incidents associated with spot-on products has been consistently high despite the implementation of spot-on product label amendments in 2011. This has resulted in a further evaluation of the spot-on incident data, the preliminary results of which are discussed below, which includes ongoing communication with experts in the field.

Other types of flea and tick control products, such as collars and shampoos, were also reported in animal incidents. There was no increase in incidents for any Canadian-registered flea control collars when compared to previous reporting years.

In the remaining incidents, animals such as dogs, cats, sheep, or cows often ingested rodenticides, insecticides, and herbicides. In all of these incidents, the typical signs included gastrointestinal effects such as vomiting and anorexia, itchy skin and hair loss, or neurological signs like tremors, as well as general signs such as lethargy.

Domestic Animal Incident Trend: Spot-On Flea and Tick Control Products
Historically, there have been a significant number of incidents reported to the PMRA 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 hazards of using dog products that contain permethrin on cats resulted in a 46% decrease in this type of misuse. 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 2016, approximately 1600 Canadian incidents of this type were reported. This was an increase from previous years, for which the average was less than 1000 incidents per year. The increase was primarily due a spot-on product containing imidacloprid, permethrin, and pyriproxyfen. Overall, adverse reactions included effects such as skin irritation, abnormal behaviour, and lethargy, as well as more serious effects such as ataxia and seizures. Animals experienced mostly minor effects which resolved rapidly (67%), 31% experienced effects which generally required medical treatment, 1% of animals experienced life-threatening effects, and just under 1% of the animals died.

Given the number of incidents and nature of the reports received, an in-depth review was conducted. The Incident Reporting Program's review of incidents related to flea and tick spot-on products has led to the PMRA's development of options to mitigate incidents occurring in dogs and cats with these products. The PMRA sought input from key stakeholders, including the Canadian Veterinary Medical Association, in order to finalize these mitigation options. The proposed mitigation includes the listing of adverse effects on product labels in order to inform consumers, as well as the proposal of additional data requirements to better predict potential effects that may occur with the use of spot-on products; this proposal will be subject to public consultation in 2018.

Environmental Incidents

There were 67 environmental incident reports (excluding the honey bee incidents discussed below) submitted to the PMRA in 2016, mostly reporting minor effects. The majority of environmental incidents occurred following the application of herbicides resulting in damage to grass or lawn.

One major incident and one moderate incident were received. Both incidents, plus an additional minor incident, involved the runoff of a product containing chlorothalonil, which resulted in fish mortality. It was considered highly probable that all three of these incidents were caused by exposure to chlorothalonil. Based on the review of these incidents as well as scientific studies received through the Incident Reporting Program, it was determined that the criteria outlined in subsection 17(1) of the *Pest Control Products Act* were met and that a Special Review was required. The aspects of concern for the special review related to the environmental fate and ecotoxicological assessment (Re-evaluation Decision RVD2018-11, *Chlorothalonil and Its Associated End-use Products for Agricultural and Turf Uses*).

Honeybee Incidents

Since 2012, 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 other jurisdictions. The 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, 2014 and 2015. 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 numbers of incidents reported in 2014 during planting were lower, with a 70% reduction in incidents during planting in 2014 compared to 2013.

The PMRA and RORB continued to track and investigate bee mortality incidents with the support of the appropriate provincial ministry. In 2016, with mitigation measures still in place, the numbers of reported incidents during the planting period were ~75% less than in 2013.

Further information on the reported incidents between 2012 and 2016 can be found in the PMRA document entitled Update on Bee Incident Reports 2012-2016.

Packaging Failure Incident Reports

In 2016, 55 incidents involving packaging failure were reported to the PMRA. Packaging failure incidents most frequently occurred during storage or use of the product. In most of these incidents, the product was packaged in a pressurized container. In one incident, minor skin and gastrointestinal effects were reported in a person following exposure to the pesticide from a leaking container. These incidents occurred with a variety of products, and no particular product or active ingredient was implicated. Assessment of the packaging failure incidents did not identify the need for any further mitigation measures.

Scientific Study Incident Reports

Fifty-three scientific studies were received in 2016. Scientific study incident reports are received when new studies sponsored by the registrant indicate that there may be new hazard or an increased risk compared to what was known at the time of registration. As with all other incidents, these reports are triaged as they are received, if the triage indicates that the study could change the current risk assessment or acceptability of the product, then a full review of the study is conducted. If the review indicates that there is no change in the risk assessment, then the study can be incorporated into the next re-evaluation of that active ingredient. In some cases a new risk is identified, and these studies result in action by the PMRA, as exemplified with studies involving the active ingredient chlorothalonil. Following the review of these studies, as well environmental incidents with chlorothalonil, it was determined that the criteria outlined in subsection 17(1) of the *Pest Control Products Act* were met and that a Special Review was required. The aspects of concern for the special review related to the environmental fate and ecotoxicological assessment (RVD2018-11).

In addition, relevant studies are integrated into the re-evaluation of older pesticides, and into the review of a new use for a registered pesticide.

Actions Taken by PMRA

During the PMRA review of new products or the re-evaluation of older pesticides, a complete analysis of all incidents involving that pesticide is integrated into the risk assessment. In doing so, the PMRA can determine whether improved label language or additional mitigation measures are warranted to further reduce pesticide exposure and prevent adverse effects.

Deltamethrin

Incident reporting information was evaluated during the review of an application for a new end-use product containing deltamethrin to control adult mosquitoes in residential and recreational areas. In the incidents reviewed involving deltamethrin, domestic animals were frequently exposed to commercial class products applied either as spot treatments inside the home or

perimeter sprays outside of the home for insect control. Based on these residential exposures, the end-use product label was modified in order to help reduce the potential for pets to be accidentally exposed during and following the use of the product.

Dichlorvos
In support of the dichlorvos re-evaluation, all incidents involving this pesticide were reviewed. Eighteen human incident reports were identified that involved dichlorvos-impregnated pest strips used to control flies and mosquitos in homes and farms. All incidents were minor or moderate in severity. Although the 'Directions for Use' section of the product labels indicated that the product was to be used in unoccupied areas only, the subjects were exposed when the strips were used in occupied areas of the home or work. Based on the incident data, it was proposed that the allowed areas of use, including the restriction to unoccupied structures only, appear on the primary panel of the product labels. For further details see PRVD2017-16, Dichlorvos and Its Associated End-use Products

Beta-cyfluthrin and Cyfluthrin
In 2015, a review of all incidents involving beta-cyfluthrin (and its related active ingredient cyfluthrin) was conducted to support the registration of two commercial class products containing beta-cyfluthrin, and for the re-evaluation of cyfluthrin. Based on this review, several mitigation measures were implemented for products containing beta-cyfluthrin, some of which involved modification of the product labels. Another measure was the requirement of an information sheet to 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). (Refer to Consultation on Beta-Cyfluthrin, Proposed Registration Decision PRD2016-21 and Registration Decision RD2017-01, Beta-cyfluthrin. While the final re-evaluation decision is pending for the active ingredient cyfluthrin, the Registrant is aware that the same mitigation measures are required for products containing cyfluthrin with the same use pattern as beta-cyfluthrin.

The registrant of the beta-cyfluthrin products also submitted a stewardship plan to the PMRA for review. The PMRA worked with the registrant to finalize the stewardship plan, which requires that an information sheet is made available to occupants of treated areas by pest control operators when using beta-cyfluthrin. In addition, the plan requires the education of all distributors of the products by the registrant on the product use (including safe handling, application and post-treatment requirements).

Follow-Up Activities based on Incident Reviews

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 required for the 2016 growing season for two active ingredients: paraquat and diquat.

Conclusions

In 2016, the Agency received 2724 incident reports. Domestic animal incidents were reported most frequently, followed by human and environmental incidents. The majority of Canadian incidents were minor in nature, and involved domestic class products that can be purchased by the general public. Commercial class products, such as those used in agriculture or applied in urban/residential settings by professional applicators, were also reported in some incidents. As in previous years, most incidents occurred from 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. A weight-of-evidence approach is used to evaluate pesticide incident data. The PMRA proposed several label improvements and risk reduction measures because of evaluations of incident report data in 2016. For example, some product labels were modified to clarify warnings for users. No risks were identified from a single incident report, however, during the evaluation of a group of incidents, several risks were identified. The review of environmental incidents, in combination with scientific study incidents, resulted in the initiation of a Special Review of one active ingredient. And most notably, the review of incidents related to spot-on flea and tick control products has led to the PMRA's development of options (with input from key stakeholders including the Canadian Veterinary Medical Association) to mitigate incidents occurring in dogs and cats with these products. The proposed mitigation includes the listing of adverse effects on product labels in order to inform consumers, as well as the proposal of additional data requirements to better predict potential effects that may occur with the use of spot-on products.

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 hc.pmra.incident-arla.sc@canada.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