First Annual Report of the Pesticide Incident Reporting Program

April 26, 2007 to April 25, 2008

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Health Canada

Canada

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Health Canada's Pest Management Regulatory Agency (PMRA) collects incident reporting data under the authority of the *Pest Control Products Act*. If a pesticide manufacturer receives information about an incident involving one of their products, they are required by law to submit that information to the PMRA. All submitted incident reports are made publicly available on the Health Canada website, specifically, on the PMRA Public Registry. It is important to note that the information presented in an incident report reflects the observations and opinions of the person reporting it, and does not include any assessment or validation by Health Canada, nor does it confirm an association between the pesticide and the effects reported.

This document provides a general overview of the incident reports received during the first year of operation of the Incident Reporting Program, as well as PMRA's assessment of the more serious Canadian incident reports. These incident reports were received between April 26, 2007 to April 25, 2008 from pesticide manufacturers and voluntary sources.

Executive Summary

Pesticides are tested and evaluated for safety of use before they are registered. However, some adverse effects may not become evident until the product is used under "real-life" circumstances. The purpose of the Pesticide Incident Reporting Program is to consider the information reported and determine if there are potential health or environmental risks associated with use of the pesticide and, if necessary, recommend regulatory action such as improvements to the registration process, improvements to product label information, and/or additional precautions to be taken when using a pesticide.

A total of 934 incident reports were submitted to the PMRA in the first year. Of these, 61% occurred in Canada, while 39% occurred in the United States. It is important to note that the low number of American incidents reported is due to the fact that pesticide manufacturers are only required to report a subset of American incidents to the PMRA, specifically: only incidents that are classified as human death, human major and domestic animal death (see Section 1 for definitions), and only if the pesticide is associated with a Canadian pesticide (that is, the same active ingredient). The number of American incidents reported to the PMRA does not reflect the total number of incidents that occur in the United States annually.

Incident reports are classified into six categories: human, domestic animal, environment, food residue, packaging failure and scientific study. One incident report may include multiple categories (for example, a packaging failure and a human effect). Domestic animal was the most common category of incident reported with a total of 539 incidents (257 Canadian and 281 American), followed by 266 reports for human health, the majority of which were minor (skin irritation, nausea, headache) (191 Canadian and 75 American). Of the remaining incidents reported, there were 85 environment incidents (the majority related to lawn damage), 36 packaging failures, 13 scientific studies, and 1 food residue incident. The majority of incidents involved Domestic Class products, while only 73 incidents involved Commercial Class products.

As previously stated, the purpose of collecting incident reports is to determine if there are potential health or environmental risks associated with use of a pesticide post-market and, if so, to take action to reduce those risks. To identify potential risks, the more serious Canadian incidents (human death, human major, environment major, environment moderate; see Section 1 for definitions) are evaluated individually to determine if there is a causal relationship between the pesticide and the effect, as well as the strength of that relationship. If it is determined that there is link between the pesticide and the effect, the potential risk from use of that pesticide is further evaluated and, if necessary, action is taken to mitigate those risks. Additional scientific data and/or multiple incident reports are used to substantiate the potential risks. Four Canadian human major incidents and two environment major incidents were reported within the first year and evaluated by the PMRA. One of the human major incidents indicated a potential risk from use of the pesticide. The pesticide label will be amended to mitigate this risk. Summaries of these incidents and the corresponding PMRA evaluations are available in Section 3.

To further identify potential risks, the complete database of incident reports is analyzed for signals based on the number of incidents reported for a particular pesticide as well as patterns in the data that link the pesticide and the reported effect. Two separate signals were detected in the database. Two hundred and twenty-four Canadian domestic animal incidents involving pesticides used to control fleas and ticks were reported. The number of incidents reported suggests there may be a potential for adverse effects in cats and dogs from the use of flea and tick control products applied to the skin. The PMRA is investigating the causes of the reported adverse effects and is working with the United States Environmental Protection Agency, product manufacturers and veterinary health professionals to address this issue. Health Canada issued an advisory on April 14, 2009 to remind consumers to follow label directions on flea and tick pest control products for use on cats and dogs.

The second signal detected involved pesticides that are used to control rodents. Although rodenticides were not as frequently reported as flea control products, incidents involving rodenticides tended to have more serious effects. To minimize exposure to rodenticides, the PMRA is proposing mitigation measures such as bait stations and limiting access to the second generation anticoagulants (see documents REV2007-04 and REV2009-05).

In addition to the efforts described above, incident reports are also incorporated into the decision process for registering and re-registering pesticides and other agency activities which may include outreach communications and, on some occasions, compliance activities.

Overall, based on the PMRA's evaluation of the information reported in the first year of the program, three potential risks associated with the use of a pesticide have been identified. One is related to human health, in particular, worker inhalation exposure when applying the herbicide paraquat. The other two are related to domestic animals either from the application of flea and tick pest control products or the accidental ingestion of rodenticides. In all three cases, the PMRA is taking appropriate action to reduce these risks. The Incident Reporting Program data is an important source of additional information that contributes to the primary objective of the PMRA which is to prevent unacceptable risks to people, domestic animals and the environment from the use of pesticides.

1. Introduction

Based on the Pest Control Products Incident Reporting Regulations, pesticide manufacturers, including registrants and applicants for the registration of a pesticide, are required to report to the PMRA information about incidents that involve their products. An incident is an effect that relates to the health or environmental risks, or the value of a pesticide. Incidents include effects on humans, domestic animals, or the environment; packaging failure that could result in human exposure or injury; excessive residues in food; and scientific studies that indicate either a new hazard, increased risk, or the presence of a component or derivative at a higher concentration than previously known.

Human, domestic animal and environment incidents are further classified by severity based on criteria outlined in the Regulations. There are four severity categories for human and domestic animal incidents: death, major, moderate and minor. The severity category of a human or domestic animal incident depends on the type and duration of the symptom(s) reported in the incident, whether medical treatment was necessary, and the duration of hospitalization, if required.

For environment incidents there are three severity categories: major, moderate and minor. In environment incidents, the organisms affected are grouped based on type, and the severity of an environmental incident depends on both the type and the number of organisms affected.

Pesticide manufacturers are also required to report a subset of incidents from the United States if the pesticide suspected to be responsible for the incident is associated with a Canadian pesticide (that is, contains the same active ingredient) This subset includes incidents that relate to those that are classified as human death, human major and domestic animal death.

Pesticide manufacturers are not required to verify the information provided in an incident report, they are only required to submit the information that they receive to the PMRA. In general, pesticide manufacturers receive information about pesticide incidents from medical professionals, the general public, or their own research. In addition to reporting an incident to the pesticide manufacturer, the public can also report incidents directly to the PMRA. Ninety-nine percent of the incidents received by the PMRA within the first year of the program were submitted via the pesticide manufacturers. All submitted incident reports are made publicly available on the Health Canada website, specifically, on the PMRA Public Registry.

It is not possible to verify the information received through incident reports. There is therefore no assurance that the information provided is accurate and, as such, it must be viewed with caution. In addition, reporting of a particular effect does not necessarily mean that it was caused by the suspected pesticide. Almost all of the symptoms reported are not specific to pesticides and can have many other causes. Assessment of causality must include other considerations such as the frequency, severity, plausibility, quality of the information contained in the report, amount of pesticide used, underlying diseases, etc. As such, when evaluating incident reports additional information is used. This supporting information includes scientific studies, other incident reports, previous PMRA evaluations, literature searches and other reference material.

2. Incident Report Data

In the first year of the program (April 26, 2007 to April 25, 2008), 934 incidents were submitted to the PMRA. It should be noted that one incident may involve multiple types of effects. For example, one incident could have both human and domestic animal effects. Of the 934 incidents reported, six had multiple effects. When counting the number of incidents by category, these incidents would be counted twice, once for each type of effect.

Domestic animal was the most common type of incident reported (539 reports; 257 Canadian and 281 American), followed by effects on humans (266 reports; 191 Canadian and 75 American) and effects on the environment (85). There were also cases of packaging failure (36) and scientific studies demonstrating an increased risk or new hazard (13). Only one incident of excessive pesticide residues in food was reported and it was actually a scientific study. The number of human and domestic animal incidents reported is much higher than the other categories because they include Canadian and American data whereas the other categories include only Canadian data.

2.1. Summary of Human Incident Reports

There were 266 human incident reports submitted to the PMRA. In some of those incidents, more than one person was reported to be affected. The total number of human subjects was 286. The majority of people reported to be affected were between the ages of 20 and 64.

The most commonly reported source of exposure for human incidents was during application of the pesticide, in particular, application of pesticides to animals (for example, flea and tick products). The route of exposure was primarily dermal followed by inhalation. The majority of human incidents were reported to the pesticide manufacturer by the person who experienced the symptoms or effects.

Most of the human incidents reported involved minor symptoms that resolved rapidly without medical treatment. Headaches, eye irritation, shortness of breath, nausea and skin irritation were the most commonly reported symptoms. Of the incidents reported to have occurred in Canada, four were classified as human major which is defined as symptoms that could be life-threatening or result in chronic disability. The PMRA evaluations of the human incidents are provided in Section 3.

2.2. Summary of Domestic Animal Incident Reports

There were 539 domestic animal incidents reported. Many incidents involved multiple animals and the total number of animals reported to be affected was 1012. The most common type of animal reported was dog (31%) followed by cat (27%) and cow (22%).

The majority of animal incidents were reported to result from the direct treatment of the animal with a pesticide, for example, from a flea control product. Dermal exposure was the most

common route of exposure reported. The most common symptoms reported were hair loss, skin discolouration, lethargy, weakness and vomiting. The PMRA evaluations of the domestic animal incidents are provided in Section 3.2.

2.3. Summary of Environment Incident Reports

Eighty-five environment incident reports were submitted to the PMRA. In 79 of these incidents the effect reported was lawn damage following the application of an herbicide. There were three minor reports involving trees and shrubs, one minor report involving aquatic plants, and two major reports involving fish. The two reports involving fish were for the same incident. The incident involved the death of approximately 5,000 fish following a fire at a pesticide packaging plant. The plant housed many different active ingredients belonging to a number of pesticide manufacturers. The PMRA evaluation of this incident is provided in section 3.1.2.

2.4. Number of Incident Reports by Application Site

The application of pesticides to animals represents the most common use scenario for domestic animal incidents and also for human incidents. The use of pesticides in an outside residential setting is the second most common use scenario for both domestic animals and humans. For environment incidents, the most common application site reported was located outside the residential setting (e.g., lawn).

2.5. Type of Product Reported

Pesticides are classified by product type depending on the type of pests they control. For example, active ingredients that control insects are classified as insecticides and those that control weeds are classified as herbicides. Almost 40% of active ingredients identified in incident reports are used to control insects. Mite and tick pesticides and insect repellents are the second and third most commonly reported types of products.

2.6. Severity Level of the Incidents Reported

Both human and environment incidents were most commonly classified as minor. For domestic animal incidents, death was the most common severity of incident reported due to the inclusion of American data. Pesticide manufacturers are required to report incidents that occur in the United States if they are classified as human death, human major or domestic animal death. In Canada, there were no reports of human death and the vast majority of incidents in all three categories were minor (Table 1). Please see Section 3 for PMRA's evaluation of the incident reports.

Table 1: Reported Canadian Incidents by Severity

Category	Death	Major*	Moderate	Minor
Human	0	4	36	169
Domestic Animal	18	9	61	186
Environment	Not Applicable	2	0	84

*Note: one of the human majors was re-classified to moderate by the PMRA.

3. PMRA Assessment of Incident Reports

The purpose of the Pesticide Incident Reporting Program is to consider the information reported and determine if there are potential health or environmental risks associated with the use of a pesticide and, if necessary, take action to prevent future incidents from occurring.

Incident reports are assessed in three ways:
1) Evaluate serious Canadian incidents individually to assess the likelihood that the pesticide exposure caused the reported effect.
2) Analyse complete database of incident reports for signals indicating potential risk.
3) Incorporate incident reports into the decision process for registering and re-registering pesticides.

The information provided in a single incident report is generally not sufficient to evaluate the level of risk associated with the use of the pesticide. Scientific data and/or multiple incident reports are required to establish reasonable grounds that the risk of a pesticide is unacceptable and to recommend appropriate action. This could include regulatory measures ranging from amending the pesticide product label to discontinuation of the product, and other preventative actions such as outreach, education or compliance follow-up.

Although American incidents supplement the database of Canadian incidents to help identify signals indicating potential risks for pesticides, American pesticides are regulated by the United States Environmental Protection Agency (US EPA). The PMRA works closely with the US EPA in both pesticide regulations and incident reporting.

3.1. Evaluation of Canadian Incidents

The more serious Canadian incident reports (human death, human major, environment major and environment moderate) are evaluated to determine if there is a causal relationship between the pesticide and the reported effect, as well as the strength of that relationship. The relationship between the exposure to a pesticide and the reported effects is expressed in terms of highly probable, probable, possible, unlikely, unrelated, or insufficient information (see Appendix 1 for definitions). If it is determined that the pesticide exposure may have contributed to the reported effect (classification of possible, probable or highly probable), than the potential risk from use of that pesticide is evaluated and, if necessary, action is taken to mitigate those risks.

Four Canadian human major incidents and two environment major incidents were reported within the first year. One human incident was reclassified to moderate by the PMRA. A description of the incidents along with the causality level is presented in Table 2. Of the remaining three major human cases, the PMRA determined there was no causal relationship between the pesticide and the reported incident (causality level of unlikely). For the human incident 2007-5671, the PMRA determined it was probable that the effects reported were due to the pesticide. For the environment major incidents (2007-5800 and 2007-5823) it was determined that it was possible that the reported effects were due to pesticide exposure. Once causality was assessed, these incidents were further evaluated by the PMRA to determine if

regulatory action was necessary. If regulatory action was deemed necessary, appropriate action was taken (see Sections 3.1.1 and 3.1.2 for details).

Table 2: Assessment of the relationship between the pesticide exposure and the reported effect for serious Canadian incidents

Incident Report Number	Active Ingredient	Category and Severity	Details of Incident	Classification
2007-9109	trans allethrin, N-octyl bicycloheptene dicarboximide, permethrin	Human Major **Note: PMRA re-classified as moderate.**	Exposed during application, 6 months later developed symptoms of irritated eye, dryness to eyes, swollen optic nerve.	Unlikely
2007-5671	paraquat, simazine	Human Major	Exposed during application of product to apple orchard. Hospitalized 4 days later with respiratory symptoms.	Probable (paraquat) (Section 3.1.1)
2007-4560	triclopyr	Human Major	Applied product, wore protective equipment. Hospitalised 17 days later with pancreatitis and respiratory failure.	Unlikely
2008-0736	dicamba, 2,4-D, mecoprop	Human Major	Applied product for approximately 1 month to kill poison ivy at cottage sometime in the past. Woman was recently diagnosed with amyotrophic lateral sclerosis.	Unlikely
2007-5800 and 2007-5823 (same incident)	multiple pesticides	Environment Major	The incident involved a fire at a pesticide packaging plant. It was estimated that 5000 fish died in a nearby creek.	Possible (diazinon and malathion) (Section 3.1.2)

3.1.1. Canadian Human Major 2007-5671

A Canadian incident report classified as human major was received by the PMRA on July 31, 2007. The information contained in the incident report indicated that Gramoxone Liquid Herbicide and Princep Nine-T Herbicide were applied by a worker using a hand sprayer for six hours in an apple orchard. Gramoxone Liquid Herbicide (Registration Number 8661) is an agricultural class product containing 200 g/L paraquat (present as dichloride) as the active ingredient; Princep Nine-T Herbicide (Registration Number 16370) is a commercial class

product containing 90% simazine and related triazines as the active ingredient.

The person presented to the hospital 4 days after applying the pesticides with apparent respiratory distress. The person also exhibited shortness of breath, tachypnea, and shaking, and exhibited conditions of pneumonitis, pulmonary edema, pleural effusions (excess fluid accumulated in the pleural cavity) and pulmonary nodes. The person was hospitalized for 12 days.

The PMRA reviewed all available Canadian and American scientific data for paraquat and simazine, as well as additional reports of paraquat poisoning (from American state based programs, American poison control center data, and international cases). The symptoms and timing of the symptoms presented in this incident are consistent with the known effects of paraquat poisoning. Thus, the PMRA evaluation concluded that it is **probable** that the effects noted in this incident report were related to exposure to paraquat, either by inhalation, ingestion, or secondary ingestion via inhalation.

A decision was made by the PMRA to reduce the exposure of applicators by updating the Gramoxone Liquid Herbicide (Registration Number 8661) label to require the use of a respirator and to add the statement “Fatal if inhaled”.

See Health Canada’s website for the full evaluation of the pesticide incident report 2007-5671 (http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_decisions/index-eng.php#epir-edirp)

3.1.2. Canadian Environment major 2007-5800 and 2007-5823

A Canadian incident classified as environment major occurred at a pesticide packaging facility on July 26, 2007. The incident involved a fire at a facility that housed a large volume of pesticide products with many different pesticides belonging to a number of pesticide manufacturers.

Although a berm was in place to contain run-off from the facility, the fire dowse water exceeded the capacity of the berm, overflowed into the storm sewer and moved directly into Spencer Creek. A major fish kill of approximately 5,000 fish was observed in Spencer Creek the day after the fire.

The Fire Marshal was on site to investigate the cause of the fire, and the PMRA obtained a copy of their final report. The Ontario Ministry of the Environment (MOE) was also on-site after the fire started and collected fish, water, and sediment samples. The MOE provided their report "Spencer Creek Restoration Action Plan" to the PMRA which discussed the laboratory results of water samples taken on the day of the fire and subsequent sampling dates. The MOE conducted an investigation of the packaging facility, the results of which can be found on the MOE website. The PMRA then conducted a causality assessment based on the results of the MOE water sampling and the environmental fate and toxicity of each of the pesticides listed in the reports.

The pesticides diazinon and malathion were detected in the fire dowse water and, given the

corresponding toxicity values of these pesticides, the reported effect are considered to be consistent with the level of exposure. For many of the other pesticides stored at the facility, their toxicity values indicate they are moderately to very highly toxic to fish. However the MOE did not test for these pesticides in the fire dowse water and, given the situation, it is unclear if these pesticides would have come into contact with the fire dowse water at the time of the incident.

Based on all the information received by the PMRA, it cannot be concluded that one particular pesticide is responsible for the incident, nor can it be ruled out that other components in the fire dowse water did not contribute to the fish kills. Although there is physical evidence confirming exposure and the reported effects are consistent with that level of exposure to diazinon and malathion there is also the potential presence of other pesticides that could have contributed to the incident. As such, the PMRA concluded that it is **possible** that diazinon and malathion contributed to the fish kills. For the remaining active ingredients assessed, the PMRA concluded that there is **insufficient information** to determine the relationship between the pesticide and the fish kills since it is unknown if they were in the fire dowse water and, if so, at what concentration.

In July, 2009, the PMRA concluded that no regulatory action is required (http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_decisions/index-eng.php#epir-edirp). However, the information reported will remain in the database and will be routinely re-examined in conjunction with any new data that is received. It is important to note that a product is only registered for use if there is reasonable certainty that no harm will result from use of the product as directed on the label. In this particular instance, release of these products in the environment was as a result of an accident, whose unusual and unfortunate circumstances are extremely unlikely to be repeated, and this has been taken into account in the review of this incident.

3.2. Evaluation of Signals

The complete database of incident reports is analysed for signals of potential risks based on the volume of incidents involving a particular pesticide and other factors. Signals are then analysed for patterns in the data that link the pesticide and the reported effect. For the first year's worth of data, the approach to detect signals relied on the overall number of incidents reported for a particular pesticide. Those pesticides with the most incident reports were further investigated for a pattern (such as same type of incidents, similar effects/symptoms, severity level of the incidents, etc.). The relationship between the pesticide exposure and the reported effects (see Appendix 1 for definitions), as well as the use of the pesticide, are used to identify potential health or environmental risks. In the future, signals will be identified by using more complex statistical analyses, however, this approach requires a large amount of data and in the first year there were an insufficient number of reports to conduct such analyses. It should also be noted that, with the new Pest Control Products Sales Information Reporting Regulations that have come into effect, the number of incidents reported for a given product will also be compared to the amount of product sold to further identify potential risks.

Two signals were detected that indicated a potential risk; both involved domestic animals. An unexpectedly high number of domestic animal incidents involving pesticides used to control

fleas and ticks were reported. Additionally, although rodenticides were not as frequently reported as flea control products, incidents involving rodenticides tended to have more serious effects.

The remaining incidents reported, including the human and environment incidents, did not indicate signals of potential risks from use of the pesticides. However, all incidents will remain in the database and will be considered in future evaluations as more incidents are reported.

3.2.1. Flea and Tick Products

Products used to control fleas are the most common type of pesticides reported, and as such, dogs and cats are the most common species involved in the domestic animal incidents. They account for approximately 40% of all Canadian incidents reported in the first year. The number of incidents reported suggests there may be a potential for adverse reactions in cats and dogs from the use of flea and tick control products applied to the skin. Adverse reactions reported range from mild effects such as skin irritation to more serious effects such as seizures and in some cases death. Approximately 10% of the Canadian incidents involved serious effects.

Incidents with flea and tick products involve the use of spot-on treatments, sprays, collars and shampoos, although the majority of the incidents relate to spot-on products. The US EPA has identified similar concerns with the use of flea and tick products. The issue is broad, involving both dog and cat flea control products, multiple types of products (although predominantly spot-on type products), multiple active ingredients and multiple formulants. No reports of human health risks (e.g. to children) have been reported.

The PMRA and the US EPA are investigating the causes of the adverse reactions and are working with product manufacturers and veterinary health professionals to address this issue. The investigation includes: ensuring product labels are appropriate, re-examining the approach to assessing pet safety, and verifying the formulations of these products. As a precautionary approach, the PMRA issued an advisory in April 2009 alerting the public and veterinary community about the concerns related to use of these products and advising pet owners of important safety tips. The PMRA continues to investigate the issue.

3.2.2. Rodenticides

Overall, rodenticides were not as frequently reported as other types of products, such as flea control products, however, the severity of the domestic animal incidents involving rodenticides tended to be greater. Two anticoagulant rodenticides, bromadiolone and diphacinone, were among the most frequently reported pesticides for domestic animal death. This signal identified in the incident reporting data is consistent with known effects of anticoagulants and is confirmed by the incident reports collected by the US EPA post-market pesticide surveillance program, which indicate the same issue.

To minimize exposure to rodenticides and thereby minimize the risk, the PMRA has proposed mitigation measures. First, all domestic class rodenticides must be sold in block or solid form

and only with bait stations, and loose bait will be prohibited. Second, the use of second generation anticoagulants (brodifacoum, bromadiolone, difenacoum, and difethialone) will be prohibited in domestic class products, which pose the greatest risk (see documents REV2007-04 and REV 2009-05). This is consistent with the approach taken by the US EPA.

3.3. Using Incident Reports in PMRA Risk Assessments and Other Agency Activities

Requests for new pesticide products or modifications to registered products are evaluated by the PMRA prior to registration to ensure the product does not pose unacceptable risk to health or the environment. In addition, older active ingredients are re-evaluated to ensure they meet current standards. The data collected through the Incident Reporting Program are considered in the PMRA's assessments of pesticides to support the conclusions of the risk assessments and identify new hazards.

In addition, review of incident reports in the database may indicate the need for additional follow-up activities. Depending on the nature and/or degree of causality of the incidents, activities may include education and outreach or compliance follow-up.

4. Five Common Ways that Pesticides are Misused

1. Placing pesticides in unmarked containers

All pesticides should be kept their original containers. Do not reuse empty pesticide containers.

EXAMPLE: Incident Report 2007-8710: (United States) A man accidentally drank herbicide that had been given to him in a pop bottle. He estimated that he ingested 2-3 ounces, mistaking it for soda pop. Shortly afterwards, he vomited several times. He was transported to the hospital by ambulance, where he had severe abdominal pain and nausea at the time of admission. Despite medical interventions, his symptoms progressed over the next three days to severe renal, cardiac and respiratory distress. He died on the fourth day.

2. Using a dog flea and tick product on a cat

Dog products are not safe for use on cats. Read the pesticide label carefully and follow the directions. They are there to make the handling of pesticides safer.

EXAMPLE: Incident Report 2008-1836: An owner applied a flea and tick product for dogs to her 3 month old cat. Shortly after, the cat began to have muscle tremors and a seizure. The owner immediately took her cat to a veterinarian. Despite aggressive treatment, the cat died that day.

3. Not reading or following the directions on the pesticide label

Read the label carefully and follow the directions.

EXAMPLE: Incident Report 2007-7272: The product was used on a young child. The child experienced redness and irritation to the application site. The label states “do not use on children under the age of 12”.

4. Mixing chemicals

Chemicals should never be mixed together, unless directly specified on the pesticide label.

EXAMPLE: Incident Report 2007-8953: A chlorine product for pools was mixed with another granular shock product in a bucket, and diluted with water. The mixture exploded. The person suffered superficial burns, shortness of breath and a headache. The label states that the product should not be mixed with any other chemicals or diluted with water.

5. Not ensuring safe placement of rodenticide products

Care should be taken when using rodenticide products, to ensure that non-target animals are not in danger of ingesting the pesticide.

EXAMPLE: Incident Report 2008-1225: A dog ingested mice bait. Approximately one week later, the dog exhibited bleeding along her paws, coughing up blood, laboured breathing, limping, pale mucous membranes, tachycardia, and muffled heart sounds. The dog was taken to the veterinarian, was hospitalized for two days, and given Vitamin K1 injections. The dog fully recovered.

Appendix 1: Criteria used to assess the degree of the causal relationship between the pesticide exposure the reported effect

Classification	**Criteria**	**Definitions**
Highly probable	1) Physical evidence and consistency, or 2) consistency, specificity and repetition	Physical evidence confirms the presence of the pesticide (e.g., leaf samples, water residues, soil residues or contaminated clothing). Additionally, and, based on the toxicity of the pesticide, the effect would be expected from the reported exposure. For animal and human incidents, medical evidence (e.g. blood or allergy tests) confirming the effect would also contribute to a classification of highly probable. If there is no physical evidence confirming exposure, but the effect would be expected from the reported exposure, the effect is specific to that pesticide (ie. there are very few other potential causes), and multiple incidents with the same or similar effects have been reported for that pesticide, the incident should be classified as highly probable.
Probable	Consistency and one of: specificity or repetition	More limited evidence suggests a relationship between the exposure, the pesticide and the effect, but physical evidence is lacking. For example, based on the toxicity of the pesticide, the effect would be expected from the reported exposure and multiple incidents with the same or similar effects have been reported for that pesticide.
Possible	Either consistency or repetition	Information may be ambiguous, although there is some correlation between the suspected pesticide and the effect. For example, abnormal leaf discolouration or headaches could be related to something other than the pesticide. This level of causality is often used when organisms are exposed to more than one pesticide.
Unlikely	Not Applicable	The effect reported is not typical for the suspected pesticide but the possibility that exposure to the pesticide caused the effect cannot be ruled out.
Unrelated	Not Applicable	1) Evidence demonstrates the effect was caused by factors other than the pesticide or, 2) the effect occurred before exposure to the pesticide.
Insufficient Information	Not Applicable	Insufficient information regarding the exposure or effect to determine whether the effects were related to the pesticide.

Physical evidence confirming exposure to the pesticide and the effect is the most important factor to establish a strong causal relationship. This could include residue data to confirm exposure occurred and medical tests or the fact that the symptoms were observed by a physician to confirm the effect. Physical evidence is one of the criteria for the causality level 'highly probable'.

Consistency of the association means the effects would be expected from the reported pesticide exposure based on the similarity of results from several studies. The effect(s) reported for an incident must be compared with the PMRA's in-house data (scientific studies and the incident reports database) and, if necessary, external data from literature searches and reference books to determine if the effect(s) reported are typical for the suspected exposure. Consistency of the association must be confirmed in order for the causality level to be 'probable' or 'highly probable' and is one of the criteria for the level 'possible'.

Specificity of the association means the effect is specific to the pesticide as opposed to being a general effect that has many potential causes. The less specific the effect is to the pesticide, the harder it is to estimate causality. If there could be other, non-pesticide related explanations of the effect, a high level of causality cannot be established. For example, headache or nausea are symptoms that would be expected from exposure to certain pesticides, however, these symptoms also have many other potential causes that are unrelated to pesticide exposure making it difficult to determine if the cause of the symptoms were due to the pesticide or something else. Other symptoms, such as decrease in acetylcholinesterase, are more specific to a certain pesticide, for example, ogranophosphate exposure. There are very few other potential causes of this effect, making it easier to establish causality.

Repetition of the effect refers to multiple incidents with the same or similar effects for the same active ingredient. The higher the number of incidents and the more similar the effect, the stronger the indicator of causality. It is highly unlikely that regulatory action would be recommended if there was only one incident reported for an active ingredient. Repetition is one of the criteria for a causality of possible to highly probable depending on the remaining criteria.