Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Discussion Document

DIS2003-03

Pesticides Adverse Effects Reporting Regulation

The new *Pest Control Products Act* (PCPA) was given Royal Assent on December 12, 2002. One of the new requirements is for registrants to report any prescribed information that relates to the health or environmental risks or the value of pest control products within the prescribed time and in the form and manner directed by the Minister. The new regulation to be made under Section 13 of the new PCPA, would specify the types of information to be reported and the time frames for reporting. Guidelines will provide more detailed information on what and when to report, as well as on the form and manner in which to report. In addition, the medical and research community, other governmental agencies and individuals will also be encouraged to report adverse effects of pesticides. The purpose of the Discussion Document on Pesticides Adverse Effects Reporting Regulation is to seek comments from stakeholders and the public regarding the proposed regulation for the reporting of adverse effects.

Submit your comments within 30 days of publication of this document to the Publications Coordinator at the address listed below.

(publié aussi en français)

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1.0 Introduction

The new *Pest Control Products Act* (PCPA) was given Royal Assent on December 12, 2002. One of the new requirements is for registrants[1] to report any prescribed information that relates to the health or environmental risks or the value of pest control products within the prescribed time and in the form and manner directed by the Minister. The proposed pesticides adverse effects reporting regulation would specify the types of information to be reported and the time frames for reporting.

An adverse effect is an effect on humans, animals, plants or the environment, including injury, toxicity, sensitivity reactions, quality deterioration or decreased value associated with a pesticide. In developing the proposed adverse effects reporting regulation, the current requirements of other countries and international bodies on post-market reporting for pesticides, such as the United Kingdom, Australia, the U.S. Environmental Protection Agency (U.S. EPA) and the United Nations Environment Programme (UNEP), were explored. Furthermore, staff members of other programs both within Health Canada and Environment Canada were consulted at various stages of the development of the early drafts of the proposed regulation.

The purpose of this document is to seek your comments regarding the proposed regulation for the reporting of adverse effects.

The adverse effects data reported under this regulation will:

- provide an early alert mechanism for significant health and environmental risks that require immediate investigation through special review;
- provide information on less significant risks for prioritizing re-evaluations, and for review during re-evaluations;
- identify trends and determine the burden of pesticide related events, e.g. types of pesticides and populations involved;
- identify adverse effects reported in relation to geographic and agricultural practices;
- provide the basis for planning, prevention and education activities in collaboration with partners such as consumers, users, industries and federal/provincial/territorial government departments and agencies;
- enhance public awareness to prevent future incidents of adverse effects;

[1] Most requirements in the new PCPA apply equally to registrants and applicants.

- lead to improving the quality of the labels currently available;

- contribute to similar international activities (e.g., International Programme on Chemical Safety) including the development of an international database on toxicological requirements of human health adverse reports for pesticides; and

- provide comprehensive information and/or reports to the medical communities and the public through appropriate communication tools.

As indicated above, the new regulation to be made under Section 13 of the new PCPA, would specify the types of information to be reported and the time frames for reporting. Guidelines will provide more detailed information on what and when to report (Appendix I and II), as well as on the form and manner in which to report (Appendix III). In addition, the medical and research community, other governmental agencies and individuals will also be encouraged to report adverse effects of pesticides.

2.0 Content of the proposed regulation

The regulation would require registrants to report information that indicates any health and environmental risks or a decrease in the value of a product and would provide time frames for reporting based on the severity of the adverse effects. The new regulation would also require registrants to provide an annual report containing summary data and a critical analysis regarding all adverse effect reports for their products accumulated during one year.

Submission of an adverse effect report, however, does not necessarily mean that the manufacturer accepts causality or responsibility. The Pest Management Regulatory Agency (PMRA) recognizes that there will probably be a number of events which the registrant will need to investigate and verify the validity of information. Registrants are required to report the adverse effects within the prescribed time frames even though they may not have fully validated the information. Registrants are free to submit supplemental information about the adverse effect reports, such as opinion or commentary they consider relevant, explaining the circumstances or interpreting the significance of the data. Registrants who fail to submit information because of the incompleteness of ongoing investigations will be considered guilty of an offence under the new PCPA.

2.1 Information to be reported

It is proposed that the regulation specify that registrants must report any information that they receive and that is:

- about incidents in which adverse effects in humans, domestic animals or the environment were associated with use of the pest control product;

- indicates that residues in excess of permitted levels have been reported;

- indicates groundwater contamination;

- about incidents in which the pest control product did not display acceptable value;

- generated through scientific studies of a type currently required under Section 9 of the existing Pest Control Products (PCP) Regulations that indicates any risks or decreased value, or through human epidemiological studies or exposure monitoring studies; and

- information in the refereed scientific literature.

Registrants will not need to report:

- information that is clearly erroneous; and

- information on formulants, contaminants or impurities that have been eliminated from the registered product and the registrant has informed the Minister in writing.

It is proposed that, following transfer of a registration from one registrant to another, the reporting requirements shall continue to apply to the former registrant with respect to prescribed adverse effects information acquired prior to the transfer or within one year after the transfer.

If any of the prescribed information comes into the possession of an employee or agent of a company that is a registrant, the information is considered to have been received by the registrant on that date. Information received by a parent or an affiliated company, located in Canada or elsewhere, is deemed to have been received by the registrant.

It is proposed that the regulation specify that adverse effects reports may be submitted in English, in French or in both official languages and that this also applies to foreign language documents.

It is also proposed that the adverse effects regulation include a provision specifying that registrants be required to maintain records on adverse effects report for 10 years from the date the report was submitted to the Minister and be required to submit those records to the Minister upon request.

2.2 Time frames for reporting

In developing the time frames required for the registrant to report adverse effects, the PMRA has taken into consideration the reporting time frames of the U.S. EPA as well as those of the Therapeutic Products Program within Health Canada. The PMRA recognizes that it is important to harmonize with the U.S. and other Organisation for Economic Co-operation and Development countries on the ways to gather information on adverse events to increase efficiency in worldwide reporting of adverse effects and to allow action to be taken on important safety and value information arising after the registration of a pesticide.

The time frame for reporting will be contingent upon the severity of the adverse effect because of the need to focus rapidly on the most significant adverse effects. It is proposed that the regulation specify the following:

1. Reports on incidents involving adverse effects in humans associated with use of the pest control product.

Severity	Time Frame
Death: includes death as a result of, or as a direct complication of, exposure to the pesticide. **Major adverse effect:** a person alleges or exhibits symptoms which may be life-threatening or result in adverse reproductive effects or in residual disability.	Report as soon as possible or within 15 days after the registrant has received the information.
Moderate adverse effect: a person alleges or exhibits symptoms more pronounced, more prolonged, or of a more systemic nature than minor symptoms. Usually some form of treatment of the person would have been indicated. Symptoms were not life threatening and the person has returned to his/her pre-exposure state of health with no additional residual disability.	Report following an accumulation of one month and submit by the end of the month following the accumulation period.

Severity	Time Frame
Minor adverse effects in humans: effects include, but are not limited to, skin rash, itching, conjunctivitis (red, tearing eyes), drowsiness, transient cough, headache, joint pain, agitation, restlessness, or mild gastrointestinal symptoms such as self-limited diarrhea, stomach cramps, or nausea. These effects are reported to have lasted less than one month. **Unknown adverse effects in humans:** a person reporting an incident to a registrant may report exposure and allege an adverse effect. Specific symptoms, however, may be unknown or unspecified. If exposure is reported, no acute adverse effect is alleged, but the reporter informs the registrant they may suffer delayed or chronic effects.	Report following an accumulation of a 12-month period as specified by the registrant and submit within 30 calendar days.

Rationale:

The PMRA has considered those terminologies currently used in the other programs within Health Canada, in other regulatory agencies, such as the U.S. EPA, and in the other organizations, such as the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use and the World Health Organization.

The U.S. EPA definitions take into account both duration and intensity of clinical effects in consideration of exposure type and severity categories of humans. The severity category definitions for humans were derived from standard definitions used by the American Association of Poison Control Centres.

In order to move toward harmonization among North American Free Trade Agreement (NAFTA) countries, the proposed time-lines for adverse effects on human health are consistent with the U.S. EPA reporting time-lines with the exception of ‘Human-major’. It is felt that the severity of this category is sufficient to elicit a more immediate response than the U.S. EPA time-lines would allow and the proposed time-lines are more consistent with the time frames for adverse drug reporting, as stipulated in the Canadian Food and Drug Regulations.

2. Reports on incidents involving adverse effects in domestic animals associated with use of the pest control product.

Severity	Time Frame
Death: includes deaths and euthanasia as a result of, or as a direct complication of, exposure to the pesticide.	Report following an accumulation of one month and submit by the end of the month following the accumulation period.
Major adverse effect: a domestic animal exhibits or was alleged to have exhibited symptoms which may have been life-threatening or resulted in residual disability. **Moderate adverse effect:** a domestic animal exhibits or was alleged to have exhibited symptoms which are more pronounced, more prolonged or of a more systemic nature than minor symptoms. Usually some form of treatment would have been indicated for the animal. Symptoms were not life threatening and the animal has returned to its pre-exposure state of health with no additional residual disability. **Minor adverse effect:** a domestic animal was alleged to have exhibited symptoms, but they were minimally bothersome. The symptoms resolved rapidly and usually involved skin, eye or respiratory irritation. **Unknown adverse effect:** symptoms are unknown or not specified.	Report following an accumulation of a 12-month period as specified by the registrant and submit within 30 calendar days.

Rationale:

The PMRA is proposing a definition scheme which is similar to that used by the U.S. EPA. The severity categories for domestic animals were developed by the U.S. EPA in consultation with the National Animal Poison Control Centre/American Society for Prevention of Cruelty to Animals.

In order to move toward harmonization among NAFTA countries, the proposed time-lines for adverse effects on domestic animal health are consistent with the U.S. EPA reporting time-lines with the exception of ‘Domestic Animal Death’. It is felt that the severity of this category is sufficient to elicit a more immediate response than the U.S. EPA time-lines would allow.

3. Reports on incidents involving adverse effects on the environment associated with use of the pest control product.

Adverse effect in the environment: Any adverse effect occurring during or after pesticide release to wildlife, beneficial insects, plants, aquatic life, or other natural resources, including biological diversity, individuals of species at risk or deterioration of soil, sediment, water and/or air quality. Adverse effects with respect to the environment include but are not limited to death, impairment of plant and animal health, contamination of water resources above the acceptable level, reproductive impairment, congenital anomaly/birth defects.

Severity	Time Frame
Severe adverse effect: an adverse effect that may result in an immediate and potentially irreversible effect on the local population at the site/field of pesticide application or in the surrounding area.	Report as soon as possible or within 15 days after the registrant has received the information.
Major adverse effect: an adverse effect that may result in an immediate or potentially long term impact on the local population at the site/field of pesticide application or in the surrounding area.	Report following an accumulation of one month and submit by the end of the month following the accumulation period.
Minor adverse effect: an adverse effect that may result in a minor reversible impact on the local population at the site/field of pesticide application or in the surrounding area.	Report following an accumulation of a 12-month period as specified by the registrant and submit within 30 calendar days.

Rationale:

The PMRA has taken into consideration those terminologies used by the U.S. EPA in describing the various types of adverse effects. However, the PMRA felt that these definitions require far too many organisms to be affected in order to trigger the reporting requirement, leading to over-summarization of the environmental adverse effects. In addition, often the severity of an environmental effect may be understated, given that organisms can originally be affected non-lethally and then move off the site to die, thus, never being detected. The PMRA also considered in the severity classification, the potential implications of the new *Species at Risk Act*. The PMRA proposes that each environmental adverse effect should be reported in detail.

There is a preference to follow the time-line outlined by the U.S. EPA for reporting major environmental effects which states that the registrant accumulates reports for one month and then submits by the end of the second month. The PMRA has added an "Environmental-severe" category, which encompasses those adverse effects (mortalities of a large number of organisms or an adverse effect on an individual of a species at risk) that may elicit a more immediate response. In some cases it is expected that the PMRA may become aware of an adverse effect occurring before the registrant has reported the adverse effect. It is anticipated that the registrant may be able to provide additional information on the incident surrounding the adverse effect. An individual report, completed with the available information, of any adverse effect that has not been reported during the previous twelve months must be submitted during the annual reporting process. In addition, the registrant is also required to conduct a concise, critical analysis of any reports received during the previous twelve months, and submit such information on an annual basis.

4. Report on Residues in Groundwater, Surface Water and Food in excess of permitted levels

Severity	Time Frame
Residues in water: a pesticide has contaminated groundwater or has been detected at a level exceeding the Canadian drinking water guidelines, the Canadian water quality guidelines for the protection of aquatic life, or any applicable provincial water quality guideline or regulation, whichever is the most conservative. **Residues in food:** a pesticide has been detected at a level exceeding the maximum residue limit (MRL) established under the *Food and Drugs Act*.	Report following an accumulation of one month and submit by the end of the month following the accumulation period.

Rationale:

In order to move toward harmonization among NAFTA countries, the detection of pesticides in water at levels greater than the established water quality guidelines is consistent with the U.S. EPA time-line for reporting detections above the maximum contaminant level and the health advisory levels. In addition, levels in food greater than the established MRL also follow the U.S. EPA time-line for reporting of detections.

5. Report on Incidents involving Unacceptable Efficacy, Crop Tolerance and Value

From the perspective of the value of the product, information regarding incidents involving poor performance (i.e., lack of efficacy) - particularly those cases that may be attributed to the development of pest resistance, undesirable effects on the host organism (e.g., crop damage) or rotational/succeeding crops, quality assurance problems and application technology failure will be considered to be reportable (routine submission of individual performance claims would not be required).

Severity	Time Frame
Substantiated incident of pest resistance: a pest having developed resistance to any pesticide (both public health and non-public health) that occurred under conditions of use, application rates and methods specified on the label.	Report following an accumulation of one month and submit by the end of the month following the accumulation period.
Efficacy failure: target pest is not controlled to expected/acceptable level and has a detrimental impact on productivity of commodity when the product is used according to label instructions. **Host/target site:** host/target site exhibits unacceptable injury or other unacceptable symptoms and has a detrimental impact on productivity of commodity when the product is used according to label instructions. **Rotational/succeeding crop:** rotational/succeeding crop exhibits unacceptable levels of crop injury and/or yield reduction. **Product quality:** product provided to marketplace does comply with the conditions of registration but nevertheless there is a problem such as leaking, contaminants, packaging problems. **Application technology failure due to pesticide use:** application technology fails or has significantly reduced efficiency caused by the use of a pesticide.	Report following an accumulation of a 12-month period as specified by the registrant and submit within 30 calendar days.

Rationale:

Under the new PCPA, the value of a pest control product must be acceptable before it can be registered for use in Canada. Requiring that value must be acceptable helps to minimize risks posed by pesticides and prevents deception with regard to their usefulness. The PMRA recognizes that adverse effects on efficacy and host/target site will, in the vast

majority of cases, involve a long time-line (e.g., a full season to determine impact on the yield). Therefore, the PMRA is proposing that this information be accumulated over a yearly time period and reported in the annual report.

6. Report on Information from Studies

Severity	Time Frame
New information generated through scientific studies of a type currently required under Section 9 of the existing PCP Regulations that indicates any risks or decreased value or through human epidemiological studies or exposure monitoring studies (details in Appendix II) and information in the refereed scientific literature.	Report as an individual report within 30 days after the registrant has received the information.

Rationale:

The PMRA proposes to harmonize with the U.S. EPA in this instance to facilitate reporting in North America

To further assist registrants, guidelines detailing the information required in this regulation are presented in the appendices.

2.3 Annual reporting

Each registrant is required to provide an Aggregate Annual Summary Report which will include all of the adverse effects reported to the PMRA within the past year in addition to those which are of a less serious nature and can be reported annually. For those reports that are of a less serious nature and have not already been reported to the PMRA, individual reports must be completed along with incorporation into the Aggregate Annual Summary Report. The report must also include a concise, critical analysis of all the data including that previously submitted for the year interval and a comparison to previous intervals, commenting on any changes in the risk/value profile of the product that may have occurred in the current interval (Appendix III).

The Aggregate Annual Summary Report must be submitted following a 12-month period that is specified by the registrant. The date chosen and any changes to this date should be communicated to the PMRA.

Rationale:

In order to make this requirement consistent within Health Canada, the annual report proposed in this document would place a similar requirement on registrants similar to that of Subsection C.01.016.2 of the Food and Drug Regulations which states, “the manufacturer shall, on an annual basis and whenever requested to do so by the Director,

conduct a concise, critical analysis of the adverse drug reactions and serious adverse drug reactions to a drug referred to in subsection (1) and prepare a summary report in respect of the reports received during the previous twelve months or received during such period of time as the Director may specify."

2.4 All other reporting

All other reports, whether required to be submitted within 15 or 30 days or accumulated monthly, will be in the form of individual reports for each adverse effect.

The PMRA is presently developing a set of reporting forms that should be used by registrants to report information related to the adverse effects to the PMRA. These forms will ensure that the level of detail necessary for an assessment will be obtained while remaining as easy to use as possible. The forms will largely reflect the U.S. EPA forms with some modification to ensure sufficient information for decision making.

The PMRA is cognizant that harmonization with other international regulatory bodies will facilitate ease of international reporting. As such, it is proposed that the PMRA forms be used if the adverse effect occurred within Canada, while the Agency will accept the U.S. EPA or other forms (such as the UNEP one) if the adverse effect occurred outside of Canada and is considered to be 'major' (according to the definitions of major as outlined in Section 2.2, items 1, 2 and 3).

3.0 Utilization and dissemination of information

As stated, Section 13 of the new PCPA requires registrants to report any prescribed information that relates to the health, environmental risks, or the value of pest control products. Section 14 requires that this information be considered and, depending on the severity of the effect, a decision must be made as to whether or not a special review of the product's registration should be initiated. In considering the severity of the effect, the PMRA will take into consideration a number of factors, including the previous submission of similar adverse effect reports, before deciding if a special review or other regulatory action is required.

It should be noted that the new PCPA provides authority to take interim action, such as amending or cancelling a registration, in the course of a special review without waiting for its completion. Thus, if warranted by the severity of an adverse effect report, a special review could be initiated and interim action could be taken immediately.

The PMRA will establish the necessary framework and policies to enable an electronic capability for the transmission of pesticide related adverse effects. This electronic capability will follow international standards for ensuring that information is secure, and supports data integrity and non-repudiation.

4.0 Disclosure of information

It is proposed that the adverse effects regulation include a provision specifying that all reports including the annual aggregated summary reports will be placed in the Register as they are received. Adverse effects of a serious nature will receive priority evaluation status to facilitate timely conclusions, necessary regulatory action as required and timely posting of the conclusion in the Register. Conclusions for all other reports will be posted in the Register when evaluation and trend analyses have been completed. The PMRA is presently developing standard operating procedures which will include time frames for the evaluation and posting of conclusions in the Register based on the severity category of the adverse effect. In addition, if it is concluded that a pesticide poses a significant risk, the new PCPA requires that information to be actively disseminated to the public, for example, through a press release.

All the information in the Register except confidential business information or confidential test data, as defined in the new PCPA, will be available publicly. Furthermore, the public will be permitted to view confidential test data in a reading room.

As indicated above, Section 14 of the new PCPA requires that reports of adverse effects be considered as a basis for initiating a special review. PMRA will also be using the adverse effects reports as a means of prioritizing chemicals for the ongoing re-evaluation program.

5.0 Comments

To assist us in undertaking an effective consultation on the proposed regulation, we would ask that you consider the following when preparing your feedback:

- explain your views as clearly and as concisely as possible
- be sure to distinguish between what you support and what you object to in the proposal
- provide the rationale for your views
- offer alternative ways to improve the proposal
- whenever possible, support your views and particularly your concerns with facts, data, or specific examples
- describe any assumptions that you used

- if you have concerns regarding the potential burden or costs of implementing the proposal or certain aspects of it, please provide specific information about the nature of those burdens and costs, as well as an estimate of the costs, an explanation of how you arrived at the estimate, and any suggestions for how costs could be reduced or minimized

- provide copies of any technical information or data you used in your comments;

- submit your comments within 30 days of the date of this document

- send your response electronically to the Publications Coordinator so that we can collate all the comments received.

6.0 Next step

Initially, the PMRA will work with the provinces and territories, through the Federal/Provincial/Territorial Committee on Pest Management and Pesticides, to examine the possibility of sharing data on adverse effects with provincial and territorial organizations and with municipalities. Similarly, the PMRA will discuss with other federal departments such as Agriculture and Agri-Food, Environment, Transport and Human Resources and Development, the need to exchange data on pesticide exposures.

Through communications programs, the PMRA will encourage the medical and research community, other governmental agencies and individuals to report adverse effects.

Appendix I Guidelines

These guidelines explain in more detail the type of information that would be required in each of the categories delineated in the Regulation. They include:

1. Incidents Involving Human Health

Major adverse effects in humans

Life-threatening effects include, but are not limited to, intracranial hemorrhage, seizures, grand mal seizures, coma, clinical evidence of renal failure, respiratory depression or bronchoconstriction requiring immediate treatment, cardiovascular instability, cardiac arrest, respiratory arrest, or patients who require mechanical ventilation. In general, life threatening effects are any condition which if untreated would likely lead to death.

Adverse reproductive effects include, but are not limited to, premature or low weight birth, spontaneous abortion, miscarriage, or stillbirth; birth defects (or adverse effects due to endocrine disruption) including mental retardation and infertility in men or women.

Residual disability is any adverse effect which lasts for months or years after the initial poisoning and limits a major activity, e.g., require continuous health care, time off work, or modification of daily activities. Examples include delayed neuropathy, renal damage requiring dialysis, permanent change in vision, and development of chronic respiratory disease such as asthma.

Moderate adverse effects in humans

Effects include, but are not limited to, a corneal abrasion, blurred vision with pinpoint pupils, high fever, disorientation (confusion, hallucinations), isolated brief seizures, profuse sweating, drooling, gastro-intestinal symptoms leading to dehydration, caustic injury to mouth or esophagus, severe muscle weakness, incoordination, tremor, or hives. More prolonged effects are those that last one month or longer, such as a persistent skin rash.

Minor adverse effects in humans

Effects include, but are not limited to, skin rash, itching, conjunctivitis (red, tearing eyes), drowsiness, transient cough, headache, joint pain, agitation, restlessness, or mild gastrointestinal symptoms such as self-limited diarrhea, stomach cramps, or nausea. These effects are reported to have lasted less than one month.

Unknown adverse effects in humans

A person reporting an incident to a registrant may report exposure and allege an adverse effect. Specific symptoms, however, may be unknown or unspecified. If exposure is reported, no acute adverse effect is alleged, but the reporter informs the registrant they may suffer delayed or chronic effects.

Although not required by the regulation, the agency would be interested in documented cases of measured exposure that do not result in symptoms. If a documented exposure occurred and, based on other available evidence, was likely to lead to an adverse effect, then a report would be filed under this category. This category can be used for reporting evidence that known exposures have not resulted in symptoms. This information is useful in establishing a No Observed Effect Level (NOEL) for the pesticide. Additionally, the reporting of exposures which do not lead to adverse effects provides a measure of a product's safety.

2. Incidents Involving Domestic Animals

Major adverse effects in domestic animals

Life-threatening effects include, but are not limited to, massive or internal hemorrhage, loss of consciousness, grand mal seizures, paralysis, cardio-respiratory depression and bronchoconstriction requiring immediate treatment. In general, life-threatening effects are any condition which, if untreated, would likely lead to death. Residual disability includes adverse effects which last for an extended period of time after the initial poisoning and may affect the life span for the animal. An example of an adverse effect which may last for an extended period of time is the case of a cat that developed severe weakness lasting for weeks to months after organophosphate exposure. An example of a residual disability that may affect the life span of an animal is the case of a dog which recovered from cholecalciferol rodenticide ingestion but is left with decreased renal function.

Moderate adverse effects in domestic animals

Effects include, but are not limited to, corneal abrasion, difficulty breathing, hyperthermia, isolated focal seizures, gastrointestinal symptoms leading to dehydration, caustic injury to mouth or esophagus, severe muscle weakness, incoordination, tremors and hives. More prolonged effects are those that last one month or longer, such as a persistent skin rash.

Minor adverse effects in domestic animals

Effects include, but are not limited to, excessive salivation, skin rash, itching, conjunctivitis, lethargy, mild gastrointestinal symptoms of a short duration and minor behavioural changes such as agitation and hyperactivity.

Unknown adverse effects in domestic animals

If a documented exposure occurred and, based on other available evidence, was likely to lead to an adverse effect, then a report would be filed under this category. This category can be used for reporting evidence that known exposures have not resulted in symptoms. This information is useful in establishing a NOEL for the pesticide in different species of animals. Additionally, the reporting of exposures which do not lead to adverse effects provides a measure of a product’s safety.

3. Incidents Involving the Environment

Severe adverse effects in the environment

An environmental adverse effect is considered severe when a mortality occurs that affects 3 times the number of individuals that is considered major. In addition, any adverse effect occurring in an individual of a Canadian species at risk.

Major adverse effects in the environment

An environmental adverse effect is considered major when the following number of individuals are noticed exhibiting one or more characteristics of an adverse effect (i.e., 10 birds died and 5 exhibiting acetylcholinesterase inhibition symptoms, therefore, equalling 15 birds affected from a single incident).

Birds:

1) ≥ 15 individuals of a flocking species
2) ≥ 5 individuals of a songbird species and other non-flocking species
3) ≥ 3 individuals of a predatory species

Amphibians:

1) ≥ 50 individuals

Mammals:

1) ≥ 25 individuals for small mammals
2) ≥ 5 individuals for large or solitary mammals

Reptiles:

1) ≥ 10 individuals

Fish:

1) ≥ 50 individuals of a schooling species
2) ≥ 10 individuals of a non-schooling species

Large Aquatic Invertebrates (i.e., crabs, lobsters, shrimp, molluscs, etc.):

1) ≥ 10 individuals

Honeybees/Beneficial Insects:

1) mortalities in ≥ 100 individuals
2) behavioural effects in ≥ 50 individuals
3) colony decline in the vicinity of treatment areas

Plants:

Trees and Shrubs:

≥ 10 trees - ≥ 1/3 of individual tree exhibits leaf abscission or discolouration (e.g., bleaching or yellowing of leaves); or significant reductions in seed or fruit yield

≥ 10 shrubs - ≥ 1/3 of individual shrub exhibits leaf abscission or discolouration (e.g., bleaching or yellowing of leaves); or significant reductions in seed or fruit yield

Herbaceous Plants:

In areas where the effects on vegetation are clearly visible. Some of these effects include the following:

- Dead or dying plants
- Visual injury - chlorosis, necrosis, bleaching, abscission, vein discolouration, terminal bud death
- Stunted vegetative growth - can be a visual symptom
- Reduced seed/fruit yield
- Reduced emergence
- Flowering - abnormal flower quality, number of flowers
- Deformities (e.g., in tubers)

In addition to the above, any adverse effect caused by a pesticide product or active ingredient currently in formal review for ecological concerns.

Minor adverse effects in the environment

An adverse effect that results in the number of individuals affected to be less than the number of individuals in the major adverse effect.

4. Residues in Groundwater, Surface Water and Food

Residues in water

For active ingredients which do not have guidelines set, the cut-off is the limit of detection. These guidelines apply to the parent compound or active ingredient and all transformation products defined by the PMRA in the residue of concern.

Residues in food

The proposed regulations will also require the reporting of information by registrants relating to the presence of pesticides in food if the level of pesticide detected in the food was in excess of an established MRL.

5. Incidents Involving Unacceptable Efficacy, Crop Tolerance and Value

Pest resistance

Information must be submitted concerning substantiation of any incident of a pest having developed resistance to any pesticide (both public health and non- public health) that occurred under conditions of use, application rates and methods specified on the label if either of the following conditions is met: (1) The survival of the suspected pesticide-resistant pest was significantly higher than that of a known susceptible pest when both the suspected resistant and susceptible pests were treated with the pesticide under controlled conditions.
(2) Biochemical tests or DNA sequencing indicate that the pest is resistant to the pesticide.

Efficacy failure

- Identify the pest which was not controlled by the pesticide application. Provide common and scientific name, i.e., lambsquarter (*Chenopodium album*);
- Quantitative report if possible, i.e., 30 plants/square metre or qualitative, i.e., heavy, light;
- Indicate the crop and variety, i.e., soybean OACBayfield;
- Reduction in quantity of yield or in other quality characteristic of crop;
- Provide appropriate growth stage of pest, i.e., redroot pigweed at 6-7 leaf stage;
- Provide appropriate growth stage, i.e., soybean at 3-6 leaf stage;
- Applicable only if perennial crop, i.e., alfalfa;
- Does this field/area have a history of pest resistence to the pesticide;
- Provide rate of application in terms of product, i.e., L/ha and active ingredient i.e., g/ha; Provide commercial name and PCP number;
- Provide commercial name and PCP of any registered adjuvants, quantity and type of fertilizer, i.e., liquid nitrogen 28-0-0 at 1.25%v/v or any other modifiers utilized, i.e., pH adjustor;
- Indicate the quantity of water applied, i.e., 100 L/ha;
- Indicate the application pressure, i.e., 275 kPa;
- Indicate county, town or other details to locate field;
- Provide precipitation levels before, on and after the date of application;
- Provide temperature at the time of application;
- Describe the type of application equipment utilized;
- Indicate if the pesticide was applied by a custom applicator or by the producer;
- Provide soil percent organic matter, soil pH and soil type of the field;
- Indicate the general topography of the field and if the damage was limited to specific areas of the field, i.e., only in low lying areas of the field.

Host/target site

- Describe the host/target site, i.e., the crop and variety;
- Describe the type of injury, i.e., chlorosis, stunting of crop;
- Indicate if the injury caused a reduction in the quantity of yield or affected other quality characteristics of the crop;
- Provide appropriate growth stage, i.e., soybean at 3-6 leaf stage;
- Applicable only if perennial crop, i.e., 2nd year alfalfa;
- Quantitative report if possible, i.e., 30 plants/square metre or qualitative, i.e., heavy, light;
- Provide rate of application in terms of product, i.e., L/ha and active ingredient, i.e., g/ha;
- Provide commercial name and PCP of any registered adjuvants, quantity and type of fertilizer, i.e., liquid nitrogen 28-0-0 at 1.25%v/v or any other modifiers utilized, i.e., pH adjustors;
- Indicate the quantity of water applied i.e., 100 L/ha;
- Indicate the application pressure, i.e., 275 kPa;
- Indicate province, county, town and other details to locate field;
- Provide precipitation levels before, on and after the date of application;
- Provide temperature at the time of application, indicate if there were extremes, i.e., hot, cold;
- Describe the type of application equipment utilized;
- Indicate if the pesticide was applied by a custom applicator or by the producer;
- Provide soil percent organic matter, soil type, soil pH of the field;
- Describe the general topography of the field and indicate if the crop injury was limited to specific areas of the field, i.e., only in low lying areas of the field;
- Provide list of the pesticides utilized in the field for the past 3 growing seasons;
- Provide list of the crops planted in the field the 2 previous growing seasons;
- Provide the 30 year mean temperature for the region and the mean temperature for the subject growing season;
- Provide the 30 year mean precipitation for the region and the mean temperature for the subject growing season.

Rotational/succeeding crop injury

- Indicate the crop and variety, i.e., soybean OACBayfield;
- Describe the type of injury, i.e., chlorosis, stunting;
- Reduction in quantity of yield or in other quality characteristic of crop;
- Provide rate of application in terms of product, i.e., l/ha and active ingredient, i.e., g/ha for all pesticides applied to previous crop;
- Provide commercial name and PCP number for all pesticides applied to previous crop;
- Provide commercial name and PCP of any registered adjuvants, quantity and type of fertilizer, i.e., liquid nitrogen 28-0-0 at 1.25%v/v or any other modifiers utilized, i.e., pH adjustors applied to previous crop;
- Indicate the time of application of pesticides in previous crops, i.e., spring application of herbicide;
- Indicate county, town or other details to locate field;
- Provide soil% organic matter, soil pH and soil type of the field;
- Indicate the general topography of the field and if the damage was limited to specific areas of the field, i.e., only in low lying areas of the field;
- Provide list of the pesticides utilized in the field for the past 3 growing seasons;
- Provide list of the crops planted in the field the 2 previous growing seasons;
- Provide the 30 year mean temperature for the region and the mean temperature for the subject growing season.

Product quality

- Describe what happened, i.e., the container was leaking;
- Describe location where the Adverse Effect was observed, i.e., in a store, in a storage shed.

Application technology failure due to pesticide use

- Describe what happened;
- Describe the Application Equipment with emphasis on any particular part of the applicator which was most effected, i.e., nozzle type if the nozzles were clogged;
- Provide rate of application in terms of product, i.e., L/ha and active ingredient, i.e., g/ha.
- Provide commercial name and PCP of any registered adjuvants, quantity and type of fertilizer, i.e., liquid nitrogen 28-0-0 at 1.25%v/v or any other modifiers utilized, i.e., pH adjustors;
- Indicate the quantity of water applied, i.e., 100 L/ha;.
- Indicate the application pressure, i.e., 275 kPa.

Appendix II New information generated through scientific studies

The registrant will provide new information indicating any risks or decreased value of a pest control product that is generated through:

(a) scientific investigations of a type referred to in Section 9 of the existing PCP Regulations, i.e., scientific investigations respecting the following:

(i) the effectiveness of the control product for its intended purposes;

(ii) the safety of the control product to persons occupationally exposed to it when it is manufactured, stored, displayed, distributed or used;

(iii) the safety of the control product to the host plant, animal or article in relation to which it is to be used;

(iv) the effects of the control product on representative species of non-target organisms relative to the intended use of the control product;

(v) the degree of persistence, retention and movement of the control product and its residues;

(vi) suitable methods of analysis for detecting the active ingredient and measuring the specifications of the control product;

(vii) suitable methods of analysis for detecting significant amounts of the control product, including its residues in food, feed and the environment under practical conditions of use;

(viii) suitable methods for the detoxification or neutralization of the control product in soil, water, air or on articles;

(ix) suitable methods for the disposal of the control product and its empty packages;

(x) the stability of the control product under practical conditions of storage and display;

(xi) the compatibility of the control product with other control products with which it is recommended or likely to be mixed;

(xii) the effects of the control product or its residues when administered to test animals for the purposes of assessing any risk to humans or animals; and

(xiii) the effects of storing and processing food or feed, in relation to which the control product was used, on the dissipation or degradation of the control product and any of its residues.

(b) Human epidemiological and exposure studies:

The registrant must submit information generated through any study for which a person has concluded, or might reasonably conclude, that a correlation may exist between exposure to a pesticide and observed adverse effects in humans. The registrant must also submit information generated through exposure monitoring studies that indicate higher levels of risk or exposure than would be expected based on previously available reports, data, or exposure estimates. Such information must be submitted regardless of whether the registrant considers any observed correlation or association to be significant.

Appendix III Aggregate Annual Summary Report

Each registrant is required to provide an Aggregate Annual Summary Report which will include all of the adverse effects reported to the PMRA within the past year in addition to those which are of a less serious nature and can be reported annually. For those reports that are of a less serious nature and have not already been reported to the PMRA, individual reports must be completed along with the incorporation into the Aggregate Annual Summary Report. The attached form is a reporting template developed by the PMRA, to facilitate the aggregate annual summary of adverse effects reporting. The instructions for filling in the fields on this form are as follows:

Product or Active Ingredient Identification: In order for the incident to be a reportable event, the product must be identified in at least one of two ways. In order of preference by the agency, they are: 1) PCP Number or, 2) Active Ingredient. The product name must also be included, if known, but must be accompanied by either PCP Number or Active Ingredient.

Submission Date: The Submission Date refers to the registrant's date of submission for this report.

Critical Analysis: Time Period Covered: Data may be accumulated for a maximum of one year then reported within 30 days (interpreted by PMRA as 1 month). The registrant should state the time period this aggregate report covers.

Total Incidents: This field represents the total number of incidents which resulted in one or more of the "Severity Category Designation and Exposure Type".

Severity Category Designation and Exposure Type: Each incident will involve a minimum of one exposure type and severity category designation but could involve multiple designations. When an exposure type and severity category designation is reported it is counted only once per incident, regardless of the number occurring in that incident. As an example, one incident involving 5 humans each having effects that would be categorized as minor would result in category H-Mn being counted just once in the aggregate report. If that same incident also included 3 occurrences of an effect in domestic animals categorized as minor then the domestic animal category designation would have a 1 placed beside D-Mn. For a given product or active ingredient, the number of incidents which have been reported during the time period covered are added beside the corresponding category designation.

Scientific Studies and Literature: Registrants should include in this area the number of scientific studies described in Appendix II as well as the number of publications from refereed scientific literature sent to the PMRA during the course of the year.

Additional Information: Registrants may use this optional area to provide supplemental information that may explain, qualify, or otherwise aid in the interpretation of information provided in the aggregate summary. There is no limit as to the amount of information that can be provided in this area. Please note that this information will not appear in the PMRA database but will be made available to the evaluators within PMRA.

Aggregate Annual Summary Report					
Company Name:	**Registrant Code:**		**Page____of____**		
Time Period Covered: From:____To:____	**Submission Date:**		**Total Incidents:**		
Product or Active Ingredient	**Severity Category Designation and Exposure Type**				
	H-De H-Mj H-Md H-Mn	D-De D-Mj D-Md D-Mn	E-Sv E-Mj E-Mn	Rw Rf	V-Rs V-Ef V-Ht V-Rc V-Pq V-At
	H-De H-Mj H-Md H-Mn	D-De D-Mj D-Md D-Mn	E-Sv E-Mj E-Mn	Rw Rf	V-Rs V-Ef V-Ht V-Rc V-Pq V-At
	H-De H-Mj H-Md H-Mn	D-De D-Mj D-Md D-Mn	E-Sv E-Mj E-Mn	Rw Rf	V-Rs V-Ef V-Ht V-Rc V-Pq V-At
Scientific Studies and Literature:					
Additional Information:					

Legend:

H-De	Human - Death
H-Mj	Human - Major
H-Md	Human - Moderate
H-Mn	Human - Minor or Unknown
D-De	Domestic Animal - Death or Euthanasia
D-Mj	Domestic Animal - Major
D-Md	Domestic Animal - Moderate
D-Mn	Domestic Animal - Minor or Unknown
E-Sv	Environment - Severe
E-Mj	Environment - Major
E-Mn	Environment - Minor
Rw	Residue in water
Rf	Residue in food
V-Rs	Value - Incidence of pest resistance
V-Ef	Value - Efficacy failure
V-Ht	Value - Host/target site
V-Rs	Value - Rotational/succeeding crop
V-Pq	Value - Product quality
V-At	Value - Application technology failure