A Summary of Comments Received on the Proposed Pest Control Products Adverse Effects Reporting Regulations Published in the *Canada Gazette*, Part I, and the PMRA's Analysis

1 General Comments on the Proposed Regulations

The proposed Pest Control Products Adverse Effects Reporting Regulations (AERR) were published in the *Canada Gazette*, Part I, on 23 October 2004 for a 75-day comment period. Comments were received from 25 respondents, comprised of industry, user groups, non-governmental organizations, other government organizations including the United States Environmental Protection Agency (USEPA) and individuals. The PMRA was also proactive in consulting with experts on specific issues.

Respondents expressed general support for the adverse effects reporting program. Non-governmental and government organizations expressed strong support, as well as opposition to any potential weakening of the program. Industry respondents (associations, registrants, user groups) recognize and appreciate the changes that were made to the proposed regulation as a result of comments made on Discussion Document DIS2003-03, *Pesticides Adverse Effects Reporting Regulation*, published on 22 May 2003.

The comments and suggestions provided by respondents to the Part I publication and the PMRA's views are summarized below. When preparing the Regulations for publication in *Canada Gazette* Part II, the PMRA will examine each comment as well as the pros and cons of integrating suggestions. All requests for interpretation of the AERR will be addressed in a guidance document.

1.1 Purpose of the AERR

Some respondents expressed concern about the usefulness of a surveillance system that does not require clinical confirmation, investigation and follow-up on reports of human and domestic animal incidents. They felt that the lack of clinical confirmation would affect the ability to determine causality. It was suggested that clinical data should be evaluated by persons with appropriate expertise (e.g., medical officers, veterinarians, toxicologists and epidemiologists). It was also suggested that the PMRA enquire into the effectiveness of similar adverse effect reporting systems, specifically the USEPA's 6(a)2 program.

The mandate of the Minister of Health under the new *Pest Control Products Act* (PCPA) is to prevent unacceptable risks to people and the environment from the use of pest control products. To determine whether the health and environmental risks of a pesticide are acceptable, it is imperative that the PMRA have access to any available information about adverse effects related to the use of that pesticide in Canada once the product is available on the market. In order to ensure that the risks of registered pesticides continue to be considered acceptable, the PMRA must be aware of and evaluate any new information that could cause their registration to be amended or cancelled. The provisions in the new PCPA and in these Regulations for mandatory reporting of adverse effects will assist the PMRA in carrying out its responsibilities and fulfilling the mandate under the new PCPA on behalf of the Minister.

The adverse effect reporting system is a postmarket surveillance system aimed at detecting pesticide related issues. Adverse effect reports will be examined by PMRA experts, including toxicologists and epidemiologists, to establish if there are reasonable grounds to believe that the

risks or value of the pesticide are no longer acceptable. In assessing the causality of the adverse effect, the PMRA will take into consideration a number of factors, including the submission of previous adverse effect reports and other toxicological information. The usefulness of the USEPA program in identifying pesticide related issues has already been well established and is the predominant reason for developing the AERR. On average, the USEPA receives over 40 000 adverse effect reports per year on human, domestic animal, environmental and other types of incidents involving pesticide products. This information has been invaluable to the USEPA in detecting pesticide related problems with registered products. In contrast, the PMRA receives almost no reports of adverse effects from industry and postmarket problems with registered pesticides will continue be difficult to identify without these Regulations.

1.2 Cost Analysis

Some respondents questioned the cost of the AERR. In response, the PMRA has initiated a cost analysis which will be provided on the PMRA website when available.

1.3 False Reports

Some respondents expressed concern that false reports of adverse effects could be made to tarnish purposefully the reputation of a particular product. These respondents suggested that an offence for making a false report be added to the Regulations.

The suggested offence cannot be added because the Regulations apply only to industry and cannot be extended to apply to a third party. The USEPA has advised that they have not received any reported cases or complaints from industry about false reports in the seven years that their adverse effects program has been operating. Even if a false report is made, it should be noted that it is very unlikely that a regulatory decision would be made on the basis of only one adverse effect report. Rather, all available information about the issue will be considered in evaluating the risks posed by the product.

1.4 Collection of Adverse Effect Reports by Industry

Concern was expressed about industry being responsible for the collection of adverse effect reports. It was feared that industry could interfere with the reporting of adverse effects by the public or could intimidate the public in some way, or they would fail to report the adverse effect to the PMRA or could enter into a non-disclosure agreement with the person who reported the adverse effect in order to negate their obligation to report to the PMRA. These respondents suggested that adverse effects should be reported directly to the PMRA either on-line, by toll-free telephone call or by mail and that contact information for reporting should be on all pesticide labels.

The obligation to report adverse effects information arises under the Regulations when the information comes into the registrant’s possession. The registrant cannot legally avoid that obligation by entering into an agreement with the information provider or anyone else. As information about adverse effects reported to the PMRA will be posted on the PMRA website, a person who has reported an adverse effect to a registrant can verify that the information has been reported to the PMRA. In addition to reporting adverse effect incidents to registrants, incidents

can be reported directly to the PMRA as well (see Chapter 13, Voluntary Adverse Effect Program, for details).

2 Title

It was suggested that the title of the Regulations should make clear that the adverse effects reported are only "possibly associated with a pest control product".

The PMRA will consider modifying the title in consultation with Justice Canada legal advisors.

3 Interpretation (Section 1)

3.1 Definition of "Adverse Effect" [section 1(1)]

Several respondents expressed the view that incidents of intentional misuse should not be excluded. These respondents believe that, particularly for domestic products, many pesticide users either do not read the label or do not understand it because it is illegible, too long or too complex. Furthermore, it is difficult to distinguish between intentional and accidental misuse. Collecting reports of adverse effects involving misuse could provide valuable information that could lead to improvements in the label, including precautionary statements.

It was also recommended that incidents of adverse effects where the label provides notice of the risk involved not be required to be reported.

The PMRA is reviewing the definition of adverse effect in light of the comments received.

4 Classification of Adverse Effects [section 2]

Many comments received on classification are addressed under Chapter 12, Harmonization with the USEPA.

4.1 Residues in Water [section 2(e)]

Some respondents did not agree with the requirement that any residues in water above the limit of detection be reported. They expressed concern that this could create an erroneous public perception that very low levels of residues pose an unacceptable risk. It was suggested that residues in water should be reported directly to the PMRA by the public agencies that do the testing. On the other hand, others supported the requirement to report any findings of residues in water above the detection limit. It should be noted that an acceptable residue level has not been established for most pesticides.

The PMRA is reviewing the requirement to report residues above the limit of detection, particularly the ability to obtain the data from other sources.

4.2 Efficacy Failure [section 2(f)]

Many respondents commented that the meaning of a "pest that poses a direct or indirect risk to human health" needs to be clarified and that most pests pose at least an indirect risk to human health. Some respondents questioned why crop phytoxicity, which they contend is a more severe adverse effect than general efficacy failure and more important than pest resistance, is not required. Others expressed the view that reporting of efficacy failure should not be restricted to public health pesticides.

The intent of the Regulations was to receive only information on efficacy failure that is relevant to public health. However, as pointed out in the comments, many pests pose a direct risk to human health and most can be considered to pose an indirect risk. As such, the definition of efficacy failure is too broad and could result in the PMRA receiving a great deal of irrelevant information that would have to be reviewed. The PMRA will further consult with experts and stakeholders on this issue and consider all possible options such as requiring efficacy failure for all products but only if reported by a public health official, limiting the requirement to pesticides that control pests that are vectors of disease in humans or removing the requirement to report efficacy failure entirely and, instead, working directly with public health officials to identify relevant incidents of efficacy failure.

4.3 Pest Resistance [section 2(g)]

Comments received regarding the reporting of pest resistance requested a definition for "pest resistance" and stated that resistance may only be evident over an extended period of time (i.e., many years) and may be difficult to prove.

The PMRA is reviewing the requirement to report pest resistance.

4.4 Packaging Failure [section 2(h)]

Some respondents questioned the requirement to report packaging failure in cases where no adverse effect had actually occurred.

It was pointed out that some product defects have the potential to cause serious injuries to users even if the defect would not be expected to cause human exposure to the pesticide. For example, total release foggers may explode and mosquito lamps may catch on fire, and these incidents would have the potential to injure people.

The PMRA is reviewing the requirement to report packaging failure.

4.5 Adverse Effects Identified in a Scientific Study [section 2(i)]

In some of the comments received, it was recommended that all scientific studies be reported, not only those indicating new or increased risks.

It was also noted that the Regulations do not include enough details to determine which studies should be reported. Registrants will need clear guidance, such as detailed reporting indicators or

triggers, to determine if a study indicates ‘any new health or environmental hazard’ or ‘any health or environmental risk that may be greater than the risk determined at the time of registration’.

The PMRA will provide details about which studies must be reported, including reporting triggers, in a guidance document.

5 General Requirements [sections 4–6]

5.1 Reports Deemed Received [section 4]

Some respondents were of the opinion that information about adverse effects received by an employee or agent of a related corporation within the meaning of paragraph 4(b) may require some time to be communicated to the Canadian registrant who would then be required to report it to the PMRA.

The PMRA is presently exploring the amount of time that would be considered appropriate for information that is received by a related corporation to then be communicated to the Canadian registrant.

6 Adverse Effect Reports [Sections 7–10]

6.1 Adverse Effects in the United States [section 8]

Many respondents disagreed with limiting the required reporting of adverse effect incidents that occur in the United States to the more serious ones. On the other hand, some questioned the legal authority under the new PCPA to require reporting of incidents that occur outside Canada. These respondents were also concerned that the Canadian mandatory reporting forms require the collection of more detailed information than the USEPA requires and that industry will incur additional costs to revise their own data collection forms.

An essential aspect of the regulatory regime under the new PCPA is the availability and use of information concerning registered pesticides. It is within the authority of Parliament to require registrants who are subject to the PCPA to report information in their possession that is relevant to their registered products, even though the information may concern events which occurred outside Canada. The PMRA is working with the USEPA to facilitate direct sharing of adverse effect reports. Once a system is in place for sharing adverse effects information directly between American and Canadian officials, the Regulations may be revised to remove the requirement to report incidents that take place in the United States

6.2 Adverse Effects Reported in the Scientific Literature [section 10]

Many respondents expressed the view that the reporting of information from the scientific literature should not be limited to the more serious adverse effects. Alternately, some other respondents commented that the requirement was unreasonable and would be overly burdensome.

The PMRA is considering removing the requirement for reporting scientific literature because literature searches can be conducted directly by PMRA staff as necessary.

7 Reporting Time Limits [sections 11–15]

Comments received on reporting time limits are addressed under Chapter 12, Harmonization with the USEPA.

8 Annual Summary [section 16]

Some respondents commented that the requirement to conduct a concise critical analysis would present a considerable resource burden on industry and recommended that it be removed. On the other hand, based on their past experience, the USEPA stated that this requirement would likely be useful to the PMRA and that it could act as an incentive for industry to take action when problems arise with their products.

The PMRA will examine the benefits of an annual summary for both industry and the PMRA.

9 Records [section 18]

Suggestions on the length of time required for record retention varied greatly. The PMRA will consider all comments.

10 Placement in the Register [sections 19 and 20]

10.1 Adverse Effect Reports and Supplemental Information [section 19]

Several industry respondents expressed concern about disclosing unverified, unresolved adverse effect reports that may unfairly tarnish products and/or registrants. They recommended that adverse effect reports not be made public until PMRA officials have reviewed the information and that PMRA comments accompany the report. Some of these respondents contend that the reports should not be made public unless there is some credible evidence to establish a causal relationship between the adverse effect and the pesticide in question or until a decision has been made on whether to initiate a special review. Some suggested that summaries of aggregated data about adverse effects should be published rather than individual reports. Others suggested that adverse effect reports should not be made public at all.

In contrast, several other respondents believed that making adverse effect reports public in a timely manner, preferably through posting on the website, is an important element of increasing

the transparency of the pesticide regulatory system under the new PCPA. This view was also a key recommendation of many witnesses during the parliamentary debates on bills C-53 and C-8.

The PMRA will examine all comments on disclosure of adverse effect reports in light of Health Canada's policy on transparency, including the recent decision by Health Canada to publicly disclose on the Health Canada website the Canadian Adverse Drug Reaction Monitoring Program database, which contains the adverse drug reaction reports. The reports are disclosed without any conclusions by Health Canada regarding causality. Before entering the database, users must read and agree to a disclaimer explaining the limitations of the data and how it should be interpreted. The PMRA would provide a similar statement outlining the limitations of the data, that it has not been investigated or verified, and that the reports are only **suspected** associations that reflect the opinion of the individual reporter and do not necessarily indicate causality of the product.

10.2 Determination of Special Review [section 20]

One organization suggested that automatic triggers for initiating a special review should be included in the Regulations and that there should be public consultation or an appeal process with respect to decisions on whether to initiate a special review.

The new PCPA will require the PMRA to evaluate the adverse effects information reported and, if there are reasonable grounds to believe that the risks or value of the pesticide are no longer acceptable, initiate a special review of the registration of the pesticide. The criteria that the PMRA will use for initiating a special review as a result of an adverse effect report will be included in a guidance document. In addition, the new PCPA also includes a provision that allows the public to request a special review.

11 Schedule

Additional comments on the schedule are addressed hereafter under "Harmonization with the USEPA". The PMRA will address requests for definitions and interpretation of terms used in the schedule in a guidance document.

12 Harmonization with the USEPA

The USEPA has required pesticide registrants to report information concerning adverse effects of their products since 1998 under section 6(a)(2) of the *Federal Insecticide, Fungicide, and Rodenticide Act*. The AERR are harmonized with the USEPA's program as much as possible with a few key exceptions, mainly the time limits for reporting the more serious adverse effects, the definition of adverse effect in the environment and the amount of detail required when reporting an incident.

12.1 Severity Classifications and Reporting Time Limits

Some respondents maintain that differences in severity classifications and reporting time lines between Canada and the United States will cause confusion, inefficiency, increased cost and incomplete data collection, especially for Canadian registrants that are also registrants in the United States. However, industry appreciates that they can use the American time lines when reporting an incident that occurred in the United States to the PMRA.

On the other hand, other respondents expressed the view that the shorter Canadian reporting time lines are an improvement compared to the American time lines. They were pleased that environmental adverse effects will be reported on an individual basis and that harm to a species at risk is included in the definition of a "severe adverse effect in the environment".

PMRA officials have discussed the categories for environmental adverse effects, including the schedule, with their USEPA counterparts and found that, based on the USEPA's experience, serious adverse effects in the environment may not be reported soon enough. PMRA experts will review the values in the schedule in light of the comments and further consultation with the USEPA and other experts.

12.2 Aggregate Reporting

Industry expressed disagreement with reporting all environmental adverse effects on an individual basis and, instead, suggested that the PMRA accept aggregate reporting for less serious incidents, as is done in the United States.

In the U.S., adverse effect reports are submitted in hard copy and need to be entered into a database by USEPA staff. Aggregate reporting helps to reduce data entry costs. Even though minor adverse effects can be submitted to the USEPA as aggregate reports, American registrants are required to provide detailed information upon request. Aggregate reporting can lead to an over-summarization of the adverse effects caused by a particular pesticide. In Canada, adverse effect reports will be submitted electronically, and therefore, data entry resources will not be required.

The PMRA recognizes the importance of harmonizing its adverse effects reporting requirements with those of the USEPA and has done so for the most part with a few differences. The PMRA will explore ways of more closely harmonizing with the USEPA by further consulting with the USEPA's 6(a)(2) team and their evaluation divisions on the quantity, quality and usefulness of data collected under 6(a)2 of the *Federal Insecticide, Fungicide, and Rodenticide Act*. While preparing the next version of the proposed Regulations, the burden on the industry, the benefits of an electronic submission system and the linkage between detailed information and an effective evaluation will be considered.

13 Voluntary Adverse Effect Program

Several comments were expressed on the necessity of developing a voluntary program through which professionals and individuals could report adverse effects directly to the PMRA.

The public can currently report adverse effects directly to the PMRA by calling 1-800-267-6315 or by emailing the Agency at pmra_infoserv@hc-sc.gc.ca. The PMRA is in the process of developing a more comprehensive program for voluntary adverse effect reporting and will consider all comments provided. As part of the new development, a webpage to (www.pmra-arla.gc.ca/english/legis/aer-e.html) has been added to the PMRA website to provide details on what is an adverse effect, why it should be reported, how to report it and other useful information.

14 Next Steps

The PMRA is in the process of revising the AERR based on comments received after its publication in the *Canada Gazette*, Part I, and further consultation with other stakeholders such as the Pest Management Advisory Council. Once complete, the AERR will be brought forward for publication in the *Canada Gazette*, Part II.