Adverse Effects Reporting

June 3, 2003

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Section 13 of the new PCPA:

An applicant or registrant shall report to the Minister any prescribed information that relates to the health or environmental risks or the value of the pest control product within the prescribed time and in the form and manner directed by the Minister.

To implement Section 13:

- AER regulation/guidelines to specify:
  - information to be reported; and
  - timeframe for reporting.

- AER program to coordinate:
  - e-receipt and evaluation of AERs;
  - implementation of decisions;
  - statistical analysis of AER data;
  - information to stakeholders and public; and
  - partnership within Canada and international.

AER regulation and guidelines:

Harmonization:

In developing the proposed AER regulation, similar systems of other countries and international bodies, such as the UK, Australia, the US EPA and the United Nations Environment Programme (UNEP), were explored. Other programs, both in Health Canada and Environment Canada were consulted.

Schedule:

- Discussion Document – May 20, 2003
- Gazette I – fall of 2003
- Gazette II – spring of 2004

AER regulation and guidelines:

What to report:

- human health, domestic animals and environmental effects;
- residues in excess of permitted levels in water and food;
- incidents involving unacceptable efficacy, crop tolerance and value;
- new information generated through scientific studies indicating any risks or decreased value, or human epidemiological studies or exposure monitoring studies; and
- information in the refereed scientific literature.

AER regulation and guidelines:

Timeframe for reporting:

- Adverse effects in humans:
  - Death & Major — 15 days
  - Moderate — 1 month accumulation & 1 month
  - Minor & Unknown — 12 months accumulation & 30 days

Adverse effects in humans:

- **Death:** includes death as a result of, or as a direct complication of, exposure to the pesticide.
- **Major:** a person alleges or exhibits symptoms which may be life-threatening or result in adverse reproductive effects or in residual disability.
- **Moderate:** 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.
- **Minor:** effects include, but are not limited to, skin rash, itching, conjunctivitis, 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:** 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.

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AER regulation and guidelines:

Timeframe for reporting (con't):

- Adverse effects in domestic animals:
  - Death — 1 month accumulation & 1 month
  - Major, Moderate — 12 months accumulation & 30 days
  - Minor & Unknown — 12 months accumulation & 30 days

Adverse effects in domestic animals:

- **Death:** includes deaths and euthanasia as a result of, or as a direct complication of, exposure to the pesticide.
- **Major:** a domestic animal exhibits or was alleged to have exhibited symptoms which may have been life-threatening or resulted in residual disability.
- **Moderate:** 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:** 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:** symptoms are unknown or not specified.

AER regulation and guidelines:

Timeframe for reporting (con't):

- Adverse effects on the environment:
  - Severe — 15 days
  - Major — 1 month accumulation & 1 month
  - Minor — 12 months accumulation & 30 days

Adverse effects on the environment:

- **Severe:** 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.
- **Major:** 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.
- **Minor:** 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.

AER regulation and guidelines:

Timeframe for reporting (con't):

- Residues in groundwater, surface water and food:
  - Residues in water — 1 month accumulation & 1 month
  - Residues in food — 1 month accumulation & 1 month

Residues in groundwater, surface water and food in excess of permitted levels:

- **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*.

AER regulation and guidelines:

Timeframe for reporting (con't):

- Incidents involving unacceptable efficacy, crop resistance and value:
  - Pest resistance 1 month accumulation & 1 month
  - Efficacy failure 12 months accumulation & 30 days
  - Host/target site 12 months accumulation & 30 days
  - Rotational/succeeding crop 12 months accumulation & 30 days
  - Product quality 12 months accumulation & 30 days
  - Application technology failure 12 months accumulation & 30 days

Incidents involving unacceptable efficacy, crop resistance and value:

- **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.
- **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:** application technology fails or has significantly reduced efficiency caused by the use of a pesticide.

AER regulation and guidelines:

Timeframe for reporting (con't):

- Information from studies:
  - new information generated through scientific studies indicating any risks or decreased value, or human epidemiological studies or exposure monitoring studies;
  - information in the refereed scientific literature. 30 days

- See Appendix 2 of AER Discussion Document.

AER regulation and guidelines:

Timeframe for reporting (con't):

- Aggregate Annual Summary Report:
  - submitted following a 12-month period specified by the registrant.

- See Appendix 3 of AER Discussion Document.

Disclosure of information:

- all AE reports (including Aggregate Annual Summary Report) will be available in the public registry as they are received, except for confidential business information and confidential test data – confidential test data may be viewed in reading rooms;

- serious AE will receive priority evaluation status and conclusions will be posted in the public registry – when risk is significant, the information will be actively disseminated to the public, for example, through a press release; and

- conclusions for all other AE reports will be posted in the public registry when evaluation and trend analyses have been completed.

Utilization of information:

- Section 14 of the new PCPA requires that AE information be considered as a basis for initiating a special review based on severity and trends;
- AE information will be used as a means of prioritizing chemicals for re-evaluation; and
- data will be shared with provincial and territorial organizations and with other federal departments.

Voluntary Adverse Effects Reporting:

PMRA will encourage the medical and research community, other government agencies and individuals to report AE.

Please submit your comments on the AER Discussion Document by June 21, 2003

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Any questions?

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