Adverse Effects Reporting Regulations

Presentation to the

Pest Management Advisory Council

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Legislative Changes and Objective

- **Three sections of new PCPA relate to reporting adverse effects:**
  - **Section 13:** registrants must report prescribed information in specified timeframe and format.
  - **Section 14:** determine whether a special review of registration should be initiated.
  - **Section 15:** make conclusions publicly available.

- **Objective of the proposed AER Regulations:**
  - to identify any potential risks to humans or the environment from the use of pesticides so corrective action can be taken when necessary.

Pre-Consultation

- a Discussion Document on the proposed Regulations was published in May, 2003 for public comment
- proposal was also discussed in meetings with stakeholders including NGO's, health care groups and representatives of pesticide industry
- PMRA considered all comments received and made several major changes when drafting the Regulations as a result

Harmonization

Pesticide Value:

- Discussion Document: incidents indicating decreased value of a pesticide would have to be reported.
- Proposed Regulations: reporting of incidents of decreased value would be limited to incidents of pest resistance and efficacy failure for pest control products that are used to control a pest that poses a direct or indirect risk to human health.

Adverse Effects Outside Canada:

- Consultation Document: report all adverse effects that occur outside Canada .
- Proposed Regulations: registrants would only have to report on incidents that occur in the U.S. if they are reportable there, are related to their pesticide, and involve a more serious adverse effect.

Harmonization

Reporting Timelines:

- Consultation Document: not all timelines are consistent with the EPA – some are longer, some are shorter. The more serious adverse effects, i.e., major adverse effects in humans, death in domestic animals and severe adverse effects in the environment, have shorter reporting time frames than are required in the U.S.

- Proposed Regulations: further harmonized timelines except for serious adverse effects where a more immediate response than the U.S. EPA time frames would be required - which are more consistent with the time frames for reporting of adverse drug reactions in Canada under the Food and Drug Regulations.

Other Major Changes

Pesticide Misuse:

- Discussion Document: not clear if incidents should be reported when the pesticide had been used contrary to label directions.
- Proposed Regulations: the regulations would exclude incidents involving use of the product in a manner that is inconsistent with the directions on the label with respect to site and application rate (except for scientific studies) or that would constitute an offence under the Criminal Code.

Residues in Water:

- Discussion Document: report when a pesticide had contaminated groundwater or had 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 was the most conservative.
- Proposed Regulations: report any findings of residues in water above the limit of detection.

Proposed AER Regulations

- **What is an adverse effect:**
  - An adverse effect is an effect that relates to the health or environmental risks or the value of a pest control product
    - it can include effects such as death, impairment of health or reproduction, pesticide residues in excess of the allowable limit etc.
- **What industry must report:**
  - Registrants and applicants for registration must accurately report any information they receive about an adverse effect that occurs in Canada or the US or that is reported in scientific literature if it relates to one of their products.

Categories and Time Limits

- adverse effects in a human:
  - death (within 15 days)
  - major (within 15 days)
  - moderate (1 month + 1month)
  - minor (12 months + 2 months)
- adverse effects in a domestic animal:
  - death (1 month + 1month)
  - major (3 months + 2 months)
  - moderate (12 months + 2 months)
  - minor (12 months + 2 months)
- adverse effects in the environment:
  - severe (within 15 days)
  - major (1 month + 1 month)
  - minor (12 months + 2 months)

Categories and Time Limits

- pesticide residues in food and water (1 month + 1month);
- efficacy failure of pesticide used for a pest that poses a risk to human health (1 month + 1month);
- packaging failure resulting in human exposure (1 month + 1month);
- pest resistance (1 month + 1month);
- scientific studies that show a new or increased health or environmental risk or hazard (1 month + 1month);

Categories and Time Limits

- adverse effects that occurred in the US and that are reportable there may be submitted according to the EPA 6(a)2 time limits;
- adverse effects published in scientific literature (12 month + 2 months);
- an annual summary (12 month + 2 months).

Other Requirements

- Annual Summary:
  - a concise critical analysis of AE reported during the past year would be required;
  - nil reporting would not be required.

- Records:
  - registrants would need to keep a record of every completed adverse effect report for six years.

Disclosure of Information

- all adverse effect reports for registered products received will be place in the public Register, including any supplemental information (comments, opinions);
- all personal information as defined in Privacy Act, CBI and test data will be removed;
- PMRA's conclusions will also be place in the Register.

Other considerations

- **Reporting Forms:**
  - registrants and applicants must use PMRA forms to submit adverse effects information;
  - draft reporting forms have been posted on the PMRA website for your information and comments.
- **Electronic Reporting:**
  - mandatory reporting of adverse effects will be done entirely electronically.
- **Proposed Date of Implementation:**
  - January 1st, 2006.

Your Comments

- **AER Regulations:**
  - Publication in Part I of Canada Gazette on October 23rd, 2004. Comments by January 6th, 2005.

- **Reporting Forms:**
  - Available on PMRA website. Same comment period as Gazette I.

What is the advice of Council concerning the proposed Adverse Effects Reporting Regulation?