

Pesticide Adverse Effects Reporting Program

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New Legislation

Three sections of new PCPA relate to AER:

- ◆ **Section 13:** Registrants must report prescribed information in specified timeframe and format (electronic reporting only)
- ◆ **Section 14:** Determine whether a special review of registration should be initiated
- ◆ **Section 15:** Conclusions should be made public

Development

Harmonization:

- ◆ Harmonization with US EPA – a major objective
- ◆ Also explored other international pesticide programs and programs in Health Canada

Have Developed:

- ◆ Process mapping
- ◆ Reporting criteria and timeframes
- ◆ Reporting e-forms
- ◆ Published Discussion Document on 20 May, 2003 – received and reviewed public comments
- ◆ Preliminary Privacy Impact Assessment



Disclosure of information:

All adverse effect reports and supplemental information will be available in the public Registry as they are received, except for:

- ◆ confidential business information,
- ◆ confidential test data, and
- ◆ personal information.

Status and conclusions will be posted as available – when risk is significant, the information will be actively disseminated to the public (e.g. press release)

In Progress:

- ◆ Drafting Regulations
- ◆ Privacy Impact Assessment
- ◆ Gazette I – January 2004
- ◆ Gazette II – August 2004
- ◆ Develop operating system
- ◆ Training (internal and registrants)

Voluntary Adverse Effects Reporting:

Phase 2:

PMRA will encourage the medical and research community, other government agencies and individuals to report adverse effects on a voluntary basis.



Any questions?

