Re-Evaluation and Special Review under New PCPA

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Objective of Re-evaluation and Special Review

- **Ensure continued acceptability**
- **Systematically review old products**
  - **Changes in data requirements**
  - **Changes in procedures of evaluation**
  - **New testing approaches**
  - **New standards**

Impact of New Act

- **What the New Act Authorizes**
- **Changes to Current Process**
- **Impact of other Requirements/Programs**
- **Transparency**

What the New Act Authorizes?

- **Clarifies and strengthens legislative foundation for Re-evaluation and special review (Sections 16-21)**
- **Timeline for initiating re-evaluation [Sections 16(1) & (2)]**
- **Triggers for initiating special review (Section 17)**
- **General process [Sections 16 (3)-(6) and 18]**
- **Scope and approach of evaluation (Section 19)**
- **Authority to confirm, cancel or amend registration of products in market (Sections 20 and 21)**
- **Precautionary Principle [Section 20(2)]**

Initiating Re-evaluation

- If last major decision made prior to 1 April 1995, re-evaluation must be initiated by 1 April 2005 or within a year after 15 years has elapsed since the most recent major decision, whichever is later
- If last major decision made on or after 1 April 1995, re-evaluation must be initiated within one year after 15 years has elapsed since the most recent major decision

  (major decision = ai registration, major new use, re-evaluation or special review)

Initiating Special Review

- When member of OECD prohibits all uses of an active for health or environmental reasons
- When a federal or provincial government department or agency has provided information indicating health or environmental risks or value is unacceptable
- Any person may request a special review. Minister decides if the request warrants initiating special review

Changes to Current Process

Current process remains same, except:

- Reconsideration of decision [Section 35(1)]
- All decisions must be consulted (Section 28)
- Notice to federal/provincial government [Sections 16(4) & 18(2)]
- No registrant's approval needed for releasing consultation statement (PACR)
- Give registrant opportunity for representation when additional info used or comparative risk assessment done [Sections 19(1)(c) and 19(5)]
- Transparency (Section 42)

Reconsideration (1/3)

- Objectives: transparency, responsiveness and accountability
- New PCPA defines process (sections 35-40)
- For all major decisions
  - Registration of new active ingredients
  - Major new uses
  - Re-evaluations
  - Special reviews

Reconsideration (2/3)

- Any person may file notice of objection (science-based with evidence) within 60 days after decision
- Minister may decide to establish review panel from established membership list
- Hearings open to public unless confidential info considered
- Info submitted to panel and panel's report are put in Register

Reconsideration (3/3)

- Regulations expected in Spring 2007
- Take effect as soon as new PCPA comes into force, regulations or not
- Will be supported by a guidance document and an internal process prior to implementation of new PCPA

Impact of other Requirements

- Incident (adverse effect) reporting
- Sustainable Pest Management and Risk Reduction
- Authority for comparative risk assessment

Product Register

What document	When put in Register
▸Announcement (sec 16/18 notice)	When sent out
▸PACR & RRD	When published
▸Data/info by registrant ▸Reference of additional data/info ▸Evaluation report ▸Section 19 & 12 notice ▸Advice	When RRD published
▸Review panel's report (RPR) ▸Data/info sub. to review panel	When RPR received

Transition from existing PCPA to new PCPA (1/2)

- Transitional actives: re-evaluation started under existing PCPA but to be finished under new PCPA
- Transparency and reconsideration apply if final decision is made under new PCPA
- When consulted under existing PCPA but final decision under new PCPA, will re-consult under new PCPA

Transition from existing PCPA to new PCPA (2/2)

- Some reviews are split between uses (e.g. 2,4-D), review streams (e.g. atrazine) or interim measures (e.g. phosmet), transparency and reconsideration apply only at final/overall decision

Questions?