Re-Evaluation and Special Review under New PCPA

John Worgan PMAC June 12, 2006

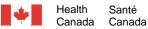




Objective of Re-evaluation and Special Review

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

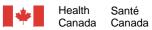




Impact of New Act

- 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)]





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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

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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 reconsult 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?

