The Proposed Review Panel Regulations

Presentation to the Pest Management Advisory Council June 2005 Francine Brunet





Health Santé Canada Canada

Introduction

- The New Pest Control Products Act
- The Proposed Review Panel Regulations
- Status and Next Steps





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The New Act

- Provides for a process to reconsider major registration decisions
- Major registration decisions are those:
 - To register new active ingredients
 - On major new uses which might result in significantly increased health or environmental risks
 - To maintain, amend or cancel uses after reevaluation or special reviews





Specifies <u>who</u> may:

- Object to decisions (any person)
- Establish terms of reference and a procedure for reviews (the Health Minister)
- Make representations to panels (panels to give any person reasonable opportunity)





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Specifies <u>what</u>:

- May be objected to (major registration decisions)
- Offences will be for persons making false representations
- Specifies <u>when</u>:
 - Objections may be filed (within 60 days after decision statement made public)





Specifies <u>how</u>:

- Objections will be managed (reject or establish panel)
- Panels will give their conclusions to the Health Minister (report)
- Decisions will be conveyed to the public and persons who objected (notices, Register)





 The Minister of Health keeps the discretion to confirm, reverse or vary the registration decisions





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The Proposed Review Panel Regulations

Needed to:

- Implement the reconsideration process under the new Act
- Replace the existing regulations respecting Review Boards under the current Act





- Discussed through initial consultation cycle in 2003*
 - PMRA Discussion Document, June 30 2003, DIS2003-05
- Comments received considered for new version





- In next version we are considering specifying eligibility criteria for individuals who might serve on review panels, such as:
 - Scientific knowledge
 - Public Service employment history
 - Potential for conflicts of interest that relate to the registration decision and that may affect their duties as a member





- Considering specifying <u>who</u> shall be removed from review panels:
 - Members at their request
 - Members who refuse or are unable to carry out their responsibilities
 - Members who no longer meet the eligibility criteria
 - Note: If a person is removed from the review panel, the Minister shall select another eligible person as a replacement unless the Minister has reasonable grounds to believe that the review may be completed by the remaining members





- Specifying <u>what</u> information is required when filing objections, such as:
 - name and address of objector
 - decision to which the notice relates
 - scientific basis for objection to the evaluations
 - evidence to support the objection, including scientific reports or test data





- Considering specifying <u>what</u> criteria will be used to determine whether panels will be established, such as:
 - scientifically founded concern about the evaluations is provided
 - the advice of one or more expert scientists would help address the objection





- Considering specifying <u>what</u> expenses will be paid for panel members, such that:
 - reasonable travel and living expenses in accordance with any applicable Treasury Board directives are paid





- Specifying <u>how</u> confidential information will be managed at hearings, such that:
 - Only participants in a review panel hearing are permitted to be present while confidential information is being considered at the hearing





- Considering specifying <u>how</u> confidential information will be managed at hearings, such that (cont.):
 - Participants in hearings will commit to through an affidavit not to disclose or use the confidential information for any purpose other than for participation in the hearing





 Would be supported by a guidance document to describe procedural matters (terms of reference, rules of procedure)





Status and Next Steps

Status:

 PMRA has considered comments received through initial consultation cycle, and is preparing to pre-publish the draft regulatory text

Next Steps:

Prepublication in Canada Gazette, Part I





Questions?



