Low Risk Pesticides: Report from the PMAC Working Group

Presentation to the Pest Management Advisory Council November 2005 Karen Lloyd





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Overview

- Background and mandate of Working Group
- Recommendations to PMAC
 - Criteria
 - Data requirements to assess risk and value
 - Regulatory options



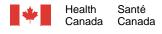


Background

November 2002: PMAC advised that:

- "Data requirements should be commensurate with potential risks posed by different types of pesticides and should not inhibit the registration of lower risk products; and
- Consideration be given to exempting very low risk products from registration or from regulation under the PCPA."





Working Group Terms of Reference

Mandate:

- To provide advice to PMAC on <u>potential regulatory</u> <u>options</u> for low risk pesticides including <u>efficacy</u> <u>requirements</u>.
- As there are existing PMRA directives and initiatives on reduced risk chemicals, microbials, pheromones and macrobials, the WG will focus on <u>other low risk alternatives</u> to conventional chemical pesticides.

Tenure:

 The working group aims to deliver a final report to November 2005 meeting of PMAC.



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Context

PCPA 2002

 7(2) The Minister shall expedite evaluations with respect to a pest control product that may reasonably be expected to pose lower health or environmental risks

Smart Regulations

- Government involvement must be assessed in light of its responsibilities, its resources and the likely effectiveness of its involvement.
- Government should focus on achieving a desired outcome.



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Criteria for Low Risk Consideration

- Low inherent hazard to non-target organisms (i.e., humans and the environment)
- Not persistent in the environment
- No "residues of concern" in target and offtarget crops
- Any formulants must be on list 4A and 4B





Tiered Data Requirements to Assess Risk

- Similar to USEPA approach to Lower Toxicity Pesticide Chemicals (2002)
- More concerns about toxicity, more data required
- Pre-submission consultation important step to identify tier and data required
 - More data may be required during evaluation phase
- Timelines would be expedited (relative to conventional pesticides), and would depend on the Tier





Tiers

- Tier 1
 Readily available scientifically-valid information
 PMRA has role in helping locate information
 Risk assessments likely qualitative
 Insufficient readily available information
 Limited dataset (existing or new) must be submitted
 Risk assessments qualitative or quantitative
 Tier 3
 Detailed data package required, similar to conventional chemical
 - Risk assessment quantitative





Data Requirements to Assess Value

- Value must be demonstrated
- Approach is to be flexible and based on weight-of-evidence (i.e., consider all components in value definition)
- Scientific information is needed to support efficacy claim
 - Efficacy claim may be less than those for conventional pesticides (e.g., reduces damage)
 - Single study may be sufficient





Regulatory Options

Registration

- Health and environmental risks and value are acceptable (following evaluations / consultations)
- Full or Conditional
- Appropriate on a product-specific basis
- Exemption through regulation (Scheduling)
 - Includes exemption from PCPA (e.g., devices) or from registration (e.g., research; certain products if used under prescribed conditions as listed in Schedule II)
 - Usually, lots of experience in registering specific products before they are Scheduled, thus risks and value evaluated
 - Too cumbersome on product-specific basis; appropriate for types/groups of products
- Ministerial authorization
 - Authorize use of unregistered products for specific purpose (i.e., research) as described in regulations
 - Product specific application; short term





Regulatory Options

- PMRA should select appropriate regulatory option based on desired outcomes:
 - Expedite access to low risk products
 - Provide level playing field
 - Provide users an opportunity to test product legally, while not compromising safety
 - Recognize value is important
 - Build public confidence
 - Be compatible with provincial/municipal legislation and practices
 - Harmonize internationally (e.g., US)
 - Keep costs to a minimum
 - Ensure compliance
- If public health claims, WG recommends product be registered



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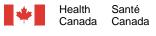
Other Recommendations

Fees

 Minimum (but some) fee should be required to expedite access

- Implementation
 - Clear guidance needs to be developed
 - Pilot project may be desirable, following development of, and consultation on, guidance
 - Investment needed: Minister should seek additional resources





The End

- Working Group feels it has completed its mandate
- Final report containing their advice / recommendations will be submitted to PMAC





Low Risk Pesticides The Path Forward: Report from the PMRA

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Develop Guidance Document

- Analyze approaches and lessons learned from other jurisdictions
 - Data needs for risk and value, criteria, timelines, cost
- Compare non conventional products being assessed to PMAC criteria
- Obtain list of low risk products approved for use in other countries
 - PMAC Low Risk Working Group will assist
 - Understand gap, barriers, potential products for "schedules"
 - Identify potential worksharing opportunities



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Develop Guidance Document

- Apply tiered approach further to propose timelines and cost for each tier
- Develop flexible approach on "value"
- Explore regulatory options further, in particular Ministerial authorization
 - In regulatory decisions for LR products, consider "desired outcomes" recommended by PMAC Working Group



Timelines

Guidance document to be drafted for public consultation by end of fiscal year.





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