Low Risk Pesticides: Report from the PMAC Working Group

Presentation to the

Pest Management Advisory Council

November 2005

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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 potential regulatory options for low risk pesticides including efficacy requirements.
  - As there are existing PMRA directives and initiatives on reduced risk chemicals, microbials, pheromones and macrobials, the WG will focus on other low risk alternatives to conventional chemical pesticides.
- Tenure:
  - The working group aims to deliver a final report to November 2005 meeting of PMAC.

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.

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 off-target 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

Tier 2

- 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

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

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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

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.