Report from PMAC Low Risk Working Group

Presented to the

Pest Management Advisory Council

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PMAC November 2002

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

PMAC November 2004

- Council members supported the idea of forming a working group to help develop a more flexible regulatory approach to low risk products.

Status

- Multi-stakeholder group of about two dozen members
- Chaired and supported by PMRA
- 4 teleconferences – lots of good discussion, no consensus on regulatory options

Agreement on Mandate

- To provide advice to PMAC on potential regulatory options for low risk pesticides, including efficacy requirements
- With recognition that there are existing PMRA directives and other initiatives on reduced risk chemicals, microbials, pheromones and macrobials, this PMAC working group will focus on other low risk alternatives

Agreement on Criteria

- Purpose of criteria is to provide an entry point to low risk program
- A scientific “low risk” rationale would need to be provided by the applicant

Agreement on Criteria

- Necessary criteria
  - Low toxicity to non-targets
  - Low inherent risk to users and the environment
  - Off-label use unlikely to cause adverse effects
  - Not persistent
  - Any formulants must be on List 4A, 4B
  - No “residues of concern” in target or off-target crops
  - First aid/safety directions must be basic

Agreement on Criteria

- Other considerations (any supporting evidence)
  - Substance widely available to public for other uses
  - Regulated under other legislation
  - Long history of safe use
  - Common food or foodstuff (mechanical processing only)
  - Non-toxic mode of action
  - Unlikely to cause resistance
  - For mixtures, how well are they characterized
  - Consistency of formulation

Agreement on Low Risk Treatment

- Product will not be given consideration for low risk treatment unless meets the low risk criteria
- Product will only be designated as low risk based on outcome of the risk assessment

Agreement on Eligibility for Low Risk Designation

- All products that meet the low risk criteria, as appropriately modified, at the time of application (pheromones, microbials, reduced risk) should be eligible for streamlined registration and designation as low risk
- Products that are evaluated under another category, e.g., reduced risk, that are judged after evaluation to be low risk, should be eligible for re-designation upon registrant request

Agreement on Tiered and Tailored Approach to Data

- Agreed in principle with USEPA methodology for determining the data and types of assessments for lower toxicity chemicals

Other Points of Agreement

- Generally felt that temporary registration should be an acceptable means to facilitate early access by users to low risk products (Further discussion needed on evidence of value necessary for temporary registration)
- Fees for low risk products should be for label review only

Issues/options requiring further discussion

- Offer non-registration option?
- How to determine efficacy for low risk products?
- Offer temporary registration?

Non-registration option

- Eligibility
  - First, prove low risk
  - No value data provided/ performance not demonstrated
- Mechanism
  - Case-by-case basis
  - PMRA would not enforce requirement for registration (can be done immediately)
  - Exemption list/ eventual scheduling

Non-registration option

- Other features:
  - Not available for “public health” applications
  - Expansions would require PMRA approval
  - Precautionary statements as appropriate
  - False and misleading claims not permitted
  - Disclaimer that not registered/ performance not assessed
  - MRL requirement as appropriate
  - Short timelines, no fee

How to determine efficacy for low risk products?

- First, prove low risk
- Can determination of efficacy/value be tailored?
- Are different benchmarks more appropriate?
- How much evidence is sufficient, e.g., other users, literature, anecdotal?
- Can users field test low risk products and provide feedback?

Temporary registration option

- First, prove low risk
- Some evidence of value/efficacy would be necessary
- Confirmatory efficacy data could be generated during period of temporary registration
- Can users field test and provide feedback?

Next steps for Working Group

- Further discussion of various registration/ non-registration options
- Preparation of discussion/issue papers
- Facilitated meeting to discuss pros/cons, practical implications
- Report to PMAC in November

Questions to PMAC

- What comments do Council members have on the progress and approaches for Low Risk products?
- Does Council identify any concerns about the use of temporary registrations while confirmatory data are being generated?
- What comments do Council members have concerning a “low risk” designation for all low risk products?