Risk Management and Decision Making Framework

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Decision Steps Components Initiation of Assessment and Management of Risk Identification of Issue **Overview** Request for Registration and Context Re-evaluation New Monitoring Results Risk to the Risk to Health Value Environment Assessment of Risk and Value Hazard Identification Efficacy Dose Response Assessment Economics/ **Exposure Assessment** Competitiveness Risk Characterization Sustainability Identification and Analysis of Options Management of Risk Selection of a Risk Management Strategy Implementation of the Strategy

(From SPN2000-01)



Monitoring and Evaluation of Results

| Enforcement and Compliance | Routine and Special Surveys | Maintaining a Modern Supporting Data Base |
|-------------------------------|--------------------------------|--|

Initiation of Assessment

- Registration request
- Re-evaluation
- New monitoring results
 - PCPA
 - Feeds and Fertilizers Act
 - ◆ TSMP



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Operationally:

- 1. Data screening and preliminary review
- 2. Divisional review teams established
- 3. Risk and value assessments
- 4. Science Review Committee (SRC) (Chief Registrar and Div. Directors)
- 5. Registration decision



Risk Management

Acceptable risk <u>AND</u> acceptable value



Risk Management Options

- Rely on measures that can be prescribed in conditions of use (i.e., the label)
- Practical? Enforceable?



Examples of Risk Mitigation Options

- Remove specific crops or uses
- Increase REIs, PHIs, PPE
- Reduce label rates / frequency of use
- Formulation change
- Buffer zones(risk mitigation often iterative)



Consultation

- New PRDDs, Regulatory Notes, PARDs for new actives, major new uses
- Committees: EMAC, PMAC, FPT
- Evolved from very little public participation
- Current PCPA poses a challenge
 - Submission information confidential
 - Requires registrant permission for disclosure
 - Proposed new legislation expand ability to consult



Conclusion

Acceptable Risk and Acceptable Value

Public Consultation (PRDD / PARD)

Registration/Continuing Registration

