



NAFTA Technical Working Group on Pesticides  
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# Microbial Pesticides – Risk Assessment and Decision Making

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# Three General Elements to Risk Assessment

- ◆ Assess potential for adverse effects or "hazard"
- ◆ Assess potential for "exposure"
- ◆ Risk = Hazard  $\times$  Exposure



# PMRA Approach

- ◆ PMRA formalized a decision-making framework based on assessment and management of risk for all pesticide products (SPN2000-01, Technical Paper: A Decision Framework for Risk Assessment and Risk Management in the Pest Management Regulatory Agency)
- ◆ framework developed mainly for chemicals, but also applies to microbials
- ◆ framework divided sequentially into 4 identifiable decision steps and components
  - ❖ underlying process is highly iterative and interactive



# EPA Approach

- ◆ Decision making based upon chemical paradigm, but each MPCA treated on a case-by-case basis
- ◆ Reduced data set compared to chemical pesticides, but hazards targeted are associated with microbes
- ◆ Classification of MPCA into classic microbial agent, GMO, or biochemical pesticide
- ◆ History of registering similar products or the same strain may affect data requirements / assessment
- ◆ Follows decision pattern as described by PMRA



# Step 1: Identification of Issue and Context

- ◆ Initiation of assessment and management of risk
  - ❖ request for registration
  - ❖ re-evaluation
  - ❖ new monitoring results



# Step 2: Assessment of Risk and Value

| <b>Risk to Health</b>  | <b>Risk to the Environment</b> | <b>Value</b>   |
|--|--------------------------------|--|
| <ul style="list-style-type: none"><li>• Hazard Identification &amp; Dose Response Assessment</li><li>• Exposure Assessment</li><li>• Risk Characterization</li></ul> |                                | <ul style="list-style-type: none"><li>• Efficacy</li><li>• Economics/<br/>Competitiveness</li><li>• Sustainability</li></ul> |



# Elements of Risk Assessment

| <b>Hazard Identification</b>   | <b>Exposure Assessment</b>  |
|--|---|
| <ul style="list-style-type: none"><li>• Adverse effects on lab animals?</li><li>• Adverse effects on NTOs?</li><li>• Type of adverse effect(s)<ul style="list-style-type: none"><li>– pathogenicity</li><li>– infectivity</li><li>– toxicity</li></ul></li><li>• Route(s) of exposure causing adverse effects</li><li>• Maximum hazard dose and/or determination of LC50/LD50/ID50</li></ul> | <ul style="list-style-type: none"><li>• Identify exposed populations</li><li>• Identify routes of exposure</li><li>• Estimate degree of exposure</li><li>• Use: quantity, frequency, conditions</li><br/><li>• Site characteristics<ul style="list-style-type: none"><li>– background levels</li></ul></li><li>• Proliferation/persistence<ul style="list-style-type: none"><li>– selection</li><li>– ecological fitness</li></ul></li><br/><li>• Dispersal</li></ul> |



# Risk Characterization

- ◆ What is the estimated likelihood of the adverse effect occurring in a given human population or nontarget group?
  - ❖ estimate potential for adverse human health effects to occur
  - ❖ estimate potential for adverse environmental effects to occur
  - ❖ evaluate uncertainty
  - ❖ describe any knowledge/data gaps
  - ❖ summarize risk information



# Risk Management Decision

- ◆ Outcome of risk and value assessments
- ◆ For new active ingredients (MPCAs), decision made by Science Review Committee comprised of senior managers (Directors), supervisors (Section Heads) and evaluators
  - ❖ conclude whether or not there exists an unacceptable risk of harm to human health and/or the environment
  - ❖ conclude whether or not the product has value
  - ❖ explore decision options



# SRC Decision Options

- ◆ If risks to health and environment acceptable and has value, i.e., can be used safely and effectively w/o modifications to proposed use, registration is granted
- ◆ If product has value, but risks to health or environment are unacceptable, mitigative options are explored to reduce risks to an acceptable level usually by limiting exposure (e.g., PPE, buffer zones, reduced rates, limit crops, lengthen PHI)
- ◆ If risks to environment or health or the product's value are unacceptable, and risks cannot be mitigated, then registration is denied



# Step 3: Management of Risk

- ◆ Identification and Analysis of Risk Management Options
- ◆ Selection of Strategy
- ◆ Implementation of the Strategy



# Step 4: Monitoring and Evaluation of Results

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



# SUMMARY

