Biopesticides Registration Improvement Course

Efficacy Data Requirements for Biopesticide Registration in Canada

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Scope of presentation

- Efficacy assessment: Is it required?
- Types of efficacy information
- Efficacy data requirements
- Efficacy assessment of biopesticides
- Challenges in efficacy assessment
- Tips for success

"…only pest control products that are determined to be of acceptable value are approved for use in Canada."

-Pest Control Products Act

What is value?

- Product's actual or potential contribution to pest management
- Considers efficacy, effect on host organisms, health, safety and environmental benefits, social and economic impact

Types of efficacy information

- Efficacy trial data
- Use history in a foreign jurisdiction

Efficacy Assessment

- Is there evidence that shows the product will work as stated on the label?

Types of efficacy trials

- Laboratory trials (e.g. Petri dish experiments; bioassays)
- Growth chamber or Greenhouse trials (e.g. pot trials)
- Small-scale field trials
- Operational trials

Efficacy Data

- How to ensure that efficacy trials result in useful information

Essential elements of efficacy trials

- Appropriate treatments that reflect the proposed use pattern
  - Application rate/s
  - Crop/site
  - Test product and commercial standard
  - Controls
  - Application interval
  - Number of applications
  - Application method

Efficacy Data Requirements

- Appropriate assessment parameter/s (direct and indirect methods)
- Appropriate statistical analysis of trial results
- Adequate pest pressure
- Sufficient number of efficacy trials
- Sufficient information on non-safety adverse effects
- Efficacy Summary Table
- Information on mode of action, pest resistance management, contribution to sustainability

Efficacy Assessment of Biopesticides

- Evidence for label claims
  - Efficacy of biopesticide when applied alone
  - Efficacy of biopesticide when used in a spray program (in rotation or in tank mixes)
  - Biopesticides as a viable component of IPM strategies
- Conditions of use
- Field trials vs. Greenhouse trials

- Scientific rationales for extrapolation to other crops (list of crops is required) or sites
- Details of IPM strategies used in the trials
- Use of foreign data
- Level of control
    - Measurable benefit approach (no determination of Lowest Effective Rate)
    - Development of appropriate label claims

Challenges

- Variability of performance under varying environmental conditions
- Formulation changes
- Wide rate range
- Trial standardization
- Variability in performance assessment

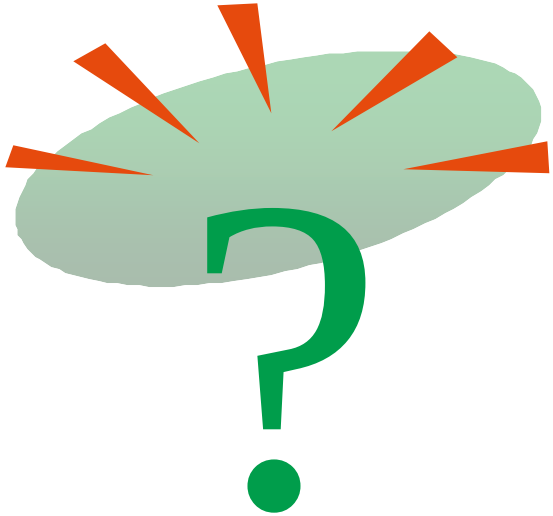
Tips for success

- Identify the biopesticide's intended uses and design appropriate trials
- Define conditions for optimum biopesticide performance
- Determine value of biopesticides (short term vs. long term effects; component of IPM strategy)
- Make effective use of scientific rationales
- Request a pre-submission consultation
- Follow pre-submission consultation advice
- Consult appropriate guidelines and directives
- Communicate with the PMRA

Resources: Efficacy Guidelines

- DIR2001-02, Guidelines for the Registration of Microbial Pest Control Agents and Products
- DIR2003-04, Efficacy Guidelines for Plant Protection Products
- PRO2010-06, Consultation on the Guidelines for the Registration of Non-Conventional Products

Questions?



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http://www.hc-sc.gc.ca/cps-spc/pest/index-eng.php/