Biopesticides Registration Improvement Course

RISK ASSESSMENT AND DECISION MAKING FOR MICROBIAL PESTICIDES 4.4

SHERYL K. REILLY, PH.D.

U.S. Environmental Protection Agency

Office of Pesticide Programs

Biopesticide and Pollution Prevention Division

Resources

Registration

http://www.epa.gov/pesticides/biopesticides/regtools/index.htm

http://www.epa.gov/pesticides/bluebook/

Online CFR: http://www.gpoaccess.gov/ecfr/

US (Microbial) Data Requirements (40 CFR 158.2100)

http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=c4d29715fa9ff8f12c12db4866c7447c&rgn=div6&view=text&node=40:23.0.1.1.9.16&idno=40

Guidelines:

http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series885.htm

Resources

REDs and BRADs

http://www.epa.gov/pesticides/biopesticides/ingredients/

Overview

Microbial Pesticides Branch –

- Registers Microbial Pesticides in the U.S.
- Establishes Tolerances and Exemptions for Residues in Food & Feed Commodities
- Conducts Risk Assessments
  - ✓ Human Health
    - Acute Toxicity/Pathogenicity
    - Higher Tier Data if Warranted
  - ✓ Product Characterization
    - Manufacturing Process
    - Batch Analyses/Product Consistency
    - Contaminants, Other Ingredients
    - Analytical Methods

Overview

Microbial Pesticides Branch –

- Registers Microbial Pesticides in the U.S.
- Establishes Tolerances and Exemptions for Residues in Food & Feed Commodities
- Conducts Risk Assessments
  - ✓ Ecological Fate & Effects
    - Target Pest Specificity/Host Range
    - Adverse Effects in Non-targets, Endangered Species
    - Persistence, Viability of AI in Environment

Overview

Microbial Pesticides Branch –

Makes Risk Management Decisions Based on Risks Identified During Risk Assessment

- ✓ **Label** – First Aid Statements, Protective Wear, Precautionary Language, Limit Uses & Use Sites, Application Methods

- ✓ **Tolerance/Exemption** – Set Limits for Residues, Uses

Common Problems - Issues

- **Data requirements not fully addressed**
  - ✓ **Inappropriate, unsupported waivers**
  - ✓ **Cited/submitted data – "similar" AI**
  - ✓ **Equivalence not demonstrated**

Common Problems - Solutions

- Pre-submission Meetings are *Beneficial*
- Address Data Requirements & Justify Waivers *Individually*
- Read Guidelines for *Each* Data Requirement
- Allow *Time* to Conduct Studies
- Alternative Data
  - ✓ *Demonstrate:* Strain Equivalence
  - ✓ *Ask:* Does this provide info described in guideline?

Phase 3

- **Primary Reviews**
- **Deficiencies Identified**
  - ✓ **75 Day Letter**
  - ✓ **May Need to Negotiate PRIA Due Date**
  - ✓ **The Action Does Not Move to Next Phase!**

Phase 4

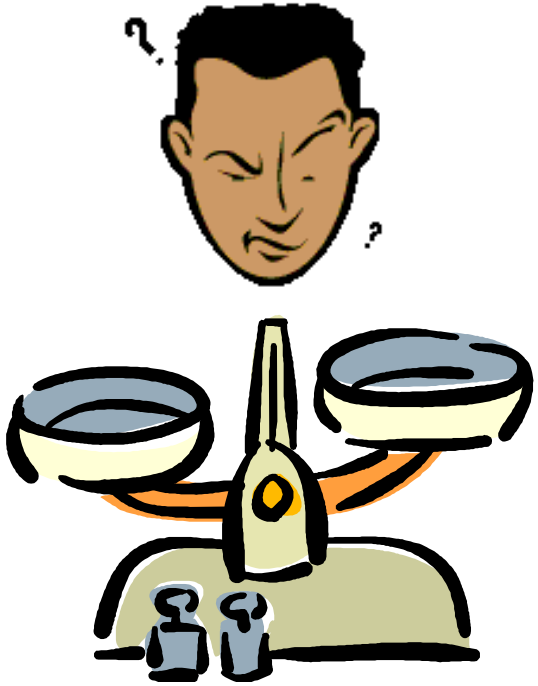
- **Secondary Review, Risk Assessments**
  - ✓**Deficiencies? → 75 day letter, negotiate, not grant, deny**

Common Problems / Issues

- **Deficiencies *often* trigger negotiations of PRIA due date**
- **Negotiations can significantly lengthen the time it takes to make a decision**
  - ✓ **Nature of Deficiencies**
  - ✓ **Review Queues**

Applications do not proceed to next phase until problems resolved

Common Problems / Issues



Guideline Studies?

Waivers, Alternate Data?

↑ CO$T

↓ Risk of Renegotiation, Not Grant, Denial

↓ CO$T

↑ Risk of Renegotiation, Not Grant, Denial

Common Problems - Solutions

- Pre-submission Meetings are *Beneficial*
- Address Data Requirements & Justify Waivers *Individually*
- Read Guidelines for *Each* Data Requirement
- Allow *Time* to Conduct Studies
- Alternative Data
  - ✓ Demonstrate Strain Equivalence
  - ✓ Does it provide same info as guideline study?

Common Problems - Solutions

- **Data, Waiver Volumes**
  - ✓ PR Notice 86-5 format
  - ✓ GLP Statement Important!
- **Data Compensation**
  - ✓ Exclusive Use (10 years) – Evidence that data owner approves
  - ✓ Compensible (10-15 years) – Offer to pay
- **Appropriate PRIA Fee Must Be Paid**
  - ✓ Include Proof of Payment
- **Fees Waived?**
  - ✓ 25% (or 50%) of the PRIA fee must be paid

Common Problems/Solutions

- Alternative data should include the information/end points as a guideline-conducted study
- When alternative data are not generated with your microbial active ingredient *isolate*, their equivalence must be demonstrated

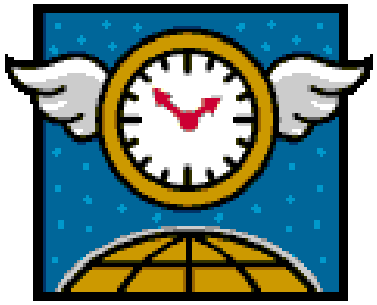
✓ (How)

Common Problems/Solutions

- **Requests for waivers of data requirements must be scientifically justified, and demonstrate why a *data requirement* is *not needed* for your product**
- **Address requests for waivers of each data requirement *individually***

It's better to ask questions before you submit your application

Significant Time Delays Can Occur When the PRIA "Clock" Starts Ticking



"There's no such thing as a stupid question." - Mom