Biopesticides Registration Improvement Course

CHALLENGES IN SUBMISSION MANAGEMENT

REGULATORY PROCESSES 3.1

SHERYL K. REILLY, PH.D.

U.S. Environmental Protection Agency

Office of Pesticide Programs

Biopesticide and Pollution Prevention Division

Overview

- **Biopesticide & Pollution Prevention Division Registers Biological Pesticides in the U.S.**
  - ✓ FIFRA Section 3(c)(5), Section 3(c)(7) – Products, Amendments
  - ✓ FIFRA Section 5 – Experimental Use Permits
- **Establishes Tolerances/Exemptions for Residues in Food & Feed Commodities**
  - ✓ FFDCA Section 408

Overview

- **Statutory Time Frames**
  - ✓ **FIFRA Section 3(c)(3)**
  - ✓ **FIFRA Section 33(f) – Decision Time Review Periods (PRIA)**

Overview

- **PRIA guarantees a *decision** by a "due date"**
- **Assumes the application is *complete***
  - **Administrative Documents**
    - ✓ **Application Form**
    - ✓ **FIFRA Label (5 copies)**
    - ✓ **Data Matrix**
    - ✓ **Certification with Respect to Citation of Data**
    - ✓ **Data Compensation**
    - ✓ **Confidential Statement of Formula**

* Not necessarily a *registration*

Overview

- **PRIA guarantees a *decision** by a "due date"**
- **Assumes the application is *complete***
  - **ALL Data Requirements Fully Addressed**
    - ✓ **Study volumes in PR Notice 86-5 Format**
    - ✓ **"Acceptable" (not deficient) Studies**
    - ✓ **Scientific rationale supports each data waiver**
    - ✓ **Alternative data provides same information as guideline study**
      - **Equivalence of test material with microbial active ingredient demonstrated**

* Not necessarily a *registration*

Overview

- **PRIA guarantees a *decision** by a "due date"**
- **Assumes the application is *complete***
  - **Fees are paid**
  - **25% (or 50%) of fees if waiver is granted**

PRIA Allows EPA 21 Days to Screen an Application for Completeness Before the Decision Time Frame Begins

* Not necessarily a *registration*

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 Data Requirements (40 CFR 158)

Biochemicals: 40 CFR part 158.2000, Subpart U

Microbials: 40 CFR part 158.2100, Subpart V

Waivers: 40 CFR part 158.45

Resources

Guidelines:

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

http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series880.htm

REDs and BRADs

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

Procedures – Phase 1

- Application received (Document Processing)
- PRIA Completeness Screen – 21 days
  - ✓ Studies Fail PR Notice 86-5 – 2 attempts to "fix"
  - ✓ Inerts checked for clearance
- Action forwarded to BPPD
- Submission Readiness Team (SRT)
  - ✓ Administrative Documents
  - ✓ Data, Waivers
- Fail – 75 Day Letter – Application does ***not*** move to next phase!

Procedures – Phase 2

- **Team Assignments**
  - ✓ Regulatory Action Leader
  - ✓ Science Reviewers

- ***Federal Register* Publications**
  - ✓ Notice of Receipt – Significant Actions
  - ✓ Notice of Filing – Petition (Tolerance, Exemption)

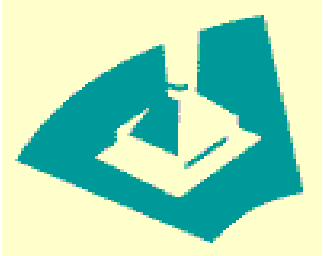
Procedures – Phase 3

- **Primary Reviews**
  - ✓Human Health
  - ✓Product Characterization
  - ✓Ecological Fate and Effects

- **Deficiencies Identified**
  - ✓75 Day Letter
  - ✓Action Does Not Move to Next Phase!
  - ✓May Need to Negotiate PRIA Due Date
- **Acceptable?** Phase 4

Procedures – Phase 4

- **Secondary Review, Risk Assessments**
  - ✓ Human health (FQPA/food uses, exposure, etc.)
  - ✓ Ecological fate, non-targets, endangered species
- **Deficiencies? → 75 day letter, Negotiate, Not Grant, Deny**
- **Biopesticide Registration Action Document Drafted (New AI) or Revised (New Uses)**
- **Final Rule Drafted ↔ OGC Concurrence**



Procedures – Phase 4

- **Prepare Documents for 30 Day Public Comment Period**
  - ✓ **Documents for Public Docket Screened for Confidential Business Information (CBI)**
  - ✓ **Cleared Documents Uploaded to Docket**
  - ✓ **Website Announces Opening of Comment Period**

Decisions – Phase 5

- **Public Comment Period (30 days) - Risk Assessments, BRAD, Proposed Decision**
- **Label Finalized**
- **Registration Notice Signed**
- ***Federal Register* Publications**
  - ✓ **Food Tolerance or Exemption**
  - ✓ **Notice of Issuance (New AI, First Food, Other Significant New Uses, EUPs) in the *Federal Register***

Common Problems - Issues

- **Administrative documents incomplete, missing**
  - ✓ Signatures/dates missing, incorrect agent
  - ✓ 86-5 Format Failure
- **Data requirements not fully addressed**
  - ✓ Inappropriate, unsupported data waivers*
  - ✓ Cited/submitted data for "similar" AI
  - ✓ Equivalence to AI not demonstrated
  - ✓ CSF Incomplete or Inaccurate

* 40 CFR 158.45

Common Problems - Issues

- **Labels**
  - ✓ Package Size Inadequate per Directions
  - ✓ False, Misleading
  - ✓ Advertising Claims
  - ✓ Claims Not Supported
    - Efficacy (Public Health Pests)
    - Storage/Stability
  - ✓ Mandatory v. advisory language
  - ✓ Storage & Disposal
  - ✓ Organic Labeling

Common Problems - Solutions

- Pre-submission Meetings are *Beneficial*
- Address All Data Requirements & Justify Waivers *Individually*
- Read Guidelines for *Each* Data Requirement
- Allow *Time* to Conduct Studies
- Alternative Data
  - ✓ *Demonstrate* equivalence of surrogate ai
  - ✓ *Ask:* same info as in guideline?

Common Problems - Solutions

- Make Sure ALL Forms are Included
- Make Sure Forms are Filled Out
  - ✓ Signatures (of "Agent of Record")
  - ✓ Contact Information
  - ✓ Dates
- Data Volumes (Including Waivers) in PR Notice 86-5 Format
  - ✓ Confidentiality & GLP Statements

Common Problems - Solutions

- **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

The PRIA Time Frame Does Not Start for 21 Days After Receipt of a Complete Package and the Applicable Fee

Common Problems - Solutions

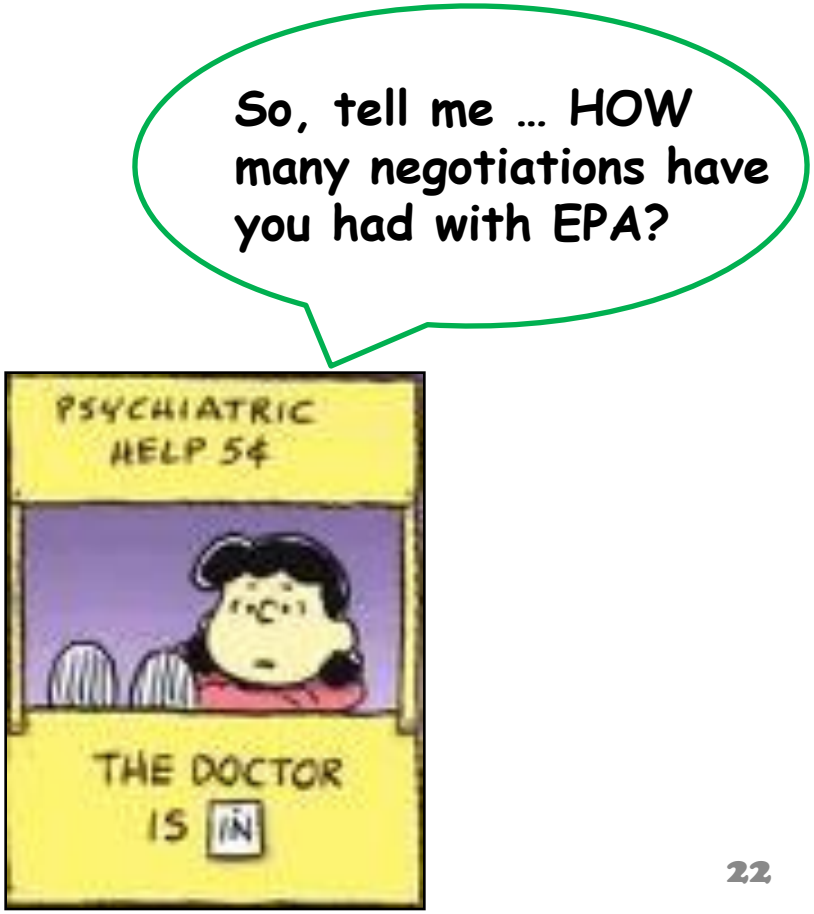
- **Submit Applications *Well in Advance* of Use Season**
- **Allow *Extra Time* to Address Problems Identified During EPA's Review**
- **Allow *Extra Time* for State Registrations**

"Free" Advice

It's Better to Ask Before Submitting an Application

Deficiencies Cost Time

and Money …



Gracias

Thank You

Merci

Bedankt

谢谢你

شكراً

Ευχαριστώ

धन्यवाद

Hvala

Grazie

Obrigado!

ขอบคุณ

Vielen Dank

Teşekkürler

Díky