

SPECIALTY CROP REGULATORY ASSISTANCE WORKSHOP

**PESTICIDE REGISTRATION IMPROVEMENT ACT  
(PRIA) FEE CATEGORIES & OTHER REGISTRATION  
RESOURCES FOR PLANT INCORPORATED  
PROTECTANTS (PIPs)**



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**OFFICE OF PESTICIDE PROGRAMS**

**BIOPESTICIDE AND POLLUTION PREVENTION DIVISION**

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# WHO REVIEWS AND APPROVES PIP REGISTRATIONS?

- **BIOPESTICIDES & POLLUTION PREVENTION DIVISION'S MICROBIAL PESTICIDES BRANCH (BPPD, MPB – AKA "PM 92")**
- **STATUTORY & REGULATORY AUTHORITY**
  - FIFRA Section 3(c)(5), Section 3(c)(7) – Registrations, Amendments
  - FIFRA Section 5 – Experimental Use Permits
  - FIFRA Section 33 – Registration Fees, Time Frames
  - FFDCA Section 408 – Establish Tolerances, Tolerance Exemptions for Residues in Food/Feed Commodities
  - 40 CFR parts 150-180
    - ▲ Part 174 = PIPs

# WHERE TO BEGIN

➤ **THE PESTICIDE REGISTRATION MANUAL  
("BLUE BOOK" )**

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

- **Chapter 3: Biopesticides**
- **Chapter 5: Registration Fees**
- **Chapter 11: Tolerance Petitions**
- **Chapter 14: Obtaining an EPA Establishment Number**
- **Chapter 15: Submitting Data, Confidential Business Information**

# WHERE TO BEGIN

➤ **THE PESTICIDE REGISTRATION MANUAL  
("BLUE BOOK" )**

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

- **Chapter 20: Forms & How to Obtain Them**
- **Chapter 21: Submitting Applications, Contacting EPA**
- **Chapter 11: Tolerance Petitions**
- **Appendix A: Guidance Documents**
- **Appendix B: Registrant Documents**
- **Appendix C: Forms Overview Table**
- **Appendix D: Examples of Completed Forms**

# WHAT IS PRIA?

- **A Statute that allows EPA to collect fees to register pesticides**
- **PRIA Established a decision\* Time Frame**
- **The Fee Category for the action Determines the Fee & Time Frame**
- **PRIA Assumes the Application is Complete When submitted:**
  - **Administrative Documents**
  - **All Data Requirements are Addressed**
  - **Fees are Paid, or**
  - **25% (or 50%) of Fees Paid if Requesting a Fee Waiver**

**\* Not necessarily a registration!**

# WHAT IS PRIA?

- **Gives EPA 21 Days to Screen Application for Completeness Before Decision Time Frame Begins**
- **Time Frames Can Be Negotiated for:**
  - **Deficiencies (e.g., Data Gaps, Unsupported Data Waiver Requests)**
  - **Risk/Issues Identified During Risk Assessment**

# EXAMPLES OF PRIA CODES FOR PIPS

CODE	ACTION	TIME FRAME MONTHS	FEE (\$)
B770	Experimental Use Permit application; new active ingredient; establish temporary tolerance or tolerance exemption; SAP review required; credit \$105,000 toward new active ingredient application that follows	15	\$173,644
B771	Experimental Use Permit application; new active ingredient; establish temporary tolerance or tolerance exemption; <u>NO</u> SAP review required; credit \$105,000 toward new active ingredient application that follows	10	115,763
B800	New active ingredient; establish permanent tolerance or tolerance exemption based on temporary tolerance or tolerance exemption; <u>NO</u> SAP review required	12	231,525
B810	New active ingredient; establish permanent tolerance or tolerance exemption based on temporary tolerance or tolerance exemption; SAP review required	18	289,407

# EXAMPLES OF PRIA CODES FOR PIPS

CODE	ACTION	TIME FRAME MONTHS	FEE (\$)
B820	New active ingredient; establish tolerance or tolerance exemption; <u>NO</u> FIFRA Scientific Advisory Panel (SAP) review required	15	289,407
B840	New active ingredient; establish tolerance or tolerance exemption; Scientific Advisory Panel (SAP) review required	21	347,288

**SAP = Science Advisory Panel**; provides external (non-EPA) advisory or peer reviews on scientific issues related to pesticide risk assessments. PIPs may undergo an SAP when new paradigms are presented to EPA . Examples include refuge changes, novel technologies, products, or uses. Discussed at pre-submission meetings with the Microbial Pesticides Branch.

**PRIA Fee Categories Table for PIPs:**

<http://www.epa.gov/pesticides/fees/tool/category-table.html#bppd>



# COMMON PROBLEMS

- **ADMINISTRATIVE DOCUMENTS INCOMPLETE, MISSING**
  - Signatures/Dates Missing
  - Incorrect Agent or Contact Information
  - PR Notice 86-5 (Formatting) Failure
- **DATA REQUIREMENTS NOT FULLY ADDRESSED**
  - Inappropriate, Unsupported Data Waivers\*
  - Cited/Submitted Data for “Similar” AI
    - Equivalence of test material to the new product/AI is not demonstrated
  - CSF Incomplete or Inaccurate

\* 40 CFR 158.45

# SOLUTIONS

- **REQUEST A PRE-SUBMISSION MEETING**
  - **DISCUSS DATA, PETITION, FORMS, FEES**
- **SUBMIT APPLICATIONS *WELL IN ADVANCE***  
**OF PLANNED USE SEASON**
- **ALLOW *EXTRA TIME* TO ADDRESS PROBLEMS**  
**IDENTIFIED DURING REVIEW & RENEGOTIATION**
- **ALLOW *EXTRA TIME* FOR STATE**  
**REGISTRATIONS**

# SOLUTIONS

- **Make Sure ALL Forms are Included**
- **Make Sure Forms are Filled Out**
  - **Signatures (“Agent of Record”)**
  - **Contact Information**
  - **Dates on all Documents**
- **Data Volumes (Including Waivers) in PR Notice 86-5 Format**
  - **Statements of Confidentiality & Good Laboratory Practices**

# RESOURCES

**PRIA DECISION TREE:**

<http://www.epa.gov/pesticides/fees/tool/decisiontree/main.htm>

**FEE CATEGORIES:** <http://www.epa.gov/pesticides/fees/tool/category-table.html#bppd>

**REDS AND BRADs:**

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

**ONLINE CFR:** <http://www.gpoaccess.gov/ecfr/>

**ONLINE PESTICIDE REGISTRATION MANUAL:**

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

# “FREE” ADVICE

ASK BEFORE SUBMITTING  
AN APPLICATION

DEFICIENCIES COST TIME  
AND MONEY

*HOW* many PRIA negotiations have you had with EPA?



Thank you!

