US Environmental Protection Agency
Office of Pesticide Programs
Biopesticides & Pollution Prevention Division
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EPA Biopesticide Submission Process
Biopesticide Registration Workshop
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What are Biopesticides (biological pesticides)?

- Certain types of pesticides derived from such natural materials, e.g., animals, plants, bacteria, viruses, protozoans, and certain materials.
- 3 biopesticide classes:
  - Microbials
  - Plant-incorporated protectants
  - Biochemicals
Numbers of Biopesticides

- >200 registered biopesticide active ingredients
- >700 products
Microbial Pesticides

◆ Consist of a microorganism as the active ingredient.

(e.g., bacterium, fungus, virus or protozoan)
Examples: *Bacillus thuringiensis* (Bt), Nuclear Polyhedrosis Viruses, *Agrobacterium radiobacter*, *Metarhizium anisopliae*
Biochemical Pesticides

- Naturally-occurring substances that control pests by non-toxic mechanisms.
- Examples: insect sex pheromones, azadirachtin, canola oil, dried blood, cytokinin
EPA: Pesticide Laws

◆ Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)
  ❖ “no unreasonable adverse effects to human health and the environment” (risk/benefit)

◆ Federal Food, Drug, and Cosmetic Act
  ❖ food tolerances

◆ Food Quality Protection Act
  ❖ “reasonable certainty of no harm”
  ❖ Aggregate human health risk from all routes of exposure
EPA: Pesticide Laws

- Endangered Species Act
- Clean Water Act
- Safe Drinking Water Act
Registration Procedures

- Presubmission Activities (e.g., meetings)
- Application Package (e.g., Forms, Format, Studies, Label(s))
- Data Requirements
- Regulatory Coordination of the Package
- Science Review of Data [Risk Assessment]
- Regulatory Review Procedures [Risk Management]
Presubmission Activities – Getting Started

- Initial discussions regarding a potential product
  - Microbial and Plant-Pesticides: Phil Hutton, Chief, Microbial Pesticides Branch, Biopesticides and Pollution Prevention Division, (703) 308-8260; email: hutton.phil@epa.gov
  - Biochemical Pesticides: Sheryl Reilly, Chief, Biochemical Pesticides Branch, Biopesticides and Pollution Prevention Division, (703) 308-8269; email: reilly.sheryl@epa.gov
Presubmission Meeting

- When: In advance of intended registration submissions
- No formal package required, background materials are helpful (at least 2 weeks prior to meeting)
Presubmission Meeting

- Discuss active ingredient and product(s)
  - Classification
  - Use patterns
  - Potential data requirements
  - Relevant policies
  - Relevant rules/petitions
- Timeframe
Special Presubmission Considerations

- 25(b) exemption
- Biochemical classification – Classification committee determines whether active ingredient is naturally-occurring and has a non-toxic mode of action
Application Package - Forms

- Registration Application Form (EPA Form 8570-1)
- Confidential Statement of Formula (CSF) (EPA Form 8570-4)
- Certification with Respect to Citation of Data (EPA Form 8570-34)
- Required Data and Data Matrix (EPA Form 8570-35)
- Formulators Exemption Form (EPA Form 8670-27)
Application Package - Format

◆ PR Notice – 86-5 [Standard format for data submitted under the Federal Insecticide, Fungicide, and Rodenticide Action (FIFRA) and certain provisions of the Federal, Food, Drug, and Cosmetic Act (FFDCA)]

◆ Order and content of submission

◆ Number of copies: at least 3
Application Package - Contents

- Submittal package consists of all studies submitted at the same time for review in support of a single regulatory action
- Transmittal letter: What is being submitted (e.g., Section 3, EUP, etc.), list of studies and support materials
- Studies, waivers, proposed label, CSF, data matrix, Forms
Application Package – Front-End Screen

- Review package to see if it meets PRN 86-5
- MRIDs assigned to studies (if pass screen)
Micobial Data Requirements

- Series 885--Microbial Pesticide Test Guidelines
  [http://www.epa.gov/pesticides/biopesticides/guidelines/series885.htm]
- Pesticide Product Identity Data
- Residue Data
- Toxicology Data
- Non-target Organisms and Environmental Expression Data
Biochemical Data Requirements

- Biochemical Pesticide Test Guidelines
  - [http://www.epa.gov/pesticides/biopesticides/guidelines/biochem2.htm]
- Physical and chemical characteristics
- Toxicology Data
- Residue Data
- Non-target Organisms and Environmental Expression Data
Efficacy Data Requirements

- Product Performance Guidelines (Efficacy)
  - OPPTS Series 810 update of Subdivision G (also see 40 CFR 158.640)
- Public health pests e.g., rodents, fire ants, mosquitoes, cockroaches
Data Requirements – Public Interest Finding

- Required for new active ingredient having a conditional registration (3(c)7(C)) in the absence of certain required data.
- Agency must determine that use of the new chemical during the period of the conditional registration will be in the public interest.
- Criteria in 51 FR 7626 (March 5, 1986)
Tolerance Petition

- Is new active ingredient for food or feed use?
- Is new use of old active ingredient for 1st food/feed use?
- If yes, a tolerance petition (exemption from the requirement of a tolerance) must be submitted
- Registrant must pay tolerance fee (or have waiver granted) prior to review by BPPD
Regulatory Review

- Package must pass Front-end and PR Notice 86-5 screen before submission sent to BPPD for review
- Submission logged into BPPD
- Directed to Microbial Pesticides Branch or Biochemical Pesticides Branch
- Submission assigned by BC or Team Leader to Regulatory Action Leader (RAL)
- RAL coordinates all regulatory activities
Regulatory Review

- No obvious deficiencies or deficiencies have been addressed then RAL publishes:
  - FR notice announcing receipt of new active ingredient (also EUP)
  - FR notice of filing for tolerance petition Public comment period (typically 30 days)
  - Public docket established
Preliminary Science Review – Start Risk Assessment

- RAL works with Branch Chief/Team Leader to select appropriate science reviewers
- RAL sends appropriate disciplinary reviews to science reviewers
- Preliminary science screen of submission is done (typically done within 1-3 months)
Preliminary Science Review – Risk Assessment

- Science reviewer(s) communicate deficiencies to RAL
- RAL communicates “deficiency letter” to registrant (75 days to address issues related to submission package (PR Notice 75-4), additional data needs will be longer)
Full Science Review – Risk Assessment

- Science reviewers perform primary (and secondary data evaluation after preliminary screen completed [Write Data Evaluation Records, Risk Assessment Documents] [Some work done by contractors]
- RAL corresponds with the registrant on additional data needs, questions, concerns etc. during the course of science review
- Timeline for complete package for new active ingredient – 6 to 15 months (add several months for any additional submissions)
More Regulatory Review cont’d

- Labels (check PR Notices)
- CSF
- Inerts
- Public Interest Finding (if a conditional registration)
More Regulatory Review cont’d

✶ Biopesticide Registration Action Document (BRAD)
  ✶ Scientific and regulatory review of new active ingredient (and products) [Integrated risk assessment and risk management]
  ✶ Plain English Fact (PEF) Sheet
✶ Prepare Final Rule for tolerance establishment or exemption (if food use for new active ingredient or 1st food use)
Regulatory (Risk) Management Review Steps

- Risk management, mitigation, and policy decisions made by Science Reviewers, RAL, Team Leader, Branch Chief, Division Director, Office of General Counsel (OGC), Office Director/Deputy Office Director, Assistant Administrator

- BRAD review by science reviewers, BPPD management, OGC
Regulatory (Risk) Management Review Steps cont’d

◆ Decision Memorandum from DD to DOD
◆ Decision Memorandum, BRAD, labels, Fact Sheet are routed through BPPD management, OGC, DOD for concurrence and sign-off
◆ DOD signs-off BRAD and Final Rule
◆ Notice of Registration for DD’s signature
Regulatory (Risk) Management Review Steps cont’d

- Final Tolerance Rule published in the FR
- Notice of Registration of new active ingredient published in the FR
- If EUP, notice of issuance published in the FR
- Timeframe for RAL activities post-science review completion 2-3 months
- Total Timeframe: ave. 18 months
Additional Post-Registration Regulatory Processes

- RAL mails/faxes Registration Notice and stamped label to registrants [For EUP: EPA Regions]
- RAL has administrative duties to close-out the submission record(s)
Useful Information

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

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