

NAFTA Technical Working Group on Pesticides
Grupo de Trabajo Técnico del TLCAN sobre plaguicidas
Groupe de travail technique de l'ALENA sur les pesticides



US Environmental Protection Agency
Office of Pesticide Programs
Biopesticides & Pollution Prevention Division

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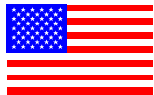
EPA Biopesticide Submission Process

Biopesticide Registration Workshop

November 13-15, 2001

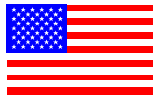
What are Biopesticides (biological pesticides)?

- ◆ 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



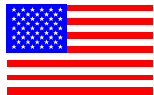
Microbial Pesticides

- ◆ 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*



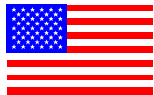
Biochemical Pesticides

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



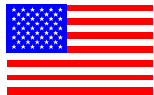
EPA: Pesticide Laws

- ◆ 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



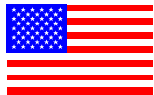
EPA: Pesticide Laws

- ◆ Endangered Species Act
- ◆ Clean Water Act
- ◆ Safe Drinking Water Act



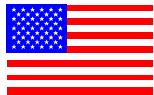
Registration Procedures

- ◆ 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]



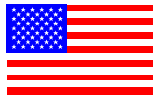
Presubmission Activities – Getting Started

- ◆ 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



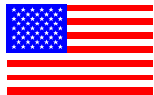
Presubmission Meeting

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



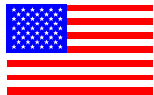
Presubmission Meeting

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



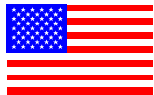
Special Presubmission Considerations

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



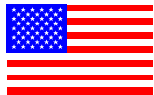
Application Package - Forms

- ◆ 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)



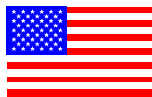
Application Package - Format

- ◆ 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



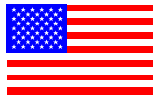
Application Package - Contents

- ◆ 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



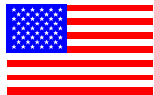
Application Package – Front-End Screen

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



Microbial 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
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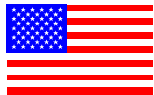
Biochemical Data Requirements

- 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



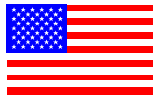
Efficacy Data Requirements

- ◆ 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



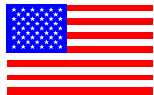
Data Requirements – Public Interest Finding

- ◆ 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)



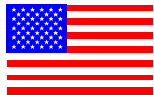
Tolerance Petition

- ◆ 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



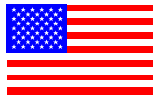
Regulatory Review

- ◆ 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



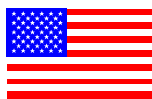
Regulatory Review

- ◆ 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



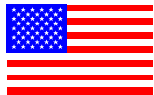
Preliminary Science Review – Start Risk Assessment

- ◆ 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)



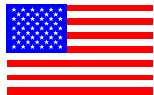
Preliminary Science Review – Risk Assessment

- ◆ 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)



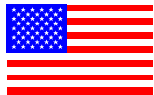
Full Science Review – Risk Assessment

- ◆ 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)



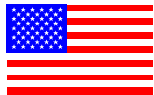
More Regulatory Review cont'd

- ◆ Labels (check PR Notices)
- ◆ CSF
- ◆ Inerts
- ◆ Public Interest Finding (if a conditional registration)



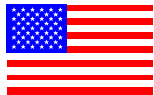
More Regulatory Review cont'd

- ◆ 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)



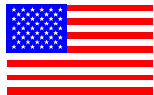
Regulatory (Risk) Management Review Steps

- ◆ 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



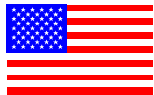
Regulatory (Risk) Management Review Steps cont'd

- ◆ 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



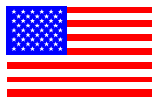
Regulatory (Risk) Management Review Steps cont'd

- ◆ 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>

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

