The IR-4 Program for Registration of Biopesticides

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• IR-4’s mission: to provide growers with safe, effective and economical tools to control pests on minor crops.

• In 1982 a mandate for biopesticides was added
WHY HAVE A BIOPESTICIDE PROGRAM?

1. Increased interest in “organic production”. Support minor crops.


4. Merging of technology. Bt was non-conventional, Bt is conventional (adoption by “conventional growers”).
Two Main Functions of Biopesticide Program

• REGULATORY ASSISTANCE

• GRANTS PROGRAM
BIOPESTICIDE TYPES

MICROBIAL

BIOCHEMICAL

PLANT INCORPORATED

PROTECTANT
Biological Pesticide Market

[Still only 1% of global pesticide market]

- Microbials $160M
- Pheromones $60M
- $40M Ben Insects
- Biochemicals $40M

[Image of a pie chart showing the breakdown of the biological pesticide market with the largest segment being Microbials at $160M, followed by Pheromones at $60M, $40M Ben Insects, and $40M Biochemicals.]
What are Biochemicals?

- semiochemicals (e.g. insect pheremones)
- natural plant and insect regulators
- Enzymes
- hormones (e.g. insect juvenile growth hormones)
WHAT IS A BIOPESTICIDE?

IR-4 is involved with registration so:

EPA definition = IR4 definition

Biopesticide does not equal organic and organic does not equal biopesticide

Spinosad has organic formulation but is not defined by EPA as a biopesticide.

EPA Biopesticides and Pollution Prevention Division

Naturally occurring product or structural equivalent

Have an indirect mode of action
WHY CONSULTANTS?

– Small Company

Companies have different Strengths

Science

Business

Conventional chemistry

Large company outside the U.S., but may lack U.S. expertise
IR-4 Submissions

Thymol/Varroa mite/Bees Sec 18

Kaolin(Surround)/Insects Sec 3

Aspergillus flavus(AF36) / Aflatoxin/Cotton  EUP

Verticillium dahliae WCS
850(Dutch Trig)/ American elm
EUP
Complex Relationships
IR-4 is a Facilitator Between Different Groups

- IR-4
- Registrant
- Toxicology Labs
- Product Chemistry
- USDA Scientist
- Contract Manufacturer
Regulatory Assistance

- Data Packages/Petitions
- EUP’s
- Contract Facilities
- Other consultants
- Cost Estimates $
- Good Laboratory Practices
PETITIONS

• PREPARATION
• REVIEW
• CONSULTING
• SUBMISSION
IR-4 REGULATORS  IR-4  REGISTRANT

Pre Registration Meeting
Determine Data Needs - Waivers
Protocol Review
Label Language
Timelines—Keeping on Track

✓ Data generation-
Which studies take longer?

✓ Petition planning-
Organize information

✓ Prompt Responses for additional Information—Keep review slot active
Experimental Use Permit

- Preregistration meeting
- Application Process
- Submission
- Facilitate Communication Between Registrants and University Cooperators
- Other consultants
SUCCESS!

- Grower need is **Fulfilled**

Product is registered
Biopesticide Industry Alliance

Ad hoc Member- Working with industry and the regulatory community on general regulatory issues
GRANTS PROGRAM

- Efficacy: Majority (Advanced Stage Projects)
- Labeled products-expansion new crop, pest

- Efficacy: (Early Stage Projects) Incomplete toxicology package
Proposals 2002 versus 2003
108 proposals $1.2 Million
2003 BP Proposals/Awards
48 total awards (~44% success rate)
2003 BP Grant Dollars
$427,100

- Early
- Advanced

Bar chart showing the grant dollars for Early and Advanced categories.
2003 BP Grant by Pesticide

- Fungicide
- Insecticide
- Pheromone
- Nematicide
- PGR
Products funded in multiple proposals

AuxiGro
Sonata
Serenade
Potassium Phosphate
Messenger
Milsana
For more information on IR-4, Contact:

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