IR-4 as a Consultant in the Regulatory Process

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

• Conventional Chemistry 1962-
  Magnitude of Residue Studies
  Regulatory
  Efficacy

• Biopesticide Program -1982
Two Main Functions of Biopesticide Program

- GRANTS PROGRAM
- REGULATORY ASSISTANCE
GRANTS PROGRAM

- Efficacy
  Majority (Advanced Stage Projects)
- Host Range Studies
- Toxicology
  Unusual (Early Stage Projects)
- Product Identity
WHY CONSULTANTS?

– Small Company

Companies have different Strengths
Science
Business
Conventional chemistry
Large company outside the U.S., but may lack U.S. expertise
Complex Relationships
IR-4 is a Facilitator Between Different Groups
Regulatory Assistance

– Data Packages/Petitions
– BPPD –CDPR Communications
– EUP’s
– Contract Facilities
– Other consultants
– Cost Estimates $
– Good Laboratory Practices
PETITIONS

- PREPARATION
- REVIEW
- CONSULTING
- SUBMISSION
Pre Registration Meeting
Determine Data Needs-
Waivers
Protocol Review
Label Language
Contact with RAL - Status
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
For more information on IR-4, Contact:

The IR-4 web site at:
http://www.cook.rutgers.edu/~ir4

IR-4 Headquarters at: 732/932-9575 (phone)
732/932-8481 (fax)

Michael Braverman      Phone Extension 610