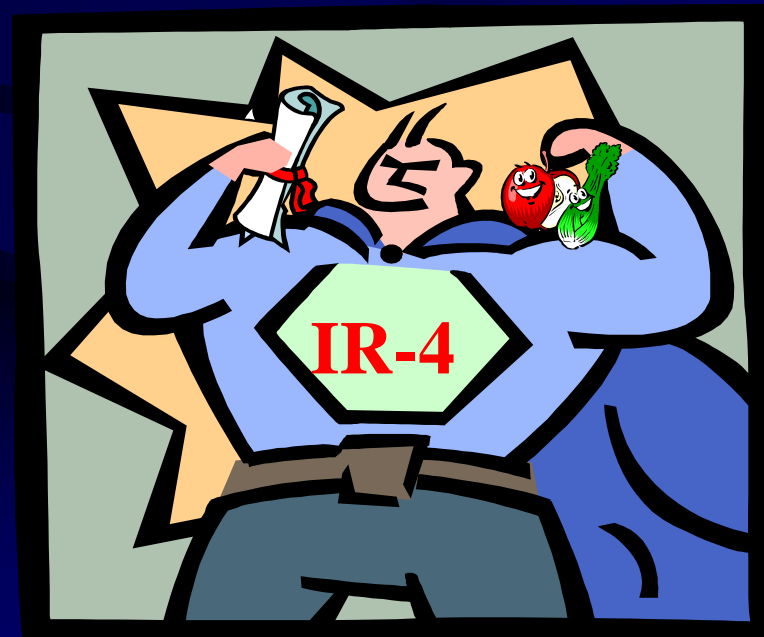


# IR-4 as a Consultant in the Regulatory Process

**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

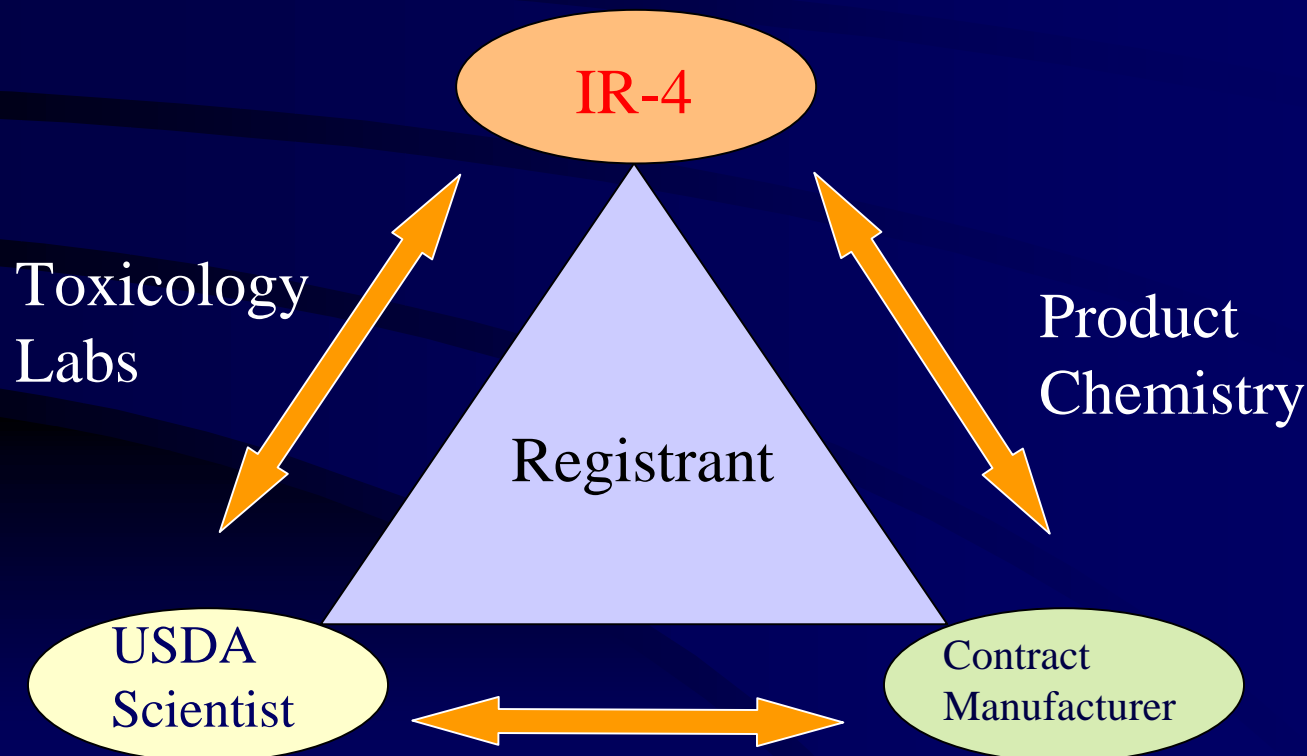
Conventional chemistry

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



BPPD-  
CDPR



REGISTRANT

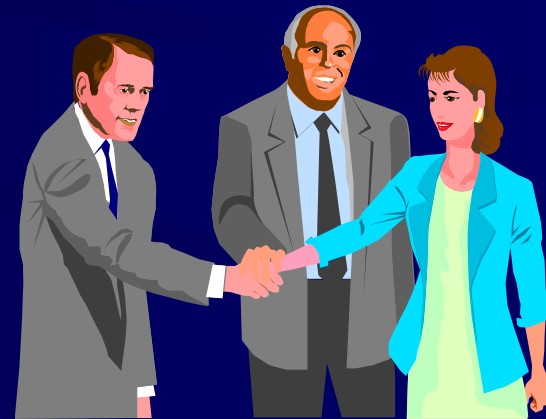
Pre Registration Meeting

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>**



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