IR-4 Project & Registration Process: Residues and Good Laboratory Practices
THANK YOU!

• Global Minor Use Summit- Lucy
• Peter and Ranajit-Aflatoxin
• USDA/FAS- Jason
• Participants!
IR-4 Mission:

To provide pest management solutions to growers of fruits, vegetables, and other specialty crops for the benefit of consumers, growers and food processors.
Specialty Crops

- Vegetables
- Fruits
- Nuts
- Herbs & Spices
- Floral
- Nursery
- Landscape
- Turf
- Christmas trees
Specialty Crops

- high value & low acreages
- 40% of U.S. agricultural production
  \[= \$45 \text{ billion in sales}\]
- 23 states derive more than 50% of agricultural crop sales from specialty crops

Low Acreage
Major Funding for IR-4 is Provided By:

- Special Research Grants and Hatch Act Funds from USDA-CSREES, in cooperation with the State Agricultural Experiment Stations
- USDA-ARS

Additional Support Provided By:
- Commodity & Industry Partners for Special Research Projects
Project Initiation

Commodity Groups

Minor Crop Growers

University Researchers

Extension Specialists

IR-4 State Liaisons

Project Clearance Request (PCR)

Discuss project with Registrant

Active Project
Research Planning

Annual Food Use Workshop
prioritizing active projects

- Growers
- Commodity groups
- University Staff

Regional Field Coordinators/
Headquarters Coordination

National Research Planning

- EPA
- Crop Protection Industry
- University Staff
- USDA-ARS and CSREES

Research projects designated
for the coming year
Data Development

Laboratory and Field Protocols are developed

Study Directors

Registrants + EPA

Field Coordinators

Lab Directors

Protocols

Good Laboratory Practices (GLP)

Laboratory Analysis

Quality Assurance Review

Field Trials
Petition Preparation

Lab and Field Data

- Study Directors Review
- QA Review
- Registrant Review

Study Directors Prepare Petition to Submit to EPA
30 Month Timeline

Project Initiation
- 0-month

Field Phase
- 2nd month

Analytic Phase
- 10th month

Petition Prep
- 22nd month

Submission to EPA
- 30th month
Product registration

The petition is sent to EPA where it is reviewed.

If everything is in order a tolerance is granted (MRL) and a registration follows.

A new product is now available for minor use.
EPA/OPP Process

RD

HED (toxicology; chemistry; occupations & residential exposure)

EFED (ecological effects; environmental fate; drinking water)

BEAD (Provides information on use and Usage of Pesticides)

Final Steps in HED Review

Federal Register Process (the final steps)
GLPs Terms and Definitions

• Testing Facility Operations
  – Standard Operating Procedures (SOPs)
    • In writing setting forth study methods that management is satisfied are adequate to insure the quality and integrity of the data
    • All deviations in a study from SOP shall be authorized by the Study Director and documented in the raw data.
    • Significant changes in SOPs shall be properly authorized in writing by Management
    • A historical file of SOPs and all revisions shall be maintained
GLPs Terms and Definitions

• Protocol
  – Each study shall have an approved written protocol which clearly indicated the objectives and all methods for the conduct of the study.
    • Title and statement of purpose
    • ID of test and reference substances
    • Name and address of sponsor and name and address of the testing facility
    • Description of test system (specifics described)
GLPs Terms and Definitions

• Protocol cont.
  – Procedure for ID of test system
  – Description of experimental design
  – Where applicable, solvents, emulsifiers and or other material used in the mixing of the test substance with the carrier
• Protocol, cont.
  – Type and frequency of test, analyses and measurements to be made
  – Records to be maintained
  – Date of approval of the protocol by Sponsor and dated signature of the Study Director
  – Statement of proposed statistical analysis
  – All changes in or revisions of an approved protocol and the reasons therefore shall be documented, signed by the SD, dated and maintained with the protocol.
GLPs Terms and Definitions

- Conduct of Study
  - Raw Data
    - Shall be recorded directly, promptly, and legibly in ink
    - All data shall be dated on the day of entry and signed or initialed by the person entering the data
    - Any change in entries shall be made so as not to obscure the original entry, shall indicate the reason for such change and shall be dated and signed or identified at the time of the change.
• Global Minor Use Summit

Global residue trials to compare residue results across various agro-eco zones

Kenya, Nigeria, Egypt, Morocco, South Africa