Registration of Crop Protection Chemicals for Specialty Crops

Michelle Samuel-Foo, PhD
IR-4 Southern Region Coordinator
University of Florida
Outline

- Introduction
- Structure
- Project clearance request (PCR) process
  - Progression of a typical field trial
    - QA
    - EPA Inspection
  - GLP residue trial example
Introduction

- IR = Interregional Project 4
- NRSP #4 (today)
- Need to procure registrations of crop protection tools to support growers of minor crops (specialty crops)

IR-4 residue trial in Puerto Rico – avocado infusion to combat Laurel Wilt disease
Rationale

- Companies that develop and sell plant protection products focus their resources in major markets where there is favorable return on investment.

- Potential sales in small markets does not justify the investment in the development of the required data for registration.

- The result is a major void for specialty crop growers to protect their crops (fruits, vegetables, herbs, ornamentals and other high value horticultural crops).
Program Mission

To facilitate registration of sustainable pest management technology for specialty crops and minor uses.
Rutgers University, (IR-4 HQ)

- Cornell University, NY (NER)
  - Field Program

- Michigan State University, MI (NCR)
  - Field Program and Analytical Lab

- University of Florida, FL (SOR)
  - Field Program and Analytical Lab

- University of California, Davis CA (WSR)
  - Field Program and Analytical Lab

USDA/ARS, MD
  Field Program and Analytical Labs
How does a project get initiated?

Stakeholders:
• Identify Pest Problem and potential Pest Mgmt Solution
• Notifies RFC and Request Assistance from IR-4

PCR's Submitted by:
• Growers and Commodity Groups
• University Research & Extension Personnel

Requests Prioritized at Annual IR-4 Food Use Workshop:
• Highest priorities added to research plan
• 2nd priorities added as budget allows

Request Reviewed by Manufacturer

Field and Lab Studies
• Measure Residue Levels in Crop/Crop Group
• Projects completed in 24-36 mths

Manufacturer adds Crop/pest to label

Tolerance Established by EPA

Data Submitted to EPA

Risk Assessment

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Southern Region Program

- Field Crop Program (Southern US)
  - 13 States plus territory of Puerto Rico
  - GLP trials plus Efficacy and Performance studies

- GLP trials in IR-4 Field Research Centers
  - ★ Citra, FL
  - ★ Homestead, FL
  - ★ Raleigh, NC
  - ★ Weslaco, TX
  - ★ Fayetteville, AR
  - ★ Mayaguez, PR
Progression of A Typical Residue Field Trial

Field Applications (Nationally)

Preparation of Petition

Good Laboratory Practice Standards

Harvest and Sampling

Residue Analysis - GC MSMS

Shipping samples to laboratory

Field data shipped to regional office

QA AUDIT

QA AUDIT

QA AUDIT

QA AUDIT

QA AUDIT

QA AUDIT
Role of QA: Quality Assurance

• Ensure that project phases are performed under Good Laboratory Compliance (GLP) standards
  • Field active phases
  • Lab active phases
  • Final petition preparation
  • GLP compliance required by EPA

• GLP Compliance mandated by US EPA
  • Documentation
  • Reporting
  • Record Maintenance
  • Record activities in ‘real time’
EPA Inspection of Trials

FROM:
Ms. Tammy White
18-4 Project Headquarters
Rutgers, The State University of NJ
590 College Road East, Suite 201
Princeton, NJ 08540

TO:

SUBJECT:
This is to inform you that the Environmental Protection Agency (EPA) will conduct a Good Laboratory Practice (GLP) inspection at North Carolina State University, Raleigh, North Carolina under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

The inspection will be conducted on September 21-24, 2009.

The purpose of this letter is to provide you with information about the inspection and to request your assistance in facilitating the inspection.

The inspection team will review the facility's compliance status with the EPA FIFRA GLP regulations at 40 Code of Federal Regulations (CFR) Part 160 and will audit those aspects of the studies listed in Attachment 1 performed by North Carolina State University.

Our records show that 18-4 Project Headquarters is the sponsor of the above-mentioned studies.

The purpose of this letter is to provide you with information about the inspection and to request your assistance in facilitating the inspection.

Please note that under the FIFRA GLP regulations at 40 CFR 160.15(b) EPA will not consider reliable for purposes of supporting a FIFRA application for a research or marketing permit any data developed by a testing facility that refuses to permit inspection and audit of the data.

We will require very specific information at North Carolina State University regarding the test substance. These include source and lot number, record of receipt, storage, test substance inventory log and custodial procedures.

We also need information on the origin of the test substance, namely, if it was sourced from a batch for contemporary commercial use or was synthesized or
<table>
<thead>
<tr>
<th>Product</th>
<th>Common Name</th>
<th>Classification</th>
<th>Target Crop</th>
<th>Location</th>
<th>Control of:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indaziflam</td>
<td>Alion</td>
<td>Herbicide</td>
<td>Coffee</td>
<td>Adjuntas</td>
<td>Grasses and broadleaf weeds</td>
</tr>
<tr>
<td>Cyantraniliprole</td>
<td>Cyazypyr</td>
<td>Insecticide</td>
<td>Coffee</td>
<td>Adjuntas</td>
<td>Coffee Berry Borer</td>
</tr>
<tr>
<td>Propamocarb</td>
<td>Previcur Flex</td>
<td>Fungicide</td>
<td>Guava</td>
<td>Juana Díaz</td>
<td>“Pythium Root Rot”</td>
</tr>
<tr>
<td>Diquat</td>
<td>Reglone</td>
<td>Herbicide</td>
<td>Banana</td>
<td>Corozal</td>
<td>Weeds – <em>Parthenium</em> sp.</td>
</tr>
<tr>
<td>Cyprodinil &amp; Fludioxonil*</td>
<td>Switch</td>
<td>Fungicide</td>
<td>Carambola</td>
<td>Corozal</td>
<td>Anthracnose</td>
</tr>
</tbody>
</table>

*Non GLP Food Use Efficacy trial conducted by Dr. Merari Feliciano
Study Title: DIQUAT-Magnitude of the Residue on Banana

• Justification and Objectives:
In 2011 IR-4 received a request for the minor use of diquat on banana for control of Parthenium sp. in bananas.

• Goal:
To establish tolerance according to The Environmental Protection Agency (EPA) Series 860 Guidelines.
- Determining magnitude of residues (MOR)
- SOPs
- GLPs
- Under provisions outlined in 40 CFR Part 160
Parthenium hysterophorus L.
Family: Asteraceae
Parthenium in South Florida

Michelle Samuel-Foo
15. APPLICATION TREATMENTS AND TIMING:

<table>
<thead>
<tr>
<th>Trt#</th>
<th>Treatment</th>
<th>Target Rate of active ingredient</th>
<th>Target Rate of formulated product*</th>
<th>Application Type</th>
<th>Spray Volume Range**</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Untreated</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>02</td>
<td>DIQUAT</td>
<td>1.0 lb/acre</td>
<td>1892 ml/acre +NIS +COC ***</td>
<td>Directed to orchard floor</td>
<td>15-50 GPA</td>
</tr>
</tbody>
</table>

*The nominal formulation concentration of the test substance will be used in calculating application rates (see Section 13 for the nominal concentration). **GPA=gallons per acre

Make one (1) application 14 days before harvest.

Apply as a banded application to the orchard floor on each side of the plant; minimum swath width of three (3) feet on each side of the plants.

Direct the application to the orchard floor. As much as possible avoid spraying the plant trunk, foliage and fruit to minimize potential plant injury.

NOTE: Do not concentrate the test substance in the treated area. The rate specified is per treated area.
Diquat on Banana

CO$_2$ Spraying Equipment Used

Placing Warning Signs on Treated Plots
17. RESIDUE SAMPLE COLLECTION:

Collect two samples from each plot. Each sample should be representative of the entire plot (except plot ends). At 14 days after last application, starting with the untreated plot, collect a minimum of 24 marketable-sized fruits per sample from at least 6 bunches from separate trees and from separate places on each of the bunches. (Remove the bags from bagged bananas.) Each sample should be collected during a separate run through the entire plot.

If needed to reduce sample weight, the bananas may be halved lengthwise, retaining one half of each fruit for the sample.

Follow proper handling practices with clean or gloved hands and clean tools to prevent transfer of pesticide residue from one sample to another. If practical, complete harvest and sample preparation for the untreated plot(s) before proceeding to the treated plot(s).

Place all samples in plastic-lined cloth bags. Bags may be obtained from the Field Research Coordinator (Section 23). Identify each sample bag** with correct Field ID number, Test Substance (common chemical name and formulation), complete sample ID (see Section 18) and harvest/sampling dates. See Section 19 for residue sample handling directions.

Cut banana fruits may be placed in plastic bags and then placed into sample bags.
Residue Sample Collection

Michelle Samuel-foo

PMA 4570/6228
## Part 7. Sample Collection and Storage

**B. Specific Sample Information and Inventory, and Treated Crop Destruction**

**Instructions:** Complete this form or provide equivalent information. Use a separate page for each sample.

**Sample Date:** Enter the date the individual samples were collected (do not enter the harvest date when this date is different from sample date). The sample ID (see protocol Section 18 for Sample ID code), a brief description of the crop part sampled (e.g., green leaves, flower buds, stem, fruit, corn, forage, etc.), the weight of the sample, the approximate time of day of completion of each sample collection, etc., sample placed in sample bag following any modifications (e.g., 10:11 a.m.), the approximate time of day that each sample was placed in a freezer, the approximate time interval between completion of collection of each sample (place of the sample in sample bag) and the placement of the sample in freezer (e.g., 41 minutes), the identification code of the freezer where the samples are stored, and the initials of the person providing the above information and the date it is entered into this form.

<table>
<thead>
<tr>
<th>Sample ID*</th>
<th>Crop Fraction</th>
<th>Weight (Include Units)</th>
<th>Approximate Time of Day or Completion of Each Sample Collection</th>
<th>Approximate Time of Day Sample Was Placed in Freezer</th>
<th>Total Time to Freezer From Sample Collection</th>
<th>Freezer ID</th>
<th>Initials &amp; Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Fruit Wheel</td>
<td>610.6g</td>
<td>9:54 a.m.</td>
<td>6:37 a.m.</td>
<td>8.5 hrs</td>
<td>unbr LEB 478949</td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>Fruit Wheel</td>
<td>591.6g</td>
<td>10:15 a.m.</td>
<td>6:37 a.m.</td>
<td>7.5 hrs</td>
<td>unbr LEB 478949</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>Fruit Wheel</td>
<td>681.6g</td>
<td>10:53 a.m.</td>
<td>6:37 a.m.</td>
<td>7.5 hrs</td>
<td>unbr LEB 478949</td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>Fruit Wheel</td>
<td>541.6g</td>
<td>11:03 a.m.</td>
<td>6:38 a.m.</td>
<td>6.5 hrs</td>
<td>LEB 478949</td>
<td></td>
</tr>
<tr>
<td>E</td>
<td>Fruit Wheel</td>
<td>553.6g</td>
<td>12:04 a.m.</td>
<td>6:38 a.m.</td>
<td>6.5 hrs</td>
<td>LEB 478949</td>
<td></td>
</tr>
<tr>
<td>F</td>
<td>Fruit Wheel</td>
<td>531.6g</td>
<td>12:05 a.m.</td>
<td>6:39 a.m.</td>
<td>6.5 hrs</td>
<td>LEB 478949</td>
<td></td>
</tr>
<tr>
<td>G</td>
<td>Fruit Wheel</td>
<td>520.6g</td>
<td>12:06 a.m.</td>
<td>6:39 a.m.</td>
<td>6.5 hrs</td>
<td>LEB 478949</td>
<td></td>
</tr>
</tbody>
</table>

* Sample ID code

Was a GLP-maintained scale used to determine weight of residue samples? **YES** **NO**

**Crop Destruct:** Describe how the (leftover) treated crop has been destroyed or handled in such a way that it cannot be consumed as human food or animal feed. Provide date(s) if appropriate. If the (leftover) treated crop was not destroyed because the pesticide use in this trial is regulated to your state/territory permit, then this should be indicated here.

Treated components were buried in the soil and covered.

All crops treated were removed from the field plot.

And buried in soil as well.

**Above Data Entered By:** [Signature]

**Date:** 09/10/12

**Trial Year:** 2012
<table>
<thead>
<tr>
<th>Crop</th>
<th>Use Pattern</th>
<th>Reglone Desiccant Rate per Acre</th>
<th>Minimum Total Spray Volume per Acre</th>
<th>Preharvest Interval (Days)</th>
<th>Precautions, Restrictions, and Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tree, Vine, Small Fruit, Vegetable Crops - Nonbearing</td>
<td>Directed spray</td>
<td>1 1/2-2 pts.</td>
<td>Ground: 15 gal.</td>
<td>Do not use for food or feed for one year after application.</td>
<td>Reglone Desiccant can be used during site preparation prior to planting and up to 1 year of harvest. Retreatment may be necessary for complete control of grasses and older established weeds. Do not allow spray to contact green stems, foliage, or fruit as injury can occur. Use a shield or wrap plant when spraying around young trees or vines. Do not graze treated areas.</td>
</tr>
<tr>
<td>Acerola (West Indian Cherry)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Almonds</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Apple</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Apricots</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Artichokes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asparagus</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Avocado</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Banana</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blackberry</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blueberry</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boysenberry</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cherries</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coffee</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Active Ingredient:**
Diquat dibromide [6.7-dihydrodipyrido (1,2-a:2',1'-c) pyrazinediyl dibromide] 37.3%  
Other Ingredients: 62.7%  
Total: 100.0%

Contains 2 lbs. diquat cation per gal. as 3.73 lbs. acid per gal.

**KEEP OUT OF REACH OF CHILDREN. CAUTION**
Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)
See additional precautionary statements and directions for use inside booklet.

EPA Reg. No. 100-1061  
EPA Est. 100-LA-001  
Product of United Kingdom  
Formulated in the USA  
SCP 1061A-L1E 0510 322779  
2.5 gallons  
Net Contents
Questions?

Contact: mfoo@ufl.edu
Considerations when placing field trials:

- EPA Growing Zone Guidelines
- Capacity at research sites/field research centers
- Timeline to registration