How the IR-4 Project Helps Growers Gain Access to Pest Control Tools and Technologies

Dr. Michelle Samuel-Foo
University of Florida
Program Mission

To facilitate registration of sustainable pest management technology for specialty crops and minor uses.

1963 - Food Program
- Ornamental Program
- Regional Offices
- ARS program
- Biopesticide program

1970 and 80’s
- Ornamental Program
- Regional Offices
- ARS program
- Biopesticide program

1990 – 2000’s
- FIFRA 88, PQPA
- GLPs
- Reduced risk chemistries
- Crop grouping
- International MRLs
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)
Organizational Structure

- Rutgers University, (IR-4 HQ)
- Cornell University, NY (NER) moved to University of Maryland in 2016
  - Field Program
- Michigan State University, MI (NCR)
  - Field Program and Analytical Lab
- University of Florida, FL (SR)
  - Field Program and Analytical Lab
- University of California, Davis CA (WSR)
  - Field Program and Analytical Lab
- USDA/ARS, MD
  - Field Program and Analytical Labs
The IR-4 Project Southern Region

- 13 Southern States plus Puerto Rico
- At UF Gainesville:
  - Regional field office
  - Analytical Laboratory
  - Quality Assurance Unit

Michelle Samuel-Foo

FSHN - Food & Environmental Toxicology Lab
IR-4 Southern Region Field Research Centers

University of Arkansas, Fayetteville, AR

NC State University, Raleigh, NC, Region II

University of Florida, TREC, Homestead FL, Region XIII

University of Florida, PSREU, Citra FL, Region III

Texas A&M, Weslaco TX, Region VI

University of Puerto Rico, Mayaguez, PR, Region XIII
The IR-4 Regulatory Clearance Process

Stage I

Stakeholders:

• Identify Pest Problem and Potential Pest Mgmt Solution

• Notifies RFC and Requests Assistance from IR-4
Stage II – Submit Project Clearance Request (PCR)
http://ir4.rutgers.edu/FoodUse/FOODRequestForm.cfm

PCRs Submitted by:
• Growers and Commodity Groups
• University Research & Extension Personnel

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

Request Reviewed by Manufacturer, EPA & IR-4 Registration Team

Stage III – Prioritize Requests

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

http://ir4.rutgers.edu/FoodUse/FOODRequestForm.cfm

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The IR-4 Regulatory Clearance Process

Stage IV – Research Planning

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

Data Petitions Submitted to

Risk Assessment
The IR-4 Regulatory Clearance Process

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- Identify Pest Problem and Potential Pest Mgmt Solution
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Requests Prioritized at Annual IR-4 Food Use Workshop:
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Request Reviewed by Manufacturer

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

Tolerance Established by EPA

Data Submitted to EPA

Risk Assessment

Manufacturer adds crop/pest to label
Locations for strategic and technical conduct of residue studies assigned

Field trials are placed according to:
- EPA growing zone guidelines
- Capacity at university field centers
- Overflow trials to CROs
- All residue trials are conducted according to EPA mandated GLP standards
**Question:** What is a PCR and how is it submitted?

**Answer:**

A PCR refers to a Project Clearance Request and it the official means of documenting interest in the registration of a chemical on a particular commodity via the IR-4 project.

- PCRs are submitted online at the IR-4 project website.
IR-4 Project Clearance Requests for Pomegranantes

Herbicide PCRs: 37%
Fungicide PCRs: 33%
Insecticides PCRs: 30%

Total No. of PCRs 46
## IR-4 Requests and Registrations for Pomegranates

### General Search of Food Request Database

<table>
<thead>
<tr>
<th>PR#</th>
<th>Priority Protocol</th>
<th>Pesticide (MFG)</th>
<th>Commodity (Crop Group)</th>
<th>Project Status</th>
<th>Performance Data Available</th>
<th>Req Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td></td>
<td>ACETAMIFRID (NISSOUP)</td>
<td>POMEGRANATE (99 = MISCELLANEOUS COMMODITY)</td>
<td>RESIDUE DONE/ONGOING, ECS DATA NEEDED/ONGOING</td>
<td>CA FL</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td></td>
<td>AZINPHOS-METHYL (ADAMA)</td>
<td>POMEGRANATE (99 = MISCELLANEOUS COMMODITY)</td>
<td>USE CANCELED</td>
<td>CA</td>
<td></td>
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<tr>
<td>A</td>
<td></td>
<td>AZOXYSTROBIN (SYNGEN)</td>
<td>POMEGRANATE (99 = MISCELLANEOUS COMMODITY)</td>
<td>RESEARCHABLE, ONLY RESIDUE DATA NEEDED</td>
<td>CA FL</td>
<td></td>
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<tr>
<td>A</td>
<td></td>
<td>BIFENTHRIN (ADAMA/AMVAC/FMC)</td>
<td>POMEGRANATE (99 = MISCELLANEOUS COMMODITY)</td>
<td>FINAL REPORT SIGNED, READY FOR SUBMISSION [No Title]</td>
<td>CA</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td></td>
<td>BUPROFEZIN (NAI)</td>
<td>POMEGRANATE (99 = MISCELLANEOUS COMMODITY)</td>
<td>USE REGISTERED</td>
<td>CA</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td></td>
<td>CHLORANTRANILIPROLE (DU Pont)</td>
<td>POMEGRANATE (99 = MISCELLANEOUS COMMODITY)</td>
<td>USE REGISTERED</td>
<td>CA</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td></td>
<td>CHLOROTHALONIL (SYNGEN)</td>
<td>POMEGRANATE (99 = MISCELLANEOUS COMMODITY)</td>
<td>POTENTIAL ECS DATA BEFORE APPROVAL FOR RESIDUE STUDY</td>
<td>CA FL</td>
<td></td>
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<tr>
<td>A</td>
<td></td>
<td>CRYOCIDE (GWAIN UP)</td>
<td>POMEGRANATE (99 = MISCELLANEOUS COMMODITY)</td>
<td>HOLD</td>
<td></td>
<td></td>
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<tr>
<td>A</td>
<td></td>
<td>CYPRODINIL + FLUOXACIN (SYNGEN)</td>
<td>POMEGRANATE (99 = MISCELLANEOUS COMMODITY)</td>
<td>MFG WILL NOT SUPPORT</td>
<td>GA</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td></td>
<td>CYPRODINIL + FLUOXACIN (SYNGEN)</td>
<td>POMEGRANATE (POST HARVEST) (99 = MISCELLANEOUS COMMODITY)</td>
<td>NOTICE OF FILING ISSUED/PROPOSAL</td>
<td>CA</td>
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</tr>
<tr>
<td>A</td>
<td></td>
<td>DIFLUENZURON (MACDERMID)</td>
<td>POMEGRANATE (99 = MISCELLANEOUS COMMODITY)</td>
<td>MFG WILL NOT SUPPORT</td>
<td>CA</td>
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</tr>
<tr>
<td>A</td>
<td></td>
<td>FENHEXAMID (ARYSTA)</td>
<td>POMEGRANATE (POST HARVEST) (99 = MISCELLANEOUS COMMODITY)</td>
<td>USE REGISTERED</td>
<td>YES CA</td>
<td></td>
</tr>
<tr>
<td>B</td>
<td></td>
<td>FENPYRAZAMINE (V-10135) (VALENT)</td>
<td>POMEGRANATE (POST HARVEST) (99 = MISCELLANEOUS COMMODITY)</td>
<td>NON-NOMINATED PROJECT, WITHDRAWN</td>
<td></td>
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</tr>
<tr>
<td>B</td>
<td></td>
<td>FENPYROXIMATE (NAI)</td>
<td>POMEGRANATE (99 = MISCELLANEOUS COMMODITY)</td>
<td>COVERED BY ANOTHER PROJECT</td>
<td>CA FL</td>
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<tr>
<td>B</td>
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<td>FLUOXACIN (SYNGEN)</td>
<td>POMEGRANATE (POST HARVEST) (99 = MISCELLANEOUS COMMODITY)</td>
<td>USE REGISTERED</td>
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<tr>
<td>A</td>
<td></td>
<td>FLUMioxAZIN (VALENT)</td>
<td>POMEGRANATE (99 = MISCELLANEOUS COMMODITY)</td>
<td>USE REGISTERED</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td></td>
<td>FLUPYRAM + TEBUCONAZOLE (BAYER)</td>
<td>POMEGRANATE (99 = MISCELLANEOUS COMMODITY)</td>
<td>COMPLETE WITH ONGOING TRIALS</td>
<td>YES CA FL GA</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td></td>
<td>FLUPYRADIFURONE (BYI 02990) (BAYER)</td>
<td>POMEGRANATE (99 = MISCELLANEOUS COMMODITY)</td>
<td>MFG SUBMISSION TO EPA</td>
<td>CA</td>
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</tr>
<tr>
<td>A</td>
<td></td>
<td>FLUXAPYRAZOX + PYRAZOXORIN (BASF)</td>
<td>POMEGRANATE (99 = MISCELLANEOUS COMMODITY)</td>
<td>RESEARCHABLE, RESIDUE &amp; ECS DATA NEEDED</td>
<td>YES CA FL GA</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td></td>
<td>GLYPHOSATE (ADAMA DREXELMANS)</td>
<td>POMEGRANATE (99 = MISCELLANEOUS COMMODITY)</td>
<td>USE REGISTERED</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td></td>
<td>IMIDACLOPRID (ADAMA BAYER)</td>
<td>POMEGRANATE (99 = MISCELLANEOUS COMMODITY)</td>
<td>USE REGISTERED</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td></td>
<td>INDAZIFAM (BAYER)</td>
<td>POMEGRANATE (99 = MISCELLANEOUS COMMODITY)</td>
<td>TOLERANCE/USE TO BE PURSUED WITH NO DATA PROPOSAL/PETITION</td>
<td>YES CA FL</td>
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</tr>
<tr>
<td>A</td>
<td></td>
<td>MANCOZEB (DOWAGR UP)</td>
<td>POMEGRANATE (99 = MISCELLANEOUS COMMODITY)</td>
<td>UNDER EVALUATION</td>
<td>YES FL GA</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td></td>
<td>MESOTRINE (SYNGEN)</td>
<td>POMEGRANATE (99 = MISCELLANEOUS COMMODITY)</td>
<td>DATA MINING PROJECT - NO PCR RECEIVED</td>
<td>YES</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td></td>
<td>METHOMYL (DU Pont)</td>
<td>POMEGRANATE (99 = MISCELLANEOUS COMMODITY)</td>
<td>USE REGISTERED</td>
<td>CA</td>
<td></td>
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<tr>
<td>A</td>
<td></td>
<td>METHOXYBENZIDIE (DOWAGR)</td>
<td>POMEGRANATE (99 = MISCELLANEOUS COMMODITY)</td>
<td>USE REGISTERED</td>
<td>HQ</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td></td>
<td>NAA (AMVAC)</td>
<td>POMEGRANATE (99 = MISCELLANEOUS COMMODITY)</td>
<td>TOLERANCE ESTABLISHED</td>
<td>CA GA</td>
<td></td>
</tr>
</tbody>
</table>
# Ongoing IR-4 Registration Studies for Pomegranates

<table>
<thead>
<tr>
<th>PR#</th>
<th>Chemical</th>
<th>Requesting State(s)</th>
<th>Project Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>10606</td>
<td>Rimsulfuron (H)</td>
<td>CA</td>
<td>Residue trials in progress (2015)</td>
</tr>
<tr>
<td>10915</td>
<td>*Oxythiapiprolin (F)</td>
<td>HI, PR, CA</td>
<td>Residue trials in progress (2015)</td>
</tr>
<tr>
<td>11724</td>
<td>*Acetamiprid (I)</td>
<td>CA, FL</td>
<td>Residue trials in progress (2016)</td>
</tr>
<tr>
<td>11020</td>
<td>*Fluopyram+Tebuconazole (F)</td>
<td>CA, FL, GA</td>
<td>Residue trials in progress (2016)</td>
</tr>
<tr>
<td>11754</td>
<td>*Fluxapyroxad + Pyraclostrobin (F)</td>
<td>CA, FL, GA</td>
<td>Residue trials in progress (2016)</td>
</tr>
<tr>
<td>10770</td>
<td>Flupyradifurone(I)</td>
<td>CA</td>
<td>Residue complete; MFG submission</td>
</tr>
<tr>
<td>11249</td>
<td>Bifenthrin (I)</td>
<td>CA</td>
<td>Final report signed; Ready for submission</td>
</tr>
<tr>
<td>10613</td>
<td>Cyprodinil + Fludioxonil (F; PH)</td>
<td>CA</td>
<td>Notice of filing issued</td>
</tr>
</tbody>
</table>

- *Residue trials to be conducted in FL
- H = Herbicide
- F = Fungicide
- I = Insecticide
- PH = Post Harvest Use
Study Title:
Fluopyram + Tebuconazole-Magnitude of the Residue on Pomegranates

• Justification and Objectives:
In 2015 IR-4 prioritized a request for the minor use of Fluopyram + Tebuconazole on pomegranates for control of Black heart disease (*Alternaria alternata* and other *Alternaria* Sp); and other fungal pathogens of the fruit and foliage.

• 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
<table>
<thead>
<tr>
<th>PR#</th>
<th>Priority</th>
<th>Pesticide(mfg)</th>
<th>Commodity (Crop Group)</th>
<th>Project Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>11020</td>
<td>A</td>
<td>FLUOPYRAM + TEBUCONAZOLE (BAYER) POMEGRANATE (99 = MISCELLANEOUS COMMODITY)</td>
<td>COMPLETE WITH ON-GOING TRIALS</td>
<td></td>
</tr>
</tbody>
</table>

**Reduced Risk Status**
- IPM Compatibility: PER METOO REQUESTOR: GOOD IPM FIT 05/15
- Reasons for Need: BLACK HEART, OR ALTERNARIA FRUIT ROT, COLLETIFORMIOSIS, CERCOSPORA, BOTRYOSPHAERIA, PILIDELIA, OTHER FUNGAL PATHOGENS OF FRUIT AND FOLIAGE

**PCR Use Pattern**
- 0:5 FL:CZA:2, PZORAR ADP:FLC:2 WEEK RE-TREATMENT INTERVAL 35-DAY PHI
- PCR Residue Requirements:
  - 10-3
  - 3-10-1 (1 DECLINE) (1 PROCESSING - JUICE)- NEED TO ANALYZE FOR EACH AI

**Residue Protocol Use Pattern**
- EGS Research Comments: MFG SUGGESTS 1 GOOD EFFICACY TRIAL TO MEET CDPR REQUIREMENTS 03/14, POSITIVE STUDY HAS BEEN COMPLETED 05/15

**Label Use Pattern Submitted To EPA**
- EPA Status:
- EPA PRIA Date:
- MR/D:

**International Status**
- Click here to view protocol

**View Performance/Crop Safety Data**
- Field Research Director Expedites: Field ID# RFC TO QA HQ RECOD: Lab ID# Lab RECOD Lab Comp Proc. ID Proc. Shipped Proc. Report Raw Data S Dir/Auditor
- Ennes, D. (Kearny): 16-CZ-22 16-TIR-30 JOLLY HQ
- Watkins, S.: 16-CZ-34 16-TIR-30 JOLLY HQ
- Ottmar, Dr. Peter: 16-FL:110 16-JIDP-07 JOLLY HQ

- Vallad, Gary: P.15:FL:DMP RECOD: NONE

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IR-4 Help Desk: Phone number: 732-932-6575 Ext 4826 Email: ir4help@arssoo.rutgers.edu

Contact Us IR-4Advocates/Training Events Links Linked Files
What’s involved in a GLP residue trial?

• Apply test chemical to target crop mimicking commercial application
• After all protocol requirements are met, crop is harvested and sent to the analytical lab
• Researcher completes Field Data Notebook
• Quality control/Quality Assurance review of data
• IR-4 HQ prepares final petition
Residue Analysis of Samples

- Chopped for subsampling
- Solvent extracted and cleaned using prep-columns
- GCMS-MS analysis for residue levels
- Analytical Summary Report
- 130-135 projects per year
Deliverables

Final phase for all data generated by the regions is a petition for a registration to US EPA.

- The IR-4 staff at HQ prepares the final petitions after collecting all the data from the regions
- Since 2004 the program has averaged close to 1000 new registrations per year

Registration = a pest mgmt tool for specialty crop grower to use
Crop Grouping (CG) Practice

• Crop Group: A group of crops that are botanically or taxonomically related.

• IR-4 promoted the concept of CG to the US EPA
  -IR-4 coordinates efforts of ICGCC (International Crop Grouping Consulting Committee)

• Crop grouping allows tolerance establishment for an entire group of similar crops, by conducting residue research on only a few crops that represent the entire group.

• A cost effective approach for the establishment of pesticide tolerances.
Crop Grouping  How does it work?

<table>
<thead>
<tr>
<th>Crop Group Name</th>
<th>Rep. Commodities</th>
<th>Commodities</th>
</tr>
</thead>
<tbody>
<tr>
<td>CG 9: CUCURBIT VEGETABLES</td>
<td>Cucumber, muskmelon, summer squash</td>
<td>Chayote (fruit); Chinese waxgourd (Chinese preserving melon); citron melon; cucumber; gherkin; gourd, edible (includes hyotan, cucuzza, hechima, Chinese okra); Momordica spp (includes balsam apple, balsam pear, bittermelon, Chinese cucumber); muskmelon (includes cantaloupe); pumpkin; squash, summer; squash, winter (includes butternut squash, calabaza, hubbard squash, acorn squash, spaghetti squash); watermelon</td>
</tr>
</tbody>
</table>

A typical residue study costs $100K (1 crop, 1 chemistry)

<table>
<thead>
<tr>
<th>Categories</th>
<th>Figures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost without CG</td>
<td>27 x 100,000 = $2,700,000</td>
</tr>
<tr>
<td>Cost with Current CP Scheme</td>
<td>3 x 100,000 = $300,000</td>
</tr>
<tr>
<td>Savings realized?</td>
<td>$2.4 million</td>
</tr>
</tbody>
</table>
EPA Crop Grouping Revisions: How does this affect Pomegranates?

- EPA is proposing revisions to its pesticide tolerance crop grouping model
- Crop Group 99 - Tropical Fruits and Miscellaneous Commodities used to include Pomegranates
- Under Proposed Rule:

  **Miscellaneous Crop Group 99**

Crop Group 23: Tropical and Sub Tropical Fruit: Edible Peel

Crop Group 24: Tropical and Sub Tropical Fruit: Inedible Peel
Pomegranates will be a Rep. crop under Tropical and Subtropical Fruit, Inedible Peel, Crop Group 24

<table>
<thead>
<tr>
<th>Representative commodities</th>
<th>Commodities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Crop Subgroup 24A. Tropical and Subtropical, Small Fruit, Inedible Peel Subgroup.</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Lychee</strong></td>
<td>Aisen; Bael fruit; Burmese grape; Cat’s eyes; Ingá; Lychee; Madras-thorn; Manduro; Matisia; Mesquite; Mongongo, fruit; Pawpaw, small-flower; Satinleaf; Sierra Leone-tamarind; Spanish lime; Velvet tamarind; Wampi; White star apple; cultivars, varieties, and hybrids of these commodities.</td>
</tr>
<tr>
<td><strong>Crop Subgroup 24B. Tropical and Subtropical, Medium to Large Fruit, Smooth, Inedible Peel Subgroup.</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Avocado, plus Pomegranate or Banana</strong></td>
<td>Abiu; Akee apple; Avocado; Avocado, Guatemalan; Avocado, Mexican; Avocado, West Indian; Bacury; Banana; Banana, dwarf; Binjai; Canistel; Cupuacú; Etambe; Jatobá; Kei apple; Langstat; Lanjut; Lucuma; Mabolo; Mango; Mango, horse; Mango, Saipan; Mangosteen; Pahoh; Papaya; Pawpaw, common; Pelipisan; Pequi; Pequia; Persimmon, American; Plantain; Pomegranate; Poshte; Quandong; Sapote, black; Sapote, green; Sapote, white; Sataw; Screw-pine; Star apple; Tamarind-of-the-Indies; Wild loquat; cultivars, varieties, and hybrids of these commodities.</td>
</tr>
</tbody>
</table>
**Question:** What is crop grouping and why is it important for Pomegranates?

**Answer:**
Crop grouping allows tolerance establishment for an entire group of similar crops, by conducting residue research on only a few crops that represent the entire group.

Pomegranates are set to become a rep crop under proposed EPA revisions.
Calendar of Upcoming IR-4 Events

- IR-4 Southern Region Priority Setting Conference Calls
  June 2016 and August 2016

- 2016 IR-4 Food Use and Biopesticides Workshops
  September 22-23, 2015; Orlando FL