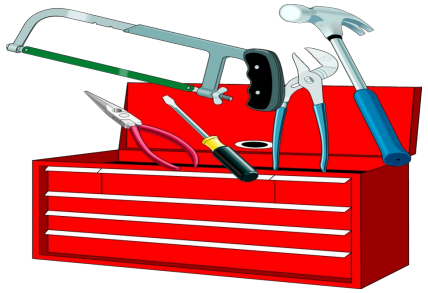
Registration Support for Pest Management Tools in Specialty Crops

The IR-4 Project: Purpose and Process

‘Deepen the Toolbox’



Roger B. Batts
Weed Science Biologist
IR-4 HQ
rbbatts@ncsu.edu

Pest Management Solutions for Specialty Crops and Specialty Uses

IR-4 Mission

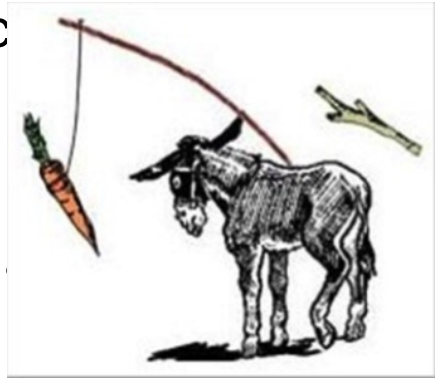
To facilitate regulatory approval of sustainable pest management technology for specialty crops (fruits vegetables, nuts, ornamentals and other horticultural crops) and other minor uses that promotes public well-being

IR-4 is the only publicly funded program in the US that addresses these issues

The IR-4 Project

Why is IR-4 Needed?

- Lack of Economic Incentive for Registrants to register products in specialty c
  - Development costs from 'discovery to jug' are estimated at $250-350M
  - Limited patent life
  - Small acreage crops = relatively small amount of product sales
  - "Just not worth the registration expenses and efforts" ('Carrot' is too sm



- Liability for Registrants
  - Specialty crops generally have a higher value per acre than row crops (Potentially large 'stick')

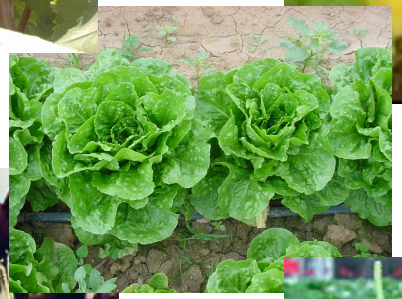
- This is not a new scenario. IR-4 was established by USDA in 1963 because of these same factors.

How IR-4 Helps Overcome these Hurdles

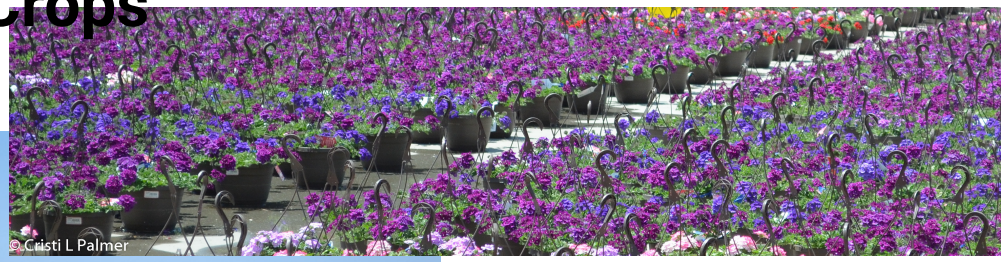
- Increase the Economic Incentive for Registrant (More appealing 'carrot')
  - IR-4 will conduct the EPA-mandated Magnitude of Residue trials to establish a Maximum Residue Level (MRL), a.k.a 'Tolerance' for a particular pesticide on particular crop. This saves the registrant >$150K per project.
  - Pesticide Registration Improvement Act (PRIA) fees are waived for IR-4 submissions. In 2023, IR-4 PRIA fee savings to registrants was more than $4.4 million.
  - Adding specialty crops to product labels can result in data protection extensions for registrants.
- Reduce liability concerns (Smaller 'stick')
  - IR-4 sometimes conducts product performance trials to help registrant make decisions on application timings and rates of crop protectants in fruits, vegetables and other specialty crops.

Programs Within IR-4

Food Crops



Environmental Horticulture Crops



Programs Within IR-4

Food Crop Program

- Majority of IR-4 effort and resources are dedicated here. Nearly 8500 new uses over the last 10 years and more that 23,000 since 1963.
- Selection of research priorities based on stakeholder input (grower groups, food processors, university research and extension specialists, etc.)

Four primary subprograms

1. Residue study management and EPA submissions to establish MRLs, maximum residue levels (a.k.a. tolerances)
2. Product Performance (efficacy and crop safety) studies related to specific product/commodity requests, when needed.
3. Biopesticide & Organic Support (initiated in 1982)
    - Regulatory guidance for registration of products
    - Research activities have been transferred to the Integrated Solutions Program
4. Integrated Solutions Program (Initiated in 2018)
    - Research support for Organic producers, including non-chemical and non-traditional technologies
    - PPWS (Pest Problems Without Solutions) projects. Screening of multiple products to identify potential solutions for the Food Crops Program
    - Research support to help mitigate Pesticide Resistance. Screening trials to help deepen the toolbox and reduce the risk of resistance.
    - Residue Reduction. Research support to help meet domestic and international mrl levels while maintaining good pest control.

Other Support Activities

- Crop Groups and Subgroups
  - EPA currently has 26 Crop Groups, many with multiple subgroups. They are based primarily on similar taxonomy, growth habit, and/or consumed portion. **Tolerances established on the Representative Crop(s) of a CG/SG apply to all members of that CG/SG.** More 'bang for the buck'. For example, conducting a residue study in watermelon will establish a tolerance for watermelon only. Conducting that same residue study on cantaloupe, the rep crop for the melon subgroup (9A), will generate a tolerance for more than a dozen crops.

9A. Melon subgroup	Cantaloupe	Citron melon; muskmelon (includes cantaloupe); watermelon

Melon	Muskmelon, including hybrids and/or varieties of *Cucumis melo* (includes true cantaloupe, cantaloupe, casaba, Santa Claus melon, crenshaw melon, honeydew melon, honey balls, Persian melon, golden pershaw melon, mango melon, pineapple melon, snake melon); and watermelon, including hybrids and/or varieties of (*Citrullus* spp.)

Other Support Activities

- Crop Groups and Subgroups
  - EPA currently has 26 Crop Groups, many with multiple subgroups*. They are based primarily on similar taxonomy, growth habit, and/or consumed portion. Tolerances established on the Representative Crop(s) of a CG/SG apply to all members of that CG/SG. More 'bang for the buck'.
  - Establishing a tolerance DOES NOT mean an automatic labeled use. Registrants may still have concerns before labeling; particularly with herbicides.
    - E/CS data on specific/new CG members may be needed.
    - The tolerance will apply to all members only if the use pattern (timing, rate, placement, etc.) matches those use to gain the rep crop tolerance.
    - Will the addition create risk cup concerns?

*Learn more on Crop Grouping: https://www.ir4project.org/fc/crop-grouping/

*Entire Crop Group Table: https://www.ir4project.org/fc/crop-grouping/crop-group-tables/

Other Support Activities

- Crop Group Expansion
  - Placing ‘orphan crops’ into established EPA crop groups can automatically get a tolerance applied to that crop. For more than 20 years, IR-4 has led, and continues to lead, the effort to find CG homes for orphan crops. A good example of this is placing okra into Crop Group **8** (fruiting vegetables) during its 20**10** expansion/revision into CG **8-10**.

Other Support Activities

8-10. FRUITING VEGETABLE GROUP	Tomato, standard size and one cultivar of small tomato; bell pepper and one cultivar of small non-bell pepper	African eggplant; bush tomato; bell pepper; cocona; currant tomato; eggplant; garden huckleberry; goji berry; groundcherry; martynia; naranjilla; okra; pea eggplant; pepino; non-bell pepper; roselle; scarlet eggplant; sunberry; tomatillo; tomato; tree tomato; cultivars, varieties, and/or hybrids of these
8-10A. Tomato subgroup	Tomato (standard size and one cultivar of small tomato)	Bush tomato; cocona; currant tomato; garden huckleberry; goji berry; groundcherry; naranjilla; sunberry; tomatillo; tomato; tree tomato; cultivars, varieties, and/or hybrids of these
8-10B. Pepper/Eggplant subgroup	Bell pepper and one cultivar of small non-bell pepper	African eggplant; bell pepper; eggplant; martynia; non-bell pepper; okra; pea eggplant; pepino; roselle; scarlet eggplant; cultivars, varieties, and/or hybrids of these
8-10C. Non-bell pepper/Eggplant subgroup	One cultivar of small non-bell pepper or one cultivar of small eggplant	African eggplant; eggplant; martynia; non-bell pepper; okra; pea eggplant; pepino; roselle; scarlet eggplant ; cultivars, varieties, and/or hybrids of these

Other Support Activities

- EPA Chemistry Science Advisory Council (ChemSAC) proposals
  - IR-4 will sometimes submit requests to EPA asking that existing data be considered, possibly reducing or removing data requirements on a certain project.
- Harmonization of International MRLs
  - IR-4 is a leader international efforts to harmonize MRLs to ‘level the playing field’ for US specialty crop growers that export their commodities.
    - Work with minor use programs in other countries.
    - Work with developing countries to establish minor use programs.
    - Identify worldwide pest control needs and testing through close collaboration with Minor Use Foundation. https://minorusefoundation.org/

https://www.ir4project.org/fc/international-programs/

The IR-4 Process

The Life of a Project at IR-4

Prioritization and Planning

= Stakeholder input is critical

Request submitted to IR-4

Continually received and reviewed

Registrant(s) review request

'Researchable' = eligible for nomination and prioritization

Online nomination process of all potential nomination requests. (Late Summer)

Trim the list from ~400 to ~100

Online 'A' nominations submitted to EPA.
1. Stop light analysis
2. Public Interest

IR-4 annual Food Use Workshop (September)

Trim the list from ~100 to following year's target

IR-4 National Research Planning Meeting
1. Study Director assignments
2. Trial site assignments
3. Analytical lab assignments

(Oct/Nov)

Consult with EPA guidelines and registrants on research needs and protocol requirements

Protocol development, review, finalization, and distribution to research sites for data generation (Nov- Feb/March)

Field Trials

Simultaneous Activities

*Annual IR-4/registrant meetings spring and summer

*Regional stakeholder priority meetings spring through late summer

To Submit a Request
https://www.ir4project.org/about-ir4/submit-a-request/

The IR-4 Project

The Life of a Project at IR-4

Data Generation

Project Initiation

0-month

Analytic Phase

Submission to EPA

30th month

Field Phase

Quality Assurance Review GLP

Petition Prep

The Need for IR-4 Continues to Increase

- Increased regulatory requirements means even lower economic incentive to registrants to pursue specialty crop labels
- Industry consolidation likely means fewer and smaller pool of registrant personnel devoted to specialty crops
- Specialty crop community will continue to need access to international markets. IR-4 will continue harmonization efforts, possibly including international field sites in residue studies.
- The crop protection industry is requiring more robust crop safety and product performance testing on specialty crops. IR-4 will likely need to increase activities and funding for its Biology team to conduct Product Performance and Integrated Solutions research.

The IR-4 Project

For More Information Contact…

IR-4 HQ

Executive Director
Dr. Jerry Baron
NC State University
1730 Varsity Dr.
Suite 210, Venture IV
Raleigh, NC 27606
jjbaron@ncsu.edu

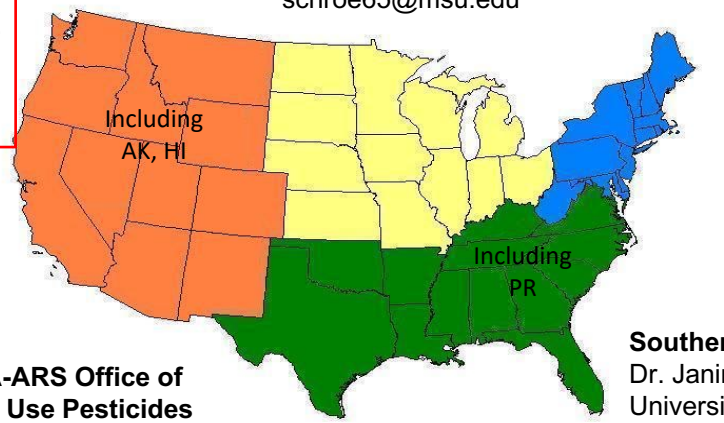
Principle Biologist – Weed Science

Roger B. Batts	(Satellite office)
NC State University	6572-A Jaycross Rd.
1730 Varsity Dr.	Fremont, NC 27830
Suite 210, Venture IV	252.281.1612
Raleigh, NC 27606	
919.515.3054	rbbatts@ncsu.edu

Regional and USDA-ARS Field Coordinators

Western Region
Dr. Kari Arnold
University of California
One Shields Avenue
Meyer Hall Room 4218
Davis, CA 95616
530.574.9181
klarnold@ucdavis.edu

North Central Region
Ms. Nicole Soldan
Michigan State University
1066 Bogue St.
Plant and Soil Sciences Bldg, Room A448
East Lansing, MI 48824
517.353.0416
schroe65@msu.edu



Northeast Region
Ms. Marylee Ross,
Univ. of MD/LESREC
27664 Nanticoke Rd.
Salisbury, MD 21801
410.742.8788 x 310
mross@umd.edu

USDA-ARS Office of Minor Use Pesticides
Dr. Alvin Simmons
US Vegetable Laboratory
2700 Savannah Highway
Charleston, SC 29414
843.402.5307
alvin.simmons@usda.gov

Southern Region
Dr. Janine Spies
University of Florida
1642 SW 23rd Dr.
Gainesville, FL
32611-0720
352.392.3991
jrazze@ufl.edu

The IR-4 Project