

The IR-4 Program

History, Infrastructure, Establishment of priorities, Coordination with the EPA and the Crop Protection Industry

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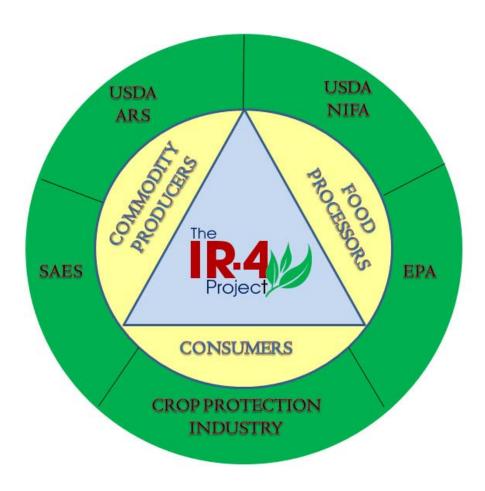


IR-4 Project

Since 1963 IR-4 has been a US government funded research program to facilitate registration of sustainable pest management technology for specialty crops and minor uses



The IR-4 Program



50 Years of providing growers with crop protection solutions.



Specialty Crops Include:

Most: Vegetables Fruits Nuts Herbs Spices





- Food Program w/ Reduced Risk Products
 - Residue trials, some efficacy & crop safety
 - Crop Grouping
 - International Harmonization, MRL's and Registrations
- Biopesticide and Organic Support Program
 - Regulatory support and efficacy
- Ornamental Horticulture Program
 - Efficacy and crop safety
- Public Health Pesticides



Who Are Our Stakeholders?

- 1. Specialty Crop & Minor Use Growers
- 2. Food Processors/Food Chain buyers
- 3. Consumers
- 4. Crop Protection Consultants/Research Providers
- 5. Funding Agency
- 6. Regulatory Agency



Grower
experiences
pest problem
Identify Pest
Management
Solution



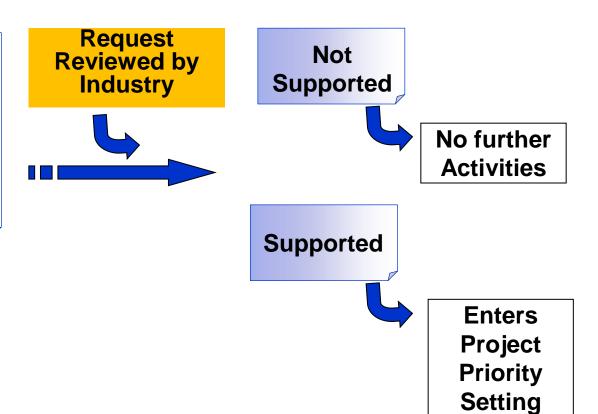








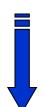
Process Starts with a Formal Request for Registration Assistance



System



400 possible projects



85 Studies

Requests Prioritized at Food Use Workshop

(September 11-12, St. Louis, MO)



Approved Research Study

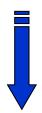
Grower, researchers & industry attend

Identify top research priorities

Use consensus decision making process



Approved Research Study



Protocol drafted and reviewed by industry and EPA (if needed).

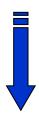
Industry provides correct info on GAP, and GLP test & reference substances

Research Initiated





Data Development

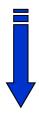


Industry reviews data, provides supporting submission documents

Submission Report



Submission Report

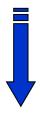


Regulatory authority conducts risk assessment

MRL



MRL



Industry updates registration and markets product

Growers have new PPP



30 Month Timeline



0-month



Analytic Phase



Quality Assurance Review GLP



22nd month



Submission to EPA

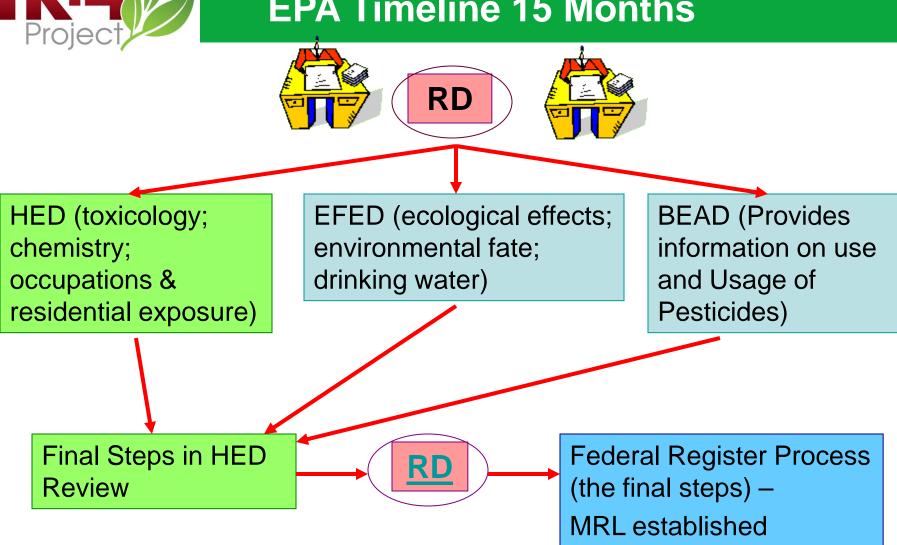
30th month



2nd month



EPA Timeline 15 Months





IR-4 National Headquarters

- Located at Rutgers University in New Jersey
- Responsible to manage and coordinate the day to day activities of the program
- Staffed with 30 full and part time Scientists, Coordinators & Administrative Personnel



IR-4 Regional Offices

- Northeast Region Cornell University, Geneva, New York
- Southern Region University of Florida,
 Gainesville, Florida
- North Central Region Michigan State University, East Lansing, Michigan
- Western Region University of California – Davis, California
- USDA ARS Companion program



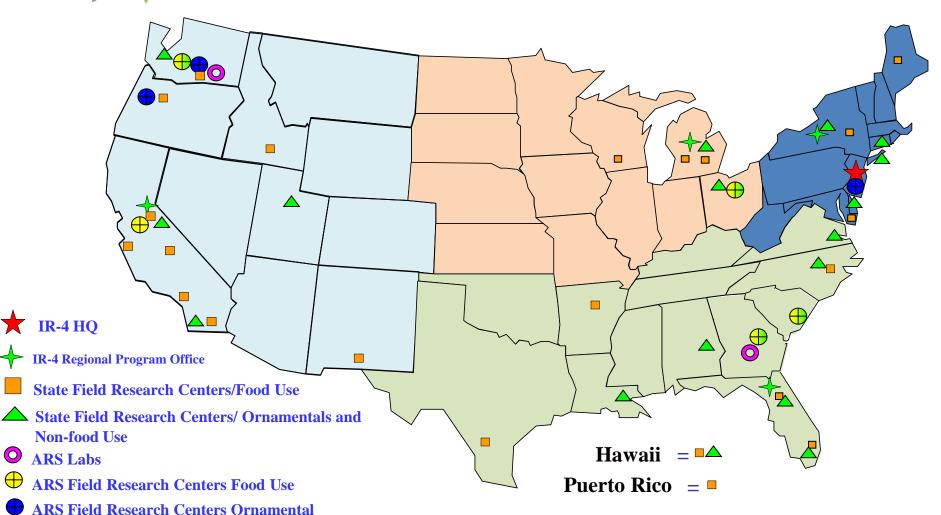
Board of Directors

- Representation from the Headquarters and each of the regions (including USDA) and Commodity Liaison Committee.
- Provides guidance and direction
 - Allocation of funds to each of the programs
 - Budgets for HQ and regional office
 - Five year strategic plan etc.



ARS Field Research Centers Ornamental and Food Use

IR-4 Project Infrastructure - Pesticide Residue work 85 studies/550 field trials





IR-4 Funding

Direct Contributions >\$18 million

,913,000
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- USDA-ARS \$ 3,920,000
- USDA-ARS/DoD \$ 250,000
- USDA-FAS \$ 500,000
- USDA-APHIS \$ 900,000
- State Ag. Exp. Stations\$ 481,182
- Donations from Industry \$ 1,420,000

Indirect Contributions

Valued at \$18 million but diminishing







NAFTA Minor Use Cooperative

Canada "Win-Win" Model

Objective:

- Address grower pest control needs with safe effective products in a manner that does not affect trade markets
- Conduct Joint Residue Studies and provide simultaneous submissions to both regulatory agencies (EPA and PMRA)
- Submissions reviewed and registrations approved in both countries at approximately the same time with harmonized tolerances/MRLs



Partnerships



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	Responsibilities	Roles	Benefits
NA Growers	Identify needs	Choose priorities	Target limited resources efficiency and obtain new tools
PMRA, EPA, SENASICA- SAGARPA, COFEPRIS-SSA	Federal Regulator – submission review, enforcement and monitoring.	Review regulatory proposals and make decisions taking in account harmonization.	Fulfills federal mandate - Greater efficiencies.
Researchers, Universities and Crop specialists	Conduct research on grower-selected MU solutions to specific pest problems.	Conducting of field trials, compilation of data supporting new MU submissions.	Contributes to science and innovation strategy.
Provinces and States	Also conducts field trials. Provinces prepare as well submissions on behalf of growers.	Advocate Provincial/States grower needs.	Obtain new Crop Protection tools for their growers.
Registrants	R&D on new crop protection tools and technologies.	Agree to label expansion and new use submissions.	Market new uses of products.
IR-4 Project and PMC and MU WG in Mexico	Facilitates registration of sustainable pest management technology for specialty crops and minor uses.	Develop necessary data to facilitate registration of crop protection tools for specialty crop growers and work jointly to facilitate North American registrations.	US and Canadian growers get national registration and access to Canadian and US markets as MRL is set and equal.



Harmonization NAFTA Level

- Regulatory environment
 - Address key science policy issues and achieve common regulatory procedures
- Crop Grouping
 - Expansion, development and harmonization of Crop Groups
- Data generation / data exchange
 - Acceptance of data and extrapolation
- Joint Reviews / Work shares
 - achieved by regulators (regular way to do business)
- MRL Harmonization
 - to facilitate trade
- NAFTA Labels
 - to facilitate a North American market for pest control products
- RCC will further promote this work



 RCC will further promote Harmonization of IR-4/PMC work

- Data Generation
- Reports
- Joint reviews
- Possible Joint workshops with Stakeholders



International Activities

- Data Many reports submitted to JMPR/Reg. Authorities
- Leadership-NAFTA, OECD, and Codex CCPR
- Capacity Building w/FAS in Africa, Asia, Central and S. America
- Crop Group Harmonization/Internationalization NAFTA/Codex
- Global Residue Study
- Global Minor Use Summit 2





Biopesticide and Organic Support Program

- 5% of the Project's efforts and resources
- Registration support and grants program for efficacy data
- Focus work with integration of biopesticides into conventional systems
- Support for organic markets
- Plant incorporated protectants
- Successes include:
 - BT (all crops), Afla-Guard,
 ENTRUST





HoneySweet Plum- Transgenic resistance Plum Pox Virus





Ralph Scorza – USDA-ARS Kearnysville



IR-4 Ornamental Program

- Established 1974
- 10% of the Project's efforts and resources
- Predominantly crop safety testing and efficacy







Public Health Pesticides

- Expand registrations for existing PHP
- Facilitate registrations for new technology and novel pesticides
- Register products outside US to protect deployed US military personnel



Partnerships Make Things Happen





Environmental Protection Agency (EPA)



- EPA/IR-4 Technical Working Group: Initiated in 1999, meets two times a year and provides educational summer tours
- Explores initiatives to facilitate minor crop tolerances;
 - crop group update
 - extrapolation proposals
 - specific chemical or crop proposals etc.
- PRIA implementation, Priority projects (Section 18s).
- EPA reviews annual IR-4 residue program
- Final report formats and electronic petition submission
- IR-4 part of US delegation to NAFTA, OECD, Codex





Canada

Health Canada's
Pest Management
Regulatory Agency (PMRA) and
Agriculture and Agri-Food Canada's Pest Management Centre

- Partnership with IR-4 began in 1996
- First IR-4 work share petition with EPA was completed in 2002
- In 2003, the Canadian government made a major funding commitment to minor crop growers through PMRA and AAFC
- 20% of projects are cooperative projects since 2003
- Over 60 joint reviews and over 100 joint registrations for minor ueses.
- MRLs are established at the same time in US and Canada



Crop Protection Industry

- IR-4 maintains at least yearly visits to update cooperative projects and discuss new technology strategies.
- Provide support for IR-4 GLP studies
 - **■**Protocol review, Test and reference substance
- Partnerships with biopesticide and chemical companies are crucial
- Despite reorganizations etc. companies continue to work with IR-4 to develop minor crop uses for their products

PRIA has presented New Petition Submission Challenges
 Provide submissions documents and risk assessment



Brasil

- Dovetail with data development
 - 2013 Research Plan
- Share data
- Promote activities at Codex
 - Crop groups
 - Data requirements/Guidelines
 - To allow greater data sharing etc



IR-4 Deliverables

- Since its inception, IR-4 has facilitated the registration of over 25,000 crop uses.
 - 14,000 food uses and 11,000 ornamental uses
- Return on investment
 - Michigan State University Center for Economic Analysis (Dec. 2011) reported that for a combined total budget of \$18 million
 - IR-4 Project efforts contribute over \$7.2 BILLION to annual US Gross Domestic Product.
 - IR-4 Project efforts support 104,650 JOBS throughout the United States.



Challenges

Fiscal Challenges:

 Importance of maintaining adequate budgets in order to have capacity and resources to conduct residue and efficacy trials



Commodity Liaison Committee

Dr. Michael Aerts, Florida Fruit and Vegetable Association

Mr. Mark Arney, Nat'l Watermelon Promotion Board

Mr. Kirk Baumann, Ginseng Board of Wisconsin

Dr. Lori Berger, California Specialty Crops Council

Dr. Michael Bledsoe, Village Farms, L.P.

Dr. A. Richard Bonanno, Bonanno Farm Trust - Chair

Mr. Bruce Buurma, Buurma Farms Inc.

Dr. Thomas G. Davenport, National Grape Cooperative

Dr. Brian R. Flood, Del Monte USA

Mrs. Ann E. George, Washington Hop Commission

Mr. Hank Giclas, Western Growers Association

Mr. John Keeling, National Potato Council

Mr. Phil Korson, Cherry Marketing Institute

Mr. Rocky Lundy, Mint Industry Research Council

Mr. Reed Olszack, Tropical Fruit Growers of S. Florida Inc.

Ms. Laura Philps, American Mushroom Institute

Mr. Ray Prewett, Texas Vegetable Association

Mr. Ray Ratto, Ratto Brothers

Ms. Lin Schmale, Society of American Florists

Mr. Todd Scholz, USA Dry Pea & Lentil Council

Dr. Alan Schreiber, Agriculture Development Group, Inc.

Dr. Marc Teffeau, American Nursery and Landscape Assoc.

Mr. Dave Trinka, MBG Marketing



Thank You!

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