The IR-4 Program

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

Daniel Kunkel. PhD
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IR-4 Project Headquarters
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
Current Objectives - Programs

• **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
Process Starts with a Formal Request for Registration Assistance

Request Reviewed by Industry

Not Supported

No further Activities

Supported

Enters Project Priority Setting System
Requests Prioritized at Food Use Workshop
(Signature 11-12, St. Louis, MO)

Grower, researchers & industry attend
Identify top research priorities
Use consensus decision making process

400 possible projects

Approved Research Study

85 Studies
Stakeholder Involvement

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
Stakeholder Involvement

Data Development

Industry reviews data, provides supporting submission documents

Submission Report
Stakeholder Involvement

Submission Report

Regulatory authority conducts risk assessment

MRL
Growers have new PPP

MRL

Industry updates registration and markets product

Stakeholder Involvement
30 Month Timeline

Project Initiation
- 0-month

Field Phase
- 2nd month

Analytic Phase
- 10th month
- GLP
- Quality Assurance Review

Petition Prep
- 22nd month

Submission to EPA
- 30th month
EPA Timeline 15 Months

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) – MRL established
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.
IR-4 HQ
IR-4 Regional Program Office
State Field Research Centers/Food Use
State Field Research Centers/Ornamentals and Non-food Use
ARS Labs
ARS Field Research Centers Food Use
ARS Field Research Centers Ornamental
ARS Field Research Centers Ornamental and Food Use

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

Hawaii = ▲
Puerto Rico = □
Direct Contributions >$18 million

- USDA-NIFA $11,913,000
- 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
Facilitating Registration of Sustainable Pest Management
Technology for Speciality Crops and Minor Uses

About IR-4

"History of IR-4 Minor Use Pesticide Registration 1963-2000"

IR-4 News

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

HoneySweet Plum - Transgenic resistance Plum Pox Virus

Ralph Scorza – USDA-ARS Kearneysville
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
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.
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 uses.
- 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.
Fiscal Challenges:

• Importance of maintaining adequate budgets in order to have capacity and resources to conduct residue and efficacy trials
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 Teffreau, American Nursery and Landscape Assoc.
Mr. Dave Trinka, MBG Marketing
Thank You!

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