IR-4’s Support for US Exports
New Strategic Plan: Vision 2020

Dan Kunkel
Associate Director, IR-4 Program
Food and International Programs
IR-4 Project

A US government funded research program

Facilitating the regulatory approval of sustainable pest management technology for specialty crops and specialty uses to promote public well-being
Objectives

• 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
**IR-4 Process Map**

**Input from:**
- growers

**Input from:** Registrants

- EPA
- Grower Reps*
- University reps*
- Extension*
- Registrants
- Specialists
  *attendees who “vote”

**IR-4**
- Identification of needs
- Prioritization (IR-4 Food Use Workshop)
- Use EPA guidelines and if needed Regulatory Advice
- Data Generation
  - Field Trials
  - Lab Analysis
- Data Collection report prep
- Regulatory Packages To EPA

**EPA**
- Review of potential projects
- ChemSAC
- Review
- Regulatory decision
- Registration (Product availability)

---

1. IR-4 reviews all possible projects with Registrant in annual review meetings.

2. IR-4 may submit project specific questions to EPA (e.g. sampling size, trial requirements) for their consideration and guidance.

3. EPA reviews list to see if any regulatory issues exist, before workshop.
30 Month Timeline

- Project Initiation: 0-month
- Field Phase: 2nd month
- Analytic Phase: 10th month
- Petition Prep: 22nd month
- Submission to EPA: 30th month
IR-4 Data

- Conduct 80 MOR studies per year on 40 or chemistries (about 550 field trials)
- Submit approximately 80 study reports to EPA each year
- EPA reviews and established Tolerances (MRLs) on 20 or more chemicals per year.
- Through crop group extrapolations etc the data supports over 700 new uses each year.
Deliverables w/Food Crops
• 36 chemicals,
• 43 different submissions
• Should address 221 specific IR-4 requests
• Cucurbit vegetables petition to propose new crops

See IR-4 2014 Annual Report for full details.
### 2014 Funding

<table>
<thead>
<tr>
<th>GROUP</th>
<th>AMOUNT</th>
<th>PROGRAM(S) SUPPORTED</th>
</tr>
</thead>
<tbody>
<tr>
<td>USDA-NIFA</td>
<td>$11,916,000</td>
<td>Food, Ornamental, &amp; Biopesticide</td>
</tr>
<tr>
<td>USDA-ARS</td>
<td>$3,570,000</td>
<td>Food &amp; Ornamental</td>
</tr>
<tr>
<td>USDA-ARS/DoD</td>
<td>$252,000</td>
<td>Public Health</td>
</tr>
<tr>
<td>USDA-FAS*/STDF</td>
<td>$350,000</td>
<td>Food (International)</td>
</tr>
<tr>
<td>USDA-APHIS*</td>
<td>$900,000</td>
<td>Ornamental (Invasive pests)</td>
</tr>
<tr>
<td>NRSP-4</td>
<td>$481,156</td>
<td>Food, Ornamental &amp; Biopesticide</td>
</tr>
<tr>
<td>Grants from Industry</td>
<td>$1,100,000</td>
<td>All</td>
</tr>
<tr>
<td>TOTAL</td>
<td>$18,569,156</td>
<td></td>
</tr>
</tbody>
</table>

*2014 was last year of funding for these grants

**Does not include in-kind contributions that are provided by State Agricultural Experiments Stations, Canada, EPA, growers and the crop protection industry. In-kind contribution valued at over $18 million annually
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 (Study Directors, Product managers, QA) & Administrative Personnel
IR- 4 Regional Offices

• 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
• Northeast Region - Cornell University, Geneva, New York
IR-4 efforts in International Cooperation

- NAFTA Technical Working Group On Pesticides and RCC
- PMRA Canada
- Brazil, Costa Rica, New Zealand MOUs
- OECD Expert Groups Guidelines
- China ICAMA Chair of CCPR
- EU – EFSA Regulation (EC)396/2005
- EPA
- Global Work-Shares & Joint Reviews
- PMC Canada minor Use program
- Codex/JMPR work
- ASEAN Harmonization of MRLs
- Crop Life International

MRL Harmonization
International Use of IR-4 Data

- Provide data to any commodity group that needs data to support export markets
  - Hop exports to the EU
  - Citrus and Berry growers to Asia markets
  - Cranberries to the EU
  - Annual JMPR submissions
International Use of IR-4 Data

- Codex/JMPR
  - Work with commodity groups and EPA to add uses (chemicals) to JMPR work plan
  - Review JMPR work plan and dovetail IR-4 data with chemicals scheduled for review
  - Work with EPA and Registrants to submit data to JMPR
  - Nominate Chemicals for JMPR review
  - Consider working with other countries to nominate chemicals or add commodities to JMPR workplan
Cooperation with MFGs

- IR-4 submits the data directly to JMPR
- IR-4 provides data to the registrant for submission to JMPR
  - Either bundled with uses they already have scheduled and plan to submit or
  - all of the uses listed are supported by IR-4 data, but the MFG makes the submission to JMPR
- The MFG submits IR-4 data that they already have in their files
<table>
<thead>
<tr>
<th>Pest Control Agent / Type</th>
<th>Commodities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetamiprid</td>
<td>Asparagus, Mustard Greens, Sweet Corn</td>
</tr>
<tr>
<td>Tebuconazole</td>
<td>Asparagus, Bulb Onion, Green Onion</td>
</tr>
<tr>
<td>Cyazofamid</td>
<td>Hops</td>
</tr>
<tr>
<td>Flonicamid</td>
<td>Canola**, mint**, strawberry**</td>
</tr>
<tr>
<td>Flupyradifurone</td>
<td>blueberry **; prickly pear cactus **</td>
</tr>
<tr>
<td>Bifenthrin</td>
<td>Head Lettuce, Spinach, Celery, Pea, Snap bean, Lima Bean, Blueberry, Grape</td>
</tr>
</tbody>
</table>

**indicates data IR-4 provided to the registrant for submission to JMPR
Support for IR-4 International Activities

• TASC - Support Market Access for Specialty Crops through harmonized Pesticide Maximum Residue Level’s (MRL’s). - expired, but hope to re-activate

• New TASC request - Enhanced Data Sets to Satisfy International Data Requirements for Establishment of Appropriate Maximum Residue Level’s (MRL’s) to support US exports.

• Minor Use Foundation.
First Global Minor Use Priority Setting Workshop: Seeking pest management solutions for growers around the world September 20 - 22, 2015 in Chicago, IL, USA
Workshop Agenda and Activities

- Plenary session with GMU updates and overview of workshop goals
  - Experiences with ideal regulatory package
    - Regulatory
    - MFG experiences
    - CLI Case Study
  - Grower comments
    - Share how existing systems have worked
    - EU, how grower groups have come together to address needs
    - Brazil experiences
- New product discussions, products with potential for global development and cover a range of solutions (conventional, biopesticides or for organic production).
- Discuss database and survey
- Set priorities
Workshop Agenda and Activities

• Review process to date (as a pilot for collating information).
• Select project leads. (coordinator, study director etc.) – set up who and how the project can be completed.
• Discuss Performance studies.
• Seek/support Funding
• Get agreements with regulatory agency of the country of the coordinator.
• Get agreements of global owners of solution chemistry – Manufacturers.
• Anticipated attendees: Crop experts, growers, regulators, and pest control products industry.
• Set time-table and action items.
• IR-4 Annual Workshop to follow (September 22-24).
IR-4 Vision for Global Research

Establish a global network of capable minor use programs that can address grower needs and generate data.

- Help establish and mentor these minor use programs (e.g. China, Brazil, Costa Rica)
- Partner with other data development groups
- Promote lower risk products
- Ease technical trade burdens
Research goes forward, following year or longer

International Organizations, Grower, researchers, Farm advisors
Identify top research priorities
Use consensus decision making process
Industry and Regulatory attend and must provide “buy in” for selected projects

Global Workshop

Funding

1000* possible projects

Global Workshop

Priorities – based on needs and funds

Research starts as soon as priorities are determined
Use Global Research Hubs

1000* possible projects

Foundation Funding

*priorities collected from survey and now listed in global database
• Updated Strategic Plan.
  – Started with a survey
    • Over 550 stakeholders responded
  – Refresh the Vision
    – See Summary: http://ir4.rutgers.edu/Other/RPMstrategicplan_Layout%201.pdf
    – See Full: http://www.ir4.rutgers.edu/Other/AnnualReports/IR-4%20Vision%202020%202013_14.pdf
IR-4 Should keep an eye on….

• New pest pressure
• Pest resistance to pesticides
• Increased need for product performance data
• Residue studies becoming more complex
• Internationalization of IR-4 data development
• Emerging science and regulatory issues
IR-4 Project Mission

Facilitating the regulatory approval of sustainable pest management technology for specialty crops and specialty minor uses to promote public well-being
Vision 2020

Plant Health Objectives

– Food Crops
  • Residue Studies
  • MRL Harmonization, International
  • Crop Grouping
  • Efficacy & Crop Safety
– Ornamentals/Environmental Horticulture
– Biopesticides/Organics
Vision 2020

• Public Heath Pesticides

• Sponsored Programs
  – Considerations
    • Grower Funded Research
    • Invasive Species Management
    • International Capacity Building
    • Import Tolerances for US based food processors
    • Pollinator Protection
    • Other?
Vision 2020

Other points

• Improving Efficiencies
• Empowering State Liaison Representatives
• Reinvestment in Infrastructure
• Development
• Land-Grant University Partnership
## 2014 Funding

<table>
<thead>
<tr>
<th>GROUP</th>
<th>AMOUNT</th>
<th>PROGRAM(S) SUPPORTED</th>
</tr>
</thead>
<tbody>
<tr>
<td>USDA-NIFA</td>
<td>$11,916,000</td>
<td>Food, Ornamental, &amp; Biopesticide</td>
</tr>
<tr>
<td>USDA-ARS</td>
<td>$3,570,000</td>
<td>Food &amp; Ornamental</td>
</tr>
<tr>
<td>USDA-ARS/DoD</td>
<td>$252,000</td>
<td>Public Health</td>
</tr>
<tr>
<td>USDA-FAS/STDF</td>
<td>$350,000</td>
<td>Food (International)</td>
</tr>
<tr>
<td>USDA-APHIS</td>
<td>$900,000</td>
<td>Ornamental (Invasive pests)</td>
</tr>
<tr>
<td>NRSP-4</td>
<td>$481,156</td>
<td>Food, Ornamental &amp; Biopesticide</td>
</tr>
<tr>
<td>Grants from Industry</td>
<td>$1,100,000</td>
<td>All</td>
</tr>
<tr>
<td>TOTAL</td>
<td><strong>$18,569,156</strong></td>
<td></td>
</tr>
</tbody>
</table>

*Does not include in-kind contributions that are provided by State Agricultural Experiments Stations, Canada, EPA, growers and the crop protection industry. In-kind contribution valued at over $18 million annually.
## Funding Request in Vision 2020

<table>
<thead>
<tr>
<th>GROUP</th>
<th>AMOUNT</th>
<th>New Fund Support</th>
</tr>
</thead>
<tbody>
<tr>
<td>USDA-NIFA</td>
<td>$15,858,000</td>
<td>Restore Capacity, Expanded E/CS, State programs, ID cost</td>
</tr>
<tr>
<td>USDA-ARS</td>
<td>$5,075,000</td>
<td>Restore Capacity, Expanded E/CS</td>
</tr>
<tr>
<td>USDA-ARS/DoD</td>
<td>$252,000</td>
<td></td>
</tr>
<tr>
<td>USDA-FAS/STDF</td>
<td>$</td>
<td></td>
</tr>
<tr>
<td>USDA-APHIS</td>
<td>$</td>
<td></td>
</tr>
<tr>
<td>NRSP-4</td>
<td>$481,156</td>
<td>Food, Ornamental &amp; Biopesticide</td>
</tr>
<tr>
<td>Grants from Industry</td>
<td>$2,500,000</td>
<td>Restore Capacity and infrastructure</td>
</tr>
</tbody>
</table>

Consider sponsored programs where stakeholders will contribute full funding to cover requested data development and regulatory activities.
Thank You

QUESTIONS?

Daniel Kunkel
kunkel@aesop.rutgers.edu
(732) 932-9575 ext. 4616