Overview of Minor Use Activities
Daniel Kunkel
Presentation Overview

• IR-4 Mission, Objectives, Structure, Process and Recent Successes
• EPA Support of Minor Uses & Crop Grouping
• Global Minor Use Activities
  – US/Canada Collaboration
  – Global Minor Use Summit
  – OECD/Codex
IR-4 Project

Mission

To Provide Safe and Effective Pest Management Solutions for Specialty Crop Growers

IR-4 is the only publicly funded research program in the United States that develops necessary data to facilitate the registration of crop protection products for specialty crops.
Current Objectives

- Food Program w/ Reduced Risk Products
  - Residue trials, some efficacy & crop safety
- Ornamental Horticulture Program
  - Efficacy and crop safety
- Biopesticide and Organic Support Program
  - Regulatory support and efficacy
- Crop Grouping
  - Regulatory initiatives
AF36/Corn Management of Aflatoxin
Experimental Use Permit-Texas and Arizona

Cooperation: Texas Corn Growers Association
Zucchini Yellows Mosaic Virus- Weak Strain- Cucurbits 
For cross protection against the wild type virus
HoneySweet Plum- Transgenic resistance Plum Pox Virus

Ralph Scorza –USDA-ARS Kearneysville
The IR-4 Project

Excellent History of Providing Crop Protection Tools to Growers

• Established in 1963 - Over 11,000 Food crop use registrations
• A true partnership between the federal government, state agricultural experimental stations, growers & commodity groups, the crop protection industry and the regulatory agencies
IR-4 Organization

• Cooperative program consisting of many independent units working together
  - IR-4 Headquarters
  - Field Research Centers
  - Four Regional Offices
  - Analytical Labs
  - USDA-ARS Program
  - State Liaisons

• Project Management Committee facilitates cooperation between/among units
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 27 Scientists/Coordinators
IR-4 Regional Offices

• Northeast Region - Cornell University, Geneva, New York

• Southern Region - University of Florida, Gainesville, Florida

• Northcentral Region - Michigan State University, East Lansing, Michigan

• Western Region - University of California – Davis, California
IR-4 Regional Centers

• Each Regional Center is led by a Regional Director

• Regional Center Personal responsible for:
  – Priority Setting and Field Research Management
  – Analysis of Residue Sample
  – Quality Assurance of data
IR-4 Regional Centers - Field

- Coordinates specialty crop and minor use pest management needs from the region
- Assist in priority setting
- Places field trials and field research
- Tracks, monitors, facilitates, and funds research work in the region
- Coordinates efforts through Headquarters
• Develops and validates analytical methods
• Analyzes samples for pesticide residue
• Coordinates efforts through Headquarters
Who pays for IR-4?

<table>
<thead>
<tr>
<th>Direct Contributions – Almost $17 million USD</th>
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<tbody>
<tr>
<td>USDA-CSREES</td>
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<td>USDA-ARS</td>
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<td>State Ag. Exp. Stations</td>
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<td>Grants from Industry</td>
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<tr>
<th>Indirect Contributions – At least $15 million</th>
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<tr>
<td>Test Chemicals</td>
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<tr>
<td>Technical Support</td>
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<tr>
<td>Employee Benefits</td>
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<td>Utilities</td>
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<td>Land Use</td>
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<td>Other miscellaneous research costs</td>
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Stage I
Food Crops

Stakeholder:

- Define Pest Problem
- Identify Pest Management Solution
- Request Assistance from IR-4
1. REQUESTER:
   Name: Rocky Lundy
   Affiliation: Mint Industry Research Council
2. PESTICIDE (Common Name Mfg): Carfentrazone / FMC
3. COMMODITY:
   CROP: Mint
   USE SITE: Field
   PARTS CONSUMED: Oil
   ANIMAL FEED BY PRODUCTS: No
   PLANTING SEASON: Late fall & Early spring
   HARVEST SEASON: July-August
   LOCAL ACERAGE: 40,000 acres
   PERCENT NATIONAL ACRES: 60%
4. TARGET PEST(S)/POTENTIAL EFFECTS: Many species of annual, bi-
   annual and perennial broadleaf and grassy weeds
5. WHY IS THIS USE NEEDED: Post emergent weed control (burn down)
   during mint dormant period?
The Regulatory Clearance Process

The Process Starts with Requests
Submitted from:
- Growers,
- Grower Groups,
- State/Federal Research & Extension Personnel

Requests Prioritized
- Top Priority Researched That Year
- Second Priorities Researched as Money Allows

Field and Lab Research
- Measure Residue levels in Crop/Crop Group
- Top Priorities completed in 30 months

Manufacturer Adds Crop to the Product Label
Tolerance Established by EPA

Stakeholder:
- Define Pest Problem
- Identify Pest Management Solution Request Assistance from IR-4

Risk Assessment

Package Submitted to EPA
Successful Strategies

- Start research on new chemistries before the first food use tolerance
- Use representative crops to obtain tolerance for entire Crop Group
- Use “Super Crop Groups” for certain reduced risk chemistries to increase efficiencies
- 30 month time frame for Priority A Food Use projects - initiation of project to submission to EPA
Deliverables
EPA & Minor Uses

• Agency Supports Minor Uses
  – Dedicated Minor Use Team
  – Open door to growers
  – STRONG partnership with IR-4

• Legislative Support
  – PRIA/Tolerance Fee waivers & exemptions
  – Exclusive Use of Data expansion
  – Other- FIFRA Title II
EPA Partnering with IR-4

- Crop Grouping
- Super Crop Groups
- Piloting
  - Work sharing
  - Electronic Submission
- Educational Activities
  - Seminars
  - Tours
Multiyear Joint Project with EPA, International Crop Grouping Consultants Committee (ICGCC) and Codex to evaluate crops groups and extrapolation

- Validate US and Canada Crop Groupings/Add new crops to existing groups and/or new groups/subgroups
- Work with International Stakeholders to modify Codex groups to better support global trade via extrapolation
  - Harmonization of crops groups is ultimate goal
Global Harmonization

IR-4 is a domestic program for domestic growers, Why involved in Global Harmonization?

IR-4 has provided domestic growers with access to numerous new pest management tools. These are OK to use if crop sold in US. Often significant problems if commodity is exported. Growers forced to use older pest management tools.

This is a serious issue to many commodity groups
NAFTA Minor Use Cooperative

Objective:

• Address grower pest control needs with safe effective products in a matter that does not affect trade markets.

• To 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
Background:

- Canadian Horticultural Council/PMRA began joint field trials with IR-4 in 1996
- From 2003 to 2007, a total of 79 projects with 235 Canadian residue field trials and 549 US residue field trials were conducted by AAFC and IR-4
- Data including residue, efficacy and tolerance have been collected
- For 2008, 19 studies conducted jointly. IR-4 provided 137 field trials and Canada provided 47 residue trials and 62 efficacy trials.
- Makes up about 20% of IR-4 residue program
Progress Report:

- Joint Review program to date
  - 18 submissions/Petitions completed
  - Currently 5 in review
  - 7 more submissions will be sent in 2009
- Minor Use Joint Reviews results
  - Resulted in more than 62 new uses
  - Reduced timeframe
- Other submissions/petitions will be submitted as “work share”
OECD Activities

- Expert Group on Minor Uses (EGMU)
- Establishment endorsed in June 2007
- Workplan:
  - Develop mechanisms to enable work sharing
  - Collaboration with the Residue Expert Working Group
  - Promote work of OECD
  - Report to Registration Steering Group (RSG)
Why a Global Minor Use Summit

NAFTA Activities
   Established programs

Codex activities
   Crop classification update, need for more MRLs

IR-4/EPA/FAO/USDA
   realized a need to have a summit

OECD Activities
   Workshops, symposia, committees

Some Working Independently some Cooperatively
Global Minor Use Summit

- **Goals/Objectives:**
  - Bring countries and organizations together and address challenges in specialty crops and minor uses;
  - Discuss requirements for residue trials and residue data generation that are acceptable nationally and internationally;
  - Discuss approaches on a harmonized data generation program and ways to share residue data developed for minor and specialty crops in support of national and international tolerances / MRLs;
  - Improve crop protection for specialty crops in *industrialized* and *developing* countries and to facilitate the trade of agricultural commodities internationally
– To support crop classification systems and crop grouping approaches in promotion of international trade under Codex;

– To support countries' access to advanced residue programs and to provide information on the establishment of such programs
Global Minor Use Summit

• **Action Items:**
  1. Development of a common web portal
  2. Development of capacity building directed to developing countries
  3. Establishment of a CODEX Working Group on specialty crops and minor uses
  4. Development of pilot projects eg crop specific database
  5. Future plans for a Global Minor Use Summit II
Action Items #1-Communications

Develop a common portal consisting of links to national data and information websites including (but not limited to)

- Crop grouping schemes
- Existing National MRL regulation
- Existing Minor Use Programs
- Pest management need/gaps
- Use Authorizations to facilitate data sharing by pesticide/crop/pests
- List server and electronic bulletin board
Global Minor Use Portal

The First Global Minor Use Summit: Striving Toward Harmonization

Nearly 300 people, representing 60 countries, registered for the first Global Minor Use Summit, which was hosted by the Food Agriculture Organization (FAO) of the United Nations and held at their headquarters in Rome, Italy. The week-long event, focusing on pesticide use on Specialty or Minor Crop, took place from December third through the seventh, 2007 and was jointly organized through FAO, the USDA Foreign Agriculture Service (FAS), the U.S. Environmental Protection Agency (EPA) and the USDA / IR-4 Project (IR-4).

The need for a global discussion stems from trade barriers due to the inconsistencies of minor crop pesticide residue standards amongst nations. IR-4 Executive Director, Jerry Baron, stated, “The purpose of the Summit is to develop a basis for future cooperation by focusing on a global agreement in pesticide policy, procedure and methodology. The overriding goal of this cooperation is to promote free and fair trade between nations.”

The Summit agenda included presentations on the first day with topics focusing on the current state of specialty crop program initiatives and challenges from regional, grower and business perspectives. Day two focused on technical initiatives and challenges, cooperation and policy considerations, with the third day putting participants to work in break-out sessions where they collaborated to provide practical recommendations for action. The final day and a half was dedicated to training sessions covering Good Laboratory Practices and data review procedures.

The outcome of the first Global Minor Use Summit included the following:

Global Minor Use Summit Action and Follow-up Items

- Information - Develop a common portal consisting of links to national data and information websites including (but not limited to):
  - Crop grouping schemes
  - Existing National MRL regulation
  - Existing Minor Use Programs
  - Pest management needs/gaps
  - Use Authorizations to facilitate data sharing by pesticide/crop/pests
  - List server and electronic bulletin board

A Portal Committee has been established to manage the development of the GMUS web based portal.

http://ir4.rutgers.edu/
Action Items  #2 Capacity Building

- Biopesticide/Reduced Risk pesticides
- Multi-lateral review efforts
- Regional coordination and cooperation
- Data generation (field trials, laboratory analysis, development of submission documents)
Action Items #3  CODEX

• Increased number of Codex MRLs for specialty crops and minor uses

• Support Codex in revising Codex Classification of Food and Animal Feeds including the consideration of the concept of representative commodities

• Establishment of a CODEX Working Group on specialty crops and minor uses – (Approved in April 2008)
Action Items #4 Pilot Projects

• Explore the concept of a simultaneous JMPR and national review to facilitate the establishment of Codex MRLs prior to national MRLs
  ➢ Continue Ongoing global joint reviews

• Investigate reasons for differences in national and Codex MRLs for specific pesticide/crop combination

• Create a crop specific database for a limited number of crops that contains a listing of use authorizations and residue trials

• Compare residues between regions to support the concept of global zoning
  ➢ Global Residue Study
GLOBAL RESIDUE STUDY
Action Items #5  Summit II

- Focus program on commodity based pest management issues utilizing results from above Action Items as identified at the first Global Minor Use Summit

- Future plans for a Global Minor Use Summit II July 2010
Global Joint Review

- E2Y45
• Proposed Workgroup on Minor Uses
  – Proposal to establish a CCPR Working Group on Minor Uses and Specialty Crops accepted by the CODEX CCPR in April 2008, chaired by US and co-chaired by Australia and Kenya
  – Objectives: to move many of the action items from the Global Minor Use Summit forward
  – TOR: to provide guidance to facilitate the establishment of CODEX MRLs for minor uses and specialty crops
CODEX Activities

- IR-4 2006 and 2007 JMPR reviews
  - Seven Cranberry Reports
  - Bifenazate
    - Pome fruit, Stone fruit, Berries and other small fruits, Nuts and seeds, Fruiting vegetables, Cucurbits Root crops, Dried Herbs (Hops And Mint)
  - Quinoxyfen
    - lettuce, melon, strawberry and peppers
CODEX Activities

- IR-4 2008 JMPR reviews
  - IR-4 Submitted
    - Imidacloprid – 11 crops
    - Spinosad – 3 crops
  - MFG Submitted – IR-4 data
    - Azoxystrobin – many crops
    - Chlorantraniliprole
    - Boscalid and Tebuconazole
CODEX Activities

- IR-4 2009 JMPR reviews
  - IR-4 Submitted
    - Indoxacarb – stone fruit, cucurbits, Southern pea, mint, cranberry
    - Methoxyfenozide – citrus, root veggies, peas and beans, cucurbits, bushberry, cranberry, strawberry, peanut, tropical fruits
    - Buprofezin – Grape, fruiting veggies, pomefruit, stonefruit, berries, tropical fruits, bean, olive, almond, cucurbits
  - MFG Submitted
    - Spirodiclofen
    - fenbuconazole
• IR-4 2010 beyond JMPR reviews
  – Fenpyroximate
  – Acetamiprid
  – Etoxazole
  – Others
Thank You!

Daniel Kunkel:
kunkel@aesop.rutgers.edu
(732) 932-9575 ext 4605