Harmonized Approaches to Crop Protection for Minor Uses: Past, Present, and Future

Daniel Kunkel, Ph.D., Associate Director, IR-4 Program
THANK YOU!!!

- IUPAC
- ACS – Ken and Brian Bret
- Most of all – the nominators.
  - Jerry, Phil Brindle, Dan Botts, Sheridawn Schoeman, Jeroen Meeussen, Barbara Madden, Lori Berger, Ray McAllister, Vivian Powell
  - And the many others that have had anything to do with it!
  - Family!!!
A publically funded program that facilitates registration of sustainable pest management technology for specialty crops and minor uses.
“Everyone who eats has an interest in the IR-4 Project whether they know it or not. The IR-4 Project is a vital part of the country’s food safety security system and should be considered a national strategic imperative”
Minor Uses

• They are: “What’s for dinner”

• Everyone should be interested in protecting minor uses or specialty crops
The OECD Guidance Document on Defining Minor Uses of Pesticides published by the OECD in 2009 states:

- “There is no one internationally or OECD accepted definition for minor use. ... The criteria and guidelines for determining what constitutes a minor use varies amongst member countries...”

- “Minor use definitions serve as an important mechanism to ensuring that minor uses that are required by agricultural producers are appropriately regulated....”

- “Minor use classifications are utilised to provide things such as guidance on the number of trials required, incentives to encourage their registration....”
Defining Minor Uses

The OECD document outlines two prominent, and often opposing approaches for OECD member countries to use in defining minor uses:

1. the ‘risk assessment’ approach, and
2. the ‘economic return’ approach

Regardless, is a situation where a grower has pest control issues that are not being addressed. .... how long do they need to go without a tool before it is considered a minor use?
Past

- Julie Borlaug – 2016, “we have to remind people that had we not had innovation in agriculture, we would not have grown out of the agrarian economy and wouldn’t have the lifestyles that we have now”
- 2,4-D registered in 1947
- 1 US farmer feeds 150 people today
Evolution of IR-4

1963
Food Program

1970 and 80's
- Infrastructure
  - Regional Offices
  - ARS program
- Biopesticides
- Ornamentals

1990 – 2008
- FIFRA 88
- Reduced risk
- Crop group updates

2009 - current
- International Maximum Residue Levels (MRLs) to support US exports
- Invasive pests/pollinators
- Organic Agriculture
- Plant Incorporated Protectants (PIPs)
- Public Health Pests
Since its inception, IR-4 has facilitated the registration of 18,000 crop uses, 1175 in 2015 and over 650 new uses to date in 2016. Also...Numerous biopesticides (sprayable BT, spinosad for organics), Biotech... Plum Pox resistant stone fruit.

Compton and Markle started in 1963

Current Executive Director, J. Baron
Trade- Past to Present

- 1980 – present...increase in the interdependence among countries, liberalization of trade
- Exports – is the major market expansion for growers/Agriculture.
- US markets are pretty mature
  - New crops, exotics..etc
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<td>63</td>
<td>116</td>
<td>141</td>
<td>162</td>
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</table>

*in Billions of dollars

USDA-FAS (http://www.fas.usda.gov/gats/default.aspx)
Long-Term Trends for U.S. Specialty Crops:
Production Stable, Both Imports & Exports Increase

Horticulture

Source: ERS Baseline
In Billions of dollars

2016 is the year of the Pulse!
Exports of Tree Nuts 2012

- EU-27: 1.73
- Canada: 0.49
- Mexico: 0.21
- China: 0.4

In Billions of dollars
Ag Trade – last 7 years

*USDA-FAS (http://www.fas.usda.gov/gats/default.aspx)
It Starts with the Pests!
• Technologies to control plant diseases and insects are limited
• Phytosanitary demands require pesticides
• Growers large and small depend on pesticides to control plant diseases, insects (and weeds)
• Pesticides will continue to play a key role in IPM programs

Comment by California Citrus Quality Council, 2012
Pesticide residue limits (MRLs)

- Pesticide residue limits (MRLs) are important for compliance of proper use of products and has become an important trade standard for agricultural commodities.
- Many countries are creating or modifying system of establishing/enforcing MRLs for imported crops and domestic use.
- The science improves, now 1 ppb is a reality.
- Regulations increase, greater complexity of moving commodities through global markets.
- More data needed, thus the Minor use problem grows/amplifies.
MRL WTO Notifications

FAS Reviewed Over 2,000 WTO Notifications in 2014

- Veterinary Drugs
- Contaminants
- Food Additives
- Pathogens
- Pesticides

0 50 100 150 200 250 300 350 400
Other trade considerations

• Cranberries from the US are often shipped to Canada for juicing
• Grapes from Canada are often shipped to the US for juicing or for wine production.
• MRLs can preclude these shipments and more efficient use of resources.
Regulations – Past, Present

• 1960s OECD, Codex (FAO/WHO)
  – Look and see, piecemeal data generation...submissions

• 1980s – EPA is up and running
  – Crop groups...kind of start..
  – Rejection rate analysis

• 1990 – clear(er) guidelines (OPPTS 860)
  – PMRA and other regulatory agencies established.
  – OECD - Pesticide Program initiated
    • Series on Pesticides No. 1, DATA REQUIREMENTS FOR PESTICIDE REGISTRATION IN OECD MEMBER COUNTRIES: SURVEY RESULTS
  – Registration review (ReReg, FIFIRA 88)
• 2000s – Joint reviews: NAFTA, OECD member countries..

• OECD - UPDATE OF THE “VISION FOR THE FUTURE: A GLOBAL APPROACH TO THE REGULATION OF AGRICULTURAL PESTICIDES” (REVISION 11; MAY 2009)
Global JR – Early examples of Work Splits

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Toxicology</th>
<th>Residue Chemistry</th>
<th>Eco-toxicology</th>
<th>Environmental Fate</th>
<th>Product Chemistry</th>
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<tbody>
<tr>
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<td>Canada</td>
<td>United States</td>
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<td>Australia</td>
<td>United Kingdom</td>
<td>Ireland</td>
<td>Canada</td>
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<tr>
<td>Spirotetramat</td>
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<td>Canada</td>
<td>Austria</td>
<td>Austria</td>
<td>Canada</td>
</tr>
<tr>
<td>Thiencarbazone/Cyprosulfamide</td>
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<td>United Kingdom</td>
<td>Canada</td>
<td>United States</td>
<td>United Kingdom</td>
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<tr>
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<td>Germany</td>
<td>United States</td>
<td>United States</td>
<td>Canada</td>
<td>Germany</td>
</tr>
</tbody>
</table>

A good start! And a lot of progress since.
Maximum Residue Limits

- Used for enforcement – proper application etc (at the local level).
- Standards for commodities in trade (domestically and internationally)
- Only set if the dietary exposure risk assessment confirms that there are no human health concerns to any segment of the population
- Generally set beneath any level of potential toxicity for human health – often by an order of magnitude
- Proper use of product would seldom result in residues at the MRL level set locally.
The technology has changed

"How do you send text messages?"
Timeline to registration

- Discovery Research: 2-5 years
- Regulatory research: 3-5 years
- EPA review: 2 years+

$300,000,000…
When each country does a separate review
- Adds time to when the grower can use the product
- Redundant reviews
- Different MRLs
*There are more than 30 countries that still “default” to Codex standards, An import standard for exports
Pesticide Global Joint Reviews

• Several national authorities evaluate a pesticide active ingredient at the same time—
  – Receive the same submission at the same time
  – Develop a joint schedule
  – Divide the work

• At the conclusion - each makes its own independent regulatory decision with the goal of harmonization of endpoint selection and MRL establishment.
Global Regulation - Future

One Global Review

ASEAN
EU Review
NAFTA Review
Codex/JMPR Review
LA Review
AU (Africa) Review
AU/NZ

Tool For Grower
Global Regulation

Codex/JMPR Review

EU Review

NAFTA Review

Codex/JMPR Review

One Global Review

MRL

Tool For Grower

AU/NZ Review

EU Review

NAFTA Review

AU/NZ

OECD ??
Global Regulation

Codex/JMPR
One Global Review

ASEAN
EU Review
NAFTA Review
LA Review
AU (Africa) Review
AU/NZ

2007
GMUS 1 Recommends…

Tool For Grower
What if....

- Each country had multiple staff do the JMPR reviews – WHO and FAO, toxicology and residue chemistry (this work would not need to be repeated “at home”) – saving resources.
- Residue definition and MRLs agreed..
- Those reviews are then taken to country reviews with further Eco-Toxicology and Environmental fate
What if....

• Let Codex Regulate trade and let Domestic agencies regulate at the local level
  – Protect the environment, workers, and enforce proper use of pesticides..and monitor imports.

• Can society continue to afford the current redundancies, to feed a growing population?

• It will not come at the expense of safety.
  – Codex regulates diet
  – Government regulates workers, environment, other – aggregate exposure
  – Still a strong check and balance
reviews

EU Review

LA Review

ASEAN

AU (Africa) Review

NAFTA Review

AU/NZ
Tools for Solutions –
What do we need to make this work

• Crop Grouping
• Global Zoning (exchangeability of field trials)
• Incentives for Industry
• JMPR/Codex Process Initiatives – become reality
• Capacity Building – more participation more robust data sets
• Global Minor Use Foundation – public support for data
• MRL Calculator, Crop group calculator
• Global Joint reviews A Global Review
• Global Guidelines, Env. Fate, field trials, etc. etc
  – Multiple countries working together
• Recognize One trade Standard
Furthering the work...

1. COOPERATION ACTIVITIES
   - Joint Research, Global Datasets

2. TECHNICAL ACTIVITIES
   - Joint reviews, CCPR, OECD

3. POLICY ACTIVITIES
   a) Continue with guideline documents (OECD, Codex)
      Eg implement exchangeability of field trials and other studies such as EFED..
   a) Legislative changes
      Recognize Trade standards (MRLs) vs local MRLs
      Mutual recognition...data, MRLs, end points etc...
### The NEED FOR PEST CONTROL CONTINUES

<table>
<thead>
<tr>
<th>Cropping System</th>
<th>Pest/Crop rank 1 - A (highest votes)</th>
<th>Pest/Crop rank 2 - B (votes)</th>
<th>Pest rank 3 – B (votes)</th>
</tr>
</thead>
</table>
| **Protected (green house)** | **Aphids /lettuce**  
**Possible Solutions:** Flonicamid, Pymetrozine, Cyantraniliprole, Sulfoxaflor, NA 11630 | **Thrips /fruiting vegs.**  
**Possible solutions:** Cyantraniliprole, Novaluran, Cyclaniliprole | **Whiteflies/fruiting veg.**  
**Possible solutions:** Flupyradifurone, Cyantraniliprole, Novaluran, NA 11630 |
| **Temperate** | **Downy mildew/leafy vegetables**  
**Possible solutions:** Ametoctradin + Dimethomorph, Acibenzolar, Zoxamide, Fluopicolide + Propamocarb, Cyazofamid, Oxathiapiprolin, Farnoxadone + Cymoxanil | **Aphids/legumes crops**  
**Possible solutions:** Flonicamid, Pymetrozine, Cyantraniliprole, Sulfoxaflor, Dinotefuran, Spirotetramat, Flupyradifurone, NA 11630 | **Weeds/leafy vegetables**  
**Possible solutions:** s-metolachlor |
| **Tropical Fruit** | **Fruit flies**  
**Possible solutions:** Spinosad, Cyantraniliprole, Kaolin, NA 11630 | **Anthracnose**  
**Possible solutions:** Trifloxystrobin + Fluopyram, Pyraclostrobin + Metiram, Mandistrobion, Isofenamid, Azoxystrobin + Difenoconazol, Cyprodinil + Fludioxonil, Penthioxyrad | **Psyllids on Citrus crops**  
**Possible solutions:** Diflubenzuron, Flonicamid, Sulfoxaflor, Buprofezin, NA 11630 |
WE CAN DO IT!

Flupyradifurone - Global Residue Project Status (IR-4 & PMC)

- GLP Study conducted under one protocol (one GAP), IR-4 was the Sponsor/Study Director.
- All samples analyzed by Bayer Crop Science Laboratory
- Study submitted for Global Joint Review Fall 2012.

- **LOWBUSH Blueberry:**
  - 3 trials in Nova Scotia (one decline)
  - 1 trial in Maine

- **Highbush Blueberry:**
  - 2 trials in New Jersey
  - 3 trials in Michigan (one decline)
  - 2 trials in North Carolina
  - 1 trial in Oregon
  - 1 trial in Quebec

- **European trials**
  - 1 trial in Spain - decline
  - 1 trial in Denmark
  - 2 trials in the U.K. – decline
  - 1 trial in Italy - decline
  - Note: 2 trials using “protected” crop.

- **Other Sites (Highbush)**
  - 3 trials in Australia
  - 2 trials in New Zealand
  - 3 trials in Chile (one decline)

26 total field sites in 9 countries (OECD countries)
### NAFTA sites only

- 13 field trials
- Lowest residue: 0.290 ppm
- Highest residue: 2.59 ppm
- Median residue: 0.834 ppm
- Mean residue: 0.912 ppm
- SD: 0.630
- Unrounded MRL: 3.431 ppm
- Rounded MRL: 4 ppm

### Global data (all sites)

- 26 field trials
- Lowest residue: 0.193 ppm
- Highest residue: 2.59 ppm
- Median residue: 0.867 ppm
- Mean residue: 0.974 ppm
- SD: 0.632
- Unrounded MRL: 3.504 ppm
- Rounded MRL: 4 ppm
ALL pest control Products

- Conventional
- Biopesticide
- Etc..
Global trade of Ag products has increased tremendously over the past 20 years – in spite of economic factors.

There is considerable regulation of pesticides at the local, national and international level to ensure consumer safety.

Pesticides have evolved to be more specific to pest and safer to humans and the environment, however these new products complicate trade.
Closing Thoughts

• This impact on trade requires considerable efforts to manage to ensure that trade continues to expand
  – Growers are impacted as it affects their pest control decisions
  – In many cases implementation delay of new products puts growers at greater risk and delays IPM and resistance management.

• What will the next paradigm shift in pesticide discovery mean? And it is coming...
Next paradigm shift in pesticide

• Biopesticides
• Inert ingredients? Essential oils
• RNAi
• Other chemicals of very low public health concern
  – potassium phosphide
  – Next generation of pest control products
• We have to let the public know – they are safe
Who will carry the flag..

• Continuity.....to keep moving in a positive direction.

• Or join the FUN!

• Greater public investment in Harmonization.
THANK YOU FOR YOUR KIND ATTENTION
Questions/Comments?

Daniel Kunkel, Ph.D.,
Associate Director, IR-4 Project phone: 732.932.9575  ext: 4616,
kunkel@aesop.rutgers.edu, web: ir4.rutgers.edu