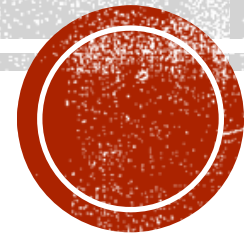


**IMPACTS OF INTERNATIONAL ACTIVITIES ON IR-4 RESEARCH**  
**SUPPORTING US EXPORTS!**

Dan Kunkel



# WHERE IS IR-4 DATA USED.....

- Definition first.... Pesticide MRL (tolerance) is used for enforcement, for proper use of product and as a standard, trade, etc. (is only part of health risk assessment)
- EPA Standard for new Registrations for US grower use (enforcement)
- Codex MRLs – recognized by many countries; used by more than 30 as import standards
- EU
- Japan, Korea, Taiwan – list of approved MRLs
- China
- And of course Canada and Mexico, our largest Ag export markets...
  - Mexico defaults to US MRL standards



# WHERE IS IR-4 DATA USED.....

**Some examples include:**

- **Hop exports to the EU**
- **Citrus and berry growers to Asian markets**
- **Cranberries to the EU**
- **Coffee to Japan**



# DATA NEEDS

- How do our export needs affect our domestic research...??



# DECLINE STUDIES

- Back in 2000---
  - Example – Cucurbit Vegetables – Cucumber, Summer Squash and Melon
    - one decline study, usually on melon from one field trial
- Today --
  - Example – Cucurbit Vegetables – Cucumber, Summer Squash and Melon
    - one decline study on each commodity – one trial for cucumber, one for summer squash and one for melon
    - In the EU they would do a decline on each commodity in half of the field trials; for these crops 2 of 4 trials for each cucumber, summer squash and melon study
    - EPA has increased requirements as well



# PROCESSING STUDIES

- Mostly the same, but sometimes different fractions or requirement for peel vs no peel
- May need more processing studies for each crop...currently do one per crop for US registration
- May need information for EU risk assessment, or to refine the risk in the US



# RESIDUE ANALYSIS

- Storage stability...zero day and coverage of storage period...
  - EPA was likely moving in this direction already
- Parent
- Parent plus metabolites
- Example – Propiconazole...
  - US has a common moiety method – everything is converted to a common derivative
  - EU uses analysis of parent and use of common derivative – so they can subtract parent from total to determine % of metabolites



# RESIDUE ANALYSIS

- **ABSTRACT:** This guidance is intended to harmonise the process for the establishment of the residue definition for dietary risk assessment by inclusion/exclusion of residues on the basis of their toxicity and the potential for exposure in the diet. The guidance provides a practical instrument including a combination of scientific tools ((Q)SAR, read across, TTC) and criteria for identification of residues for which hazard identification and characterisation is needed, to characterise pesticide metabolites and to define compounds that should be included in the residue definition for dietary risk assessment. It is proposed to make use of all information available, including mechanistic understanding, in order to support the decision process and to enable the risk assessors to provide the risk manager with detailed information on toxicity and exposure of every single metabolite as well as on the uncertainties connected to the proposal. The guidance document is complemented by three practical case studies which are intended to demonstrate the applicability of the proposed decision scheme.
- © European Food Safety Authority, 2016





# NUMBER OF FIELD TRIALS

- EPA cut-offs...
  - 3, 5, 8, 12, 16, and 20, depending on production and diet
- Codex cut-offs...
  - 3, 4, 5, 8, and maybe 12, depending on production and diet
- EU cut-offs...
  - 4 and 8, depending on production and diet

The problem occurs when the US is 5 and Codex and EU is 8...or when we have 3 and the EU and Codex are 4 or even 8.

Field trial separation is stricter too, but EPA continues to get stricter as well.



# TECHNICAL ASSISTANCE FOR SPECIALTY CROPS (TASC)

- USDA-FAS grants to support US trade
- Enhanced Data Sets to Satisfy International Data Requirements for Establishment of Appropriate Maximum Residue Level's (MRL's) to support US exports
- IR-4 did much of this under the NIFA grant in the past...
- 2017 – **31** field trials supported by TASC
- Analytical labs will receive extra funding as well



# GUIDELINES . . . .

- EPA – OPPTS 860.1500 and so on...
- NAFTA Crop Field Trial Requirements
- OECD Guidance on Crop Field Trials
- Codex Manual
- EU
- The regulatory agencies are allowing for more substitution of data sites from other countries.

