



# **TECHNICAL INITIATIVES AND CHALLENGES – DATA GENERATION**

**NAFTA COUNTRIES – CANADA,  
MEXICO, UNITED STATES**

**Ken Campbell  
Pest Management Centre  
Agriculture and Agri-Food Canada  
Dan Kunkel, U.S. IR-4  
Felix Valera, SAGARPA**





## What Type of Data Are Produced?

- Residue data on Canadian crops following OECD GLP standards, also acceptable to US EPA.
- IR-4 and Mexican data as per EPA GLP standards. Residue data used to calculate MRLs using same statistical methodology in US and Canada.
- Canada requires value data for registration; while not needed in US, data must be available.





## Are There Guidelines for Generating Data?

- Canada – PMRA Directive 98-02 – Residue Chemistry Guidelines.
  - PMRA Efficacy Directive for Plant Protection Products.
- US – EPA Directives – OPPTS Harmonized/860 Residue Chemistry Test Guidelines.
- Also for NAFTA – “Food and Feed Crops of the United States – Second Edition”.
- AAFC conducts a presubmission consultation with PMRA to ensure, up-front, that all data requirements are clear and subsequently met.
- Additional data such as processing, metabolism, environmental fate and occupational exposure may be required.
- Datamining may reduce the number of trials required.





## How Are Data Generated and Funded?

- Data are generated by AAFC Pest Management Centre (PMC) directly, and via eight accredited field and eight accredited lab contractors, by registrants, commodity groups and provincial authorities. Sometimes specific to meet Canadian requirements.
- Canadian funding for PMC from the Federal Government.
  - About Cdn\$8 million for Minor Use.
  - Outside of AAFC some work done by provincial minor use coordinators, commodity groups, and the manufacturers.
- US funding from USDA-CSREES \$10.67M, USDA-ARS \$3.9M, state Agricultural Expt. Stns \$0.5M, and grants from industry. Data generated by IR-4 and State Universities.
- Mexican funding from Registrants.





## Data Acceptance: Nationally / Internationally

- Canada – data generated according to OECD standards – acceptable to PMRA and EPA.
- Data generated for joint projects with IR-4 acceptable to both regulatory agencies.
- US – data generated according to EPA standards
- Mexican data for joint projects by IR-4 / Mexico accepted by US EPA.





## What are Specific Program Outputs, and How Many of Each?

- Canada makes submissions to PMRA for the registration of new minor uses.
  - 36 new priorities are selected with stakeholders each year, and another 10-15 joint projects with IR-4, resulting in 40 – 50 submissions being sent to PMRA annually with about 100 new uses.
- IR-4 sends to US EPA 175 data packages which equates to approximately 800 clearances annually.
  - As well, IR-4 supported 21 Emergency Exemptions (Section 18s).
  - A record year resulted in 1,100 new use clearances.





## Is the Output Available in a Public Forum?

- Canadian registration packages not publically available:
  - data can be examined in PMRA “reading room”.
  - no other mechanism available to share data.
  - when public funds expended, data that is not company confidential and will be shared.
- U.S. registration packages themselves not publically available, but can be shared to aid U.S. stakeholders.





## How Are Data Stored? How Readily Available are They?

- Canadian submissions are made electronically, and by paper copy, sent with a CD and covering letter to PMRA. They are also stored electronically, and original GLP data is in hard copy (paper).
- U.S. data is stored in electronic form, and in paper form, since 'official' data is all residue / GLP data.





## New and Ongoing Initiatives

- Canadian “A” Priorities Without Solutions – “**APWS**”
  - to search for a solution to a crop/pest problem where none is obvious.
  - e.g. in 2006 two problems identified at priority setting meeting: green mould on mushrooms, and BLW control on ginseng.
  - Results:
    - two products identified which control green mould equal to the current product, which is available only through emergency registration.
    - One herbicide identified to control many weeds in ginseng with no apparent crop damage.
  - In 2007 six projects underway to assess potential solutions.





## New and Ongoing Initiatives (cont'd)

- Canada working with IR-4 “Up-front” with registrants on new compounds which have high-potential to help Canadian producers.
  - to test (sometimes with a confidentiality agreement) at an early stage, a new chemistry that has the potential of addressing many minor use issues.
  - screening trials prior to registration of a new chemistry may fill a technology gap use or product. The new minor use could be registered at the same time as the new chemistry, saving years in the minor use process.





## New and Ongoing Initiatives (cont'd)

- IR-4 will continue to conduct the magnitude of residue data for minor crops, which may broaden in scope due to increased submissions to JMPR (OECD) and for increased MRLs to other countries.
- Mexico has conducted joint review projects with US IR-4 on avocado. This joint work may increase in future.





## If Residue Data not Generated, Where is it Obtained?

- Where joint projects with IR-4 are conducted, trials are conducted in both countries and all residue data are shared, and jointly submitted. This is acceptable to the regulators.
- Data are also obtained from registrants.
- Data for certain trials conducted under the same, or similar conditions may be used in place of conducting additional trials.
  - e.g. some greenhouse trials conducted in Europe may be acceptable for a North American registration.
  - Data, or MRLs developed in one country may be acceptable to another regulator.





## What Are The Current Data Needs?

- All NAFTA countries require magnitude of residue data to be able to conduct risk assessments, and to set an MRL.
- Value data (efficacy and crop tolerance) need to be available in the U.S. but are not required as part of the submission for registration.
- Submitted value data are required for registration in Canada and Mexico.
- In Canada, as well, dislodgeable foliar residue and occupational exposure data may be required, to ensure worker protection.





## Funding and Resource Issues?

- Canadian funding is exclusively through the Government of Canada to the Pest Management Centre of Agriculture and Agri-Food Canada. “In-kind” contributions of residue analyses by registrants are very helpful.
- IR-4 funding is through appropriations from the federal government, and from industry sources.
- Mexican funding is through Registrants.





## What are Technology / Data Sharing Issues?

- Technical issues such as rates, carrier volumes, method of application, timing, etc. make data sharing more difficult, because the GAP in countries may be different, and applicability of data may not be relevant.
- Ownership of minor use data for credit toward data protection is being discussed and a proposal being developed at PMRA.
- Publically generated data in one country is usually available to other countries, because the development of MRLs based on science is beneficial to both importing and exporting countries.



## Are Countries Willing to Use Other Data?

- Data from other sources will be used if:
  - it is acceptable to the regulator
  - permission is received from the author, or,
  - the data is in the public domain (published).
- Data mining can save considerable resources, by reducing the number of trials required.
- Zones, use patterns, soil types, climate, etc can impact the usability / transferability of data.





# Thank you!

## Canada

[www.agr.gc.ca/prrmup](http://www.agr.gc.ca/prrmup)

[www.agr.gc.ca/ppelrrp](http://www.agr.gc.ca/ppelrrp)

## United States

[www.ir4.rutgers.edu/](http://www.ir4.rutgers.edu/)

## Mexico

[www.sagarpa.gob.mx](http://www.sagarpa.gob.mx)

