

# EPA Regulatory Update

## 2015 MRL Harmonization Workshop

Barbara Madden, Minor Use Team Leader  
Registration Division  
Office of Pesticide Programs, U.S. EPA  
[madden.barbara@epa.gov](mailto:madden.barbara@epa.gov)  
(703) 305-6463

San Francisco, California  
June 3 & 4, 2015



# EPA's Office of Pesticide Programs

- Principal Business
  - Based on high quality scientific evaluations and open transparent processes:
    - Protect human health and the environment.
    - Ensure access to safe and effective pesticides and pest management technologies.
- International efforts linked to meeting these goals.



# OPP: Role in Engaging in International Registration Activities

- Leadership
  - Promote joint registration reviews and harmonization efforts internally and externally
- Advocacy/Championship
  - Identify opportunities for collaboration and cooperation
- Foster Communication
  - Promote dialogue between regulatory authorities
  - Promote dialogue with and among all stakeholders



# Opportunities

- NAFTA and Regulatory Cooperation Council (RCC)
- Organisation for Economic Co-operation and Development (OECD)
- Joint Meeting on Pesticide Residues (JMPR) and Codex Committee on Pesticide Residues (CCPR)
- Other Opportunities
  - Trade negotiations
  - Bilateral partnerships
  - Commodity /chemical specific issues



# Global Joint Review

- Global joint review process for review of new active ingredients.
  - Goal – align regulatory endpoints, MRLs and decisions to extent possible.
  - Countries involved continues to increase (Australia, Brazil, Canada, China, EU member states, Japan, Korea, Mexico).
  - Expansion of companies involved.



## Global Joint Review

- Nineteen Joint Reviews for new active ingredients have been completed since 2007.
- Currently there are eleven global/NAFTA joint reviews ongoing for new active ingredients.
- Fourteen new active ingredient global joint reviews are scheduled for submission in 2014 - 2018.



# Pending New Active Ingredient Joint Reviews

- Benzovindiflupyr (Solatenol) – fungicide (**CN, MX, US**)
- Bicyclopyrone – herbicide (AU, **CN, US**)\*
- Cyclaniliprole (IKI-3106) – insecticide (AT, AU, BR, **CN, US**)
- Fluensulfone – nematocide (**CN, US**)\*
- Flupyradifurone – insecticide (AU, **CN, US**)\*
- Halauxifen-methyl (XDE-729) – herbicide (AU, **CN, US**) – 2014\*\*
- Isofetamid – fungicide (**CN, US**)\*\*
- Mandestrobin (S-2200) – fungicide (**CN, US**)
- Oxathiopiprolin – fungicide (AU, CH, **CN, JP, KR, MX, PH, US**)
- Pyriofenone – fungicide (**CN, US**)
- Tioxazafen – nematocide (**CN, MX, US**)

\*application completed in the US

\*\*application completed in Canada



## Global Joint Review

- EPA and PMRA are currently conducting a retrospective analysis of what has worked well and what could be improved.
- In past, meeting to discuss the global joint reviews was held on outside of the OECD meeting.
- Since EPA representative to OECD is no longer from Registration Division it is unclear as to where/when the planning meeting will be held in the future.





## North American Initiatives

- Strong partnership between EPA and PMRA regarding worksharing and joint reviews of new active ingredients, use expansions and minor uses routine business; Increased participation by Mexico.
- IR-4 and PMC cooperatively conduct joint residue trials for projects identified by the minor use/specialty crop growers in both countries.
- Crop grouping effort involving NAFTA partners (EPA, IR-4, PMRA & PMC), the International Crop Grouping Consulting Committee (ICGCC) and Codex to evaluate crop groups.



## North American Initiatives

- Regulatory Cooperation Council (RCC) built on the success of NAFTA initiatives.
- Result of pilot - minor use joint reviews can include import MRL/tolerance requests if the agencies are petitioned.
- Proposed revisions to the field trial requirements for a "NAFTA submission" are currently being considered.
  - Relative to the sum of field trials currently required by the US and Canada, the joint field trial requirements may result in a 20-50% reduction in the number of trials required in each country, depending on the specific crop, but PMRA and EPA will receive more data.



## U.S.-EU Free Trade Agreement (TTIP)

- In his 2013 State of the Union Address, President Obama announced the U.S. would begin talks on a Trans-Atlantic Trade and Investment Partnership (TTIP).
- The U.S. has begun negotiating a “free trade agreement” with the European Union (EU).
- OPP is involved in discussions with the European Commission on matters regarding reviews of pesticides.
- May be an opportunity to re-engage EU regarding global joint reviews.



## Asia-Pacific Economic Cooperation

- APEC has 21 members (Australia, Brunei, Canada, Chile, People's Republic of China, Hong Kong-China, Indonesia, Japan, Republic of Korea, Malaysia, Mexico, New Zealand, Papua New Guinea, Peru, The Philippines, Russia, Singapore, Chinese Taipei, Thailand, The United States, and Viet Nam).
- U.S. EPA OPP is participating in the APEC Food Safety Cooperation Forum/Food Standards of Australia and New Zealand (FSANZ).



# Asia-Pacific Economic Cooperation

- Co-Chaired a Workshop on the *Harmonization of Pesticide Maximum Residue Limits (MRLs) for Imported Foods in APEC Member Countries*.
- The primary goal of this project is to develop a guidance document for establishing import MRLs for imported foods where no domestic equivalent MRL exists.
- The 2<sup>nd</sup> Expert Workshop will be held on the margins of the 5<sup>th</sup> APEC Food Safety Cooperation Forum in the Philippines in August of 2015.



## Other Initiatives

- OECD members as well as JMPR/Codex have agreed to use same calculation procedures when establishing MRLs.
- However, regulatory procedures to establish crop groups MRLs are not aligned.
  - JMPR, Australia and New Zealand calculate group MRLs using the median residue of the datasets within the "5 times range."
  - The United States and Canada calculate group MRLs using the maximum residue of the datasets within the "5 times range."
  - The EU does not agree with the use of "5 times range."



## Calculating Crop Group MRLs

- Despite the use of OECD calculation procedures, this difference in comparison of the median versus the maximum value has resulted in differences of crop group MRLs between Codex and the United States based on the submission of data and GAP submitted by the United States.
- The United States will present a paper to the OECD RCEG (Residue Chemistry Expert Group) this July proposing that national authorities revisit the use of the 5X range whether it be the median or the maximum value and determine if agreement can be reached on the use of a statistical approach to determine when it is appropriate to establish crop group MRLs.
- At the recent CCPR meeting the United States proposed that JMPR participate in this activity and provide their input into the development of an aligned method for the establishment of group MRLs.



## Other Initiatives

- The U.S. EPA and Crop Life America continue to analyze data from various global zoning projects.
- Carmen Tiu of Dow Agro Sciences and David Miller and James Nguyen of U.S. EPA are taking the lead on this effort.
- Compared data from Canada and US and determined the field trial residues in Canada are NOT significantly different from that in the US.
- Compared data from Northern Europe and Southern Europe and determined the field trial data are NOT significantly different between Northern and Southern Europe.



# Preliminary Global Zoning Analysis

## (Combined CLA+DAS+IR-4 Database)



- 8 different companies + IR-4
- Final Analysis includes data of:
  - Crop-Pest combinations that have field trials in more than 1 zone, same number applications, similar PHIs, proportions of <LOD or <LOQ are not too high
  - 23 Crops, 9 Chemicals, 33 Crop-Chemicals (34 Crop-Chemical-Commodities)
  - Distribution of Crop-Pest by Zone:
    - 5 Crop-Pest have data in all 4 zones
    - 15 Crop-Pest have data in 3 zones
    - 13 Crop-Pest have data in 2 zones
    - EU and NA each has data of 32 Crop-Pest, AU-NZ has 21 Crop-Pest, and SA has 10 Crop-Pest

Type of Pesticide	Number of field trials					
	AF	ASIA	EU	NA	SA	AU-NZ
Fungicide	.	1*	24* + 65	41	3	.
Insecticide	5*	7*	233	220	32	95

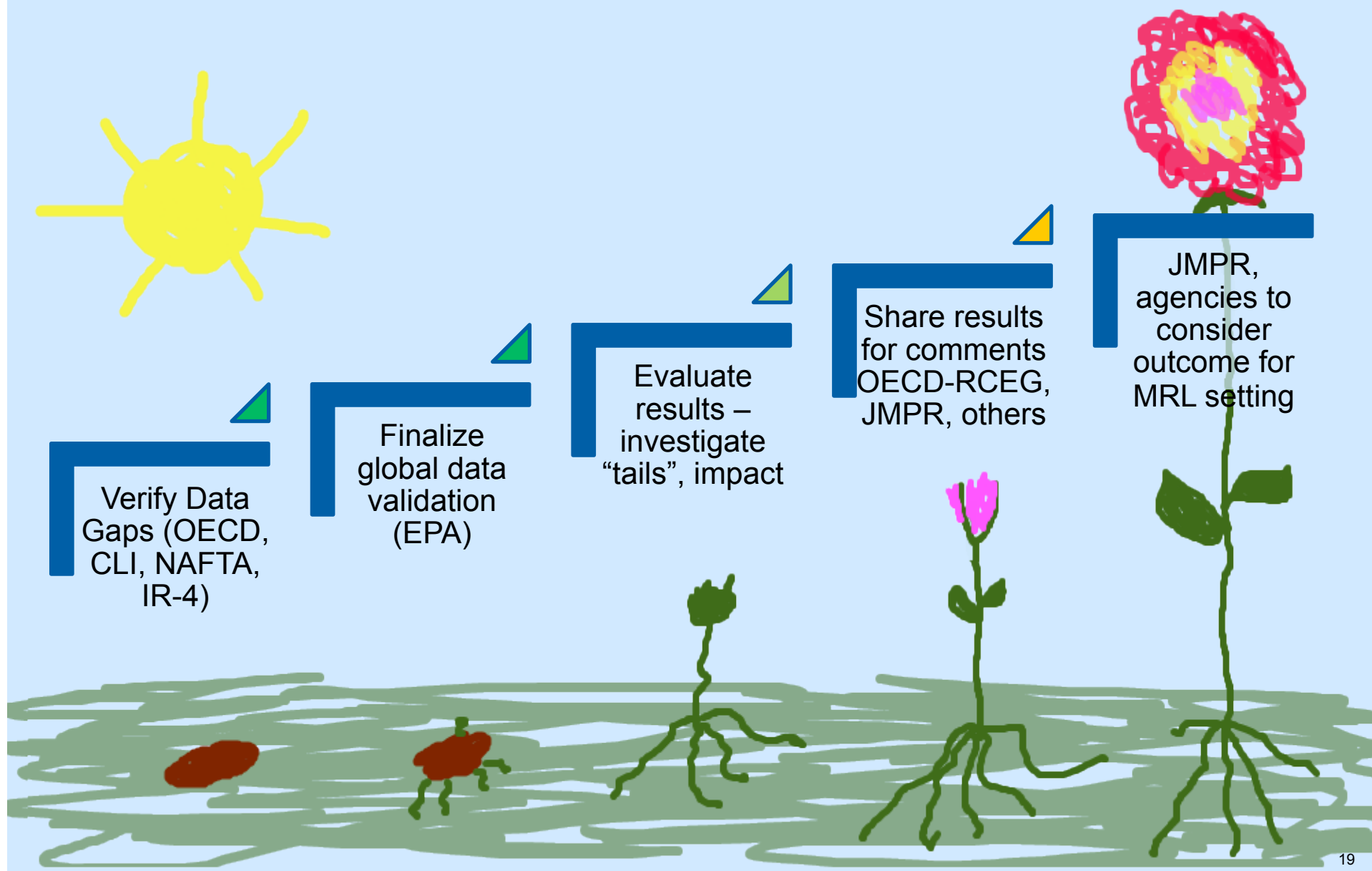
\*: These field trials were not included in the final analysis due to small number of Crop-Pest in Africa and Asia



## Global Data Set

- Compared data from Australia, New Zealand, Europe, North America and South America and determined field trial residues between zones are NOT significantly different.
- The results support use of residue data for global programs, and exchangeability between countries, to support MRL setting and harmonization.
- Results of these analysis have been presented to JMPR, CCPR, OECD.

# Current Zoning Analysis & Next Steps





## Other Opportunities for MRL Harmonization

- As part to the crop grouping effort, EPA plans to eventually convert any pre-existing, old crop group tolerances to the new groups.
- This conversion will be effected both through the registration review process and petitions to establish new tolerances for a pesticide.
- Crop group conversions and registration review are opportunities for EPA to harmonize MRLs.



## Shared Responsibility

- Registrants or other petitioner's including IR-4 need to play an active role in addressing existing international MRLs when submitting their petitions.
- When requesting U.S. tolerances registrants should also have a plan for submission of same residue data to Canada, Codex, and other national authorities.
- When requesting crop group conversions consider international MRLs and look for opportunities to align.
- Use registration review process to identify trade irritants.

[Learn the Issues](#)

[Science & Technology](#)

[Laws & Regulations](#)

[About EPA](#)

Search EPA.gov



## Pesticide Registration

[Contact Us](#) [Share](#)

[Pesticide Registration Home](#)

[About Pesticide Registration](#)

[Electronic Submission of Applications](#)

[Pesticide Registration Manual](#)

[Fees and Waivers](#)

[Registration Information by Type of Pesticide](#)

[— Antimicrobial Registration](#)

[— Biopesticide Registration](#)

[— Conventional Registration](#)

[— Inert Ingredient Regulation](#)

[Requirements and Guidance](#)

[— Data](#)

[— Forms](#)

[— Labeling](#)

**You are here:** [EPA Home](#) » [Pesticide Registration](#) » [Minor Uses and Grower Resources](#)

# Minor Uses and Grower Resources

This web page provides growers, pesticide manufacturers (registrants) and other interested parties with information about EPA programs designed to ensure safe pesticide tools are available, particularly for those interested in pesticides for the minor uses. A major part of this effort involves the partnerships with other organizations and stakeholders.

On this page:

- [Minor Use Crops and Pesticides](#)
- [International MRLs](#)
- [NAFTA Minor Use Joint Reviews](#)
- [Crop Grouping](#)
- [Exclusive Use Periods](#)
- [Definition of a Minor Use](#)
- [Related Information](#)

## Minor Use Crops and Pesticides

Minor use crops have fewer than 300,000 acres in production in the United States. The small acreage may provide insufficient economic

### Resources

#### Registration Information

- [Reduced Risk Pesticide Program](#)
- [Workplan for Registration](#)
- [Guidance on PRIA fee waivers and Exemptions](#)
- [IR-4](#) [Exit](#)

#### Tolerance/MRL Information

- [US Tolerances \(40 CFR Part 180\)](#)
- [Canadian MRLs](#) [Exit](#)
- [Codex MRLs](#) [Exit](#)
- [Index to Tolerance Information](#)

#### Contact

- Barbara Madden



- Questions?
- Thank you.