US EPA Perspectives on Harmonization of International MRLS

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Harmonization of MRLs is Essential to Achieving US EPA Office of Pesticide Programs Goals

- International marketplace
- Impact on U.S. health and environment
- International acceptance of safer products
- Opportunities to collaborate on international fora
OPP International Goals

- **Goal #1: Strengthening Protection**
  - Strengthen food safety, public health and environmental protection, domestically and globally

- **Goal #2: Enhance Regulatory Decisions through Collaboration**
  - Improve science base and enhance regulatory efficiency by leveraging scientific and regulatory resources with the international community

- **Goal #3: Conserve Resources**
  - Conserve resources of U.S. consumers, growers, and industry stakeholders through more efficient and coordinated regulatory processes

- **Goal #4: Minimize Barriers**
  - Minimize international trade issues related to pesticide regulatory requirements & facilitate trade and fair competition
Opportunities

- **MRLs**: Codex Alimentarius; Codex Committee on Pesticide Residues (CCPR)

- **OECD**: Global Joint Reviews; Working Group on Pesticides; Registration and Risk Reduction Steering Groups; Expert Groups; Test Guideline Program; Task Force on Biocides; Biopesticides Steering Group

- **FAO/WHO**: Joint Meeting on Pesticide Residues (JMPR); Joint Meeting on Pesticide Management (JMPM)

- **North American Collaboration**: Work Sharing/Joint Reviews; Technical Working Group on Pesticides, Regional Coordination Council (RCC)

- **APEC**: Import tolerance pilot project
MRLs: Harmonization – Scientific Underpinnings

- OECD MRL Calculator
- Global Zoning Project
- Crop Grouping
- Global MRL database (GlobalMRL.com)
OECD MRL Calculator

- NAFTA calculator (US, Canada, CA)

- OECD Workgroup formed in 2008 with the goal of harmonizing the calculation of MRLs across the OECD
  - Practical implementation of sound statistical methods
  - Simple to use
  - Clear and unambiguous MRL proposal
  - Harmonize EU and NAFTA procedures to the extent possible

- Working Group on Pesticides approved draft OECD MRL calculator in 2010

OECD MRL Calculator Implementation

- EPA uses OECD MRL calculator as standard practice

- If Codex MRL exists, law requires EPA to harmonize with Codex, if feasible/practical
  - Section 408(b)(4) of the Federal Food, Drug, and Cosmetic Act (FFDCA)

- Reviewers must describe reasons for non-harmonized tolerance
  - Harmonization with key trading partners
  - Unique use patterns (higher application rates in the US)
OECD MRL Calculator Challenges

- Different perspectives on field trial data
  - Statistical techniques for handling censored data
  - Replicate samples or non-independent field trials

- Ultimate goal to develop common practices with respect to the use of and input to the OECD calculator which will garner global acceptance
Global Zoning Project

- Exchangeability of Field Trial Residue Data between Zones
Why Global Zoning Project?

- Currently crop field trials are required to be conducted in a variety of (specified) zones
  - Zones are specific to each country/region

- However climatic (zonal) differences may not have as much of an impact on residues as might be commonly or traditionally believed.

- There may be an advantage to the MRL setting process in being able to combine field trials from across a larger (global) database.
  - Save field trial resources
  - A more robust MRL can be estimated
  - Same data set = better harmonization
Global Zoning Work Completed

- Joint project between US EPA, Canada’s PMRA, Interregional-4 Project, and Crop Life America

- Question: Are there systematic differences in pesticide residue concentration between zones?

- Comparisons of synthetic data sets reflecting different growing regions using statistical methods

- Field trial residues are not significantly different between geographic zones

- April 18, 2016 draft publication available on Codex website
Global Zoning Next Steps

**Current Work**
- Evaluate the “exchangeability” of residues between the US and Canada as a test case using a real residue database
- Extend the method to a global basis based on datasets collected from around the work

**Future Work**
- Internal and External Review of Work
- Policy development
APEC Import Tolerance Pilot

- Asia-Pacific Economic Cooperation (APEC)

- Pilot to determine the feasibility of acceptance of other National Authority/JMPR reviews of residue chemistry data to support establishment of import tolerances

- Streamlined approach to establishing import tolerances

- Will require US EPA risk assessment/safety finding
APEC Import Tolerance Pilot Status

- 10 chemical/crop combinations submitted since the inception of the pilot
- 3 additional chemical/crop combinations were self-identified by the Agency
- A wide variety of uses included under the pilot, including hops, legumes, tea, olive, oats, barley, wheat, ginseng, banana, and coffee
- Participation by major agrochemical companies

Two projects complete: Boscalid on the legume subgroup 6A and Ametoctradin on hops
APEC Import Tolerance Pilot Challenges

- Initial reluctance amongst registrants to submit pilot candidates
- Initial reluctance of science reviewers to accept reviews from other regulatory authorities
- Importance of enforcement methodology as part of submission
- Differing tolerance definitions
APEC Import Tolerance Pilot Lessons Learned

- Pre-submission meetings to discuss the submission should be first step in the process
- Confirm an appropriate analytical method
- Review the state of the risk picture for existing uses
APEC Import Tolerance Pilot Successes

- All submissions to-date have been successfully reviewed
- The Agency saw significant savings as compared to “traditional” reviews.
- Tolerances for boscalid on legume subgroup 6A and ametoctradin on hops were published six weeks before the PRIA due date
APEC Import Tolerance Pilot Successes (cont.)

- EFSA and JMPR reviews were of high quality and sufficient for verifying scientific integrity of data and supporting tolerance levels.

- Reviews from individual countries were also sufficient for verifying scientific integrity of data and supporting tolerance levels.

- All reviewers reported a positive experience.
The Agency plans to continue to encourage submissions under this pilot to gain experience with additional national authorities.

At the completion of the currently submitted actions, the Agency should be positioned to understand if this can be transitioned to a standard business practice.
Conclusion

- Thank you
- Questions?