



EPA Partnerships and Progress on MRL Issues—A Regulatory Perspective

2010 MRL Workshop – Global Regulations

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Pesticide Regulation & International Harmonization Initiatives

- Pesticide Regulation
 - Protect human health and the environment
 - Provide society access to pesticides and their associated benefits
- International efforts linked to meeting these goals



Roles of Registration Authorities in International Activities

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



Partnerships and Progress

- **Basic Tool Development/Building Blocks**
 - **OECD provided the forum with establishment of Working Group on Pesticides (WGP) and Registration Steering Committee (RSG)**
 - **Harmonized guidelines**
 - **Standard templates for data reviews**
 - **Standard dossiers**
 - **Makes joint reviews and work sharing possible and now an efficient and effective way of doing business**
- **Joint Reviews (NAFTA)**
 - **Demonstrated joint reviews could be done & the many benefits (since 1997)**
 - **Paved the way to global joint reviews**



Partnerships and Progress

- Further tool development
 - NAFTA MRL Calculator to OECD Calculator
 - JMPR and CCPR providing input
 - Current version in testing phase within OECD
- Other Initiatives
 - Global residue program
 - Cross-walk for terrestrial field dissipation studies
 - Residue chemistry expert working group – harmonization of residue chemistry guidelines, etc.
 - IT enhancements



Partnerships and Progress

- **Partnerships**
 - Built strong working relationships with other national regulatory authorities
 - Address not just chemicals but difficult issues all are facing, e.g.,
 - persistent chemicals
 - pollinator issues



Partnerships and Progress

- **Minor Use Initiatives**
 - IR-4 – Canada partnership
 - Expert Group on Minor Uses (OECD)
 - Global Minor Use Summit held in December 2007; 2nd one in planning stages
 - Codex Minor Use Group
 - Revision of Crop Groups/ Representative Crops



Codex Committee On Pesticide Residues (CCPR)

- Efforts expanded to international standard setting body
- Pilot to explore JMPR recommending MRLs for global joint review chemicals before national governments or regional authorities
 - JMPR would work in parallel with the joint review team
 - Approved at April CCPR meeting
 - Expect to pilot sulfoxaflor at 2011 JMPR



Codex Committee On Pesticide Residues (CCPR)

- Establishment of a Codex Electronic Working Group on Minor Uses and Specialty Crops
 - Facilitate establishment of MRLs for minor uses
 - A focus has been helping developing countries understand and effectively use Codex system to establish MRLs for their commodities



Codex Committee On Pesticide Residues (CCPR)

- Revision of the Codex Classification of Animal Foods and Feeds (and selection of representative commodities)
 - Many differences in MRLs result from differences in crop grouping systems and different use of representative crops
 - Trying to obtain as much global input into the revision as possible
 - Very important for developing countries—may get MRLs for their crops by simply including them in the classification system



Joint Meeting on Pesticide Residues (JMPR)

- Worksharing
 - Extensive use of work sharing established in JMPR as direct result of work sharing being used for joint reviews
 - Examining the toxicological endpoints selected by governments that have already reviewed a chemical is now an established first step for JMPR
- MRL Calculator
 - Routinely using NAFTA calculator as a tool
 - Has resulted in much greater transparency in JMPR MRL recommendations
 - JMPR will test new “OECD” calculator and has had significant input in its development



Progress on Specific Initiatives: Joint Reviews

- **NAFTA Joint Review Program**
 - Progress towards a North American Workplan
 - Minor uses program coordination continues
- **Global Joint Reviews**
 - Now standard way of doing business
 - Expansion of countries involved (Brazil, Japan most recently; expect China and possibly Kenya in the near future)
 - Inclusion of EFSA in global joint reviews
 - Expansion of companies involved (9 currently involved)



Progress on Specific Initiatives: Joint Reviews

- Beginning to see “complete” application packages being developed and submitted
 - Submitted to all potential users at the same time
 - Submitted for import tolerances where needed at the same time
 - Submitted to Codex in the following year (or willing to pilot submitting to Codex at the same time)



Progress on Specific Initiatives— Completed & Current Joint Reviews (At Least Trilateral)

- **PROGRESS TO DATE**
 - Completed: 6
 - In Progress: 6
 - 2010 – 2012: 9 (planned submissions)
- **POWER OF “GLOBAL” PROCESS**
 - Chlorantraniliprole: Australia, Canada, Ireland, United Kingdom, U.S., New Zealand
 - Submitted 2007
 - Registered in Joint Review countries 2008
 - Codex MRLs established in 2009
 - Currently registered in over 50 countries



Progress on Specific Initiatives: Trade Irritants

- **Trade Irritant Initiatives**
 - **US/Canada Grower Priority Data Base**
 - Major tool to facilitate harmonization of MRLs between Canada and the US
 - Useful to regulators, manufacturers, growers
 - www.mrlharmonization.com
 - **Possible Expansion of Efforts to Identify MRL Priorities in Other Markets**



Summary

- Much progress made on international initiatives
- Individual initiatives share many of the same goals and build on each other
- Relationships built among national and regional authorities make additional progress faster and easier



Conclusion

- Global initiatives are on a roll!
- Need to ensure
 - Strategic value of well coordinated international work is recognized and valued at the highest levels
 - Synergies are leveraged to the greatest extent possible
 - Adequate and appropriate resources devoted to this area