



EPA MRL Harmonization Initiatives

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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)**
- **OECD**
- **Joint Meeting on Pesticide Residues (JMPR) and Codex Committee on Pesticide Residues (CCPR)**
- **Other Opportunities**
 - **Bilateral partnerships**
 - **Summits**
 - **Commodity /chemical specific issues**



North American Initiatives

- Progress towards a North American workplan
- IR-4 (US) and PMC (Canada) partnerships
- Worksharing and joint reviews of new active ingredients, use expansions and minor uses routine business; Increased participation of Mexico.
- Resolving trade irritants/technology gap retrospectively and consideration prospectively; Grower Priority Data Base.
- Regulatory Cooperation Council – initiative to identify mechanisms to encourage registrants to submit applications for joint review to Canada and the US that include increased numbers of minor uses. Will help facilitate equal access to products and uses in both countries as well as align maximum residue limits where possible,

Global Initiatives through OECD

- **Global joint review process for review of new active ingredients and use expansions**
 - Goal – align regulatory endpoints, MRLs and decisions to extent possible
 - Countries involved continues to increase (Australia, Brazil, Canada, China, EU member states, Japan, Korea)
 - Expansion of companies involved
- **Tool development – OECD calculator ; residue chemistry expert working group (harmonization of residue chemistry guidelines)**
- **Coordination of issues – pollinator protection and persistent**
- **Minor Use Initiatives**
 - **Expert Group on Minor Uses (EGMU) - projects aimed at increasing number of products registered for minor uses**

Codex Committee on Pesticide Residues (CCPR) Initiatives

- CCPR Meeting in Shanghai, China, April 2012
 - The 7^h year that the accelerated MRL elaboration process along with the criteria for decision making were used with great success.
 - 271 pesticide/commodity MRLs based on consideration of 19 pesticides advanced to Step 8 and will go for adoption in July 2012 by Codex Alimentarius Commission. 251 advanced to Step 5/8 saving years in time.
 - 23 pesticide/commodity MRLs associated with 7 pesticides were advanced to Step 5 only; due to either potential dietary intake concerns or country concerns based on other information not considered by JMPR.

Codex Committee on Pesticide Residues (CCPR) Initiatives

- 59 pesticide/commodity CXLs for 8 pesticides were recommended for revocation because they are no longer supported or deemed by JMPR to have potential dietary intake concerns with no alternative GAP, replaced based on additional data, or uses no longer supported.
- 43 pesticide/commodity MRLs for 10 chemicals were returned to Step 6 or 7 or 4 due to dietary concerns and are awaiting further review by JMPR.
- 38 MRLs were held at Step 4 due to dietary concerns, awaiting additional data, or an acceptable GAP

Codex Committee on Pesticide Residues (CCPR) Initiatives

- Revision of Codex Classification of Animal Food and Feeds (aka Crop Grouping)
 - First crop group advanced to Step 8 and recommended for adoption by CAC – fruits. Great accomplishment.
 - Proposed additional crop groups and representative commodities.
- CCPR Working Group on Minor Uses and Specialty Crops reestablished and chaired by France; co-chaired by Kenya and Thailand.
 - Working on defining number of field trials required for minor crops by JMPR.

Codex Committee on Pesticide Residues (CCPR) Initiatives

- Pilot Project – JMPR recommends MRLs for a new active ingredient that is a global joint review prior to national authorities establishing MRLs.
 - Sulfoxaflor – total evaluation of pilot project will be done next year; recommendations from JMPR already used by global joint review partners but global joint review is not completed.

Codex Committee on Pesticide Residues (CCPR) Initiatives

- Proportionality Concept
 - JMPR applied concept of proportionality to estimate MRLs on 5 compounds and 5 commodities when residue data according to GAP were not sufficient for a recommendation of a MRL.
 - Useful tool for JMPR
 - Some delegations at CCPR opposed advancement of these MRLs stating the need for further guidance and criteria.
 - Electronic Working Group established to be co-chaired by Australia and Germany; US will participate.

Codex Committee on Pesticide Residues (CCPR) Initiatives

- Resources for JMPR meetings
 - Funding needed for both WHO and FAO
 - EPA working with WHO and FAO on measures to increase capacity
 - 2013 JMPR meeting in jeopardy if funding not in place by January 2013.
 - Outreach to commodity colleagues globally to gain support

Progress on Specific Initiatives: Codex Committee on Pesticide Residues (CCPR)

- **Revision of Codex Classification of Animal Food and Feeds (aka Crop Grouping)**
 - Resolved coding system issues
 - Large groups may be advanced as completed
- **CCPR Working Group on Minor Uses and Specialty Crops – chaired by US; co-chairs Australia and Kenya**
- **US lead initiative coming out of the Global Minor Use Summit – a pilot project for a process for the JMPR to recommend MRLs before national or regional authorities established MRLs.**



Bilateral Initiatives

- **Japan:**
 - Sharing of US EPA reviews to support MRLs on Positive List
 - Global joint review partner
- **Brazil:**
 - Participation in global joint reviews
- **China:**
 - ICAMA and EPA continue cooperation workshops and high level delegation meetings.
- **Taiwan:**
 - Sharing of reviews that support MRLs
- **Korea:**
 - Cooperation with KFDA



Other Initiatives

- Global Minor Use Summit II – held February 2012
 - EPA one of 4 organizers along with USDA, IR-4, and FAO
 - Recommendations focus around 5 themes
 - Coordination and collaboration
 - Communication
 - Incentives
 - Capacity Development
 - Registration of products for minor uses and MRL establishment



Other Initiatives

- **Work closely with USDA /FAS on chemical/commodity/country issues arise and provide technical support**
- **Work with commodity groups on chemical/commodity issues**



EPA's Minor Use Webpage

- www.epa.gov/pesticides/minoruse/
- Page redesigned and updated to provide practical and useful information for growers and other interested parties regarding ongoing activities that impact the minor use community.
- These activities include ongoing crop grouping project; how to obtain a Codex MRL; MRL data base; activities regarding NAFTA and cooperation on MRL alignment.
- Webpage provides easy one-stop access to multiple useful links including the workplan for registration of new actives and uses, guidance on PRIA fee waivers, joint reviews, crop grouping tables, and Canadian MRLs.



Summary

- **Much progress made on international harmonization initiatives.**
- **Individual initiatives are all have same goal and build on each other.**
- **Multiple initiatives pursued.**
- **Success depends on coordination across various US Federal Agencies, other national authorities, international organizations, and stakeholders.**
- **Stakeholder initiatives compliment government initiatives.**