



EPA Initiatives: Partnerships and Coordination Involving MRLs

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EPA's Office of Pesticide Programs

- **Principal Business**
 - **Protect human health and the environment**
 - **Ensure that society has access to pesticides and the associated benefits**
- **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



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 a way to global joint reviews



Partnerships and Progress

- **Global Joint Reviews**
 - Standard way of doing business
 - Expansion of countries involved (Brazil, Japan)
 - Expansion of companies involved (9 involved)
- **Expansion to international standard setting body**
 - JMPR/Codex
- **Further tool development**
 - NAFTA MRL Calculator to OECD Calculator
 - JMPR and CCPR providing input
 - Codex member countries being surveyed for wider input on policy issues

Partnerships and Progress

- **Other Initiatives**
 - Global residue program
 - Cross-walk for terrestrial field dissipation studies
 - Residue chemistry expert working group – harmonization of residue chemistry guidelines, etc.
- **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
- **Bilateral Initiatives**
 - Work sharing
 - Involvement in global reviews in various capacities



Partnerships and Progress

- **Partnerships**
 - Built strong working relationships within US Federal Government and with other national regulatory authorities – capacity building and establishing contacts
 - Involvement of EFSA in global joint reviews
 - Address not just chemicals but issues all are dealing with. For example:
 - persistent chemicals
 - pollinator issues
- **Expansion of Global Review of Agricultural Use Pesticides**
 - International Public Health Pesticides Workshop
 - Partnering with other government agencies and international standard setting bodies

Progress on Specific Initiatives: NAFTA

- **Joint Review Program –**
 - Progress towards a North American Workplan
 - Minor uses program coordination continues
- **Trade Irritant Initiative**
 - **US/Canada Grower Priority Data Base:**
 - Information source for users to identify potential trade barriers, trade irritants and resolution priority; designed to provide support for orderly and expedited consideration and removal of potential trade issues in the NAFTA region

Progress on Specific Initiatives: NAFTA

- **7 NAFTA Labels Approved**
 - Far-Go Granular Herbicide (US) and Avadex MicroActiv Herbicide (CN) –a triallate product of Gowan Company (Jan. 2007)
 - Gavel 75 DF Fungicide—a combination mancozeb and zoxamide product of Dow (later sold to Gowan) (May 2007)
 - Reflex Liquid Herbicide—a fomesafen product of Syngenta (Oct. 2007)
 - Simplicity Herbicide—a pyroxsulam product of Dow (Feb. 2008)
 - Revus Fungicide—a mandipropamid product of Syngenta (Aug. 2008)
 - Discover (US)/Horizon 60 NG Herbicide (CN) – a clodinafop-propargyl product of Syngenta (Oct. 2008)
 - Axial TBC (US)/Broadband Herbicide (CN) – a pinoxaden-florasulam product of Syngenta (Nov. 2008)

Progress on Specific Initiatives: NAFTA

- NAFTA LABELS in progress
 - Triallate (liquid)
 - Spinosad/Naturalyte
 - Ipconazole
 - Halosulfuron
 - Azadiractin
 - Hexythiazox
 - Phosmet
 - Flutolanil
 - Saflufenacil
 - Metaflumizone
 - Fluopyram

Progress on Specific Initiatives: Current Joint Review/ Work Shares

- Decisions Completed:
 - Pyrasulfotole (herbicide): first trilateral joint review completed in August 2007. Participating national authorities: Australia, Canada, U.S.
 - Spinetoram (insecticide): NAFTA joint review completed in September 2007; Canada and U.S. (Will have MRLs for 7 crops/crop groupings adopted in July 2009).
 - Difenocoum (rodenticide): Decision completed September 2007: work share since chemical was already registered in the EU (Finland – rapporteur member state).
 - Florasulam (herbicide): Decision completed September 2007: work share since chemical was already registered in Canada and Australia.
 - Tembotrione: Decision completed September 2007 in US; work share with Canada.

Progress on Specific Initiatives: Current Joint Review/ Work Shares

- Joint Reviews/Work Shares Completed (Con't)
 - Pyroxsulam: Herbicide – Australia, Canada, US
 - Chlorantraniliprole: Insecticide (reduced risk) – Australia, Canada, EU (IR,UK), NZ, US; “global joint review” registered April 2008. (Now registered in 36 countries and will have Codex MRLs for 11 crops/crop groupings adopted in July 2009).
 - Mandipropamid: Fungicide (reduced risk) – under review in US first; subsequently in Canada. (Will have Codex MRLs for 15 crops/crop groupings adopted in July 2009).
 - Thiencarbazone/Cyprosulfamide: Herbicide - Canada, EU (UK), US
 - Spirotetramat: Insecticide (Reduced Risk) - Canada, EU (Austria), US (Now registered in 11 and another 9 likely in 2009; will have MRLs for 17 crops/crop groupings adopted in July 2009).

Progress on Specific Initiatives: Current Joint Review/ Work Shares

- Joint Reviews/Work Shares In Progress
 - Metaflumizone: Insecticide - under review in US, Canada, EU (UK), Australia.
 - Saflufenacil: Herbicide – Australia, Canada, US
 - Pyroxasulfone: Herbicide – Australia, Canada, US
- Joint Reviews in Pre-Submission Discussion Phase
 - 12 global reviews for new active ingredients under discussion

Progress on Specific Initiatives: Bilateral Initiatives

- **Japan:**
 - Sharing of reviews for chemicals with MRLs on Positive List
 - Global joint review partner
- **Brazil:**
 - Possible global joint review partner
- **China:**
 - ICAMA and Ministry of Agriculture Study Tour in US – May 2008; Workshops held in 2009 on dietary risk assessment; regulation of inerts; health effects and environmental risk assessment.
- **Taiwan:**
 - Sharing of reviews for MRLs under review

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

- CCPR Meeting in Beijing, China, April 2009
 - The 4th year that the accelerated MRL elaboration process along with the criteria for decision making were used with great success.
 - 293 pesticide/commodity MRLs based on consideration of 22 pesticides advanced to Step 8 and will go for adoption in July 2009 by Codex Alimentaris Commission.
 - 29 pesticide/commodity MRLs were advanced to Step 5 only; due to either potential dietary intake concerns or country concerns based on other information not considered by JMPR.
 - 115 pesticide/commodity CXLs for 25 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.
 - 33 pesticide/commodity MRLs at various Steps were withdrawn for various reasons.
 - 57 pesticide/commodity MRLs for 16 chemicals were returned to Step 6 or 7 or 4 due to dietary concerns and are awaiting further review by JMPR.

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**



Summary

- **Much progress made on international harmonization initiatives**
- **Individual initiatives all have same goal and build on each other**
- **Relationships built among US Federal Agencies and other National Authorities**