EPA Initiatives: Partnerships and Coordination Involving MRLs

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2009 MRL Workshop
San Francisco, California
June 3 - 4, 2009
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; 2\textsuperscript{nd} 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 Alimentarius 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