



EPA Update on International Registration Activities

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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**
- **Emphasis on getting reduced risk pesticides registered in multiple global markets and international standards (Codex) established**

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 to Engage and Promote Collaboration and Harmonization

- NAFTA
- OECD
- Joint Reviews
 - New Active Ingredients
 - New Use Expansions
- Bilateral Collaborations
- Codex: Joint Meeting on Pesticide Residues (JMPR); CCPR (Codex Committee on Pesticide Residues)
- Public health Pesticides (vector control)

Specific Initiatives: NAFTA

- Joint Review Program
 - Minor use program continues
- Trade Irritant Initiative
 - Trade Irritant 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.

Specific Initiatives: NAFTA

- Commodity specific projects to eliminate trade barriers
 - NAFTA TWG piloting commodity project on potatoes, tomatoes, pulse crops – many resolved. (www.epa.gov/oppfead1/international/naftatwg/2007/projects/foodresidue/potato-completion.pdf) (for other commodities just substitute “tomato” or “pulse” for “potato” in website address)
 - No Real Trade Irritants – number of cases where Canadian and US MRLs differed numerically but in reality the actual residues are in compliance with the MRLs of producing and importing country. (on website soon)
 - Avocado Project – between Mexico and US
 - Same website as above but substitute “avocado” for “potato-completion”.

Specific Initiatives: NAFTA

○ 4 NAFTA Labels Approved

- Far-Go Granular Herbicide (in the US) and Avadex MicroActiv Herbicide (in Canada) –a triallate product of Gowan Company (January 31, 2007)
- Gavel 75 DF Fungicide—a combination mancozeb and zoxamide product of Dow (May 16, 2007)
- Reflex Liquid Herbicide—a fomesafen product of Syngenta (October 3, 2007)
- Simplicity Herbicide—a pyroxsulam product of Dow (February 27, 2008)

Specific Initiatives: NAFTA

- NAFTA LABELS in progress
 - Triallate (liquid)
 - Spinosad
 - Clodinafop-propargyl*
 - Cymoxanil & Famoxadone
 - Glyphosate
 - Metaflumizone
 - Mandipropamid*
 - Tembotrione*
 - Several other new chemicals

*Complete in U.S.-- labels pending completion of reviews in Canada



Specific Initiatives: OECD

- Lessons learned and harmonization issues arising from global joint reviews
- Expert Group on Minor Uses (EGMU)
- Residue Chemistry Expert Group (RCEG)
- IT Workshop – held April 2008
- Chemicals with PBT type characteristics
- Benefits of worksharing/joint reviews

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): (*reduced risk*) NAFTA joint review completed in September 2007; Canada and U.S.
- 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: (herbicide) Decision completed September 2007 in US; work share with Canada
- Mandipropamid: (fungicide) (*reduced risk*) – under review in US first; subsequently in Canada.
- Pyroxsulam: (herbicide) – Australia, Canada, US
- Chlorantraniliprole: Insecticide (*reduced risk*) – Australia, Canada, EU (IR,UK), NZ, US; “global joint review” registered April 2008.

Current Joint Review Work

- Joint Reviews/Work Shares in Progress
 - Spirotetramat: Insecticide (Reduced Risk) - Canada, EU (Austria), US
 - Thiencarbazone/Cyprosulfamide: Herbicide - Canada, EU (UK), US
 - Metaflumizone: Insecticide - under review in US, Canada, EU (UK), Australia.
 - Saflufenacil: Herbicide – Australia, Canada, US
- Joint Reviews in Pre-Submission Discussion Phase
 - 14 global review under discussion (conventionals)
 - Discussions in progress for global review of biologicals and antimicrobials also



Current Joint Review Work

- **Cooperative Re-evaluation /Registration Review**
 - **Potential for countries at the beginning stages of their new review programs**
 - **One pilot chemical being coordinated through the Registration Steering Group (RSG) and Working Group on Pesticides (WGP) as a partial workshare**
 - **Two pilot chemicals were selected for work sharing under NAFTA**
 - **Clomazone**
 - **Clofentezine**

Global Joint Reviews: Lessons Learned

- Global JRs are complex projects but benefits outweigh the process challenges.
- Opportunity (collaboration & discussion) to work on new actives with other jurisdictions strengthens regulatory science
- Global JR process provides an incentive for industry to create a single, high-quality data package that is consistent with the needs of all regulators.
- “Lessons Learned” discussions are being routinely scheduled among evaluators, coordinators, and decision-makers (Mexico 2007; Paris 2008)
 - Step-by-step analysis of each project stage for recently completed joint reviews
 - Purpose is to clarify assumptions and apply lessons learned to ongoing projects.



Global Joint Reviews: Lessons Learned

- Communication and coordination are becoming more effective/efficient both during the planning stages and also post-dossier receipt
- Project Plan format is continually being revised to incorporate refinements (e.g., added milestones, more detail, process improvements)
- Quality of the global JR documentation is improving (OECD format).
- Science issues/challenges are being documented for further discussion (e.g., science issues “matrix”).

Codex Committee on Pesticide Residues (CCPR)

- CCPR Meeting in Hangzhou, China, April 2008
 - Continued support and use of accelerated MRL elaboration process: 261 pesticide/commodity MRLs based on consideration of 18 pesticides advanced to Step 8. Emphasis on newer compounds (reduced risk) to be reviewed by Codex.
 - Prioritizing reduced risk chemicals.
 - Revision of Codex Classification of Animal Food and Feeds (aka Crop Grouping)
 - CCPR Working Group on Minor Uses and Specialty Crops – chaired by US; co-chairs Australia and Kenya

Bilateral Initiatives

- Japan:
 - Sharing of reviews for chemicals with MRLs on Positive List
 - Food Safety Commission - collaboration
 - Global joint review partner
- Brazil:
 - Global joint review partner
- China:
 - ICAMA and Ministry of Agriculture Study Tour in US – May 2008
 - Further cooperation efforts planned in 2008-2009
- Taiwan:
 - Sharing of reviews for MRLs under review; review of recent 200 MRL list undergoing review in Taiwan.

Bilateral Initiatives

○ CAFTA

- **OPP is working with FDA, USDA and the University of Maryland Joint Institute for Food Safety and Applied Nutrition (JIFSAN) to expand pesticide work with countries that are part of the new free trade agreement with Central America and the Dominican Republic.**
- **In addition to ongoing projects in pesticide worker safety training and container recycling, focusing on food safety.**
- **Goal of food safety project would be to improve safety of imported commodities to the US**
- **Opportunity to ensure food safety for US consumers while strengthening capacity in CAFTA-DR to protect the environment and public health, and, promote harmonized standards to facilitate trade.**

Codex Committee on Pesticide Residues (CCPR)

- CCPR Meeting in Hangzhou, China, April 2008
 - New initiative introduced: JMPR recommendation of MRLs before national governments establish MRLs for joint review active ingredients; electronic working group established lead by US with possible pilot for 2009 JMPR; encourages MRL harmonization.
 - US continues to try to modify priority list of chemicals for JMPR review criteria to include pesticides that yield no residues on commodities in trade.
 - More transparency on setting of MRLs by JMPR



Public Health Pesticides – Vector Control

- Collaboration with agencies and organizations involved in vector control.
- Summit planned for 2009.



Summary

- Significant increase in activity in global joint reviews for new active ingredients; “second entry” JRs for use expansions being considered.
- Initiatives among NAFTA countries directed toward systematically resolving trade irritants
- Minor Use initiatives
- Codex initiatives
- Increase in bilateral collaboration and cooperation