Global Regulatory Initiatives

Global Minor Use Summit, Rome Italy
4 December 2007

Lois Rossi
Director, Registration Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
Overview of Presentation

- Importance of Global Initiatives
- Background
- Lessons Learned
- NAFTA Results
- Beyond NAFTA—the OECD Vision
- Codex: JMPR/CCPR
- Current initiatives
Global Initiatives

- Significant amount of successful work completed on
  - Joint reviews
  - Work sharing
  - Trade irritants
- This work is building on itself and rapidly expanding
- Finding ways to expand these efforts further and make them work *for everyone* on a truly global basis is a major goal of this summit
Background: Definitions

- Joint Review
  - Dossier is received by all participating national authorities at the same time
  - A formal process ensues with targeted time lines for all participating authorities
  - Workload is split between authorities; reviews of data are exchanged and peer reviewed; and a collaborative risk assessment is undertaken with the goal of harmonization to the extent possible
Background: Definitions

- **Work Sharing**
  - Dossier is received by one national authority and is reviewed
  - Later the dossier is received by another national authority and reviews are sent from the first authority to the authority receiving the dossier later
  - Reviews from one (or more) countries are used in MRL setting in another country
  - Reviews from one (or more) countries are considered in establishment of international standards
Background: Definitions

- Trade Irritants
  - Arise when different MRLs are established in different countries or
  - No MRL exists in a potential importing country
Potential of Collaborative Joint Reviews

- Truly a change in paradigm
  - Regulatory Authorities
  - Crop Protection Industry
  - National Minor Use Programs & Commodity Groups
The “Old” Paradigm

- Independent Reviews
  - Duplicate resources for industry and regulators; take more time
  - Many times produce differing results
  - Require additional resources to address differences later on (e.g. trade irritants)
The “New” Paradigm—Benefits from Collaborative Joint Reviews

- National Regulatory Authorities
  - Savings in resources needed for primary reviews of data
  - Availability of wide range of scientific and regulatory expertise
  - Minimization of trade irritants
  - Global availability of newer, safer pesticides advances goal of protecting human health and the environment
The “New” Paradigm—Benefits from Collaborative Joint Reviews

- Extension to International Forums:
  - Work share projects have resulted in Codex Joint Meeting on Pesticide Residues (JMPR) considering reviews done by national authorities on a routine basis as a means to make process of establishing MRLs more efficient and timely.
  - Possible output of Joint Review is a JMPR style monograph.
The “New” Paradigm—Benefits from Collaborative Joint Reviews

- Minor Crops
  - Resource savings make more resources available to address minor uses
  - Authorization of chemical uses (and hence MRL establishment) occurs at the same time globally
  - MRL harmonization more likely
  - Global residue program
    - Sharing of data to support uses including minor uses
    - Use extension (for minor crops)
Lessons Learned: Fundamentals of Work Sharing/Joint Reviews

- Harmonization of data requirements
- Availability of chemical review schedules
- Acceptability of single formatted dossier (OECD)
- Development of standard review format: templates (NAFTA, OECD), monograph (OECD)
- Development and building on working relationships (risk assessors and risk managers)
Lessons Learned: Joint Review Process (NAFTA)

- The NAFTA joint review program has been in existence since the early 1990’s
- It has become very efficient, popular, and successful
- The next few slides provide some detail on how the joint review process would generally work
Joint Review Process

- Pre-submission consultations between participating countries and prospective registrant
- Single data submission accepted by all regulatory authorities at the same time (dossier in OECD format)
- Data screen conducted by all countries to ensure completeness and quality
- Work split between participating countries and lead country selected
- Joint review teams created in both countries and project plan developed
Joint Review Process (continued)

- Data reviews conducted by the primary reviewer according to the negotiated work split
- Summary reviews of data posted for comments by secondary reviewers
- After addressing all comments, final data summaries are posted by the primary reviewers
- Selection of harmonized regulatory endpoints
Joint Review Process (continued)

- Participating countries independently conduct risk assessments for human health and environment
- Assessment results are exchanged
- Consultation between participating countries to reach a harmonized regulatory determination (goal)
- Common definition of the pesticide residue and harmonized MRLs for treated crops
- Individual publication of regulatory decision (at the same time)
NAFTA Work Sharing/Joint Review: Results

- To date, 18 Joint Reviews; 13 Work Shares; and 12 minor uses have been completed for conventional chemicals
- In 2005, two new active ingredients (both reduced risk) were registered in record time (14 and 16 months)
### Compounds Registered Under NAFTA Joint Review Program (Conventional)

- Azoxystrobin (’97—pilot)
- Cyprodinil (’98)
- Diflufenzopyr (’99)
- Fenhexamid (’99)
- Zoxamide (’01)*
- Acetamiprid (’02)
- Pyraclostrobin (’02)
- Mustard seed (’03)
- Clothianidin (’03)
- Pyrosulfotole (’07)—

*included Mexico

- Famoxadone (’03)
- Boscalid (’03)
- Spirodiclofen (’05)
- Pinoxaden (’05)
- Aminopyralid (’05)*
- Topramezone (’05)
- Prothioconazole (’07)
- Spinothalam (’07)
- Pyrosulfotole (’07)—

*included Mexico trilateral w/ Australia
NAFTA Work Share Compounds (Conventional)

- Sulfosulfuron ('99)
- Flucarbazone Sodium ('00)
- Thiamethoxam ('00)
- Foramsulfuron ('02)
- Iodosulfuron-methyl ('02)
- Clothianidin ('03)
- Cyazofamid ('04)
- Novaluron ('04)
- Paraquat ('05) (with Mexico)
- Iprovalicarb ('02 with Canada; '05 with Mexico)
- Novaluron (06')
- Florasulam ('07)
- Tembotrione ('07)
NAFTA Joint Review of Minor Uses

- Minor Use Joint Review SOP approved by NAFTA Executive Board in December 2005 – 8 month review time planned
- 2006
  - fenhexamid: ginseng {Minor Use Pilot Project} (complete)
  - s-metolachlor: pumpkin and winter squash (complete)
- 2007
  - imidacloprid/cymoxanil/famoxadone: caneberry (complete)
  - fenamidone: carrot (complete, however not registered in CN due to insufficient residue data)
  - fluazinam: broccoli, blueberry, snap bean, mustard greens, and cabbage (complete)
- 2008
  - acetamiprid: strawberry
  - cymoxanil/famoxadone: celery
  - novaluron: mustard greens and stone fruit (peach)
  - Cyazofamid: carrots
NAFTA: Addressing Trade Irritants

- Focus shifted from a commodity based process to a more sustainable process
- Developing database to provide readily accessible information on specific trade irritants
  - Valuable tool for regulators and crop protection industry
  - Will ensure trade irritant issues addressed, to the extent possible, through regular work processes
Beyond NAFTA

- Benefits of NAFTA Joint Review recognized
- Numerous discussions with industry on expansion of joint review beyond NAFTA
- U.S. champion of OECD vision statement
Background: Early International Efforts

- 1991 idea of cooperation among national pesticide regulatory authorities advanced by OPPTS senior leadership
- Purpose: To facilitate licensing of pesticides and trade, providing quicker access to market for newer, safer substances
- OECD sponsored workshop held in Washington, DC in 1991; pilot study done comparing studies and results on several chemicals that had been reviewed by multiple national authorities
Background: Early International Efforts

- Results of pilot showed similar data bases were reviewed by each national authority and similar conclusions were reached.
- Through OECD/Registration Steering Group (organized in early 1990s) several projects done over the years comparing reviews on specific pesticides (i.e., Cornelia project).
- 2004 OECD vision statement developed.
OECD Vision Statement

- OECD has adopted a vision that by the end of 2014, through the cooperation of OECD member countries working with relevant stakeholders, it will ensure that:
  - Levels of risk arising from pesticide use is minimized
  - Regulatory system for agricultural pesticides is harmonized and data reviews are in the OECD format
  - Preparation of dossiers is coordinated globally by industry and work sharing opportunities are maximized
  - Work sharing arrangements between regulatory authorities in OECD countries are routine
  - Generation of single monograph for each active substance becomes commonplace
  - Countries ensure that benefits derived from work sharing are taken into other international forums (e.g., JMPR)
Current Joint Review/ Work Shares

- **Decisions issued in 2007:**
  - **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.
  - **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
Current Joint Review Work

- **Chlorantraniliprole**: Insecticide (Reduced risk) - Australia, Canada, EU (UK and Ireland), NZ, US.
- **Spirotetramat**: Insecticide (Reduced Risk) - Canada, EU (Austria), US
- **Thiencarbazone/Cyprosulfamide**: Herbicide - Canada, EU (UK), US
- **Pyroxsulam**: Herbicide - Australia, Canada, US
- **Mandipropamid**: Fungicide (Reduced risk) – under review first in the US; subsequently in Canada
- **Metaflumizone**: Insecticide - under review in US, Canada, EU (UK), Australia.
Future Joint Reviews: Pre-Submission Phase

- Planned Submissions: 2008-2010
  - 6 Conventional Pesticides
    - Minimally trilateral reviews
    - One review includes possibility of global residue program
  - 4 Biologicals
  - 1 Antimicrobial
Summary

- Joint reviews are becoming the standard way of doing business
- For EPA---Give Percentage of work that is joint
Efforts focused on faster setting and adoption of MRLs—especially for reduced risk chemicals

- MRLs recommended by JMPR approved (if there are no objections at CCPR) using accelerated process
- Changed ratio of new/existing chemical reviews from 50:50 to 70:30
- Adopted criteria for decision-making on MRL advancement
  - Necessary to have a documented and recognized safety concern to object to advancement of an MRL recommended by JMPR

Work share projects have resulted in JMPR considering reviews done by national authorities on a routine basis

Global joint review to develop JMPR monograph as an output

Work on Crop Classification Revision
  - Harmonized
  - Promotes use of crop groupings and representative crops
Summary

- Collaboration between national regulatory authorities
  - Is fast becoming the standard procedure
  - Facilitates harmonization; aids minor uses
  - Enhances ability to meet goals of protecting public health and ensuring growers and other pesticide users have access to appropriate tools
Challenge to Summit Participants

- We must find ways to expand these efforts further and make them work for everyone on a truly global basis

- Thank you for your attention and I look forward to working with you on these initiatives in the future