

Global Regulatory Initiatives

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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

- NAFTA Work Shares/Joint Reviews - first Joint Review 1997
- 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)
- Clothiandin ('03)
- Famoxadone('03)
- Boscalid ('03)
- Spirodiclofen ('05)
- Pinoxaden('05)
- Aminopyralid ('05)*
- Topramezone ('05)
- Prothioconazole ('07)
- Spinoteram ('07)
- Pyrosulfotole ('07)—
trilateral w/ Australia

*included Mexico

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

- Joint Reviews/Work Shares in Progress:
 - 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

Codex: JMPR/CCPR

- **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