



Joint Evaluations as a Mechanism for Advancing International Harmonization for the Regulation of New Active Ingredients

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Outline of Presentation

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Background – Why is EPA/OPP Involved in International Efforts



- Food production and distribution are global
- Pesticides are developed and marketed globally
- Scientific research and advances in risk assessment and management are global
- Decisions on pest control and pesticide management made in one country can have global repercussions
- Therefore, to achieve public health and environmental protection goals and fulfill our statutory and treaty mandates, our pesticide program must actively engage with international partners



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 with and among all stakeholders
 - Promote dialogue between regulatory authorities



Definitions

- **Global Joint Review:** Several national authorities evaluate a pesticide active ingredient at the same time-- they receive the same submission at the same time, develop a schedule, and divide the work; at the conclusion each makes its own independent regulatory decision with the goal of harmonization of endpoint selection and MRL establishment.
- **Work Sharing:** One national authority has completed work on the chemical and other national authorities subsequently use the completed reviews in completing their reviews on their own schedule.

Global Reviews - Roles



- Roles Countries/Regional Authorities Can Perform in a Joint Review
 - Primary Review: Conduct initial review of assigned studies and write draft study evaluations; address peer review comments and write final study evaluations
 - Peer Review: Conduct secondary review of assigned studies and provide comments to the primary reviewer; excellent for capacity building
 - Observer: Access to all data and information; full participant in meetings and full understanding of reviews; no work assignments; excellent for capacity building
- Different countries play different roles at different times and for different chemicals

Global Reviews – Pre-Submission



- Pre-submission consultations between participating countries and prospective registrant to discuss:
 - the new active ingredient (or new use) and the joint review process
 - data submission/data requirements (including common requirements and country specific requirements or uses)
 - potential review timelines
- Lead country (role of review coordinator) selected
- Work split negotiated between participating countries (primary reviewers selected and peer review countries identified)
- Review teams in participating countries created
- Review project plan developed

Global Reviews – Examples of Work Splits



Chemical	Toxicology	Residue Chemistry	Eco-toxicology	Environmental Fate	Product Chemistry
Pyrasulfatole	Australia	Canada	United States	United States	Australia
Pyroxsulam	United States	Australia	Australia	Canada	United States
Chlorantraniliprole	United States	Australia	United Kingdom	Ireland	Canada
Spirotetramat	United States	Canada	Austria	Austria	Canada
Thiencarbazone/ Cyprosulfamide	United Kingdom	United Kingdom	Canada	United States	United Kingdom
Saflufenacil *Australia peer reviewer	Canada	Canada	United States	United States	United States
Fluopyram *Japan peer reviewer	Germany	United States	United States	Canada	Germany



Global Reviews - Registration Package

- A single dossier, in the OECD format, is submitted to all regulatory authorities at the same time
- Data screening is conducted by all countries to ensure completeness and quality



Global Reviews – Scientific Evaluation

- Data reviews conducted by the primary reviewer according to the negotiated work split
- Reviews of data are posted for comments by secondary (peer) reviewers
- After addressing all comments, final data summaries are posted by the primary reviewers

Global Reviews – Risk Assessments/Monograph



- Selection of harmonized regulatory endpoints (*goal not requirement*)
- Participating countries independently conduct risk assessments for human health and environment
- Assessment results are exchanged
- Monograph drafted; reviewed; and finalized

Global Reviews – Regulatory Decisions



- Each national authority makes its own independent regulatory decisions, however, there is consultation between participants to try and reach
 - common definition of the pesticide residue and harmonized Maximum Residue Limits (MRLs) for treated crops
 - harmonized regulatory decision
- Each national authority issues a regulatory decision within approximate same time period

Global Reviews - Results/Outcomes



- Generally: Same scientific conclusions arising from same data
- Completed work shows high percentage of agreement in:
 - toxicological endpoints selected
 - MRLs established
- Additional national authorities and companies becoming involved—the next slides explain why

Benefits of Global Reviews — Regulatory Authorities



- Complete data submissions – all data required for each country sent to all countries
- Sounder scientific conclusions (that serve as a basis for more timely regulatory decisions)
- Fewer resources required for evaluation of data submissions and for peer review
- Additional resources available for problem-solving
- Harmonized MRLs
- Strengthens international working relationships and cooperation on pesticide issues

Benefits of Global Reviews — Registrants



- Time, costs and uncertainty associated with new chemicals, new uses, and defending existing products in re-registration programs is minimized
- Ability to submit one uniform package (application) to multiple regulatory authorities saves resources
- Earlier access to global market for new products
- Easier introduction of new lower risk chemicals: growers less likely to use new chemicals if they cannot export their products



Benefits of Global Reviews— Growers

- Able to use to new, lower risk chemicals on exported commodities
- Countries adopt harmonized MRLs which minimize trade barriers

Benefits of Global Reviews— The Public



- Higher degree of public confidence in the regulatory system
- Efficient use of limited resources
- Lower risk chemicals used world-wide sooner

Opportunities to Engage and Promote Collaboration and Harmonization



- NAFTA - TWG (North American Free Trade Agreement – Technical Working Group on Pesticides)
- OECD (Organization for Economic Co-operation and Development) including the Working Group on Pesticides (WGP) and Registration Steering Group (WGP)
- Codex Alimentarius (WHO + FAO): Joint Meeting on Pesticide Residues (JMPR); CCPR (Codex Committee on Pesticide Residues)

Specific Initiatives: NAFTA



- *Tolerance/MRL Harmonization Group*
- *Grower Priority Database*
- *NAFTA label*
- *Crop Groupings Project*

Specific Initiatives – NAFTA MRL Calculator



- **Conventional method**
 - Based on the highest residues from field trials reflecting the most conservative use pattern(s)
 - Highly dependent on professional judgment of individual scientists
- **New Statistical Method (MRL Calculator)**
 - Provides a defined method
 - Should result in consistent decisions on tolerance setting
 - NAFTA endorsed in 2005
 - JMPR recognizes and is using the procedure
 - Actively promoting its use with other groups (OECD and JMPR)



Specific Initiatives – NAFTA Grower's Priority Database

- **Grower's have developed a database of priority harmonization issues between the U.S. and Canada**
 - Difference in numerical MRLs
 - No MRL/registration in one country (technology gap)
 - Priorities entered for several minor crops
 - Governments will use the results to remedy the problems in the most cost-effective and sustainable manner

Specific Initiatives – NAFTA Label



- Efforts in past to develop a NAFTA label have not succeeded due to barriers identified primarily by industry.
- Grower groups, particularly in border states, continue to press for NAFTA label
- Task Force was formed to:

Specific Initiatives – NAFTA label (*continued*)



- Develop a product list of identical products registered in US and Canada; identify measures that could allow transport of these products across border.
- Pursue development of a NAFTA label and address various barriers that have been previously identified.

Specific Initiatives (NAFTA) – Crop Groupings and Representative Crops



- Supports minor crops and conserves resources
- Places all known food crops into one of 22 crop groups
- Allows data from major crops to be extrapolated to minor crops
- Advantages
 - Additional tools for minor use growers
 - Health protective
 - Saves government resources



Specific Initiatives - OECD

- **Vision Statement – “*By promoting work-sharing, the OECD Pesticide Programme helps governments more efficiently and effectively protect human health and the environment and work towards the goal of sustainable development.*”**



Specific Initiatives - OECD

- **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 fora (e.g., JMPR);



Specific Initiatives - OECD

- Forum to bring partners together to promote joint reviews and discuss common issues.
- OECD Expert Group on Minor Use
- OECD Residue Chemistry Expert Group
- OECD MRL Calculator

Specific Initiatives - Codex: JMPR/CCPR



- Establishes MRLs for Use in International Trade
- JMPR (Joint Meeting on Pesticide Residues)
 - Risk assessment work by FAO/WHO expert groups
 - Make recommendations to the CCPR
- CCPR (Codex Committee on Pesticide Residues)
 - Risk management work (most countries represented)
 - Make recommendations to the Codex Alimentarius Commission (CAC) for establishment of Codex MRLs



Specific Initiatives - Codex: Harmonization

- Work share projects have resulted in JMPR considering reviews done by national authorities on a routine basis
- Expect pilot of new process to allow Codex to recommend MRLs before or at the same time as national governments involved in global joint reviews
- OECD MRL Calculator Project
- Work on Crop Classification Revision
 - Goal is a single harmonized classification system
 - Promotes use of crop groupings and representative crops



Summary

- **Proven that collaboration and harmonization enhances ability to meet goals of protecting public health and ensuring growers and other pesticide users have access to appropriate tools**
- **Joint reviews and related projects have been shown to be a win-win for all involved (growers, industry, government, public)**