



***GLOBAL REVIEWS: New
Pesticide Active Ingredients***



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.



History—Early Efforts

- OECD
 - Early initiatives (case studies)
 - Development of tools
- NAFTA (North American Free Trade Agreement) Joint Reviews and Work Sharing
 - Learning by doing



OECD: Early Initiatives

- OECD sponsored workshop held in Washington, DC in 1991; pilot project compared studies results on several pesticide active ingredients that had been reviewed by multiple national authorities
- Through OECD/Working Group on Pesticides and the Registration Steering Group several projects have been completed over the years that compared reviews on specific pesticides
- Results of early projects showed similar data bases were reviewed by each national authority and similar conclusions were reached
- OECD vision statement developed in 2004



Where We Want to Be-- The OECD Vision

- By the end of 2014:
 - Levels of risk arising from pesticide use are minimized
 - Regulatory system for agricultural pesticides is harmonized and data reviews are in a standard format (OECD has developed review templates)
 - Preparation of dossiers is coordinated globally by industry and global reviews 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/Codex)

OECD

Tool Development

- Harmonization of data requirements (OECD)
- Submissions: Single formatted dossier including all studies generated and acceptable to all national authorities (OECD dossier format)
- Reviews: Standard review format used by all national authorities:
 - templates for study reviews (examples: NAFTA, OECD)
 - monograph for risk assessment (OECD format)



NAFTA Work Sharing/Joint Review: Results

- First NAFTA Joint Review was completed in 1997
- To date, 22 Joint Reviews and 11 Work Shares completed
- In 2005, two new active ingredients (both reduced risk) were registered in record time (14 and 16 months)
- Use of Joint Reviews and Work Sharing has expanded to include:
 - Addition of new uses (especially for minor uses)
 - Re-evaluation of older chemicals
- Routine way of doing regulatory work for the US and Canada



Beyond NAFTA

- NAFTA joint review program has become very efficient, popular, and successful
- Benefits of joint reviews and work sharing clearly recognized
 - By chemical registrants
 - By national authorities
 - By agricultural producers
- Numerous discussions with industry on expansion of joint reviews beyond NAFTA
- Global Reviews have begun and are fast becoming the way of doing business for new pesticide active ingredients
- Global work sharing also continues to expand



How Global Reviews Work

- The next several slides provide some detail on the global joint review process as it has been worked out over the years
- There are still improvements to be made
- Development and building of working relationships among the scientists and risk managers of the various national authorities is very important and is continuing to expand and grow
- Global review process



Pre-Submission

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

Examples of Work Splits on Global Reviews

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 was also a partner on secondary reviews	Canada	Canada	United States	United States	United States
Fluopyram	Germany	United States	United States	Canada	Germany



Registration Package

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



Scientific Evaluation

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



Risk Assessments/Monograph

- Selection of harmonized regulatory endpoints (*goal*)
- Participating countries independently conduct risk assessments for human health and environment (why?)
- Assessment results are exchanged
- Monograph drafted; reviewed; and finalized



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 MRLs for treated crops**
 - **harmonized regulatory decision**
- **Individual country issuance of regulatory decision within approximate same time period (goal is same time)**



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



Results— Completed and Current Global Reviews

- Pyrasulfatole: first trilateral joint review completed August 2007; Australia, Canada, U.S.
- Pyroxsulam: Australia Canada, U.S.
- Chlorantraniliprole: Australia, Canada, Ireland, United Kingdom, U.S.
- Spirotetramat: Canada, Austria, U.S.
- Thiencarbazono: Canada, United Kingdom, U.S.
- Saflufenacil: Australia, Canada, U.S.
- Fluopyram: Canada, Germany, United States



Benefits of Global Reviews— Regulatory Authorities

- Complete data submissions – all data required for each country sent to all countries
- More sound 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



Future Work Plans

- Planned Submissions: 2009-2010
 - 12 Conventional Pesticides
 - Minimally trilateral reviews
 - Some global submissions include global residue program
 - 4 Biologicals
 - 1 Antimicrobial



Codex/JMPR MRLs

- Let's think globally and focus efforts on faster setting/adoption of MRLs (especially for reduced-risk pesticides)
- Global reviews to coordinate/develop JMPR monograph as an output
- Work on harmonized crop classification promoting use of crop groups and representative crops
- Use a globally accepted method for calculating MRLs
- Use numerical rounding schemes (one global MRL)



Codex/JMPR: Fluopyram MRL Pilot

- New paradigm
- JMPR to conduct an independent and parallel review and recommend MRLs before national governments
- Ongoing global joint review – fluopyram (EU, US, Canada, and Japan)
- Target completion date 2010



Summary

- Collaboration between regulatory authorities enhances ability to meet goal of protecting public health
 - Agricultural food production
- Let's encourage global initiatives for harmonization
- Let's move these initiatives forward