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

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<tr>
<th>Chemical</th>
<th>Toxicology</th>
<th>Residue Chemistry</th>
<th>Eco-toxicology</th>
<th>Environmental Fate</th>
<th>Product Chemistry</th>
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*Australia was also a partner on secondary reviews
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.
- **Thiencarbazone**: 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 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/J MPR MRLs

- Let’s think globally and focus efforts on faster setting/adoptions of MRLs (especially for reduced-risk pesticides)
- Global reviews to coordinate/develop J MPR 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)
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