

International Regulatory Cooperation and Harmonization

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International Regulatory Cooperation: Outline

- Harmonization: a key component
- A complex process
- Benefits
- Standardizing approaches
- Key accomplishments
- Results
- Next steps

International Regulatory Cooperation: Harmonization a key component

WHY?

1. To share the work of evaluating pesticides (efficiency)
2. To facilitate access to new pest control chemistry and technology
3. IRC is a major focus of the External Advisory Committee on Smart Regulation

Harmonization a key component

It is a complex process requiring:

- Understanding of methods and practices used to regulate pesticides in other countries and
- A willingness on the part of all parties involved to work toward converging approaches

Harmonization: Benefits

- reduces duplication of effort
- streamlines the pesticide review process
- facilitates the introduction of newer and safer pest control products in the same time frame
- leads to better regulatory decisions

Harmonization: Background

Since 1996 the PMRA has been working with:

- The US EPA and Mexico in the NAFTA Technical Working Group on Pesticides
- The OECD Working Group on Pesticides
- Involving in each case both senior management and evaluators at the working level – top/down and bottom/up

Harmonization : How we are getting there...

Standardizing:

- the type and scope of studies required
- protocols used in these studies
- submissions from industry
- approach to evaluation and monograph preparation
- electronic tools
- approach to risk assessment

Harmonization : Key Accomplishments - The basics:

1. NAFTA

- harmonization of Canada/US data requirements for agricultural chemicals
- substantial agreement on protocols used in ag chemical studies
- templates for PMRA/EPA study and evaluation reports
- electronic tools

Harmonization : Key Accomplishments - The basics:

1. NAFTA (continued)

- harmonized approach to evaluation and monograph preparation PMRA/EPA
- harmonized approach to risk assessment
- e-PRS system launched – shared with NAFTA partners
- harmonized science policies under stringent new US FQPA

Harmonization : Key accomplishments

2. OECD/GLOBAL

- OECD universal submission formats agreed upon
- Using PMRA/EPA template model, commencing work on OECD pesticide and chemical templates, electronic tools
- OECD Worksharing Workshop early 2005

Harmonization : Key accomplishments

2. OECD/GLOBAL (continued)

- Risk assessment harmonization ongoing with both EPA and OECD
- In non-ag pesticides, harmonizing environmental exposure approach through OECD
- MOU signed with Australia 2004 to facilitate work sharing and joint reviews
- New PCPA will allow review sharing post registration

Harmonization: Results (continued)

- Joint Reviews routine with the United States; Mexico participation increasing
- Ultimate goal is trilateral reviews, decisions in the same timeframe, same MRLs
- About 50% of all new chemical reviews are JR or workshare
- The Re-eval program depends heavily upon EPA reviews

Harmonization: Results (continued)

- As of March 04, approximately 70% of the conventional reduced-risk chemicals (active ingredients) registered in the U.S. and 31% of the biopesticides are registered or pending registration in Canada

Harmonization: Next steps

- Continued work through OECD to complete development of globally harmonized templates, with harmonized electronic tools
- Cooperate in the development of new regulatory science via NAFTA and OECD
- (e.g. toxicology and food residue chemistry)
- Encourage greater industry participation in joint reviews and worksharing in both the NAFTA and global context, particularly in support of RR and biopesticides; and for existing pesticides

Next Steps (continued)

- Develop closer regulatory cooperation with Australia and the European Commission in the area of worksharing and joint reviews
- Further work on resolving remaining differences in risk assessments e.g. worker exposure
- Further work (EPA/PMRA) on harmonizing MRLs through re-evaluation
- Additional work on harmonizing crop residue zones

What is the advice of Council concerning the approach to Harmonization?



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