New Developments – Harmonization and the PCPA

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What is harmonization?

- Does not mean “identical” rather being close enough that worksharing and Joint Reviews can routinely occur

- Means finding acceptable approaches that will maintain current high levels of protection of health and environment - not simply accepting another country’s decision

Definitions

- **Joint Review:**

  a formal process with specific time lines

  workload is split up between the countries

  reviews of data are exchanged, peer reviewed

  cooperative risk assessment

  goal of harmonized and simultaneous registration decision

- **Work Share:**

  ad hoc exchanges of information

  can include the division of work and collaboration on decisions for new active ingredients, new uses and reassessment of older pesticides

Approach to Harmonization

- Aggressively pursued through the NAFTA TWG and the OECD WG on Pesticides
- Methodical stepwise approach
- Learn by doing

Stepwise Approach to Harmonization

- Data requirements and study protocols
- Standard templates for study reports and study evaluations
- Standard formats for industry submissions and country reviews
- Compatible electronic tools for submission and review
- Risk assessment methods
- Decisions harmonized to the extent possible

Stepwise Approach

- Parallel review 1995
- First joint review – 1996 – reduced risk chemicals
- JR - Microbials and pheromones – 1997
- JR- NAFTA priorities- alternatives to OPs and MeBr
- JR – complete or partial electronic submissions, OECD formats, multiple active ingredients
- Minor uses

Harmonization Status

- Two operational programs for Joint Reviews / work sharing for new and existing pesticides (NAFTA)
- Many data requirements harmonized (NAFTA/OECD)
- Many study protocols harmonized (NAFTA/OECD)
- Universal formats for pesticide submissions and country reviews completed (OECD)

Harmonization Status

- Templates for study reviews and study reports harmonized (NAFTA) and underway (OECD)
- Compatible electronic tools
- Risk assessment approaches being harmonized, e.g., cancer, MTD, DNT, others (NAFTA/OECD)

Recent Developments

- Minor uses (AAFC/IR-4/PMRA/EPA)
- 3 potential Joint Review – electronic submissions
- Looking for opportunities to share reviews with the EU

Benefits of harmonization

- Earlier/simultaneous access to newer safer pest management tools
- Earlier re-evaluation using up-to-date science
- More efficient process for evaluation and re-evaluation
- Opportunity for improved and similar decisions

Benefits of harmonization

- Eliminates duplicate data generation and some country-specific requirements
- Assemble once electronically in standard format and submit globally
- Removal of trade barriers through similar MRLs

Key Issues

- How to increase industry interest and participation in Joint Review process
- Need industry permission to share reviews and discuss interpretation of data with other countries

New
Pest Control Products Act

Objectives:

- Strengthens health and environmental protection
- Makes the registration system more transparent
- Strengthens post-registration controls on pesticides

Making the Registration System More Transparent

- Consultation on major registration decisions
- Reconsideration of major registration decisions by review panels
- Public registry
  - Detailed evaluation reports
- Test data in reading room
- Sharing confidential information

Consultation

- Consultation on major registration decisions
  - New active ingredients
  - Major new uses
  - Re-evaluations and special reviews
- Consultation document
  - Proposed Regulatory Decision Document (PRDD) or Proposed Acceptability for Continued Registration (PACR)
    - Summaries of risk and value assessments
    - Proposed decision and rationale

Reconsideration of Decisions

- Reconsideration of major registration decisions
- Anyone may file a notice of objection
  - within 60 days of publishing RDD or RRD
  - detailed evaluation reports and test data available
- Review panel may be established
  - if not, written reasons provided

Reconsideration of Decisions

- Open process
- Recommendations considered in deciding to confirm, reverse or vary original decision
- New regulations required

Register

- Confidential business information (CBI)
  - Not available to public
- Confidential test data
  - Public may inspect in reading room
- All other information available through public registry (electronically or hard copy)
  - Status of registered pesticides
  - Applications
  - Re-evaluations and special reviews
  - Detailed evaluations of risks and value

Confidential Business Information

- Definition of CBI
  - Financial information
  - Manufacturing processes
  - Methods for determining a product's composition
  - Formulants *not* of health or environmental concern
- Identity and concentration of formulants that *are* of concern not included in definition of CBI
- CBI - not in public registry

Public Registry

- Information must be available:
  - in as convenient a manner as practicable
  - electronically, as soon as reasonably practicable

Public Registry

- Public may obtain a copy of any information in Register except:
  - confidential test data (CTD)
  - confidential business information (CBI)

- Key information not previously available:
  - applications
  - detailed evaluation reports (monographs)

Sharing Confidential Information

CBI and confidential test data can be shared, *in confidence*, with:

- federal regulators
  - to protect health, safety or the environment
- federal and provincial/territorial regulators
  - when health, safety or environment is endangered
- regulators in other countries
- medical professionals
  - to make diagnosis or give treatment

Sharing Confidential Information

- MOUs will be developed with OGDs
- Agreements will be developed with provinces, other countries

Sharing Confidential Information

- CBI and confidential test data can be shared, *in confidence*, with:
  - a review panel established to reconsider a registration decision
  - a person or body requested to provide advice