

Pesticide Regulation and Harmonization

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2003 Report of the CESD

- ◆ A sound evolving framework for evaluating pesticides
- ◆ A process similar to the US and other OECD countries
- ◆ Efficacy reviews similar to most OECD countries



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 – tebufenozide 1995
- ◆ First joint review – 1996 – reduced risk chemicals
- ◆ Microbials and pheromones – 1997
- ◆ Expanded chemicals 1998 and then modifications to the process

Stepwise Approach

- ◆ Chemicals Expanded - 2002

Group 1A RR, 1 active, 2 products

Group 1B RR, >1 active, 2 or more products

Group 2 non reduced risk NAFTA priorities
OP and methyl bromide alternatives

Group 3 negotiated JRs
electronic submissions/components, OECD
formats, multiple active ingredients



Stepwise Approach

- ◆ Microbials and pheromones – 2002
reduced time line for pheromones
- ◆ Import MRLs – workshare only
- ◆ Second entry and Minor Use Pilots for post FQPA actives
- ◆ Minor uses (AAFC/IR-4/PMRA/EPA)

Performance on Joint Reviews

- ◆ From July 1, 1996 to December 31, 2003:
- ◆ 32 Joint Review submissions
- ◆ 66% met the review timeline
- ◆ Timeline missed by range of 1 to 51 days
- ◆ predictability



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)

Cancer risk assessment for children

- ◆ Differences in cancer risk assessment for children became evident through JRs
- ◆ We analyzed differences - PMRA through contract, EPA through SAP
- ◆ Very similar conclusions
- ◆ EPA SAP recommended approach that we can accept
- ◆ Awaiting whether EPA will agree



Benefits for the public

- ◆ Access to newer safer pest management tools on food and in residential areas
- ◆ Earlier re-evaluation using up-to-date science

Benefits for industry

- ◆ Eliminates duplicate data generation and some country-specific requirements
- ◆ Assemble once electronically in standard format and submit globally

Benefits for growers

Facilitates worksharing and therefore:

- ◆ Removal of trade barriers through similar MRLs
- ◆ Earlier / simultaneous access to newer safer pest management technologies

Benefits for regulators

- ◆ More efficient process for evaluation and re-evaluation
- ◆ Opportunity for improved and similar decisions

Key Issues

- ◆ Need industry permission to share reviews and to discuss interpretation of data to maximize worksharing
- ◆ Need to increase industry participation in JR process

Future Focus

- ◆ Continue to resolve differences
- ◆ Develop process to promulgate MRLs faster
- ◆ Increase ability to share work, e.g., modified joint review with the US
- ◆ Increase work sharing with EU and others
- ◆ Encourage industry to continue participating – need permission to share reviews
- ◆ Under the new PCPA, worksharing will be facilitated



Question to PMAC

- ◆ What advice does the Council have to further harmonization and in particular to encourage more joint reviews?