

Canada – Regulatory and MRL Overview

California Specialty Crops Council MRL Workshop

June 1, 2011 Peter MacLeod



Agenda

- MRLs – the Good, the Bad and the Ugly
- New Canadian Policy Developments
- US – Canada Harmonization
- New Government Priorities
- Grower / Registrants coordination



Representing the developers, manufacturers and distributors of plant science innovations – pest control products and plant biotechnology – for use in agriculture, urban and public health settings



PMRA MRL Initiatives

- MRLs are now established directly by PMRA under the Pest Control Products Act (former FDA process was much more complicated and slow).
- 7858 MRLs are now published in the PMRA MRL spreadsheet as of May 2011.
- Conversion to searchable database from excel table underway.

PMRA MRL Initiatives – 0.1 ppm Default

- PMRA is continuing to reduce reliance on the default MRL of 0.1 ppm by adopting US tolerances at or below 0.1 ppm where use patterns are consistent.
- On March 18th, the PMRA established over 500 MRLs that previously relied on the default 0.1ppm level.
- This work will continue but reliance on the 0.1 ppm default will continue for some time particularly for older chemistry.
- Next up US tolerances above 0.1 ppm.

PMRA MRL Initiatives

- CropLife encourages the agencies to establish domestic/import MRLs simultaneously for crops which local registration is not possible (rice, citrus, tropical fruit, etc., in Canada). A domestic submission to EPA should be considered as import MRL submission to PMRA.
- Harmonized MRLs should be established in both countries, especially if the tox end points are identical/similar and the US tolerance passes the PMRA dietary risk assessment. This will decrease agency workload and help prevent different MRLs.

PMRA MRL Initiatives

- CropLife is also concerned with the PMRA's process of notifying registrants, growers and foreign governments of new MRLs. It seems that the MRL proposal and publication process used by the PMRA to promulgate and announce MRLs takes many months and sometimes years.
- This delay slows the import and export of commodities treated with new chemistries.

PMRA MRL Initiatives

- PMRA and EPA recently announced that starting in April 2011 both agencies along with other OECD countries would be using an OECD MRL Calculator to provide statistically robust and scientifically defensible MRLs. This approach should contribute to the international harmonization of MRLs.
- The OECD MRL Calculator will replace and supersede the NAFTA MRL Calculator.

PMRA MRL Initiatives

- PMRA and EPA continue to align crop groups and representative crops in order to streamline the establishment of MRLs. We recognize this effort and encourage its continuance.
- PMRA recently released a Regulatory Directive - Revisions to the Residue Chemistry Crop Field Trial Requirements.
- Some new crops including those grown in greenhouses were added but for 25% of all crops listed, residue trials requirements were increased.

PMRA MRL Initiatives

- The impact is increased cost of generating residue data and evaluation.
- Industry would have preferred PMRA to issue a Proposal for consultation rather than a Directive with a 2012 starting date.
- CropLife Canada is engaging the PMRA to discuss the reasons for the increases and to try to find ways to mitigate the increased costs.
- The additional requirements, especially for minor crops means that in some cases registrants will not pursue registration leading to an increase in the Technology Gap and MRL issues.

PMRA MRL Initiatives – 0.1 ppm Default

- Bottom line
- PMRA is making progress on MRLs
- Import MRLs a PMRA priority?
- MRL Database working well / helping
- Work with registrant/regulators critical
- Package MRL with Canadian uses
- Keep communication going

Harmonization Initiatives

- NAFTA Joint Reviews of new actives and of minor uses have been successful in providing growers on both sides of the border with new tools at the same time. Establishment of harmonized MRLs has enabled trade.
- Growers and registrants should maintain their focus on the NAFTA approach where possible and should continue to encourage the PMRA and EPA to continue to harmonize their regulatory systems.

Harmonization Initiatives

- CropLife Canada Harmonization Wish List
 - Continue Global Joint Review Activities
 - Helps ensure uses and MRLs harmonized
 - Utilize the reevaluation/reregistration process to harmonize uses and MRLs
 - Use reviews already completed from other jurisdictions to fullest extent possible
 - Complete NAFTA TWG projects related to science issues unresolved (dermal absorption, ground water, soil studies, crop treated, etc.)

Canadian Political Climate

- New majority Conservative government.
- Election platform included the following:
“....Canadian farmers want access to the latest innovations, to succeed in the global economy....
We will revise current approval processes to allow for international equivalencies in such products.
We will eliminate needless duplication, while protecting our national sovereignty and maintaining the highest safety standards.”
- Currently determining the impact.

Government Initiatives

- Many convergent pressures on PMRA
 - Budget
 - Workload
 - Inter Government jurisdictions
 - Stakeholders divergent views on harmonization (Users, Industry, ENGO's, Opposition Party)

Government Initiatives

- Currently many concurrent activities
 - Canada / US Regulatory Cooperation Council
 - Canada Red Tape Reduction
 - NAFTA TWG
- Results?
- Recognize the tremendous success to date through the NAFTA TWG.
- Strong commitment of agency leadership.

Grower / Registrant Coordination

- How to improve?
- Good cooperation/coordination currently exists
- Government interactions
 - Use our collective strengths
 - Get involved (Meetings, Discussions, NAFTA TWG)
- Ongoing communication is key

- Thank you!
- Questions
 - Peter MacLeod
 - Vice President Chemistry
 - CropLife Canada
 - macleodp@croplife.ca
 - 416 622-9771
 - www.croplife.ca