

Crop Protection Products Initiative

Presentation to RCC Stakeholder Dialogue Session June 20, 2013

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Overview of the initiative

<u>Objective</u>

 Building on an already established pesticide joint review program of new chemical activities, further align crop protection products (pesticides) expanded use reviews and establishment of maximum pesticide residue limits (MRLs) and tolerances in both countries.

Key Deliverables

- Agree on use of specific science approaches
- Alignment of specific registration processes
- Development of shared registration application forms, templates, and electronic tools



Action Item 1: Encourage Joint Submission of Use Expansions and Fully Aligned Labels

Successfully completed use expansion registration for minor use crops.

•Resulted in harmonized Maximum Residue Levels (MRLs), eliminating potential trade barriers.

•Issues identified were resolved; PMRA and EPA agreed to use same principles in ongoing joint review projects.



Action Item 2: Develop Joint Guidelines for Residue Field Trials

EPA and PMRA agreed on the joint use of residue trials for use expansions where possible.

•Anticipate developing joint principles for a field trial guideline;

 Agreed on the use of the proportionality concept in certain cases; and

•Continue to develop harmonized crop groupings, resulting in the need for less residue data to support a greater number of crops.



Action Item 3: Address Obstacles to Joint Registration

Completed analysis of regulatory timelines for pesticide actions:

Identified many areas of existing timeline harmonization; and
PMRA and EPA are working to manage differences in timelines with the joint review projects.

Agreed to the content of the joint draft Confidential Statement of Product Specifications (CSPS) form:

Conducting pilot to populate new form using existing data; and
PMRA and EPA have begun discussions on the development of an electronic tool and shared portal.



Action Item 3 (continued): Address Obstacles to Joint Registration

Currently mapping registration processes to further harmonize approaches and timelines.

 Anticipate harmonizing business rules that are required for a joint IT strategy; and

•PMRA and EPA discussing opportunities for collaboration including submission formats and forms on all registration actions.



Action Item 4: Align Data Collection Processes and Procedures for Residue Trials

Initiated pilot project on development and use of harmonized report templates.

- Gap Analysis Complete, movement towards harmonization
 - Study Protocol Differences identified and adjustments being made to study protocol;
 - Raw Data Field Notebook implementing harmonization where possible for 2014 field season;
 - Analytical Summary Report IR-4 and PMC using same template; and
 - Final Report Joint PMC and IR-4 pilot projects completed using OECD template, to be submitted to EPA/PMRA later this year.



Action Item 4 (continued): Align Data Collection Processes and Procedures for Residue Trials Agreed to consider Canadian Priority Projects in the US prioritization.

- Currently dovetailing research (18 joint projects in 2013)
 - Outreach to Canada/US registrants, state and provincial representatives to identify potential joint projects;
 - Joint PMC/IR-4/registrant meetings taking place May-July, 2013 for 2014 planning;
 - IR-4/PMC Meeting in September to identify possible joint research projects for coming year and also meet with PMRA/EPA to determine joint review/work share plan for the coming year; and
 - IR-4/PMC committed to an increased emphasis on joint projects, possible movement towards a joint priority setting process with stakeholders.



Process for the next three months for ongoing alignment work

- Continue to work on tasks identified in the workplan and included input from stakeholder meeting.
- Regular consultation opportunities to seek input on specific tasks: e.g., Confidential Statement of Product Specifications form.
- Continue and expand the opportunities for joint Government (EPA / PMRA) and Industry (Canada & US) workplanning meetings.



Next steps and key issues

- Explore undertaking additional pilots (combining use expansions and MRL / tolerance establishment).
- Explore expanding scope to consider a US / Canada Information Technology Strategy.