# *Crop Protection Products Initiative*

**Webinar presentation**

**January 16, 2014**


*Health Canada*
*Marion Law, Chief Registrar*
*Registration Directorate*

*Environmental Protection Agency*
*Lois Rossi, Director*
*Office of Pesticide Programs*
*Registration Division*

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# RCC Path Forward

- An initial 29 item RCC Action Plan was announced in December 2011. We are now entering the final months of the initial Action Plan.
- In recent Canada Gazette and Federal Register consultations, PCO/OIRA received stakeholder submissions representing 160 organizations. Canada and the US are committed to another phase of work and are considering input received with Departments.
- Canada and the US will develop an outline of a forward plan for regulatory cooperation by the Spring, building on progress to date and lessons learned through the implementation of the initial Action Plan.
- Both governments plan to engage stakeholders in the development of the next phase of work

# Overview of the Crop Protection Products initiative

## Objective

- 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
- Development of approaches/processes to further align submission outcomes (e.g., pilot Minor Use submission)
- Alignment of data collection and reporting documentation for residue trials

# Progress update

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

Successfully completed a pilot project to register additional minor uses and establish MRLs/tolerances within the submission.

- Resulted in harmonized Maximum Residue Levels (MRLs), eliminating potential trade barriers;
- Resulted is shorter review time for import MRL review;
- PMRA and EPA agreed to use same principles in ongoing joint review projects; and
- The approach is being applied, as appropriate under the minor use joint review programs in EPA/PMRA.

# Progress update (cont.)

## Action Item 2: Develop Joint Guidelines for Residue Field Trials

- Developing joint principles for a field trial guideline;
- Agreed on the use of the proportionality concept under certain conditions as proposed at the 45th CCPR meeting of 2013; and
- Continue to develop harmonized crop groupings, resulting in the need for less residue data to support a greater number of crops.

# Progress update (cont.)

## Action Item 3: Address Obstacles to Joint Registration

Completed analysis of regulatory timelines for pesticide actions:

- Identified many areas of existing timeline harmonization;
- PMRA and EPA are working to manage differences in timelines with the joint review projects;
- Alignment between US-EPA and PMRA one-year storage stability study data requirements; and
- Leveraging of second entry joint review approach has alleviated impact of registration process differences, and to a degree, timeline differences between PMRA and EPA.

# Progress update (cont.)

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

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

- Completed a pilot to populate the new form using existing data; and
- The development of a wizard tool to support the CSPS has been initiated between EPA and PMRA.

Currently mapping registration processes to further harmonize approaches and timelines:

- Anticipate harmonizing business rules that are required for a joint IT strategy; and
- Efforts towards the alignment of IT Tools (such as a shared electronic submission gateway and a common e-CSPS wizard tool) have been initiated.

# Progress update (cont.)

## Action Item 4: Align Data Collection Processes and Procedures for Residue Trials (IR-4, PMC)

Documentation for data collection and reporting has been aligned to the extent possible.

- Final Reports aligned in OECD format pilot project and submitted to PMRA/EPA with registrant new active ingredient joint review.
- Aligned research protocols and raw data field notebooks to be implemented for the 2014 field trial season.
- PMC's new analytical laboratory completing their first final analytical report, based on IR-4 template.

# Progress update (cont.)

**Action Item 4 (continued): Align Data Collection Processes and Procedures for Residue Trials**

PMC and IR-4 continue to undertake minor use joint projects for joint regulatory review by PMRA/EPA.

- 15 new joint projects undertaken for 2014.
- PMRA/EPA workplan for 2014 joint regulatory reviews established.
- Continuing stakeholder engagement to encourage joint projects.

# Ongoing Alignment Work

Analysis of stakeholder feedback has highlighted key areas where continued regulatory cooperation could deliver significant benefits:

**Cooperation in product reviews and approval**

- Collaborate on aligning submissions, analysis, and approval processes

**Cooperation in regulatory system reliance**

- Reduce and eliminate duplicative requirements by recognizing success of each others' work

**Cooperation in regulatory standard-setting**

- Partner on regulatory standards development, and science guidance (e.g., 21st Century Toxicity Testing)

# Next Steps for Crop Protection Initiative

- Initiate discussions with project leads to review our accomplishments;
- Identify achievements under each action item that will be put in place as a result of the Action Plan;
- Engage stakeholders in this dialogue;
- Initiate discussions on exploring an EPA/PMRA cooperative agreement.

# Questions