Pest Management Regulatory Agency (PMRA) Priorities for 2012-2013

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Canada

Overview

- Pest Management Regulatory Agency (PMRA)
  - Mandate
  - Structure
- PMRA Priorities
- International Collaboration

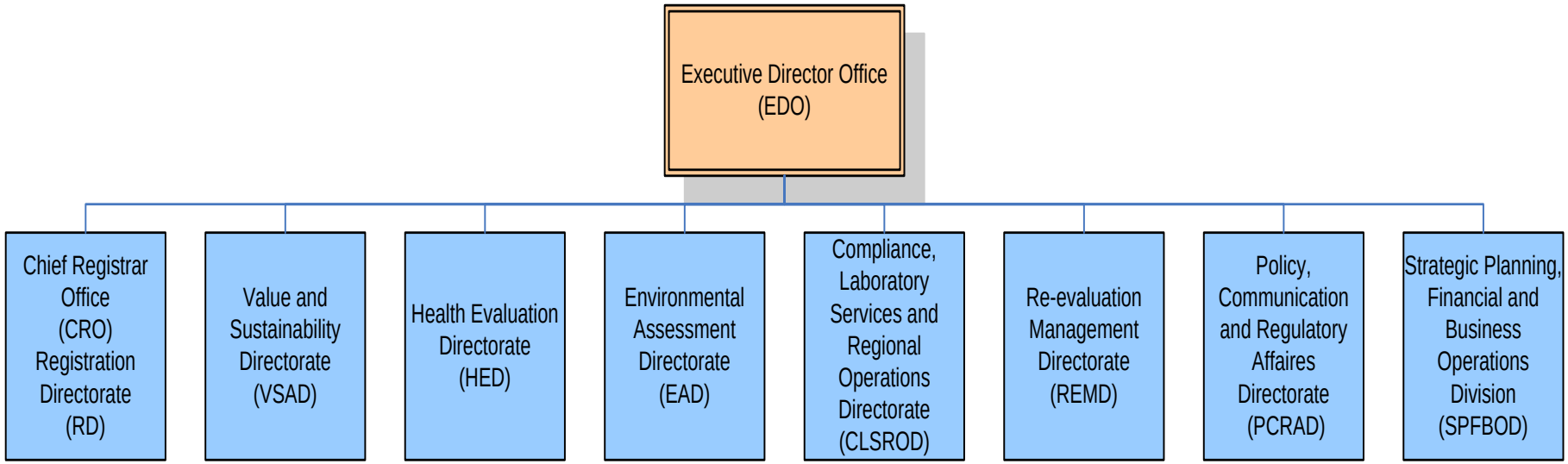
Pest Management Regulatory Agency (PMRA)

Mission:

- Protecting the health and environment of Canadians and supporting Canadian competitiveness by regulating pesticides and their use in an effective and transparent manner.
- Consistent with this, Health Canada's Pest Management Regulatory Agency:
  - Seeks to minimize health and environmental risks posed by pest control products and encourage the development and implementation of innovative, sustainable pest management strategies by facilitating access to pest control products that pose lower risks and by other appropriate measures;
  - Ensures that only those pest control products that are determined to be of acceptable value are approved for use in Canada
  - Supports sustainable development designed to enable the needs of the present to be met without compromising the ability of future generations to meet their own needs;
  - Encourage public awareness in relation to pest control products by informing the public, facilitating public access to relevant information and public participation in the decision-making process;

Pest Management Regulatory Agency (PMRA)

Structure:



Agency Priorities

- People
- Complete implementation of our regulatory change agenda
- Meet performance expectations on core regulatory activities
- Enhance science development to meet current and future regulatory needs

Complete Implementation of our Regulatory Change Agenda

- Change specific aspects of the submission management process to reflect a risk-based approach
  - E.g. Notification of specific product changes
- Streamline older chemicals program.
- Transform value assessment.
- Enhance our e-environment.

Meet Performance Expectations on Core Regulatory Activities

- Maintain strong international collaboration for joint reviews, work sharing, C&E activities
- Lead and/or participate in international regulatory activities through OECD, CODEX, NAFTA and Regulatory Co-operation Council (RCC)

Enhance Science Development to Meet Current and Future Regulatory Needs

- Strong international collaboration
- Priorities for health and environment
- 6NR partnerships (Canadian)
  - Research and monitoring

International Collaboration

Regulatory Co-operation Council (RCC)

- Prime Minister Stephen Harper and President Barack Obama created the U.S. – Canada Regulatory Cooperation Council (RCC) on February 4, 2011.
- The RCC released the Joint Action Plan on Regulatory Cooperation on December 7, 2011 (www.trade.gov/rcc)
- The RCC hosted an outreach event in Washington, DC January 30-31, 2012
- The RCC made draft work plans for each of the 29 initiatives available for public comment until mid-February.
- Comments have been incorporated and final work plans will be released shortly

Regulatory Co-operation Council (RCC)

Outcome – Crop Protection Products:

Goal:	Facilitate equal access to products and uses in both countries, align maximum residue limit (MRLs)/tolerances where possible.
Approach:	Identify mechanisms to encourage registrants/applicants to submit applications for joint regulatory review to Canada and the US that include increased numbers of minor uses.

Regulatory Co-operation Council (RCC)

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

Goal: Address the technology gap and trade irritants.

Approach:
- Obtain simultaneous receipt of application packages and fully aligned labels.
- Develop one joint workplan for all actions related to use expansions.

Regulatory Co-operation Council (RCC)

Action Item 1: Tasks

3-6 Months:

- Conduct outreach to stakeholder community.
- Initiate planning and submission of a joint pilot application that includes minor uses and import MRLs.

6-12 Months:

- Joint review of data supporting pilot application.
- Continue dialogue with stakeholder community:
  - Work to resolve barriers to joint applications and use expansions, and
  - Initiate discussions on development of incentives process and criteria for joint applications and use expansions.

Regulatory Co-operation Council (RCC)

Action Item 1: Tasks, cont.'d

- 12-18 Months:
  - Complete review of the pilot application and prepare decision documents.

- 18+ Months:
  - Evaluate pilot application.
  - Consider feasibility of including import MRLs in minor use applications.
  - Measure success, e.g. number of joint uses, aligned MRLs, product availability in U.S. and Canada.

Regulatory Co-operation Council (RCC)

Action Item 2: Develop Joint Guidelines for Residue Trials

Goal: Move towards each country/agency accepting the other's review resulting in concurrent, aligned decisions.

Approach:

- Maximize the reliance on and acceptance of food safety data (e.g. food residues) generated in either the U.S. or Canada to support regulatory decisions in both countries.

- Develop joint guidelines for generation of residue field trial studies to support registration in the United States and Canada.

Regulatory Co-operation Council (RCC)

Action Item 2: Tasks

- 3-6 Months:
  - Review existing/ongoing residue field trial data generation to determine priorities for submission of joint reviews and use expansion.
  - Continue development of harmonized crop groups to leverage least amount of data to maximum number of crops/uses.
  - Establish workgroup to explore concept of proportionality of pesticide residues.

Regulatory Co-operation Council (RCC)

Action Item 2: Tasks, cont.'d

- 6-12 Months:
  - Establish workgroup to consider exchangeability and translation of field trial residue data among regions and between countries.
  - Develop principles for a joint field trial guideline.
  - Analyse results of proportionality project and if possible, establish criteria to support use of this concept to support registration.
  - Initiate and complete legislative process to adopt policy or regulatory changes in both countries.

Regulatory Co-operation Council (RCC)

Action Item 2: Tasks, cont.'d

- 12-18 Months:
  - Pilot a program between PMC & IR-4 and registrants to develop residue field trial data based on principles established and reflected in the joint guidelines.
  - Continue development of harmonized crop groups.
- + 18 Months:
  - Data from pilot program to be submitted to EPA/PMRA for review and evaluation for acceptability.
  - Implement joint field trial guideline.
  - Consider development of harmonized guidance for all commodities.

Regulatory Co-operation Council (RCC)

Action Item 3: Address Obstacles to Joint Registration

Goal: Eliminate regulatory obstacles preventing the joint submission and registration of pest control product applications into the US and Canada.

Approach:
- Identify flexibilities in regulatory processes and procedures.
- Enhance the use of existing tools to measure progress.
- Develop new opportunities to align EPA and PMRA work and workplans.

Regulatory Co-operation Council (RCC)

Action Item 3: Tasks

- 3-6 Months:
  - Initiate analysis of current registrations processes in each country to identify areas that are not aligned.
  - Identify guidance documents, directives, and policies which could be revised to better align registration processes in both countries.
  - Develop a process/strategy/governance structure for working through issues.
  - Explore further aligning of positions going to CODEX.

Regulatory Co-operation Council (RCC)

Action Item 3: Tasks, cont.'d

- 6-12 Months:
  - Develop a process/strategy to identify and address existing technology gaps and trade irritants.
  - Discuss development of joint guidances/directives which will align registration processes and also meet the legislative requirements in both countries.
  - Develop alignment, action plan and timelines to develop/revise documents identified above.

Regulatory Co-operation Council (RCC)

Action Item 3: Tasks, cont.'d

- 12-18 Months:
  - Obtain input and feedback from stakeholders.
  - Explore feasibility of process change to product re-evaluation.

- 18+ Months:
  - Develop and implement aligned regulatory processes and establish on-going governance structure to oversee the new approach.
  - Measure success by evaluating number of uses, new active ingredients, status of trade irritants and technical gaps using existing tools such as the Grower Priority Database.

Regulatory Co-operation Council (RCC)

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

Goal: PMC or IR-4 to lead the generation of residue data, and each country/agency accepts these data.

Approach: Align data generation priorities, reporting processes and workplan, to the fullest extent possible, in order to support increased numbers of joint reviews of minor use expansions.

Regulatory Co-operation Council (RCC)

Action Item 4: Tasks

- 3-6 Months:
  - Initiate gap analysis of data collection procedures to identify key differences between US and Canadian residue study protocols and final reports.
  - PMC and IR-4 initiate alignment of workplan for joint projects for joint review by EPA/PMRA including outreach to stakeholders to identify priorities.
  - Review the possibility of combining efficacy field trials and residue field trials.

Regulatory Co-operation Council (RCC)

Action Item 4: Tasks, cont.'d

- 6-12 Months:
  - Conduct ongoing gap analysis of data collection procedures to identify key differences between US and Canadian raw data field notebook (RDFN) and analytical summary report and obtain agreement on aligning data collection procedures and reporting.
  - Develop options for aligning the workplan for joint projects for joint review by EPA/PMRA including vision of moving toward joint priority setting.

Regulatory Co-operation Council (RCC)

Action Item 4: Tasks, cont.'d

- 12-18 Months:
  - Complete gap analysis of data collection procedures and conduct pilot on joint residue study.
  - Align workplan for joint projects for joint review by EPA/PMRA.
  - Achieve agreement on data collection procedures and reporting to fullest extent possible.
- 18+ Months:
  - Ongoing work towards alignment of workplans for joint projects for joint review.
  - Maintain ongoing dialogue to ensure alignment is maintained.
  - Develop the process for holding a joint food use workshop.
  - Hold joint food use workshop (long-term; must allow time for process).

Regulatory Co-operation Council (RCC)

Ongoing Actions

- PMRA and EPA working on a pilot application:
  - Aligned joint submission,
  - New uses and MRLs/tolerances
  - Look at “peer review” approach
- PMRA and EPA working on common CSF/Product Specification Form.
- PMRA working towards PRIA 3 timelines PMRA considering streamlining their value assessment to focus more on value than efficacy.

Regulatory Co-operation Council (RCC)

Ongoing Actions, cont.'d

- Stakeholder Outreach:
  - Hold stakeholder conference calls
  - Develop a communication strategy to proactively address potential issues
  - Attend existing stakeholder meetings:
    - Crop Life Canada (May 9, 2012) and Crop Life America: Spring Conference (April 5-6, 2012) and Registration Committee (April 10, 2012)
    - Minor Crop Farmer Alliance (March 14, 2012)
    - Canadian Horticulture Council (March 13, 2012)
    - Minor Use Priority Setting Meetings (March 19-22, 2012)
    - Canadian Federation of Agriculture (February 21, 2012)
  - Look for opportunities to engage stakeholders in the Action item