Crop Protection Products Working Group: Crop Protection Products Work Plan

Canada Lead: Richard Aucoin, Executive Director, Pest Management Regulatory Agency (PMRA), Health Canada
U.S. Leads: Steven Bradbury, Director, Office of Pesticide Programs, Environmental Protection Agency (EPA)

Deliverable outcome	Identify mechanisms to encourage registrants to submit applications for joint regulatory review to Canada and the US that include increased numbers of minor uses. This will help facilitate equal access to products and uses in both countries, as well as align maximum residue limits (MRLs)/tolerances where possible, in cases where the application is based on data generated with Canadian or US government support on minor uses and specialty crops. The goal is to facilitate equal access to effective means of pest control in both countries as well as to align MRLs whenever possible. Building on existing collaboration and ongoing work between Canada and the United States related to approval of Crop Protection Products, the PMRA and EPA will produce a document that provides a high-level overview of the process that led to the current level of cooperation in joint regulatory product review and approval developed between Canada and the United States. The paper will include how greater regulatory cooperation might occur including reliance on the outcomes achieved through each others regulatory system, and a framework outlining an ongoing systemic mechanism to align Canada-United States approaches to product review and approvals for crop protection products. Stakeholder Outreach: - Hold quarterly stakeholder conference calls - Develop a communication strategy to proactively address potential issues			
Action Items	**Action Item 1: Encourage Joint Submission of Use Expansions and Fully Aligned Labels** Building on the already established process of joint EPA/PMRA pesticide reviews, and in order to eliminate technology gaps and trade irritants, PMRA and EPA will work toward the simultaneous receipt of fully aligned labels and submission packages and the development of one joint submission workplan for all actions related to use expansions.	**Action Item 2: Develop Joint Guidelines for Residue Trials** To maximize the reliance on and acceptance of food safety data generated in either country to support regulatory decisions, PMRA and EPA will develop joint guidelines for generation of residue field trial studies. Ultimately, each country/agency could accept the other's review; and the review would result in concurrent, aligned Decisions.	**Action Item 3: Address Obstacles to Joint Registration** Building on already established cooperation on the joint review of pesticides (NAFTA joint reviews and global reviews), PMRA and EPA will eliminate regulatory obstacles preventing the joint submission of pesticide applications into the US and Canada by identifying flexibilities in regulatory processes and procedures, enhancing the use of existing tools (e.g, databases) to measure progress, and developing new opportunities to align EPA and PMRA work, workplans, and regulatory	**Action Item 4: Align Data Collection Processes/Procedures for Residue Trials** In order to support increased numbers of joint reviews of minor use expansions in PMRA and the EPA, Pest Management Center (PMC) and IR-4 will align priorities, procedures, and regulatory agendas to the fullest extent possible, including data collection and reporting processes and workplans. As for Action Item 2, this alignment would mean that either PMC or IR-4 could lead the development of the

IR-4: Formerly Inter-Regional Research Project Number 4 (IR-4 Project), also referred to as the Minor Crop Pest Management Program.
PMC: Pest Management Center, Agriculture and Agri-Food Canada

			agendas.	residue data; each country/agency could accept the other's review; and the review would result in concurrent, aligned decisions (either registration and MRLs in both countries, or registration and MRL in one country with an MRL in the other).
	Interim Deliverables			
3-6 Months	**Tasks:** • Conduct outreach (e.g., a summit) to registrant community to discuss the joint submission of use expansions. The summit would include such topics as: o Identification of barriers; o Potential incentives; o Submission of shared labeling (NAFTA label); o Joint planning; and o Formal submission processes. **EPA and PMRA** • Initiate the planning and submission of a pilot application of an aligned joint submission for a use expansion that includes a significant number of minor uses and domestic and import MRLs/ tolerances. Pilot application will use IR-4/PMC data. December 2011 spirotetramat submission will serve as this pilot. **EPA, PMRA, IR-4, PMC**	**Tasks:** • Review existing and ongoing work to determine highest value priorities for future joint review of use expansions. **PMRA and EPA** • Continue the development of harmonized crop groups to leverage least amount of data to the maximum number of crops/uses. **PMRA, EPA, IR-4, and PMC** • Establish a PMRA/EPA workgroup to explore the concept of proportionality of pesticide residues. **PMRA and EPA**	**Tasks:** • Initiate analysis of current registration in each country to identify areas that are not aligned, including submission formats, application forms, product specification forms. **PMRA and EPA** • Identify guidance documents, directives, and policies which could be revised to align registration processes which occur in both Canada and US. (See also Action Item 1 – registrant community outreach) **PMRA and EPA** • Develop a process/strategy/governance structure for addressing roadblocks, elevating issues, and working through barriers. These barriers can include disharmonized processes and/or differences in decisions, policies, regulations and laws. **PMRA and EPA** • Explore further aligning positions to Codex. **PMRA and EPA**	**Tasks:** • Initiate gap analysis of data collection procedures to identify key differences. **PMRA, EPA, PMC and IR-4**: o Identify differences between US and Canadian study protocols and final residue reports. o Confirm adoption of OECD field trial template for final study report. • Initiate alignment of workplan for joint projects for joint review by **EPA/PMRA PMC and IR-4**: o Actively outreach to stakeholders to identify priorities and potential joint projects. o Explore the possibility of holding a joint food use workshop. • Review the possibility of combining efficacy field trials and residue field trials. **PMC**
6-12	• Jointly review IR-4/PMC data supporting the pilot application over a	• Establish a PMRA/EPA workgroup to consider:	• Using the analysis of current registration in each country, construct	• Ongoing gap analysis of data collection procedures to identify key

IR-4: Formerly Inter-Regional Research Project Number 4 (IR-4 Project), also referred to as the Minor Crop Pest Management Program.
PMC: Pest Management Center, Agriculture and Agri-Food Canada

Months	negotiated timeline of 15 months. **PMRA and EPA** • Based on the results of initial registrant community outreach efforts, work internally and with stakeholders to resolve barriers to joint submission of use expansions, product amendments, and shared labels. **PMRA and EPA** • Initiate discussions on the development of an incentives process for joint submission of use expansions, including the possible assignment of a certain regulatory status or classification (e.g., a RCC registration), if certain criteria are met (i.e., use expansions and registrations are submitted jointly; shared labeling; etc…). **PMRA and EPA** • Develop the criteria for an incentive process and identify submissions that may qualify to be considered as pilots. **PMRA and EPA**	○ The exchangeability and translation of food safety data among regions and between countries and consider the 'Single Region' concept for the design and execution of residue trials in US and Canada**.** ○ Developing the principles of a joint field trial guideline. **PMRA and EPA** • Analyze the results of the determination of proportionality projects to establish criteria for use of these concepts to support registration. **PMRA and EPA** • Initiate and complete the appropriate legislative process required to adopt policy or regulatory changes in both countries (e.g. change to crop grouping, policy on adoption of food safety data, etc.). **PMRA and EPA**	a plan to move towards alignment. **PMRA and EPA** • Develop a process/strategy to identify and address existing technology gaps and trade irritants, particularly those identified in the US/Canada Grower Priority Database. **PMRA and EPA** • Initiate discussions of the feasibility of developing joint guidances, directives which meet the legislative needs of both countries but align registration processes. **PMRA and EPA** • Develop action plan and timelines to revise documents identified in above tasks. **PMRA and EPA**	differences. - Identify differences between US and Canadian raw data field notebook (RDFN) and analytical summary report. - Obtain agreement on aligning data collection procedures and reporting; undertake more joint projects. **PMRA, EPA, IR-4 and PMC** • Develop options for aligning the workplan for joint projects for joint review by EPA/PMRA: - IR-4 and PMC: Introduce to stakeholders at 2012 individual food use workshops the vision of moving towards holding a joint food use workshop. **PMRA, EPA, IR-4 and PMC**
12-18 Months	• Review the pilot submission. Hold team meetings between EPA and PMRA evaluators to discuss science findings, make decisions in both countries, and prepare decision documents. Discuss feasibility. **PMRA and EPA**	• Pilot a program between PMC and IR-4 and registrants to develop residue field trial data on commodity/commodities based on draft guideline principles and recommendations from the PMRA/EPA workgroup. **PMRA, EPA, IR-4, and PMC** • Continue the development of harmonized crop groups. **PMRA and EPA**	• Engage stakeholders to obtain feedback and input. See also Action Item 2 and stakeholder outreach. **PMRA and EPA** • Explore feasibility of process change to re-evaluation of pest control products. **PMRA and EPA**	• Complete gap analysis of data collection procedures to identify key differences: - Hold pilot for implementing alignment on joint residue studies. **PMC and IR-4** • Align the workplan for joint projects for joint review by EPA/PMRA: - Determine feasibility and potential options for holding a joint food use workshop through

IR-4: Formerly Inter-Regional Research Project Number 4 (IR-4 Project), also referred to as the Minor Crop Pest Management Program.
PMC: Pest Management Center, Agriculture and Agri-Food Canada

				consultation with stakeholders. - EPA/PMRA develop a joint screening process for review of projects prior to workshop. - Undertake more joint projects. **PMRA, EPA, IR-4 and PMC** • Achievement of agreement on data collection procedures and reporting to the fullest extent possible. **PMRA and EPA**
Beyond 18 Months	• Evaluate the successes and potential improvements to the pilot submission. Identify challenges, obstacles, and areas to improve the approach. Determine the feasibility of adopting this approach as a best practice. **PMRA and EPA** • Measure successes by evaluating the number of uses established jointly currently and after 12-18 months and the current status of trade irritants and technical gaps [using existing tools, such as the grower priority databases and MRL databases]. **PMRA and EPA**	• Data generated by pilot project submitted to EPA/PMRA for review and evaluation for acceptability (long-term; must allow time for data generation). **PMC and IR-4 and registrants** • Implement joint field trial guideline. (long-term; must allow time for approval process in both countries) **PMRA and EPA** • Consider development of harmonized guidance for all commodities. **PMRA and EPA**	• Develop a governance structure and a framework which outlines an ongoing systemic mechanism to ensure that Canada-United States approaches to product reviews and approvals for crop protection products are aligned. The framework will include key elements such as, building and maintaining relationships, common programming, work-sharing and joint reviews, collaboration on the analysis, testing and standard setting procedures for OECD and cooperation in international fora. • Measure successes by evaluating the number of uses, new active ingredients registered, and the current status of trade irritants and technical gaps [using existing tools, such as the grower priority databases and MRL databases]. **PMRA and EPA**	• Ongoing work towards alignment of workplans for joint projects for joint review by **PMRA, EPA, IR-4 and PMC.** • Maintain ongoing dialogue to ensure alignment is maintained (i.e. If one country wants to make a change or international standards change). **PMRA, EPA, IR-4 and PMC** • Develop the process for holding a joint food use workshop. **PMC and IR-4** • Hold joint food use workshop (long-term; must allow time for process). **PMC and IR-4**

IR-4: Formerly Inter-Regional Research Project Number 4 (IR-4 Project), also referred to as the Minor Crop Pest Management Program.
PMC: Pest Management Center, Agriculture and Agri-Food Canada

Contact Information:

Marion Law, PMRA: marion.law@hc-sc.gc.ca, 613-736-3705
Lois Rossi, EPA: rossi.lois@epa.gov, 703-305-5447
Manjeet Sethi, PMC: Manjeet.Sethi@agr.gc.ca, 613-759-7431
Jerry Baron, IR-4: jbaron@AESOP.Rutgers.edu, 732-932-9575

IR-4: Formerly Inter-Regional Research Project Number 4 (IR-4 Project), also referred to as the Minor Crop Pest Management Program.
PMC: Pest Management Center, Agriculture and Agri-Food Canada