Department/ Agency	United States	Canada
	US Environmental Protection Agency – Office of Pesticide Programs	Health Canada – Pest Management Regulatory Agency

Regulatory Area to be Addressed	**Pesticides**
	The US Environmental Protection Agency's (US EPA) Office of Pesticide Programs (OPP) and Health Canada's Pest Management Regulatory Agency (PMRA) are working together to: A. Collaborate on a bilateral pesticide re-evaluation for three neonicotinoid pesticides (i.e., imidacloprid, thiamethoxam, and clothianidin) employing a new pollinator risk assessment framework B. Develop best practices for coordinated work planning for the re-evaluation of registered pesticides C. Develop new and/or alternative approaches to testing and assessment, including reducing the need for animal testing wherever possible D. Align pesticide residue trial requirements by prospectively determining the number of residue field trials required for joint registrations E. Jointly develop information technology solutions that facilitate the submission of applications to either regulatory authority

Work Stream A	**Pollinator Protection and the Neonicotinoid Pesticides** The US Environmental Protection Agency's Office of Pesticide Programs (OPP) and Health Canada's Pest Management Regulatory Agency (PMRA) are collaborating on a bilateral pesticide re-evaluation for three neonicotinoid pesticides (i.e., imidacloprid, thiamethoxam, and clothianidin) employing a new pollinator risk assessment framework. This collaboration provides for a more efficient use of limited resources and furthers the collective ability to continue to protect pollinators.

Progress to Date
On January 6, 2016, a joint progress report for the pollinator risk assessment of the neonicotinoid insecticides, and the first preliminary pollinator risk assessment for imidacloprid were published by PMRA and the US EPA.

Next Steps	July 2016 to December 2017

The EPA and PMRA will continue to collaborate on a bilateral pesticide re-evaluation process for three neonicotinoid pesticides (i.e., imidacloprid, thiamethoxam, and clothianidin) with a focus on pollinator protection.
 	
Planned deliverables include:
• Complete the risk assessments and mitigation actions for neonicotinoids through joint PMRA-EPA efforts
• Collaborate in preparing:
  ○ A revised pollinator risk assessment for imidacloprid, incorporating additional data and comments received, targeted for joint publication in December 2016
 	
  ○ Preliminary pollinator risk assessments for clothianidin and thiamethoxam, targeted for joint publication in December 2016
 	
  ○ Revised pollinator risk assessments for clothianidin and thiamethoxam, incorporating additional data and comments received, targeted for joint publication in December 2017
	December 2016
	
	December 2016
	
	December 2017

Work Stream B	**Pesticide Re-evaluation** Both PMRA and EPA produce multi-year re-evaluation/registration review schedules, in order to inform stakeholders and manage science and regulatory workload. PMRA and EPA may benefit from aligning, within the constraints of their respective legislative requirements, the timing of key science work for certain pesticides. Scheduling of collaborative work would allow for more efficient planning with respect to data requests, efficiencies in review of studies and relevant scientific literature.

Planned Initiatives	July 2016 to 2018
Identification of 2-3 existing chemicals to be used as pilots for the purpose of developing best practices for collaboration.	Fall 2016
Development of best practices for closer alignment on the periodic re-evaluation of existing chemicals, which defines which steps in the process are most appropriate for alignment, using the 2-3 identified existing chemicals as pilots.	2018

Longer Term Goals	
Publish the best practices document once the pilot chemicals are sufficiently advanced. Identify and publish a schedule of collaborative reviews, using the best practices.	2019 – 2020

Work Stream C	**Integrated Approach to Testing and Assessment (IATA)** There is widespread agreement that a reduction in the number of animals used and the refinement of testing to reduce suffering should be important goals in the development and implementation of testing methods that avoid the use of live animals. The Guiding principles for more ethical use of animals in testing are the Three Rs (3Rs), namely, reduce, refine and replace animal testing. These principles are now followed in many testing establishments worldwide. Health Canada's Pest Management Regulatory Agency and the US Environmental Protection Agency's Office of Pesticide Programs (OPP) continue to be part of ongoing efforts focused on developing new and/or alternative approaches to testing and assessments. This includes reducing the need for animal testing wherever possible while continuing to be health-protective. The project will build upon the concept of the 3Rs: reduce, replace or refine animal studies, to the extent possible, by focusing efforts on developing new guidance on alternate approaches to acute toxicity testing in animals.

Planned Initiatives	July 2016 to 2018
Initiative A: Guidance on Waiving Acute Dermal Toxicity Tests for Pesticide Formulations	
US EPA and the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods conducted a retrospective analysis of oral and dermal acute lethality studies relevant to EPA's regulation of pesticides and developed a draft waiver guidance.	Completed

PMRA will assess the US EPA document, which was circulated for external comments in March 2016, from the Canadian Regulatory perspective.	2016
Finalize a US EPA-PMRA guidance document on this topic.	2017
The joint approach will also provide an opportunity for both Agencies to consider submitting such guidance to the OECD for the development of an international guidance document on this topic.	Date to be developed with OECD
Initiative B: In vitro Alternative Assays Analysis – Eye Irritation and Skin Sensitization	
Assess existing data in order to determine the potential utility of in vitro methods in place of the currently-required in vivo tests.	2016 – 2017
Develop and consult on draft joint guidance document(s).	2017
Finalise and publish joint guidance document(s).	2018

Longer Term Goals
Expand the use of alternative methods of testing for acute oral, dermal, and inhalation toxicity, along with skin and eye irritation and skin sensitization (often collectively referred to as the “six pack studies”).

Work stream D	**Alignment of Pesticide Residue Trial Requirements** As part of the assessment process prior to the registration of a pesticide, both Health Canada and the US Environmental Protection Agency must determine whether the consumption of the maximum amount of residues that are expected to remain on food products when a pesticide is used according to label directions will not be a concern to human health. A process which can support simultaneous domestic registrations in both Canada and the United States to further align the data requirements and the establishment of Maximum Residue Limits (MRLs) will be beneficial to facilitate trade while protecting public safety. Building upon the first phase of the RCC projects, particularly in regards to the initiative of further aligning the establishment of maximum pesticide residue limits/tolerances in both countries, Health Canada's Pest Management Regulatory Agency together with the US Environmental Protection Agency's Office of Pesticide Programs (OPP) have now initiated a new project under this initiative. This project is designed to prospectively determine the number of residue field trials required for joint registrations.

Planned Initiatives	July 2016 to 2017
Initiative A: Streamline / Reduce Residue Field Trial Requirements to support Joint Projects between Canada and the United States	
Re-assess Canadian and US field trial requirements for representative crops in the NAFTA Residue Chemistry Crop Groups based on total combined Canadian and US Production statistics to allow more efficient use of resources for both the minor use program and pesticide registrants, and to encourage more joint US/Canadian registrations.	2016
Develop and consult on a draft joint guidance document.	2016
Finalise and publish a joint guidance document.	2017
Initiative B: Streamline Residue Chemistry Data Requirements for Seed Treatment Uses and Potato Seed-Piece Applications	
Conduct a retrospective analysis of all seed treatment residue data that have been submitted to PMRA/US EPA.	2016
Develop a tiered approach to data requirements to streamline existing residue chemistry data requirements, where possible.	2016
Develop and consult on a draft joint guidance document.	2016
Publish joint guidance document.	2017

Longer Term Goals	
Explore the utility of sharing and/or incorporating the science-policy work/concepts related to field trial data, developed under RCC, into either existing or new projects at the international level (e.g., OECD).	Date to be developed with OECD

Work Stream E	**Joint IT Solutions** The US Environmental Protection Agency's Office of Pesticide Programs (OPP) and Health Canada's Pest Management Regulatory Agency (PMRA) are working together to jointly develop information technology solutions that facilitate the submission of applications to either regulatory authority. The solutions include an eDossier Builder based on the OECD Global Harmonised Submission Transport Standard (GHSTS) which will support common applications at a global level, and electronic software to enhance and facilitate the entry of data into the Electronic Confidential Statement of Product Specifications form (eCSPS).

Progress to Date
Initiative A: eDossier Builder
The Alpha version of the eDossier Builder was completed in March 2015 with input from the OECD working group, including members from PMRA and EPA.
Reference build-version development, with periodic review by the OECD working group, is currently proceeding and will be presented at the OECD Working Group on Pesticides meeting in late June 2016
Initiative B: CSPS Software Development for Electronic Submission
PMRA and EPA validated the data dictionary and functional requirements for the development of an electronic Confidential Statement of Product Specifications (eCSPS) builder tool.

Next Steps	July 2016 to Spring 2017
Initiative A: eDossier Builder	
The Reference build-version is expected to be completed by May 2017.	May 2017
Implementation steps include communication and training on the tool, as well as an IT project to integrate it internally into PMRA's Electronic Pesticide Regulatory System (ePRS). The EPA is also considering integration options to receive GHSTS packages.	May 2017
Initiative B: CSPS Software Development for Electronic Submission	
PMRA will continue working with the EPA as development of the tool will begin in Summer 2016, beginning with the selection of an approved contractor.	Summer 2016
Once a contractor is selected, the first deliverable will be a detailed project plan, compete with key milestones and timeframes for the anticipated 6-month project.	Fall 2016
Once a beta-version of the tool is available, PMRA and EPA will collectively plan and perform a pilot with external stakeholders and determine a potential implementation/release strategy based on comments and test results.	Spring 2017