

2019-2020 RCC Work Plan: Pesticides

Canadian Department: Health Canada, Pest Management Regulatory Agency

United States Department/Agency: Environmental Protection Agency, Office of Pesticides Program

Regulatory Cooperation Statement:

Health Canada's Pest Management Regulatory Agency (PMRA) and the United States (U.S.) Environmental Protection Agency's (EPA) Office of Pesticide Programs (OPP) are working together to foster an atmosphere of ongoing cooperation, collaboration, and regular communication to better align regulatory approaches in the following areas:

- A. Alignment of Pesticide Residue Chemistry
- B. Joint Review (JR) Process Improvements (New Chemicals/Uses)
- C. Pesticide Re-evaluation and Post-Market Joint Reviews
- D. Pollinator Protection and Neonicotinoid Pesticides
- E. Pest Control Emerging Technologies
- F. New Approach Methodologies (NAMs)
- G. Emerging Pesticide Issues

Work Plan:

Initiative	Desired outcome(s)	Activities	Reporting
Workstream A: Alignment of Pesticide Residue Chemistry [by harmonizing use of the Organization for Economic Cooperation and Development (OECD) Maximum Residue Limit (MRL) Calculator]	Further development of joint standardized requirements that assist in establishing and aligning maximum residue limits.	<ul style="list-style-type: none">• A set of case studies will be documented by Canada and the U.S. to determine reasons for non-harmonized Crop Group MRLs within North America to eventually enable development of a standardized and consistent method for determining Crop Group MRLs.	

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		<ul style="list-style-type: none"> • An MRL calculator project is ongoing between Canada and the U.S. in order to align OECD MRL calculator inputs, which would lead to harmonized MRL values. <ul style="list-style-type: none"> ○ Since the Exchangeability / Interchangeability of Field Trial data between geographic regions has been demonstrated, development and implementation of policies surrounding Exchangeability is anticipated to be explored to further support alignment. In addition, input policies related to field trials with side-by-side designs, with non-independent results, and/or conducted in support of tolerance/MRL listings for crop groups is anticipated to be developed. 	
<p>Workstream B:</p> <p>Joint Review (JR) Process Improvements (New Chemicals/Uses)</p>	<p>Harmonization in the timing of key scientific work for certain pesticides, where possible.</p>	<p>Scheduling of collaborative work would allow for more efficient planning with respect to data requests, and efficiencies in review of studies and relevant scientific literature.</p> <ul style="list-style-type: none"> • Continuing to review JR procedures as well as requirements, evaluation criteria, timing, etc. • Based on “lessons learned”, pilots identified as per previously identified efficiency improvement measures. • Two pilot projects (initiated October-November 2017) are currently underway: broflanilide and inpyrfluxam. As new active ingredients (AIs) are 	

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		<p>submitted for JR, the teams should evaluate the appropriateness of collaborating under the pilot as opposed to a full formal JR.</p> <ul style="list-style-type: none"> • Progress is being made on identified “efficiency improvement measures” – outcome of pilots will inform next steps. 	
<p>Workstream C:</p> <p>Pesticide Re-evaluation and Post-Market Joint Reviews (JRs)</p>	<p>Harmonization in the timing of key scientific work for certain pesticides, where possible.</p>	<p>PMRA and EPA continue discussions with respect to work sharing of re-evaluation/re-registration of active ingredients.</p> <ul style="list-style-type: none"> • Ongoing discussions/ cooperation between PMRA and EPA with respect to work-sharing of re-evaluation/re-registration of active ingredients to align the timing of key science work for certain registered pesticides when possible. • Scheduling of collaborative work under consideration, in particular for the next round of re-evaluation (post-2022), which would allow for more efficient planning with respect to data requests, and efficiencies in review of studies and relevant scientific literature. 	
<p>Workstream D:</p> <p>Pollinator Protection and Neonicotinoid Pesticides</p>	<p>Ongoing cooperation, collaboration, and regular communication.</p>	<ul style="list-style-type: none"> • PMRA and EPA/CalDPR will continue to collaborate on the pollinator re-evaluation of the neonicotinoid pesticides where possible. • Working together, every effort will be made to provide timely information to each other ahead 	

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		<p>of any major announcements, publication of risk assessments, or regulatory decisions pertaining to the neonicotinoid pesticides where possible.</p>	
<p>Workstream E:</p> <p>Pest Control Emerging Technologies (including RNA interference [RNAi], genetically-modified mosquitoes, etc.)</p>	<p>Increased efficient planning and international collaboration, with respect to regulatory approaches and data requirements/requests.</p>	<p>Continue to evaluate novel technologies (e.g., RNAi-based pesticides, genetically-modified mosquitoes) and build upon the input from their respective Science Advisory Panel meetings, informing each other of developments. (Note: EPA is the lead on genetically-modified mosquitoes).</p> <ul style="list-style-type: none"> • <u>RNAi-based pesticides</u>: PMRA and EPA to continue to work collaboratively through the OECD Expert Group on RNAi Pesticides, with initial efforts focusing on the environmental impact of RNAi pesticides (e.g., development of a working document “Effects on Non-target Organisms from Exposure to RNAi-based pesticides and Environmental Fate”). 	
<p>Workstream F:</p> <p>New Approach Methodologies (NAMs) (including Integrated Approach to Testing and Assessment (IATA))</p>	<p>Further expansion of the use of alternative methods of testing for acute oral, dermal, and inhalation toxicity, along with skin and eye irritation and skin sensitization (collectively referred to as the “six pack studies”)</p>	<ul style="list-style-type: none"> • <u>NAMs/IATA: (skin sensitization, eye and skin irritation)</u>: <ul style="list-style-type: none"> ○ PMRA and EPA continue involvement with a multi-stakeholder initiative on the potential utility of in-vitro alternative assays analysis for eye and skin irritation. ○ PMRA and EPA are actively involved with OECD’s proposal for developing a New Performance Based Test Guideline (PBTG) for defined approaches and test methods for skin sensitization. The PMRA also provided 	

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		<p>input on the EPA’s Interim Science Policy: Use of Alternative Approaches for Skin Sensitization as a Replacement for Laboratory Animal Testing, which was published for public comment on April 4, 2018.</p> <ul style="list-style-type: none"> ○ EPA is in the process of finalizing and posting the Guidance for Waiving Acute Dermal Toxicity Tests for Pesticide Technical Chemicals and Supporting Retrospective Analysis. This guidance allows EPA to harmonize with PMRA which published guidance on dermal waivers for both formulations and technical chemicals in 2017. ● <u>Other potential items for collaboration:</u> <ul style="list-style-type: none"> ○ Explore waiver criteria for cancer bioassays; PBPK modelling and other newer assessment techniques (e.g., Tox 21, integration of in vitro vs in vivo testing in risk assessments); capacity building towards application of new technologies. ○ Risk Communication: Canada and U.S. need to provide a strong foundation and understanding for the use of Tox 21 and use of in vitro assays to gain stakeholder support and public confidence. Explore possibility of 	

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		<p>using Tox 21 in the traditional risk assessment and integrate in vitro in hazard process to show proof of concept.</p> <ul style="list-style-type: none"> ○ EPA recently released final waiver guidance for sub-acute avian dietary studies supported by a retrospective analysis that shows the study provides little regulatory value in the majority of pesticide cases. Consider additional areas of cooperation and communication specific to ecological risk assessment. 	
<p>Workstream G:</p> <p>Emerging Pesticide Issues (including hemp production, drone technology, etc.).</p>	<p>Ongoing cooperation, collaboration, and regular communication.</p>	<ul style="list-style-type: none"> • <u>Hemp</u>: Hemp production in the U.S. is now a legal crop and has been legal for a number of years in Canada (for fiber production). U.S. is committed to providing updates on hemp related issues. • <u>Drones - unmanned aerial vehicles (UAVs)</u>: Canada is currently a member of the OECD Working Subgroup on drones/unmanned UAVs and is also participating in a Canadian working group on drones. Both working groups are gathering appropriate information to inform the regulatory requirements needed to approve this application technology in Canada. 	