NAFTA Technical Working Group on Pesticides
Grupo de Trabajo Técnico sobre del TLC Plaguicidas
Groupe de Travail Technique de l'ALENA sur les Pesticides

2018 NORTH AMERICAN FREE TRADE AGREEMENT TECHNICAL WORKING GROUP ON PESTICIDES WORK PLAN

Jointly developed by partners of the NAFTA TWG from the United States of America, Canada and Mexico

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This NAFTA TWG on Pesticides work plan is intended to provide strategic guidance for 2018 and to provide guidance to the NAFTA TWG partners participating in the internal activities associated with the NAFTA TWG on Pesticides. The NAFTA TWG on Pesticides anticipates this work plan will be a living document and will be re-evaluated during the year to ensure recommendations from the NAFTA TWG on Pesticides meetings can successfully be carried out.

The development of this work plan is based on the 2016-2021 NAFTA Strategic Plan (STRaP) to describe activities envisioned in the year 2018. It is expected that each year, the existing, annual work plan could be updated or a new one developed based on topics and issues discussed during the most recent NAFTA TWG on Pesticides yearly meeting. This work plan does not create or confer legal rights or impose any legally binding requirements on the NAFTA TWG, or any other party. The purpose of this work plan is for sharing information, consistent with the NAFTA TWG STRaP and to uphold the objectives of transparency. It is not intended to serve any other purpose, and should not be construed to represent formal dissemination of any agency determination or policy.

INTRODUCTION:

The 5-year STRaP is presented in broad terms with high level activities and objectives. During the 2015 NAFTA TWG Meeting, NATFA partners agreed that during the development of the strategy, an annual work plan should accompany the strategy that would reflect the decisions agreed upon during the NAFTA TWG meetings. It was envisaged the yearly work plans would be specific in nature and should

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focus on action items that fit under three primary objectives of the strategy for that year. The work plan will set timelines and identify the country and organization responsible for leading each item.

Priorities and other assumptions may change during the first half of the year that may warrant a mid-year review and adjustments to the work plan. All the activities proposed for calendar year 2018 are based on the availability of adequate budget, resources and approval of key information collection requests.

OBJECTIVES OF THE FIVE-YEAR STRATEGY

The NAFTA partners decided to focus on three strategic objectives designed to propel the TWG into the future. Achieving these objectives will require a concerted effort on the part of regulators, industry, and growers and other stakeholders.

- **Objective 1:** Identify trade barriers and approaches to promote equal access and simultaneous introduction for pest management tools
- **Objective 2:** Encourage cooperation on joint reviews of new pesticides and uses, and the re-evaluation/re-registration review of pesticides to increase efficiency and quality of decision making
- **Objective 3:** Work cooperatively on priority science and regulatory issues and practices including data requirements, science approaches and policies for data interpretation, risk assessment, risk management and communications of regulatory decisions

2018 WORK PLAN:

OBJECTIVE 1: Identify trade barriers and approaches to promote equal access and simultaneous introduction for pest management tools

Discussion Summary: Un-harmonized *Maximum Residue Limits* (MRLs) are still identified as a main problem by growers and the industry, due to, for example, more countries developing their own national MRL policies and approaches for imported commodities.

Discussion Points:

- *Alignment of Maximum Residue Levels (MRLs):* NAFTA partners discussed the importance of reflecting on the purpose of aligning MRLs, which commercial blocks we must consider, as well as what participation should we expect from Latin American countries to help strengthen the position of the NAFTA partners in international forums like CODEX, APEC, etc.
- Considering the new Mexican regulations to be implemented in 2018, the countries agreed to collaborate on training, as well as the development and/or review of the "Import Tolerances" document written by USA and Canada.
- Workshop in 2018: Mexico plans to hold a workshop on MRLs early in 2018 and NAFTA partners discussed the importance of inviting industry and government associations to establish concerns regarding the MRLs, share information and identify areas of national and international collaboration.

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OBJECTIVE 2: Encourage cooperation on joint reviews of new pesticides and uses, and the re-evaluation/re-registration review of pesticides

Discussion Summary: Canada and the United States presented the "lessons learned" after nearly two decades of experience with the NAFTA joint reviews. Drawing upon this experience, a proposal that looks to efficiency improvements for the joint review process were presented and recommended as pilot. The importance of engaging Mexico more consistently and deeply in the joint review process was discussed.

Discussion Points:

- *NAFTA Joint Review Process:* Look for additional flexibilities, such as a hybrid joint review and workshare process where a joint review is undertaken in certain areas together with a workshare approach in other areas.
- Over the course of the next year, work to identify a joint review submission that could be piloted with the aim of determining what impacts if any the revised process would have on science collaboration and the overall efficiency of the joint review process. This would be an important opportunity to launch a real training case for Mexican experts from SENASICA, COFEPRIS and SEMARNAT on joint reviews, and to consider industry's participation.
- *Re-evaluations:* Considering workload challenges, NAFTA partners discussed the need for enhanced sharing of their respective plans for the review of pesticides already on the market, with a view to identifying joint review opportunities.

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OBJECTIVE 3: Work cooperatively on priority science and regulatory issues

Discussion Summary: The NAFTA countries will consider enhancing their cooperative work on priority science and regulatory issues to help countries work more efficiently, addressing common concerns such as pollinator protection and building solid working relationships ~~between scientific staffs~~ among scientific staff.

Discussion Points:

- *Pollinator Protection:* NAFTA partners discussed the progress on their respective approaches and opportunities for increased sharing of information on outcomes; Mexico is committed to continue sharing results from the project still ongoing on bees.
- Mexico raised the need for, and requested training on, risk evaluation for the use of pesticides on pollinators, based on a real case study, aiming to identify and consider opportunities to establish key activities on this item.
- *Cumulative Risk Assessment:* the USA EPA and CAN PMRA discussed the need to continue their work in this area and of sharing their methodologies.
- *New Scientific Methodologies:* the USA EPA and CAN PMRA discussed the importance of keeping current of emerging science (e.g. biotechnology) and novel approaches (e.g. Integrated Assessment and Testing Approaches).

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2018 Work Plan ACTION ITEMS

Action	Lead	Target Date	Status
Part A: Work Plan Items with Discrete Deliverables			
1. Ongoing work of field trial reduction project: • To determine and reduce number of field trials required for joint projects intended to support simultaneous domestic registrations in both USA & CAN (in consultation with IR-4/PMC) • To finalize the draft guidance document for consultation purposes • To outline when the reduced trial requirements can be used by registrants and IR-4/PMC • To include a table with the number and location of the trials for the crops considered for this project	CAN/USA	Winter 2018	Canada: Completed. PMRA published ("Joint Canada/United States Field Trial Requirements" (Science Policy Note SON2017-02) on July 11, 2017. USA: EPA's document is pending publication in early 2018.
2. Harmonize use of the OECD MRL Calculator for Crop Group MRLs • To develop a reliable statistical method for determining appropriateness of Crop Group MRLs.	CAN/USA	Fall 2018	Canada/USA: PMRA and EPA are working closely together to further align the approaches and data inputs to the OECD MRL calculator and the resulting MRLs. The guidance document that will be produced from this project will be a major step in ensuring all residue chemistry evaluators are applying a consistent approach to calculate Crop Group MRLs.
3. Cumulative Exposure Methodology • To prepare document on methodology / framework • To share their methodologies, noting where similarities exist and then propose a joint methodology, which could be taken to OECD for consideration	CAN/USA	Early 2018	Canada: Completed. PMRA published "Cumulative Health Risk Assessment Framework" (Science Policy Note SPN2018-02) on 17 April 2018 and shared final document with EPA. USA: USA methodology has been completed. See the links at the bottom of this webpage: [HYPERLINK

Action	Lead	Target Date	Status
			"https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides"].
Part B: Work Plan Items for which Actions are Ongoing (i.e., no Discrete Deliverables)[1]			

4. Joint Review Process Improvements:
 	
• Based on "lessons learned", identify a submission to pilot as per the efficiency improvement measures.
  ○ Identify potential project and timeline
  ○ Determine what parts will be joint review and what parts will be workshare
  ○ For independent and workshare portions, determine how issues or differences and resolution/conclusions will be documented.
  ○ Propose that industry continue to populate harmonized chemistry template.
  ○ Determine if Tier II summaries should still be required for toxicology (acute and chronic) and environmental data.
  ○ Consider best mechanism for information sharing.
 	
• Continue reviewing procedures among countries to share information related to joint reviews, that include requirements, evaluation criteria, timing, communication, etc.
	CAN/USA/MEX	Ongoing	Ongoing cooperation, collaboration, and regular communication.
			
			Four potential pilot projects identified: broflanalide, S-2399, trifloxalin (BAS 850H), and XDE-2020.

5. Re-evaluation: • Continued cooperation and identification of areas to collaborate with respect to re-evaluation joint reviews	USA/CAN	Ongoing	Ongoing cooperation, collaboration, and regular communication.

[1] In addition to the specific work plan items listed in Part A which have clearly defined deliverables, Part B lists those work plan items for which Canada, the United States and Mexico have achieved a steady state of ongoing cooperation and collaboration which reflects the current way of doing business among NAFTA partners.

Action	Lead	Target Date	Status
6. Pollinator Protection and Neonicotinoid Pesticides: • To inform each other regarding pollinator protection work, including monitoring activities • To develop training on risk evaluation of pesticides on pollinators, based on a real case, for Mexican evaluators, next year. • To share final results of the Mexican project on bees, when available • To share information respecting neonics reviews and decisions taken	MEX/CAN/USA	Ongoing	Ongoing cooperation, collaboration, and regular communication. <u>Canada/USA</u>: Canada's PMRA and US EPA/CalDPR will continue to collaborate on the pollinator re-evaluation of the neonicotinoid pesticides where possible. Working together, CAN, USA and MEX will make every effort to provide timely information to NAFTA regulatory partners ahead of any major announcements, publication of risk assessments, or regulatory decisions pertaining to the neonicotinoid pesticides where possible.
7. Biotechnology • Continue to evaluate novel technologies (e.g., RNAi-based pesticides) and build upon the input from their respective Science Advisory Panel meetings, informing each other of developments.	CAN/USA	Ongoing	Ongoing cooperation, collaboration, and regular communication. RNA-i based pesticides: PMRA and US 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").

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Action	Lead	Target Date	Status
8. New Science Technologies • Continue to stay updated on new science technologies and Integrated Assessment and Testing Approaches (IATA) • On-going activities on skin sensitization, eye irritation & skin irritation	CAN/USA/MEX	Ongoing	Ongoing cooperation, collaboration, and regular communication. <u>Canada/USA</u>: IATA (skin sensitization, eye and skin irritation): US EPA and PMRA publications that waive Acute Dermal Toxicity studies (November 2016 and June 2017, respectively), are examples of deliverables under both the NAFTA and RCC Work Plan on IATA. 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 input on the US 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.

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