2019 NORTH AMERICAN WORKING GROUP ON PESTICIDES

Proposed agenda items for the June 11-13, 2019, meeting, in Philadelphia

Vision: Explore a second generation of regulatory collaboration as the driver of further alignment to continue to provide North American growers with safe, innovative and effective pest control innovations that allow them to remain competitive domestically and globally.

Principles:

1. In preparation for implementation of the United States, Mexico, Canada Agreement (USMCA):[1]
    a. Establish a working group under USMCA, building upon the success of the North American Free Trade Agreement (NAFTA) Technical Working Group on Pesticides (NAFTA TWG) and supporting Industry Working Group (NAFTA IWG) with terms of reference to guide co-development of work plans and their execution; [2]
    b. Move beyond the current grower/regulated party/regulator relationships in North America toward deeper collaboration, starting with idea generation (i.e., the June meeting in Philadelphia) and idea validation through to proof of concept including regulatory experimentation (e.g., pilot projects).

Proposed Agenda Items

A. Panel Discussion: Alignment of North American crop-protection regulations: Where are we at, what direction should we be going and why?

Concept: Take stock of pesticide-relevant regulatory alignment that has occurred in North America over the past 25 years, the benefits of this alignment and the gaps still needing to be addressed from the viewpoint of growers in order to build a common understanding of why this work is so critical for their long-term competitiveness and success.

Objective: Stimulate discussion that informs an objective assessment of where to focus stakeholder and regulatory efforts in a re-invigorated pesticide working group under USMCA.

Approach: Government and industry presentations on each topic (i.e., stocktaking, benefits and gaps) followed by discussion that engages the grower, registrant and regulatory participants from all three countries.

Supporting Documentation:

A. TWG 2008-2013 and previous accomplishments reports.

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[11] Note that the agreement has a different title in each market with the name of the country you are standing in being named first e.g., if you are in the United States, it is USMCA, if you are in Canada is CUSMA, if you are in Mexico it is MUSCA.

[2] see Annex for the NAFTA TWG 2016-21 Strategic Objectives and Priority Work Areas

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B. 2014-2018 accomplishment report (would need to be drafted).

B. Increased grower participation in re-evaluations and other post-registration reviews.

Concept: Explore the appropriateness of current and potential entry points in re-evaluation and post-registration reviews.

Objective: From a grower perspective in each of the three countries, identify what works well and where the gaps are in these reviews that would address their competitiveness interests (e.g., a full risk/benefit analysis (economic, agronomic, grower-driven environmental impacts).

Approach: North American growers would present their views followed by discussion with all participants.

Supporting Documentation:

A. Grower presentations.

C. Panel Discussion: USMCA-the potential of free trade agreement negotiations as drivers of regulatory cooperation

Concept: Some view the level of ambition in the negotiation of regulatory cooperation for these two agreements to have been low – if so, what might medium and high levels of ambition look like?

Objective: Identify potential areas for trilateral work on a second generation of policy coordination (e.g., the art of the possible) in North America and how successes could be scaled internationally (e.g., formalization of regulatory best practices on MRLs in future trade negotiations).

Approach: Invite former trade negotiators and industry leaders that were actively involved to share their views on the opportunities presented in the final the text of the SPS, TBT and Good Regulatory Practices chapters in USMCA.

Supporting Documentation:

A. As pre-reads, summary analysis and text of the relevant USMCA chapters.

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D. Do growers need more than aligned MRLs as outputs of global joint reviews?

Concept: Build common understanding of the current benefits and challenges to North American participation in joint reviews and global joint reviews. The United States Environmental Protection Agency (US EPA) and Canada's Pest Management Regulatory Agency (PMRA) are increasingly the sole participants of "global" joint reviews, and the number of joint reviews appear to be on the decline. Given the level of effort and resources required to carry out joint reviews both agencies have proposed work sharing and/or a focus only on the establishment of harmonized MRLs as a more pragmatic and sustainable approach than full joint reviews.

Objective: Stimulate discussion to inform an objective assessment of where to focus efforts to address the challenges regulators face in participating in North American and global joint reviews.

Approach: Presentations by US EPA, PMRA, COFEPRIS/SAGARPA/SEMARNAT and industry followed by discussion with all participants.

Supporting Documentation:

A. Regulator and industry presentations.

E. What framework would better support Mexico's participation in global joint reviews and other beneficial activities.

Concept: Identify why past North American joint review and other beneficial bilateral and trilateral regulatory cooperation activities concerning pesticides have not always been successful in including Mexico's participation and jointly explore potential solutions.

Objective: To better understand how to successfully engage Mexican regulatory officials in North American joint-reviews and other regulatory cooperation activities (e.g., MRL and import tolerance setting) with a view to scaling this model for use with other markets that do not independently conduct full reviews. For example, the OECD is the first filter for global joint reviews, meaning developing countries are not present.

Approach: Use the document, *Joint Review Process for Pesticide Registration for Mexico and its Commercial Partners,*[3]as the basis for presentations by SENASICA, SAGARPA and SEMARNAT followed by facilitated discussion with professional simultaneous interpretation provided to facilitate clear understanding among regulators, growers and registrants participating.

Supporting Documentation:

[3] Original title in Spanish: *Procedimiento para registro de plaguicidas a través de un programa de evaluación conjunta llevado a cabo por las autoridades mexicanas con socios comerciales*

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A. English translation of *Joint Review Process for Pesticide Registration for Mexico and its Commercial Partners*.
B. Presentations.

F. Pest control risk communication and outreach

Concept: Explore how to bolster public confidence in North America's pesticide regulatory systems, and increase awareness of the benefits that pesticides bring to the agriculture and urban/non-agriculture sectors in North America. For example, PMRA's January 11, 2019, statement on glyphosate is anticipated to be very helpful in balancing public discourse on the safety and value of pesticides in Canada and abroad.

Objectives:

- Explore how regulators and growers could better engage in evaluations and communication of decisions; and
- Collaboratively enhance public confidence in the pesticide regulatory systems in each market.

Approach: Lived-experience grower presentations from all three countries on regular outreach and risk communication best practices and areas that present challenges followed by discussion.

Supporting Documentation:

A. Grower presentations.

G. Roles of registrants, regulators, growers and civil society in a pesticide regulatory environment that supports innovation.

Concept: Identify the constraints each group places on regulatory systems that make these systems less agile and less predictable.

Objective: Stimulate discussion to inform an objective assessment of where to focus efforts to address the challenges regulators face in participating in global joint reviews.

Approach: Present RNA-i based pesticides and unmanned application equipment (field sprayers and other drones) as case studies for each group to identify their anticipated roles and how this might impact the regulatory environment.

Supporting Documentation:

A. Presentation on PMRA and US EPA collaborative work in the OECD Expert Group on RNAi Pesticides, including the document, "Effects on Non-target Organisms from Exposure to RNAi-based pesticides and Environmental Fate").
B. Presentation on unmanned equipment (could include demonstration as part of the pre-program).

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H. Status Report EPA/PMRA joint review pilot project

Concept: Build upon the ongoing work in Asia-Pacific Economic Cooperation countries to harmonize import tolerances and the joint US EPA/PMRA pilot co-initiated in 2018 to experiment using Australia's APVMA[4] approach in North America.[5] While US EPA/PMRA indicated in a July 2018 call with the NAFTA IWG that an assessment would not be available until the results and analysis of the pilot were completed, we understand the approach has already proven to be very popular with evaluators in both agencies and is already being used more broadly than originally set out in the pilot.

Objective: Inform potential process improvements mid-stream in the US EPA/PMRA pilot to facilitate earlier adoption of lessons learned to-date.

Approach: Case-study pre-reads prepared as backgrounders for separate presentations by regulators and industry that share lessons-learned to-date for at least two actives under the pilot to serve as catalysts for idea co-generation in discussion with all participants.

Supporting Documentation:

A. Two case studies as pre-reads prepared by industry.

I. Increasing the credibility of civil society engagement in re-evaluations and other post-registration reviews.

Concept: Explore appropriate North American civil society entry points in re-evaluation and other post-registration reviews.

Objective: To work competently and collaboratively on joint reviews with a broader range of stakeholders.

Approach: Invite a small number of moderate North American environmental civil society groups to present on their perceived role in the review processes in all three countries followed by discussion with all participants on how to appropriately empower civil society to more productively contribute to balanced outcomes.

Supporting Documentation:

A. Civil society presentations.

[4] Australian Pesticides and Veterinary Medicines Authority

[5] In the US EPA/PMRA pilot, studies that have previously been submitted and assessed by a competent regulator to support a registration application are accepted for subsequent evaluations without the need to re-do this work, eliminating duplication of analytical effort and reducing review times.

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ANNEX: 2016-21 Strategic Objectives and Priority Work Areas

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

The ability to align MRLs has importance for the value of products and equal access to global markets. Over the years, the TWG has been collaborating with affected stakeholders to identify trade barriers and promote alignment of MRLs through joint review programming. We plan to continue identifying current trade barriers by using innovative approaches.

- **MRL Alignment:** Encourage registrants to consider potential export markets of agricultural commodities intended for treatment with proposed new pesticides or new uses as a way to reduce the number of use expansion submissions and reduce potential trade barriers. The TWG will also meet in advance of Codex meetings to discuss each country's anticipated position when possible in order to better align our positions.
- **Expansion, Development and Harmonization of Crop Groups with Specified Representative Crops for Field Crop Residues Studies:** Continue ongoing work, through the International Crop Grouping Consulting Committee (ICGCC) for harmonizing crops, on the process for developing new/additional crop groups. Revise the existing guidance document as new scientific information becomes available.

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.

Joint reviews of applications for new pesticides and MRLs continue to expand beyond North America.

Additionally, NAFTA countries have begun to take a more active role as observers or secondary reviewers of data assessments, thereby, increasing the TWG's technical capabilities in risk assessments. To manage the risks associated with pesticides on the market, it is important to conduct periodic re-evaluations of those pesticides with the most current scientific knowledge and standards. The re-evaluation of pesticides demonstrates the commitment NAFTA countries have in ensuring their safe use.

- **Increasing Simultaneous Registration of Biopesticides:** Seek opportunities with biopesticide manufacturers for their simultaneous submission of registration applications to NAFTA countries to provide opportunities for joint review. Biopesticides continue to make strides in providing efficacious, lower risk pesticide management tools for growers. Multiple country submissions and joint reviews will provide growers and other pesticide users with more choices for pest management.
- **Minor Use Joint Reviews:** Continue the focus on pesticide registration for minor uses. Work with the minor crop grower communities, the U.S. Interregional Research Project #4 (IR-4) program, and the Canadian Pest Management Centre program to:
    1. Identify pest control gaps,
    2. Follow the established minor use joint review procedures to enable joint submissions of registration applications in U.S. and Canada, and
    3. Make simultaneous regulatory decisions in both countries within a 10-month timeframe.

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- **Coordination of Registration Review and Re-evaluation:** Continue to identify opportunities for countries to work-share on pesticides. Work shares that are currently ongoing include the following pesticides: glyphosate and neonicotinoids.

Objective 3: Work cooperatively on priority science and regulatory issues and practices including data requirements, science approaches and policies for data interpretation, and risk assessment and communications of regulatory decisions.

Scientific challenges remain in working through differences in data requirements and risk assessment processes among NAFTA countries. The TWG identified the following opportunities of joint scientific collaboration to facilitate alignment of data requirements, risk assessment methods, and better aligned regulatory decision making among NAFTA countries.

- **Pollinator Protection:** Share information on policies, risk assessments, initiatives, and actions to improve the countries' protection of pollinators. EPA and PMRA will provide training to SAGARPA and SEMARNAT on the process for conducting pollinator risk assessments.
- **Alignment of Data Requirements/Science Policies:** To facilitate a common approach and efficiencies in joint reviews and work sharing among EPA, PMRA and Mexico, all countries will continue to consider the alignment of data requirements and science policies. This includes developing and completing guidance for the review and interpretation of specific data and guidance related to risk assessment methodologies (e.g., cumulative exposure) and novel technologies such as Ribonucleic Acid Interference (RNAi).
- **Integrated Approaches to Testing and Assessment (IATA):** EPA and PMRA will continue to work on initiatives related to Chemical Testing in the 21st Century. An example of this type of work includes a bilateral effort by EPA and PMRA to develop an Organization for Economic Co-operation and Development (OECD) Guidance Document that builds upon the existing EPA and PMRA guidelines on waiving/bridging acute toxicity studies, and a continuation of their joint efforts to work with stakeholders on alternative approaches for the acute toxicity studies.

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