July 06, 2018

NAFTA Technical Working Group on Pesticides
Grupo de Trabajo Técnico del TLCAN sobre Plaguicidas
Groupe de travail technique de l'ALENA sur les pesticides

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July 06, 2018

Subject: February 22, 2018 letter from Industry Working Group (IWG) Input regarding the NAFTA Industry - Government Interface and NAFTA TWG Meeting held November 7-8, 2017

Dear Members of the IWG:

Thank you for your letter dated February 22, 2018, which provided a comprehensive summary of events from the November 2017 meeting, and also some recommendations for moving forward on several items.

As you have noted, the three strategic objectives designed to propel the TWG into the future (as per the 2018 NAFTA Work Plan, attached) are as follow:

- **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

In reviewing your letter and the major areas identified, in addition to progress to date already captured in the attached 2018 Work Plan, please note the following:

1) Maximum Residue Limits

As you know, governments recognize that international differences in maximum residue limits (MRLs) can occur as a result of differences in both methods and data available to regulators at the time of MRL establishment, as well as other factors. Though MRL differences rarely reflect differences in risk, it is acknowledged that aligning MRLs globally has become increasingly important to reduce barriers to the movement of treated agricultural products around the world. Domestic and international collaboration is critical in resolving these issues, which are of high importance to registrants, growers, and respective economies.

Work continues among international partners under the Regulatory Cooperation Council (RCC), North American Free Trade Agreement (NAFTA), Organization for Economic Co-operation and Development (OECD) and the Codex Alimentarius Commission on science policies relevant to establishing MRLs internationally. Through the RCC initiative, new scientific methods and process improvement strategies have been developed to further streamline data requirements for establishing MRLs among jurisdictions. The work on two key methods: exchangeability and proportionality, developed under the RCC, were successfully incorporated into the second edition of the OECD Guidance on Crop Field Trials, which was published on September 7, 2016. Of importance is that all stakeholders, including members of the NAFTA Technical Working Group on Pesticides, supported the proposal to publish the outcome of the RCC work on these two methods in the OECD Guidance (in lieu of publishing national documents), as this would provide for a broader acceptance of these methods by all OECD-member countries.

As part of both the NAFTA and RCC initiatives, work on streamlining Joint Canada/United States Field Trial Requirements was recently completed and published in June, 2017, and North American Agencies continue to work collaboratively when submitting nominations to the Codex Alimentarius Commission. In addition, as noted in your letter, continued collaborative efforts resulted in the development and publication in early 2018 of guidance for reduced residue chemistry data requirements for seed-treatment uses.

At the CCPR50 meeting, Canada submitted a proposal to conduct an assessment of the benefits, challenges and proposed possible solutions to the participation of the JMPR in an international joint review of a new compound, which was supported by the member countries including the US and Mexico, and endorsed by the CCPR Committee. An Electronic Working Group (EWG) has been created with next steps being to perform the assessment and develop a discussion paper to be presented for discussion at CCPR51. This EWG is co-chaired by Canada, Costa Rica and Kenya, with the following terms of reference (TOR):

i. To identify and assess the benefits, challenges and proposed solutions to the participation of the JMPR in an international joint review of a new compound, using previous national and international experience to inform the assessment, such as the sulfoxaflor pilot project;
ii. This assessment of benefits, challenges and proposed solutions will include, but will not be limited to, considerations such as resource efficiencies, timelines, enhanced communication and cooperation between competent authorities and the JMPR Secretariat, and science policy issues; and,
iii. On the basis of the above considerations, to develop a discussion paper to be presented for discussion at CCPR51.

2) Registration Review/Re-Evaluation

As acknowledged in your letter, Canada and the US are facing increased pressure in our respective post-market review programs. We are challenged to complete re-evaluation mandated timeframes due to limited resources, legal inquiries and other factors. Nevertheless, both countries are committed to finding solutions to this challenge, including ways to better align our schedules and increasing the sharing of reviews, where appropriate. We believe we can build on our experience with the re-evaluations of glyphosate and neonicotinoids. However, alignment of post-market reviews poses some challenges to be overcome, such as significant variations in use pattern between countries and legislative differences (e.g., timing of cyclical reviews). The US and Canada have public schedules for reevaluation that provide transparency for the time of reevaluation, data requirements and decisions which offers an opportunity for industry to effectively prepare prior to the initiation of post-market reviews.

3) Joint Review Workshop Proposal

We appreciate the comments provided, and will take them into consideration. However, given the constraints within which all regulators must function, it is vital that resources be aligned towards strategies that will allow more efficient and productive cooperation.
Because a pilot to examine streamlining of the joint review process has just been initiated, it is

somewhat premature to plan a workshop at this time. Timing for a "lessons learned" discussion can be revisited once the pilot is further along. In addition, results of this pilot may identify opportunities for "second wave" joint reviews as these have historically posed a challenge due to discrepancies in review timelines between agencies.

Regarding the inclusion of Codex/JMPR as a partner in the joint review process, discussions are currently underway to examine the potential for another pilot to determine if the Codex/JMPR process can be initiated earlier in the overall active ingredient review process, in order to better align the Codex/JMPR process with the joint review process.

4) Proposed Workgroups to Support Initiatives

Regarding the need for more interaction among regulators and the stakeholder community in the timeframe between the annual NAFTA TWG meetings, we look forward to hearing about specific proposals, at which time we can consider whether work groups are needed.

Regarding the suggestion re: Guideline and Study review harmonization (International Council on Harmonization), as you are aware, governments are already participating in the development of guidelines at the OECD level (http://www.oecd.org/env/ehs/pesticides-biocides/seriesonpesticides.htm). Progress has been made in this area in recent years through various OECD initiatives (e.g., Extended One Generation Reproductive Toxicity Study Test Guideline; OECD Testing and Assessment Guidance 237: Considerations for Waiving or Bridging of Mammalian Acute Toxicity Tests), as well as through NAFTA initiatives (e.g., Interpretation of Developmental Neurotoxicity Studies), which also support the goal of reduced animal testing, as well as the application of broader approaches such as Risk21. Given the involvement of NAFTA collaborators in other ongoing initiatives in this area, formation of an International Council on Harmonization would be of limited value / benefit at this time. The three NAFTA countries will continue to support work initiated at the OECD-level, especially regarding topics that overlap with NAFTA objectives and goals, in efforts to promote a broader alignment of science-policy work. If there are specific guidelines that Industry/Grower Groups would like to propose for consideration, we look forward to receiving a list of proposals.

5) Next Meeting

Finally, regarding the planning of the next NAFTA TWG meeting, we would like to propose tentative dates of June 11-13, 2019 in Philadelphia. As we did last year, we would like to request that the IWG take on the role of coordinating input from Stakeholders (e.g., Industry, Grower Groups) for the purpose of providing us with a draft agenda for the "Stakeholder-Government" session (and the "Workshop" day if applicable) for our consideration. The provision of this input to us by the end of the 2018 calendar year would assist with the planning of the 2019 meeting and in encouraging broader participation from the stakeholder community. Our goal would be to arrange for another NAFTA ExB-IWG teleconference in January 2019 to further explore possible agenda items/opportunities and to discuss next steps.

July 06, 2018

Sincerely,

for

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US EPA

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