February 22, 2018

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Mr. Richard Keigwin
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U.S. Environmental Protection Agency, 7501P
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RE: Industry Working Group (IWG) Input regarding the NAFTA Industry - Government Interface and NAFTA TWG Meeting held November 7 -8, 2017

Dear Mssrs. Aucoin, Fragoso, and Keigwin:

CropLife America (CLA), CropLife Canada (CLC) and PROCCYT (Mexico) are pleased to join together with agricultural associations from all three NAFTA countries to submit the following letter. The signatories of this letter represent developers, producers, vendors and distributers of crop protection and plant biotechnology products, as well as the farmers, processors and exporters of a vast array of commodities from Canada, the USA and Mexico.

On the first day of the NAFTA Technical Working Group on Pesticides (TWG) meeting, a half-day stakeholder session was hosted by the regulatory agencies. We want to thank the respective pesticide regulatory agencies for providing an opportunity for public stakeholder input during this portion of the TWG meeting. Members of the NAFTA Industry Working Group (IWG) worked together to provide this input to the TWG.

Recommendations

The two top priorities focused on by the NAFTA Industry Working (IWG) group in 2016 and 2017 were international joint reviews and the need for Maximum Residue Limit (MRL) harmonization among the NAFTA countries and across the globe along with some specific recommendations. Once again, in an effort to improve efficiencies, ensure new technologies are made available to growers across the NAFTA region at the same time, and ensure improved harmonization of MRLs, we are asking the regulatory agencies to re-engage in joint reviews of "second wave" crops that are submitted after the initial approval of new active ingredients.

The IWG appreciates the recent response from the Agencies to the IWG letter summarizing and submitted following the 2016 TWG meeting. We appreciate the Agencies' acknowledgement of the IWG perspective and input and the commitment to discuss the Joint Review process and potential efficiency improvements. We also acknowledge the Agencies' commitment to the Codex process and efforts to align MRLs and reduce potential trade barriers. Further, we would welcome at the appropriate time the opportunity for industry to collaborate with the Agencies and discuss the concerns expressed relative to product persistence.

At this most recent meeting, the IWG focused its presentation on two areas. The first was to recognize and provide examples of the progress achieved to date with respect to harmonization among the Agencies, particularly as it relates to science and policy. A good example of this was the recently released memorandum, "Reduced Residue Chemistry Data Requirements for Seed Treatment Uses." The second priority was to provide examples of misalignment among the Agencies, with opportunities to enhance the regulatory processes and science approaches in each country through increased harmonization. Further to this, the IWG encourages and is very interested in collaborating with the Agencies on new approaches relative to the broader topic of "Risk21" harmonized approaches to product testing. We also proposed the concept, pioneered by the pharmaceutical industry, of an International Council on Harmonization (ICH) to support harmonized approaches on guidelines for study development, and on the review and interpretation of the studies. This fits well with the long-term goals of reducing animal testing and employing a new scientific framework and approach for testing the safety of pest control technologies to man and the environment.

Maximum Residue Limits

As noted above and during the meeting, the timely establishment of harmonized MRLs is of critical importance to the grower stakeholders, to permit the use of crop protection tools as they become available, while allowing free trade of treated commodities produced in NAFTA countries with their trading partners around the globe. In response to this priority noted during the 2016 meeting, we want to recognize and thank the Agencies for supporting and coordinating the MRL workshop and the opportunity to focus on the topic on the second day of the 2017 TWG meeting.

In discussions following the TWG meeting, the topic of the past "Codex MRL Pilot" was raised. Currently, JMPR does not initiate the review of the data to support a new MRL until a reviewing country has completed the process and established a country-specific MRL. A few years ago, the active ingredient sulfoxaflor was evaluated by JMPR during its initial registration process under a pilot project to include Codex/JMPR as a partner in the international Joint Review process. This would offer three benefits: sharing of reviews, which should insure efficiencies among regulatory agencies; increased likelihood of harmonized MRL establishment; and, most importantly, reduce the amount of time in which it takes to establish an internationally recognized Codex MRL. By participating in the joint review process and establishing harmonized MRLs with Codex earlier in the process, this would significantly reduce the potential for international trade barriers.

Ultimately, the sulfoxaflor pilot did not lead to the desired result. We strongly encourage the NAFTA agencies to raise this topic with Codex/JMPR representatives, to evaluate if processes have progressed sufficiently, to resolve past issues, and to consider another pilot.

Finally, this coalition would like to recognize the increased efforts by the Agencies regarding the Codex process. The additional funding and resources to support an extraordinary JMPR session to address the current backlog and facilitate continued trade are appreciated by all stakeholders. The willingness of the Agencies to provide training to new science reviewers to insure consistent high-quality science reviews are completed under the JMPR review is significant to the overall effort. We also appreciate the Mexican authorities' public demonstration of their renewed commitment to active involvement and attendance at the Codex meetings. We believe participation in the aforementioned training sessions would also greatly enhance the effectiveness of their involvement.

Registration Review/Re-Evaluation

One common theme throughout the 2017 NAFTA TWG meeting was the need to seek efficiencies in an era of diminishing resources (funding and personnel) at the regulatory agencies. This is particularly true in the USA and Canada. Registration review/re-evaluation requires significant resources that compete with other parts of the program, such as review and approval of new technologies. Further, mandated timelines for reevaluation place additional burdens on limited resources. The stakeholders strongly encourage the Agencies to coordinate these activities and share resources. Recommendations provided as a way to improve efficiencies were to harmonize the approach used and the targeted timelines for the individual active ingredients. Furthermore, sharing reviews and outcomes between the Agencies would significantly reduce the necessary resources and likely lead to more harmonized decisions. Harmonized decisions offer the benefit of allowing growers in all countries access to the same technologies with similar use directions and (hopefully) harmonized MRLs. Without harmonized approaches, existing pest control tools could be lost or their uses severely limited. Particular modes of action might be lost, or certain risk mitigation measures could reduce their utility in resistance management programs. Sharing reviews during the re-evaluation process would foster similar approaches for joint reviews of new technologies also, as encouraged and supported by the regulated community.

Joint Review Workshop Proposal

During the past three TWG meetings, the stakeholders strongly encouraged a workshop on joint reviews to evaluate progress, lessons learned, and opportunities for improvement. To enhance this proposed workshop, we suggest adding a "how to" element to the program. This would greatly benefit participation by smaller companies, to understand the mechanics of the process and likely lead to an increase in the number of companies participating in joint reviews. It could be an excellent training opportunity for reviewers within the agencies, and would improve the process through information exchange. Lastly, this would provide an excellent opportunity for capacity building in Mexico as well as other countries who are interested and willing to participate, providing longer-term benefits.

The registrants are proposing to organize this effort with significant opportunity for input and participation from the Agencies, in order to reduce your burden. Please see the next section below with a suggestion how this proposal could be further developed.

Proposed Workgroups to Support Initiatives

Rick Keigwin acknowledged the need for more interaction among regulators and the stakeholder community in the timeframe between the annual NAFTA TWG meetings. This would enhance and accelerate the development of the various initiatives identified in the IWG presentations, IWG letters, responses from regulators, and the NAFTA TWG strategic plan.

To this end, the IWG and grower stakeholders suggest the development of workgroups made up of regulators and stakeholder representatives that can meet more frequently to develop these initiatives. A few ideas for suggested workgroups have been identified by the IWG and growers for Agency consideration that may not be addressed in existing venues/structure. These include:

- Joint reviews
    - Second wave submissions
    - Joint Review workshop
    - Codex/JMPR joint review pilot, number 2
    - Registration review/re-evaluation coordination
- Guideline and Study review harmonization (International Council on Harmonization)

In a time of diminishing resources and increasing workload for all, joint reviews and the suggested areas for workgroups offer opportunities for efficiency improvements, while ensuring timely access to new crop protection technologies for producers.

Highlighted among the key areas are:

- Allowance for second-entry joint reviews for major and minor crop uses, which has been successful in the past and would provide resource benefits.
- Continued strong engagement in the Codex MRL process.
- Accept import tolerance submissions in and from all NAFTA countries to facilitate trade.
- Continued effort to meet predictable timelines for registration decisions.
- Enhance the peer review process to achieve mutual acceptance of data reviews for new uses and the re-evaluation process, which would provide significant resource benefits to the regulatory agencies involved.
- Together with the IWG, organize a workshop on joint reviews to evaluate progress, lessons learned, and opportunities for improvement.
- Encourage participation by COFEPRIS in joint reviews, and support continued capacity building for Mexico.

We believe there is good alignment of the IWG points, presented at the 2016 and 2017 meetings and highlighted in this letter, with the "NAFTA TWG Five-Year Strategy 2016-2017" strategic plan:

- 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;" and
- 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 communication of regulatory decisions."

We believe the NAFTA TWG and its annual meetings are a valuable venue to gather stakeholder input, and we encourage the Agencies to continue hosting this meeting.

We encourage establishing the meeting date for the 2018 meeting by the first quarter in 2018, using the communication distribution lists established prior to the 2017 meeting to inform all stakeholders. In addition to the proposed workgroups listed above, we should schedule two interim teleconferences with Agencies' Executive Leadership and stakeholders to review progress towards goals and actions.

Again, we thank you for all your hard work and efforts in the areas of international joint reviews, work sharing, support of new and emerging science and technology, and trade harmonization under science-based regulation.

Respectfully,

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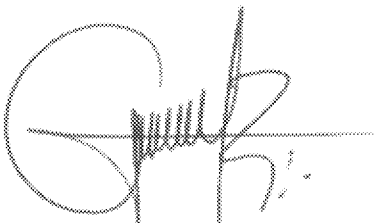

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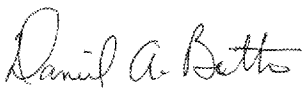

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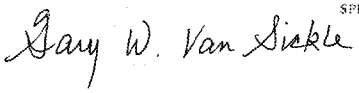

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