STAKEHOLDER-GOVERNMENT MEETING SUMMARY
2019 Trilateral Stakeholder Workshop and Conference on Pesticides
Arlington, Virginia
03-05 September 2019

The North American Free Trade Agreement (NAFTA) Technical Working Group on Pesticides (TWG) met in Arlington, Virginia, USA from September 03 to 05, 2019. The meeting was hosted by Rick Keigwin, Director of the Office of Pesticide Programs (OPP), United States Environmental Protection Agency (US EPA). Mr. Peter Brander, Chief Registrar and Director General, Registration Directorate of Health Canada's Pest Management Regulatory Agency (PMRA) and Amada Vélez Méndez, Director General of Safety in Food, Fisheries and Aquaculture from Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria (SENASICA) were also in attendance as heads of the Canadian and Mexican delegations, respectively. The meeting was attended by other government officials from the US EPA, PMRA, SENASICA, as well as from the United States Department of Agriculture/Foreign Agriculture Service, Agriculture and Agri-Food Canada, growers, registrants, and other stakeholders from all three countries.

Day-1: Stakeholder-Government Session

Agenda Item 1: Opening Remarks and Introductions

1.1 Industry Working Group: John Abbott, Syngenta USA Head of Delegation for the Industry Working Group (IWG), welcomed participants to the meeting and introduced Alex Dunn, Assistant Administrator, Office of Chemical Safety and Pollution Prevention (OCSPP) and the NAFTA Technical Working Group on Pesticides (TWG) Heads of Delegation: Rick Keigwin, USA; Peter Brander, CAN and Amada Vélez Méndez, MEX.

1.2 US EPA, Office of Chemical Safety and Pollution Prevention (OCSPP): Alex Dunn, OCSPP Assistant Administrator, welcomed the meeting participants to the offices of the US EPA. She encouraged openness, candidness and bringing new ideas forward during the meeting. She acknowledged that regulators wanted the opportunity to learn from stakeholders' experiences to build toward the future and invited stakeholders to let regulators know about areas where government support of innovation would be most useful.

Agenda Item 2: Science and Policy Alignment/Process Improvements

2.1 Regulatory Perspectives on Policy Landscape in North America and Internationally-Harmonized Approach, What the Future Could Hold?

2.1.a Rick Keigwin, US EPA, summarized regulatory challenges faced in the USA that still exist even after over 20 years of NAFTA. He noted the focus of international joint reviews has been on conventional and not biopesticide products, but that US EPA has started to rethink its international engagement with

respect to other areas, such as emerging technologies. He thanked the meeting participants for their engagement and indicated that he was looking forward to hearing their ideas.

2.1.b Peter Brander, PMRA, shared Richard Aucoin's regrets for not being able to attend this year's meeting. He stated that NAFTA's regulatory cooperation goal of attaining the highest standards of human health and environmental protection in the region established 25 years ago. He also expressed that NAFTA countries are continuing to work together including supporting joint reviews.

2.1.c "Science Alignment and Policy/Process Improvements: Regulator Perspectives": Amada Vélez Méndez, explained that SENASICA is one of three agencies with a mandate for pesticide regulation in Mexico. She stressed the importance of ongoing international cooperation in terms of establishing risk-based maximum pesticide residue limits (MRLs) including those for the vegetables and fruits that Mexico exports internationally. She informed the meeting that SENASICA has launched an initiative to promulgate a new law on pesticides that consolidates what is currently spread across six different laws and three government agencies (COFEPRIS, SEMARNAT and SENASICA).

2.2 Registrant Perspectives on Taking Stock of Pre-market and Science and Policy Alignment/Process Improvements-Global Market Landscape

2.2a "Industry Working Group Presentation Take Stock of Pre-Market-Science and Policy Alignment/Process Improvements": John Abbott, Syngenta/IWG, highlighted successes achieved to-date by the NAFTA TWG on Pesticides which included:

- Joint reviews are now standard for North America;
- Significant harmonization using OECD guidance for study development/conduct;
- Alignment on the one-year dog study (conditionally required);
- Waiver of immunotoxicity study in USA;
- Establishment of MRL regulations in MEX;
- Accepting foliar residue data with similar use rates to support approval for seed treatment use;
- JMPR efforts underway to support MRL harmonization & timing (parallel review);
- Dermal acute toxicity study waiver guidance issued for end-use products;
- Risk-based approaches to regulatory decisions; and
- Aligned cumulative risk assessment approaches.

He also outlined areas for improved harmonization for consideration in the development of the TWG's workplan in the following subject areas (see annex for details):

- Joint reviews and post-market reviews;
- Human Health assessment; and

- Environmental Safety Assessment.

2.3 Producer/Grower Perspectives on Science and Policy Alignment, Process Improvements-Current and Future Needs

2.3.a Rachel Roberts, Mushroom Institute, sent regrets as she was unable to participate in the meetings.

2.3.b "Growers' Perspective on Science and Policy Alignment": Allison Nepveux, US Grains Council, provided an overview of the complexity of how grain moves from the farm, to storage and then to bulk purchasers and export elevators, and finally to market as the context for why international buyers want to know what crop protection products are used on the farm and what the regulatory approach is both in the market where products are produced and the destination export markets. She indicated there is a trend for countries to develop their own systems for setting MRLs instead of harmonizing with Codex or supplier MRLs. This makes it very challenging to track what the import requirements are and to accurately identify missing or misaligned MRLs that impose commercial risks of shipment rejection. Grain movement is incredibly complex and harmonization of MRLs is critical for the global supply chain.

> *Question* – What difference would it make if there were global harmonization of MRLs?
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> *Allison Nepveux:* USA farmers understand the importance of trade and the need to follow the USA label and this has been done in a great way. However, the lack of MRL harmonization is a big problem. Codex and international harmonization are important to facilitate trade and to assure that growers have access to the full suite of crop protection products they need to remain competitive.
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> *Question* - What happens if there's an MRL issue at a receiving country's port?
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> *Allison Nepveux: S*o far, rejections at port are rare, but each situation is handled differently. If the shipment is refused entry, the exporter needs to find another market which can be a challenge and costly to arrange. While this issue hasn't stopped a lot of trade yet, growers are paying closer attention because of the increasing risk presented by missing and misaligned MRLs. We rely on regulators and harmonization of systems.

2.3.c "Science and Policy Alignment, Process Improvements: Grower Perspective": Rodney Volk, Pulse Canada, provided a grower's perspective about trade liberalization and market access, the importance of crop protection technology, non-tariff trade barriers and current and future needs. The importance of trade for CAN pulses is that while CAN produces only 8% of the global supply of pulses, CAN pulses account for over a third of all international trade of pulses. Global trade liberation has been beneficial

for CAN growers , however, as more countries move away from Codex to national/positive MRL lists and near-zero import tolerances, being able to continue to use critical crop protection technologies is being threatened by trade risks. Access to these technologies and to export markets are both critical to remain competitive. Deeper collaboration with growers and policy alignment among and between regulators is needed now more than ever. Timely product approvals/joint reviews and fewer zero/near zero import tolerances are needed. If zero tolerances are accepted, there can be no innovation. The Trilateral TWG has the opportunity to be a model for the level of regulatory cooperation needed globally.

> *Question:* How are pulses for export handled and how do you manage MRL issues?
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> *Rodney Volk:* The number of pulse growers in CAN has increased because it has become an important rotational crop. With the increased acreage, awareness of MRL issues has also increased. Like the grains example, bulk vessels are used for exports , however, most pulses are shipped in containers. Commodity associations keep growers up-to-date on trade risks through their "keeping it clean" websites and social media.

2.3.d "Improvement Opportunities in the Supply Chain of the Mexican Hass Avocado": Katia Aguilar, Mexico Avocado Growers Association, gave a presentation on improvement opportunities in the supply chain of the Mexican Hass avocado industry. Mexico is the main producer, consumer and exporter of Hass avocados in the world. There's a growing demand for product in the USA an CAN and there are opportunities to open new markets in Asia and the Middle East but without MRLs for these export destinations, this is difficult to do.

Agenda Item 3: Pollinator Issues

3.1 Mexico – "Study of Some of the Factors that Influence on the Loss of Bee Colonies in Different States of Beekeeping Importance of the Mexican Republic, 2017": Adriana Correa, National Autonomous University of Mexico, presented findings of a study of factors that influence the loss of bee colonies in MEX. The methodology, survey responses and summary of findings were discussed. Production and the productivity showed a downward trend with climate change and parasitic diseases (mainly by Varroa destructor) identified as the main risk factors.

Agenda Item 4: Producer/Grower Participation in Post-registration Reviews

4.1 "Grower Participation in Post-Registration Reviews": David Epstein, Northwest Horticulture Council (NHC), shared an overview of the NHC and outlined the US EPA's registration review and cumulative risk processes. He also outlined opportunities for early stakeholder engagement and the importance of grower input.

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4.2 "Growers Participation in Post-Registration Reviews": Ian Epp, Canola Council of Canada, gave an overview of the Canola Council of Canada and presented information on how post-registration decisions affect growers and the importance of consulting growers in the re-evaluation process. Generation of additional data to support the re-evaluation process is needed because the lack of data leads to overly-conservative decisions. Allowing growers to fully contribute in this process is mutually beneficial, as is dialogue with regulators.

Agenda Items 5: Panel Discussion: Could Trade Negotiations Drive Deeper Regulatory Cooperation on Pesticides?

Gord Kurbis, Canada Grains Council served as moderator for this panel.

Aaron Fowler, Chief Ag Trade Negotiator/CAN, spoke about the dynamics of free trade agreement (FTA) negotiations and other forums that advance stakeholders' pesticide interests. Trade agreements deepen partnerships by negotiating rules that are fair and transparent and that do not obstruct trade. Cooperation is the basis for negotiations. When NAFTA began, there was a dedicated group to address non-tariff barriers to trade including sanitary and phytosanitary issues. Regulatory cooperation is also a key component of the new agreement.

Jason Hafemeister, Secretary's Trade Counsel/USDA, began his remarks by asking what kind of trade agreements we want? As free traders, for farmers, all trade agreements are welcome. However, regulatory views on FTAs are less clear as some see trade agreements as something that can result in better outcomes, and some are concerned that trade agreements pose unnecessary constraints. He questioned if trade agreements would continue to exist in the future as there is a threshold issue. How many issues can you put in the boat before it sinks?

Craig Thorn, DTB Associates/Registrant Trade Advisor noted that elimination of most tariff and non-tariff barriers was done through NAFTA and it is very clean in this regard. The new agreement will bring in some new areas of trade liberalization (i.e., digital trade) and some new rules but how to resolve disagreements is anticipated to still be an issue. Forums like the TWG needs to continue to meet.

> *Question*: There are about 300 trade agreements around the world, if there were to be a more ambitious effort to increase regulatory cooperation, what would the hard obligation look like?
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> *Jason Hafemeister, USDA*: When you get into regulatory policy and start asking people to make changes, it gets very hard. So, you should begin by looking at existing agreements, and then ask how you can strengthen the existing rules. Looking at international SPS standards, we start to bump up against resistance. Risk assessment is based on scientific principles and this is an area that would need to be fleshed out in the obligations. He suggested: 1) Look at USA laws; 2)

Incrementally strengthen existing agreements; 3) Identify a test case or prototype in one area that has a unique problem that needs a unique solution that allows you to be more targeted.

Craig Thorn, DTB Associates: You could outline possibilities but for purposes of pesticide regulation there is a lot of scope and so sector-specific regulation would be a good objective as an obligation.

Question: Is an obligation like what exists in Mercosur possible (i.e., deferral to Codex or the exporting country MRL when there is a missing Mercosur MRL)?

Aaron Fowler, CAN: Mercosur consists of four countries that know each other very well and who have a degree of mutual regulatory comfort. This could be a model, but there would need to be similar circumstances between the negotiating parties or these would need to be developed. This may not be an out of the box solution you can simply drop into the negotiations.

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DAY-2: Stakeholder-Government Session

Agenda Item 6: Regulatory Opportunities & Challenges to Emerging Technologies

6.1.a "Regulatory Opportunities & Challenges to Emerging Technologies: RNAi": Greg Watson, Bayer Crop Science, provided a presentation on RNAi, explaining that RNAi is a natural process that is not new to agriculture and the system is well known. He urged regulators to remain engaged in international RNAi forums as what is needed are: Risk-based assays, more work on harmonization including agreement on data requirements and field-efficacy testing approaches that are appropriate for low-risk biological products like these.

6.1.b "UAV Applications and the Regulatory Challenges": Neill Newton, Syngenta, outlined the advantages of drone use and some of the challenges, noting there isn't one drone that is suitable for all application types and that no industry standards exist yet. This points to the need for more regulatory/industry dialogue both domestically and internationally to provide well-built solutions that ensure safe and sustainable use of crop protection products that are applied with these new application systems.

6.1.c "An Integrated Approach for Chemical Evaluation and Risk Assessment Decisions": Doug Wolf, Syngenta, provided an overview of how Risk 21 could be used as an integrated approach for product evaluations and risk-assessment to focus discussion and study designs that enable a more-efficient and resource-appropriate evaluation of risk.

6.2.a "Regulatory Updates on Application of Pesticides": Alma Tovar Diaz, SENASICA, shared proposed pesticide regulatory updates in Mexico.

> *Question*-What are the timeframes to develop the new pesticide regulations and are US EPA and the PMRA going to be involved?
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> *Alma Tovar Diaz:* SENASICA consulted with different sectors in Mexico and considered existing US EPA guidance (e.g., applicators' guidance) in the drafting of the OECD proposal. She indicated there are short timeframes of the project and the intent to finish before the end of 2019.

Agenda Item 7: North American Public Interest Group Engagement: *Identification of NGO interests and potential alignment*

7.1 "Multi-Stakeholder Collaborations to Advance non-Animal Approaches": Amy Clippinger, People for the Ethical Treatment of Animals (PETA International Science Consortium Ltd."), presented on multi-stakeholder collaborations to advance non-animal approaches. She identified four areas where there is an opportunity to replace in vivo testing with in vitro test methods: eye irritation and corrosion; inhalation toxicity; ecotoxicity and carcinogenicity. Given there are several anatomical and physiological differences between rodents and humans, non-animal approaches for toxicity and carcinogenicity may be other promising opportunities to explore.

Agenda Item 8: North American/International Harmonization of MRLs

8.1: Registrant Perspectives

8.1.a "CODEX: CCPR-51, Collaborative Industry/Government Approaches to Achieve One MRL": Ray McAllister, CLA, gave a presentation on how a single MRL approach could enable global cooperation on MRL setting, eliminate demand for import tolerance regulations; facilitate residue monitoring and regulatory compliance; increase clarity for all value chain stakeholders ; increase confidence in regulatory agencies and their decisions, and facilitate trade.

> *Question:* Are we wasting our time, is this possible?
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> *Ray McAllister:* Continued dialogue has value and even small steps will lead us to our objectives.
>
> *Question:* How would hazard-based approaches be accommodated?
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> *Ray McAllister*: MRLs facilitate trade and are a compliance tool to assure that pesticides have been used according to the label.

8.2: Producer/Grower Perspectives

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8.2.a "Trade Implications of Missing and Misaligned MRLs": Gord Kurbis, Canada Grains Council, outlined the issues producers and growers face with respect to missing and misaligned MRLs. He presented the following as solutions to consider exploring: Mitigate risks of noncompliance through interim deferral to Codex MRLs (i.e., industry coordination through the International Grain Trade Coalition-IGTC); improve the efficiency of Codex's MRL-setting process (i.e., industry coordination through the International Agri-Food Network-IAFN); mitigate short-term trade risks through value chain assessment (i.e., driven through national commodity associations like Canada's 'Keep it Clean' initiative).

Question: Do you think pressure on the EU will change their approach and the impacts?

Gord Kurbis: The EU's approach is unlikely to change and a best-case would be for the EU to adhere to risk-based import tolerances.

8.3: Government Perspectives

8.3.a "Trade in the Time of Disharmonized MRLs: the USA Approach": Rachel Vanderburg's-USDA, Foreign Agricultural Service, focused on the importance of agricultural trade to economic growth and global food security and the need to grow more, waste less and move it around better. Issues of concern noted were international MRL standards, missing and misaligned MRLs, how MRL violations are handled viz a viz commercial risk, and hazard vs risk assessment approaches.

8.3.b "CCPR, Proposed Guidelines for the Harmonization of Concepts & Criteria for the Recognition of Compounds of Low Public Health Concern that are Considered Exempted from the Establishment of CODEX MRLs": Dan Kunkel, IR-4, spoke on behalf of Codex, with a focus on biological products. There is currently no recognition or standards set by CCPR for biological products (many of which are being used in integrated pest management). The 2019 mandate for CCPR was to develop common criteria for the identification of compounds of low public health concern that may be exempted from CXLs and/or that do not give rise to residues; provide harmonized Codex definitions as appropriate; and to provide examples of compounds that meet the criteria to facilitate the development of the guidelines. Based on these considerations, proposed guidelines will be presented for consideration at CCPR-52.

Question: How might biological products be used in conventional farming systems?

Dan Kunkel: Early-season insects need to be kept in-check and the use of biologicals and beneficial insects can be part of the management approach. Specific crop programs need to be developed and adjusted in response to the pest pressures as they are identified.

Question: How do see this being applied to larger-acreage crops?

Dan Kunkel: If you look at everything as a whole, you can develop a program that integrates all of these resources.

8.3.c "JMPR Parallel Review Pilot: Update and Next Steps from CCPR-51": Natalie Doré, Agriculture and Agri-Food Canada, spoke about the role of Codex MRLs and gave an overview of the current pilot project to accelerate their establishment. She outlined why it is beneficial to invest in Codex's work on pesticide residues and the benefits and challenges of JMPR engaging in parallel reviews. CCPR-51 confirmed the value of continuing to explore the pilot and tasked a working group to present draft terms of reference/ a manual to CCPR-52 for consideration.

Question: This is a good tool for harmonization but we also need a faster approach for setting MRLs. Is there an opportunity to also reduce the timing?

Natalie Doré: Yes, this is the objective.

Question: When will you share the criteria for the molecule to be used for the case study?

Natalie Doré: A pilot project is proposed and registrants will be invited to bring molecules forward for consideration.

Question: When will the draft terms of reference be posted on the eWG?

Natalie Doré: The draft process is anticipated to be published in mid-September 2019.

8.3.d "North American/International Harmonization of MRLs: State of Regulation for MRLs": David Soriano, SENASICA, gave an overview of Mexico's pesticide regulation requirements and MRL authorization.

Question: With reference to MRLs published by COFEPRIS, what efforts are being taken to assure that the correct information is available?

*David Soria*no: COFEPRIS and SALUD, are responsible for updating this information. He committed to convey the participant's concerns to them.

Item 9: Wrap-up and Next Steps

As the IWG chair of the meeting, *John Abbott, Syngenta,* noted the good discussion and the wealth of good ideas put on the table. He point to the need to consider where to go from here given the pending transition from NAFTA to the new treaty. He reiterated industry support to combine the work of the Regulatory Cooperation Councils (RCC) with the work initiated under the new trade agreement. He then invited the TWG delegates to share their thoughts about what they heard and how best to combine regulator and industry interests?

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Peter Brander PMRA/CAN: The bilateral RCC workplans should be identical to the NAFTA workplan to reduce the reporting burdens and to focus on getting things done. From a regulatory perspective , the trilateral meeting gives regulators a venue to discuss and make plans to act on the opportunities and issues presented. He acknowledged that trade is important and while it may not be part of regulatory mandates, there is a need to look at structuring future trilateral meetings so regulators can focus on human health and the environment as well as having experts from trade come together.

Amada Vélez Méndez's, SENASICA/MEX: Mexico is drawing up a new law on pesticides and would like human health and environmental assessment and trade to all move in the same direction. She indicated that MEX supports the inclusion of international trade in the agenda for this trilateral forum and that the concept of One MRL is of great interest to MEX.

Rick Keigwin's, US EPA/USA: There are three areas of interest. 1. Harmonization and Trade - If we're approaching 80% of MRLs that are harmonized or being harmonized, this is significant and shows that we've achieved a lot. This can serve as a model for other areas of international cooperation. Trade is a large component. We need to discuss mandates of individual governments and figure out how to further engage in trade negotiations. 2. Advances in science – we need to keep up with advances in science and as new techniques come on-line, we have to remain aligned in the relevant scientific areas. 3. Technology – technology is moving faster than regulatory policy development and we need to ensure regulatory policy development keeps pace with emerging technology.

Comments from the floor and Responses:

IWG MEX– From an industry perspective, this was a very good meeting. One of the important topics discussed was in vitro testing. We should consider putting more attention in this area. MRL harmonization is a critical topic but it will be quite difficult to agree on One MRL. I would like to request that PMRA and US EPA continue to engage with COFEPRIS as there are many things still to accomplish in MEX.

IWG CAN – This has been a good session. The main topics included joint reviews, which we've been doing for years and the issues surrounding MRLs which are important to trade. Something else that should be at the top of the list is the re-evaluation of older chemistries. I don't know if Mexico has a mandated process in this area but there is a 15-year re-evaluation requirement in the USA and in CAN. In CAN, this is very big for growers because we risk losing domestic registration of uses. Maybe during the next meeting or in another year this should be made a prime topic.

IWG CAN – We need to maintain close collaboration among all three countries as the implementation process for the new trade agreement proceeds: I don't want to see work undone when the new agreement is ratified. If you look at the export markets that MEX has, we need to encourage Mexican

participation in JMPR and CODEX. It would be great to have Spanish-speaking-country experts in the JMPR space.

IWG USA - "Continuity" is a word that comes to mind. Please keep the NAFTA meetings going and keep the flow of information going to allow for new people to replace those that move on to other positions or leave.

IWG CAN – I'm impressed that regulators are in listening mode. Process wise, how can we work together to prioritize the work now, later and in 10 years from now?

> *Rick Keigwin, US EPA/USA:* The TWG delegates are not the right group to answer that question. Technical people will do this.
>
> *Peter Brander, PMRA/CAN*: Regulators need time to look at what has been discussed and then speak with the IWG leads to narrow down the list of topic areas.

IWG CAN - Would it be helpful if industry prioritized their recommendations?

> *Peter Brander, PMRA/CAN* asked to defer that point until the TWG had time to discuss the outcome of the meeting and next steps.
>
> *John Abbott, Syngenta,* committed to have the IWG prioritize the action items from the meeting and to share them with the TWG Executive Board.

IWG CAN - When is the next meeting and where?

> *Peter Brander, PMRA/CAN,* confirmed that Canada will host the next meeting, suggesting the timing be the spring of 2021 due to the USA election cycle. He also indicated there will be conference calls in the interim, that a plenary meeting may be needed and that the TWG would like to hear more about regulatory and trade issues of the future.

IWG USA - The trade issues are not going to change and regardless of upcoming USA elections, we should have a meeting in one year's time. The trade issues are huge, and we want to ensure progress continues to be made and not stop. Talking to regulators is important. We can't wait another 25 years to be aligned on the remaining 20% of MRLs.

IWG CAN – We have a common goal, to produce safe, nutritious food for our customers. From a grower perspective, asking for grower input is appreciated, and I would like to see a meeting within the next one-year timeframe. There are trade implications, such as harmonization of pesticide regulations for pesticides and farmers that do not have access to pesticides that other countries do. Harmonization from a fairness perspective is key.

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IWG USA – Two points, 1. It would be difficult to have One Codex MRL, but a good place to start would be to focus on biopesticides due to their low health and environmental risk profiles. 2. MEX should consider implementing true risk-based assessments with a sound scientific approach during development of their new regulations. This should be in concert with the USA risk and science-based approach.

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ANNEX: IWG-Proposed Topics for Inclusion in the TWG Work Plan

Joint reviews: Areas for Improved Harmonization

- Enhance MEX's involvement and seek opportunities to increase engagement with other agencies around the globe (including JMPR) as potential joint/parallel review partners to enhance MRL harmonization.
- Allowance for second-entry joint reviews for major and minor crop uses.
- Further harmonization of data requirements for pesticide registration in North America.
- Modify Wave 2 Acceptance ("Tailgating Policy");
    - Allowance for submission of additional label uses (crops) within a specified timeframe, post submission of a new active ingredient but prior to the initial (Wave 1) decision without jeopardizing the Wave 1 timelines, provided set criteria are met; and
    - Form an industry/ government team to develop acceptable criteria with the goal of implementation in 2020.
- Broader adoption of Risk 21 approaches.
- Expansion of the use of waivers (e.g., expand application of non-animal methods, frameworks and guidance for increasing speed of acceptance, expand acceptance of study waivers to include cancer bioassays.
- Align data requirements, risk assessment processes and timelines for new technologies (e.g., RNAi, drones, precision agriculture, label access by growers)
- MEX: Facilitate minor label changes.
- MEX Pesticide Law: US EPA and PMRA actively engage in the development of the new law.

Human Health: Areas for Improved Harmonization

- Expand development and use of new approach methods (NAMs) for toxicity testing, for both new active ingredients and for re-registrations.
- Continue to evaluate and adopt the use of in-vitro human dermal absorption for non-dietary risk assessments.
- Apply alternative approaches, including acute toxicity estimate (ATE) calculations, for evaluating formulations.
- Use of toxicokinetic data (TK) for dose selection in toxicology studies and improved understanding of dose-response.

Human Health Assessment: Areas for Improved Harmonization

- Measures to address and prevent divergence in selection of end points for dietary and non-dietary risk assessments.

- Use of Safety Factors to derive ARfD, ADI and operator safety – Need to align.
- Official Mexican Standard for MRLs (10/4/2017): technical criteria for dietary risk assessments (appendix A-NOM) should be aligned with the above-mentioned points.

Environmental Safety Assessment: Areas for Improved Harmonization

- Pollinators – Tiered approach to testing honeybees and harmonized decisions.
- Birds – Acute oral test species and dietary test requirements.
- Non-target arthropod testing and lack of risk paradigm.
- Earthworm testing.
- Align Bioconcentration-Factor testing requirements.
- Accept higher-tier testing and risk refinement.
- Environmental exposure modeling (e.g., water and spray drift).
- Use of water monitoring data for ecological assessments.
- Higher-tier environmental exposure/residue studies.
- Vegetative Filter Strips (VFS) – Continue to work together to advance science collaboration among regulators, registrants and researchers.

Other Areas for Improved Harmonization

- Re-evaluation/Registration Review harmonization:
    - Registration Review 2.0 opens in 2022; US EPA dockets are now under consideration - this presents an opportunity for harmonization.
    - Seek grower input on value assessments and understand their needs prior to finalization of changes to use/labels.
- Establish import MRLs in MEX and completion of MEX's MRL data base.
- MEX: In collaboration with industry, develop a risk-based protocol for review of molecules considered for possible cancellation.