



Grupo de Trabajo Técnico Trilateral de
América del Norte sobre Plaguicidas

North American Trilateral Technical
Working Group on Pesticides

Groupe de travail technique trilatéral
nord américain sur les pesticides

**North American Trilateral Technical Working Group on Pesticides
(March 23rd and 24th 2022)
SUMMARY**

The North American Trilateral Technical Working Group on Pesticides met virtually with stakeholders, on March 23rd and 24th 2022. The executive presidency of the Group was in charge of Mexico, under the coordination of the National Agri-Food Health, Safety and Quality Service (SENASICA), through Q.F.B. Amada Velez Mendez, Director General for Agri-Food, Aquaculture and Fisheries Safety (DGIAAP). By the USA, Edward Messina, current Director, Office of Pesticide Programs, Environmental Protection Agency (OPP-EPA), and by Canada, Peter Brander, Executive Director, Pest Management Regulatory Agency (PMRA), Health Canada. Other government officials of the agencies were present, among them, the US Department of Agriculture, Agriculture and Agri-Food Canada, the Federal Commission for the Protection against Sanitary Risks (COFEPRIS), the Ministry of Environment and Natural Resources (SEMARNAT), and the Ministry of Agriculture and Rural Development (SADER), from Mexico. Likewise, it was attended by representatives of the crop protection industry, growers, exporters and stakeholders from the three countries, as well as observers from Brazil, Chile, Colombia, and China.

**DAY 1 (March 23rd 2022, 8am-11:30am Central Time)
GOVERNMENT SESSION – STAKEHOLDERS: REGULATORY SCIENCE**

1. Welcome by the President of the Executive Board – Mexico

1. a. Opening Remarks, Executive Board

a. Amada Velez Mendez, Director General from SENASICA

Amada Velez, as head of the host country of the meeting, welcomed the attendees, on behalf of Dr. Victor Manuel Villalobos, Secretary of Agriculture, and Dr. Javier Trujillo Arriaga, Chief Director of SENASICA; she also thanked the participants, including authorities and participants in general. She highlighted the following messages:

- The need to have a close collaboration with our main trading partners in North America, in order to guarantee that our farmers have access to the same tools that help them both in the production and in the commercialization of their products.
- This group should continue to collaborate in the exchange of useful information to solve problems that arise in each region, considering that science, innovation and development represent the long-term way to increase agricultural productivity, and face the challenge of feeding a growing population in a sustainable way.
- For this reason, the meeting includes the government bodies with the greatest powers in the regulation of pesticides.
- This digital format allows greater dissemination and audience, without the need to move.

1. b. Edward Messina, OPP-EPA



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He began by thanking Amada Velez and the Mexican delegation, and the following stands out from his message:

- 2021 was a busy year for the EPA, which completed more than 5000 pesticide registration actions, accelerated responses in relation to the COVID-19 pandemic to give stakeholders the tools for crop protection and disinfection.
- Approximately 35 draft risk assessments, 60 proposed interim decisions and 75 interim decisions were published, and more than 700 record review labels were reviewed.
- They made significant efforts to reach out to stakeholders.
- Among the priorities of the OPP are registering pesticides, providing technical assistance for funding under the applicable statute, registering existing pesticides, advancing science-based decisions, etc.
- In addition to these priorities OPP has also improved education programs for pesticide user safe use, and it was announced that work will continue on actions in relation to the Endangered Species Act (ESA) law.
- Work is also being done on the creation of the Climate Change Adaptation Implementation Plan, so that the OPP can take measures to address the problems of climate change.
- As for ESA, it was reported that included active ingredients will be reviewed, to assess if there are negative affects one endangered species, and if appropriate, mitigation measures would be included from the outset, rather than waiting years for the consultation process to conclude.
- He reported on the issuance of two registers of weed control herbicides in conventional and genetically modified corn, cotton and soybean crops.
- The Office is expected to continue to do great work in collaboration with SENASICA and PMRA colleagues, and our engagements with stakeholders in the pesticide community.
- He thanked the opportunity to intervene, as well as his collaborators and colleagues from the other US agencies.

1. c. Peter Brander, Executive Director, Pest Management Regulatory Agency (PMRA), Ministry of Health, Canada

He thanked the Mexican delegation, particularly Amada Velez. for organizing the meeting and pointed out the following:

- He was proud of the important work that the PMRA continues to do in exceptional circumstances, while staff continue to work remotely to follow public health recommendations in Canada. Despite this, the performance of premarket reviews remains high, and several key initiatives have progressed.
- They continue to actively participate in the Joint Review program, with North American and global partners, highlighting the multiple benefits of this.
- They have made progress in the modernization of pesticide labels, involving national stakeholders in sessions on the standardized content of labels for agricultural uses, making great progress.



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- They continue to work on the development of new technologies, such as ozone and ultraviolet generating devices, which must comply with the applicable regulation.
- They face challenges, such as maintaining public confidence in the pesticide regulatory system, communicating risks, placing greater emphasis on science-based decisions.
- Harmonization is possible and critical to building public trust. So there are several communication campaigns.
- The transformation activities of the PMRA are being and will continue to be carried out to strengthen the monitoring and protection of public health and the environment. This approach is based on: improved transparency, increased use of “real-world” data and independent advice, strengthening human health and environmental protection, specific revision of the Pest Control Products Act.
- Opportunities for collaboration with stakeholders continue to be sought and the discussions and presentations of the Working Group are awaited with interest.

Opening Remarks – Industry Working Group

a. Juan Cortina, Representative of Farmers, President of the National Agricultural Board, CNA, for the acronym in Spanish

In his statement, he stressed the importance of the meeting, thanking the invitation to it. Additionally, he commented:

- In the context of the characteristics of the agricultural sector and the challenges it faces, from climate change, water scarcity, growing population, health emergency and the ongoing war, it is important to have crop protection products and are the most used to combat pests and weeds, but also to evolve to offer more innovative and specific technologies to farmers, to face them.
- Failure to use or inefficient use would affect production, consequently, raising prices of products for the consumer, if we consider a weak economic recovery derived from the pandemic and inflation that globally will face given the current conditions.
- He mentioned the impact of the conflict between Russia and Ukraine on grain prices - and fertilizer prices - coupled with the decreasing availability of a key herbicide for weed control in Mexico.
- Therefore, it is essential to make a comprehensive assessment, where both health, environmental, agronomic and socio-economic aspects are considered, clearly establishing a cost-benefit analysis in decision-making and, of course, taking into account the perspectives of the impacted sectors.
- Also, the importance of considering risk mitigation measures, before prohibiting the use of certain products, which could magnify the low productivity of most crops in Mexico.
- He provided data on agricultural exports, which, if bans on highly hazardous pesticides were adopted as currently promoted, would affect that activity.



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- On the other hand, he mentioned that various quarantine pests are kept under control through the Programs directed by the Ministry of Agriculture, and that they use some pesticides that are classified as highly dangerous.
- He made a respectful call to regulators to analyze these issues to find a balance between the food production that our country requires and the protection of health and the environment. Likewise, focus efforts on promoting efficient regulations and serving the objectives of sustainable development.
- He concluded by pointing out that the actions focus on field surveillance in terms of good use and handling of the products and offered the support of the industry for this.

b. Roberto Escalante, Industry Representative, President of the Crop Protection, Science and Technology Association, A.C.

In his speech, he thanked the opportunity to participate and highlighted the following messages:

- They are confident that the exchange of information will lead to harmonisation actions to facilitate compliance with trade agreements.
- The industry is ready to work with governments to establish the best regulatory platform in the use of their products.
- We are working hard for a more competitive, sustainable and better quality of life for farmers and their families in Mexico.
- He respectfully requests the authorities to work more closely to present more efficiently and directly their views on better regulation, which will result in the expected benefits for our country's agriculture.
- They propose further harmonization with the US and Canadian governments on the risk analysis approach to product evaluation.
- Collaboration between countries is vital to be able to offer new solutions to the countryside, friendly to the environment and that promote more sustainable agriculture, hoping that the discussions these days, help to align strategies that give greater fluidity and speed.
- Understanding the problem of lagging behind in terms of records, we are certain that, if we collaborate, we can make progress. In this sense, it will also be very valuable if the representatives of the governments present here, to share your experiences during the pandemic in terms of self-management, the challenges you have faced and the solutions you have found; with this Mexico we will be able to, report on the best practices implemented in your countries and adopt those policies and measures that contribute to strengthening our regulatory processes and, above all, our contribution to the safe and sustainable production of food.
- He concluded by thanking SENASICA for its leadership, and reiterated his orders to continue collaborating in what was deemed necessary.



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c. Luis Eduardo Gonzalez, industry representative, president of the Mexican Union of Manufacturers and Formulators of Agrochemicals, A.C.

Mr. Gonzalez thanked the opportunity to participate, greeted the other participants, and gave the following messages:

- An overview of the food industry and production, and the challenges it faces, involving the various sectors, was presented.
- On modern agrochemicals, he mentioned that they are one of the most important public health innovations of scientific advancement, with in-depth contributions.
- Food production continues to face major challenges, such as climate change and degradation of natural resources, misinformation about scientific evidence around hazardous substances, which has become a tool to manipulate public understanding and debate, causing confusion, doubt and mistrust of science, and COVID-19 and the recent Russian-Ukrainian conflict.
- He noted the privileged phytosanitary status of Mexico worldwide, the product of the work that the Mexican government has done in coordination with the guilds, as well as the mission of SENASICA to keep pests and agricultural diseases controlled for the maintenance of food production and supply.
- Although Mexico is a powerhouse in food production, when dissecting the sector, it sees a lagging producer, which requires training, technology inputs, among others. They must therefore be brought to the forefront with their access to innovative technologies.
- It calls for society to become aware of how the products that are produced in the field reach the table of each household, and the importance of the appropriate use of inputs, to generate economic development.
- Although the agrochemical industry contributes to food production and compliance with national and international regulatory standards, there are areas of opportunity to strengthen the commercial relations of the block's partners, one of them is the harmonization of the regulation of food production and its inputs, hence the importance of the meeting, where the sectors converge, so that positions based on science are analyzed and set.
- That is why they join this important and outstanding meeting, wishing you success.

2. Updated information on the revised Strategic Plan and Terms of Reference

This topic was introduced by Zoe Emdur from EPA. She stated that during this cycle, the secretariat hopes to resume the revisions of strategic plan and terms of reference. The work has not been discussed since 2020, and updates were not finalized at that time. The 3 countries will be working in the first part of this year to review it, with the goal of being able to have a preliminary report of the changes made, on which comments would be expected.

Peter Brander commented that the PMRA fully supports the EPA's approach and awaits the updating of the documents to continue the work of the group; while Amada Velez comments that this work



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plan must be able to help solve the challenges posed, jointly to continue the activities that the world situation poses us.

3. Review of the Mexican Regulatory System, OECD. Manuel Gerardo Flores, OECD Representative in Mexico

Manuel Flores thanked and greeted all those present, including authorities and participants, subsequently explained the objective of the research, highlighting that a key element was the broad participation of the groups involved to be able to include recommendations, including experts, including Peter Brander from Canada. The peer review was a very important aspect of the work of the OECD with its member countries, which guarantees the impartiality and transparency of the analysis.

The report is available on the Internet, has four sections: context of regulation, central aspects of it, best practices in regulation and evaluation and recommendations. Among these recommendations, the report suggests that the authorities would benefit from adopting a policy of mutual recognition, and recognizing that pesticide management is shared by national and local government and the general public, essential for goals and objectives and effective coordination; also, that a pesticide law would be very good, because it would address the full life cycle of pesticides, with the same weight for the protection of human health and reflect international developments.

Regarding the re-registration of pesticides, they considered that the country would benefit if it expedited the delivery of records, the digitization of processes, online records, as well as considering the early approach in the stages, to those involved.

After the presentation, Gabriela Moreno of COFEPRIS commented, derived from the questions, that the study served to resume the review of the pesticide registration regulations, whose recommendations allow reviewing the regulatory processes for registration, extension and modifications, ensuring that attendees will be pleasantly surprised with the regulatory changes, but emphasizes that these changes will take time to implement them.

Amada Velez adds that SENASICA is enthusiastic about the study, although the competition is limited to certain areas, but we want farmers to have tools for pest control in the Mexican countryside. It is essential to have a single work policy as a country, to be very clear about where we are going to focus our efforts, what we want for health, agriculture, the environment. The work carried out by the experts is very important and valuable and at SENASICA it is expected that soon work can be done on the analysis of the document, and see what aspects can be incorporated into Mexican regulation, including the generation of a new law as recommended.

4. Post-Market Reviews – Collaborative Opportunities



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a. Industry outlook. Chris Davison, Vice President, Stakeholders and Industry Relations, Canola Council of Canada

He presented background information on the canola industry in Canada, including its worldwide market. He mentions market access trends, increased complexity, access to innovation and technology, sustainability and biofuel standards, and the impact of Canadian regulations. They are concerned due to the importance of their market, that regulations are increasingly complex and fragmented, the divergence of regulations against the speed of innovations, and the risks that this entails.

They point out that the lack of regulatory consistency stifles progress and that the lack of harmonisation of MRLs is unpredictable for trade and further complicates regulatory compliance. They point to the growing pressure to abandon science-based regulations, confusing the difference between danger and risk in policy-making, and that this leads to unscientific approaches to crop protection products.

Their main challenge is to meet the demand for food, animal feed, fiber and fuel, which is aggravated by geopolitical situations, post-COVID protectionism, increased competition, climate, supply chain problems, etc. In the Canadian context, they point out to be able to count on efficient assessments based on science, and timely; also, that as you advance in a continuous re-evaluation model, the industry will be more involved in the decisions that are made and the good experience of the benefits that this provides.

b. REGULATOR'S PERSPECTIVE. Gabriela Moreno and Alejandra Martinez, COFEPRIS; Elissa Reaves, EPA and Margherita Conti (Regi Mathew)

COFEPRIS

In the intervention of Gabriela Moreno, it was highlighted that in the knowledge that the deadlines for resolving pesticide registration applications are short, which has led to delays in care, changes are analyzed in the regulatory process, in the specific regulations for the matter, including protocols, reference methodologies for MRLs, requirements for in vitro toxicological studies. While for low-risk pesticides or bio-inputs such as plant nutrients, a life cycle different from the current one and its registration procedure, as well as other deadlines for attention, according to the needs of the trade to have products that allow to overcome problems such as illegality and misuse of products already registered.

The amendments to the regulation also incorporate certain criteria for classifying high-hazard pesticides and low-risk pesticides, since it is necessary to adjust the balance between what actually causes damage to health and the environment against the most appropriate alternatives or those that do not cause or identify damage associated with their use. The situation of records of undetermined validity is also being reviewed, as well as the withdrawal of products based on scientific evidence, the use of which has been confirmed as causing damage to human health or the environment.



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For her part, Alejandra Martinez mentions that in Mexico the evaluation of products is carried out based on danger, that is, the intrinsic properties of the substance, since, unlike other countries, Mexico is still lagging behind in the risk assessment. It mentions that it is a challenge to comply with the deadlines established by the regulation, as noted in the OECD report. In the case of applications for extension of registration, they are being entered online, which already somehow addresses one of the recommendations made by that Agency.

The considerations to be taken into account to improve regulation are to eliminate or prohibit the use of highly dangerous pesticides, based on danger assessment, since a challenge to be faced is that post-registration surveillance is carried out, which is only observed in the case of export products, but there is no information on the exposure of occupationally exposed or open personnel in the use of the products. The re-evaluation is projected to 10 years, 5 years more than is currently established, or earlier if there is a problem to human health. Thus, it is thought that harmonization can be achieved, the procedure is known and with these discussions, the alliance can be initiated or strengthened in order to successfully register pesticides.

Elissa Reaves, EPA

Elissa began her presentation by showing the legal basis for the process of re-evaluation of pesticide records (Federal Insecticide, Fungicide and Rodenticide Act, FIFRA, Federal Food, Drug and Cosmetic Act (FFDCA), Food Quality Protection Act (FQPA), Endangered Species Act (ESA)), which takes a long time, and explained the process.

The EPA registration review process was outlined, presenting the following data: by the end of October 2022, 726 cases must be completed, 676 Preliminary Risk Assessment Documents (DRAs) have been published, 605 Proposed Interim Decisions (PIDs) have been published, as well as 554 Interim Decisions and final decisions

As for highlights in the registration review, they note that they need additional time for about 80 chemical cases, including organophosphates, carbamates, neonicotinoids, *Bacillus thuringiensis*, ethylene oxide, formaldehyde, etc. The Registration Review Calendar updated each quarter can be found at: <https://www.epa.gov/pesticide-reevaluation/upcoming-registration-review-actions>

In the case of ESA (Endangered Species Act), there are case study chemicals selected for registration review, the EPA is scheduled to complete 6 biological evaluations of ESA nationally for registration review in Fiscal Year 2022, and implementation of the biological opinions of the U.S. Fish and Wildlife Service and the U.S. National Marine Fisheries Service.

Regi Mathew, PMRA



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An overview of the pesticide re-evaluation program was provided, indicating the applicable law, as well as the time in which it is carried out. In this process, the registrant has the opportunity to submit information, after which the evaluation is carried out, the response proposal is published for consultation, and the comments are taken into account before making a decision. Priority is given to the re-evaluation of pesticides, with considerable progress being made, for those registered around 1995, so that risk issues are promptly addressed. It was also mentioned that feedback from other regulatory partners is considered.

Work is under way with stakeholders to develop a systematic approach to improving decision-making and addressing risk assessment issues in a timely manner. There is a publicly available updated five-year work plan to inform them of the proposed and final decisions of the re-evaluations, as well as future plans.

Amada Velez indicated that there are points of convergence that can support better interaction with the regulatory partners. This exchange is valuable to continue improving on the subject.

5. Regulatory approaches for new technologies – drones (UAV/UAS)

a. CONTEXT: CropLife America, Sarah Hovinga, Regulatory Policy Analyst, Digital Farm, Bayer USA

Sarah notes that drones are part of the solution towards practices that positively affect the climate and the sustainability and climate change goals, so the application of pesticides using drones should be incorporated into the current regulatory framework for its use authorization according to current risk assessments.

She mentions some of the benefits of the use of drones, such as the flexibility to apply in areas of difficult access, a low cost compared to another type of application and derived from the optimization of the same, less operator exposure, reduce the amount of water, improve soil health, reduce emissions.

A comparison is made on the situation of the application of technology and its regulation worldwide, with Asia-Pacific being the most advanced in regulation with more than 30 years using this technology, while Latin America is in general analyzing the issue to regulate it. In North America, the US is the most advanced country in the regulation and authorization of use. In general, risks from drone applications are covered by existing risk assessment guidelines, however, it is necessary to generate additional data on drift, operator exposure, and residues. This is addressed in several stakeholders' groups.

The mission of the CROPLIFE America working group is to evaluate existing data to evaluate or generate data on traditional and aerial application methods with drones, to identify equivalences or gaps, with a focus on four areas: registration-label, drift, residues in the crop, and operator exposure. For each of these areas, the working group makes recommendations, that it would be appreciated to closely share them, from generating guides in a sufficiently clear language for field personnel, a



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standardized method to measure drift, develop new prediction models or adapt existing models to estimate drift; likewise, make comparisons of residues with respect to the different types of application (ground-air), and allow or facilitate regulation through the relevant laws, develop a clear or specific language for the application with drones, and user guides.

In this regard, the industry continues to work with the EPA to facilitate the registration and recommendation of this type of application, as well as with stakeholders, and thus to contribute to sustainable sowing.

b. REGULATOR'S PERSPECTIVE. I. For the EPA, PMRA and Mexico to discuss their respective work in this area

David Soriano, Director of Biosafety for Genetically Modified Organisms, SENASICA

He indicates that there is an official Mexican norm on aerial applications of pesticides, which after many years of its publication, it is known that there are areas of improvements, not only related to the use of new technologies but to have accurate information on the products applied. In the norm review group, the need for complementary regulations to ensure protection of the environment and human health was identified. Therefore, COFEPRIS, SEMARNAT and SADER decided to design a new regulatory instrument in which the three authorities participate in the monitoring.

In both cases, both in the revision of the current norm and in the new instrument that is intended to be generated, it is sought to differentiate the conditions of traditional aerial application from those of application with drones, considering at all times the characteristics of each.

He concluded by saying that, at this point, the importance of the exchange of technical and scientific information that counterparts can generate, with the intention of having the most available information and being able to grant farmers tools that help them in the production of their crops, reducing the risks to human health and carrying out actions that protect the environment.

Amy Blankinship, EPA, and Ross Breckels, PMRA

Amy and Ross shared that, the EPA does not have an established policy related to the application of pesticides with unmanned aerial systems (UAS), nor data requirements or implementation on pesticide labels. There are no established risk assessment frameworks or approved models to assess drift produced by emerging technologies such as UASs. Therefore, the priority for the EPA is to understand the exposure scenarios presented by the UAS and how they compare with current technology; also, work continues towards a standard policy and risk assessment method to assess the potential risk of UAS applications, and they propose to work with several UAS stakeholders/working groups.



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In the case of Canada, Ross indicated that the Remotely Piloted Aircraft Systems (RPAS) application does not appear on registered product labels. Applicants are encouraged to gain information through the “Pre-Submission Consultation” program. The use of RPAS in Canada is under study, although with the proper permits, it is allowed in research trials for efficacy studies.

PMRA is developing data requirements, in consultation with other jurisdictions, to support RPAS applications. Draft data requirements include aspects related to value (crop coverage, product efficacy), environment (operating conditions: height, speed, configuration; pulverization volume and droplet size; pulverization deposition and drift data), human health (mixer/charger exposure; pilot/applicator exposure; bystander exposure), crop residues/maximum residue limits (MRLs). PMRA is also involved in the OECD Subgroup on Drones, in the North American Remotely Piloted Aerial Application systems (RPAAS) working group, in workshops and conferences, and with interested parties.

Ongoing work includes sharing federal regulatory perspectives to RPAS working groups; collecting/exchanging RPAS information through the OECD Drone Subgroup.

Areas for possible regulatory alignment are identified: data requirements for environmental and health assessments; pulverization drift models; operator/bystander exposure models. As for areas with unique federal regulatory requirements: flight regulations; unique conditions of use for each country; pesticide registration decisions for use in RPAS; independent risk assessments and risk management decisions.

b. II. REGULATOR'S PERSPECTIVE. For PMRA to present a status update of the work of the OECD on drones and potential next steps. Ross Breckels, PMRA

Regarding the update of the OECD sub-working group on drones, it is commented that it is a working group formed in August 2019, by a multidisciplinary group and led by the United Kingdom, with the participation of the European Commission, the United States, Canada, Australia, Slovakia, Hungary, Japan, China and the Plant Protection Industry. Its objective is to generate guidance on the data needed to support the application of pesticides by means of drones, recognising the various risks of conventional applications (both terrestrial and aerial), with the aim of establishing their future viability (taking into account the pace of technological advances).

The report considers some common operating conditions, such as small multirotor units, nozzles under the rotor or mounted on the boom, as well as typical RPAS operating ranges.

The report also considers data on application effectiveness, water volumes, operator exposure, and the need to establish standard protocols for testing.

Derived from the above, the 2022 work plan includes a change of focus following the release of the analysis of specialized publications, with the new mandate of: encouraging the generation and



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presentation of information and (or) regulatory data to the relevant government agencies, including those represented in the OECD, through five work areas, based on the nine recommendations contained in the report.

The five work areas consist of: (1) development of an empirical standard drift curve to estimate off-target exposure from drone applications and to develop a publicly available mechanistic model for predicting spray deposition and drift; (2) establishing a database to group certain drone platforms to reduce the burden of testing and to surveying manufacturers about future trends in drone use and design; (3) developing best practice material and promoting recommendations for researchers conducting drone drift studies; (4) developing standard methodologies that support regulatory decision making; and (5) encouraging manufacturers to develop improved spray systems, including pump systems, nozzle placement, and closed transfer loading systems.

c. Registrant's perspective:

I. Presentation of the work of the Industry Task Force on Drones. Greg Watson, Regulatory Policy Analyst/Manager, Bayer, USA

The group is multinational, with work areas already in progress. As an industry, mention the areas you will be working in. A key aspect of the Unmanned Aerial Pesticide Application Systems Task Force (UAPASTF) is to submit recommendations to regulatory agencies to respond to global data needs. Through an interim agreement they can work together, to create the structures and funds for operation and research, with three work areas coming from the OECD: development of exposure models, risk assessment and drift information, it will be seen that it is not part of the working group. There is an agreement that allows collaboration, not only with registrants but with manufacturers and other interested parties.

II. Use of drones in Agriculture, Alberto Margarito Garcia, Professor-Researcher, Autonomous University of Aguascalientes, Mexico

Dr. Margarito in his speech thanked the opportunity and commented that all the timely and necessary information for the applications should be considered. Precision agriculture is the basis for optimizing agriculture. The use of drones for agriculture already occupies an important place globally, so the parameters to be used must be taken into account, in addition to those that are already established and that should not change. He mentions that you should have a tailored suit for each product, considering whether the farmer knows the proper practices and the result is appropriate. He mentioned that several biological effectiveness studies have been carried out, in several crops, in which it was contemplated what type of product to apply, mode of action and problem to control; as well as the case of multispectral studies for the application at the right time and place of pesticides.

7. New Approach Methodologies – Animal Testing



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a. Regulatory perspective. EPA and PMRA to discuss non-animal acute toxicity assessment methodologies they currently use in dossier evaluation

I. Deborah Ramsingh, PMRA

It was mentioned that acute toxicity studies in mammals remain a mandatory requirement for classification of acute health hazards, and may include information on acute toxicity by oral route, dermal route and inhalation, acute eye and skin irritation, and acute skin sensitisation.

Following a retrospective analysis, the routine requirement for a mammalian acute dermal toxicity study was eliminated, and in line with its commitment to apply the “3Rs” principle (reduce, refine and replace) to animal toxicity testing, PMRA always assesses whether methods that do not use animal testing for the classification of acute hazards and for labelling are feasible (and should be encouraged). Requests for exemption from the requirement to submit test data on acute dermal toxicity are routinely examined, as established in the relevant Directive.

Furthermore, as a member of the OECD Expert Group on Skin and Eye Irritation, PMRA has contributed comments and inputs to the new and revised guidelines for in vitro test methods; a draft guideline on defined approaches to serious eye damage and (or) eye irritation is being developed; and PMRA will consider whether in vitro test methods can be applied, to determine eye and skin irritation by weighing the evidence for hazard classification and labelling.

Also, the PMRA, as a member of the OECD Expert Group on defined approaches to determining skin sensitisation, will take into account the in vitro test methods used to determine skin sensitization, as well as the guideline on defined approaches in the framework of a weighted assessment of the evidence for hazard classification and labelling.

About the update on the non-animal testing essays approach, currently, the regulatory assessment of pesticides for use in Canada is based primarily on animal studies. Thanks to the flexibility of the Pest Control Products Act (PCPA), PMRA may consider alternative and new methods to replace animal testing.

Advances to date, include removal of the routine requirement to conduct a year-long toxicity study in dogs; removal of the routine requirement for a one-year acute dermal toxicity study; validation and acceptance of the use of data obtained exclusively in vitro to estimate the degree of absorption of pesticides through the skin.

It mentions collaborative activities, among which are the ReCAAP Project: Rethinking the Carcinogenicity Assessment of Agrochemicals, HESI – Institute of Health and Environmental Sciences, CAAT – Centre for Alternatives for Animal Testing, OECD in vitro initiatives.



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In summary, the PMRA has made progress and continues to seek opportunities to apply non-animal testing methods to obtain the required data by regulations and also to eliminate information gaps; Canadian regulatory policies will take into account new approaches to toxicity testing, to ensure consistency and continued collaboration with governments in other countries; Canada continues to actively participate in various international initiatives that seek to reduce animal testing while protecting human health.

II. Monique Perron, EPA

Monique shared updates on EPA's efforts to reduce animal testing and its use of NAMs. The US regulations provide EPA with flexibility to consider waiving required animal studies and/or utilize alternative test methods on a case-by-case basis. Study waivers have greatly contributed to EPA's ability to reduce its reliance on animal testing and several EPA waiver guidance documents are available for consultation when evaluating the need for study requirements.

The EPA is one of 17 regulatory and research agencies in the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), which helps with the development, validation, and regulatory acceptance of NAMs. EPA also works with multiple national and international organizations on a wide range of projects to develop and implement NAMs for regulatory decisions. In June 2020, EPA published the EPA NAM work plan that outlines the Agency's objectives and strategies to reduce the use of animal testing and updated the work plan in December 2021. EPA recognizes that that NAM work plan will continue to evolve as the Agency gains additional knowledge and experience. The NAM work plan can be found on the EPA website.

8. Regulatory efficiencies – Self-certification

Douglas Hines, Product Chemistry Expert, Regulatory Affairs, ADAMA. He comments that, as a historical context, there have been two drastic incidents in the supply chain in the last 5 years, the industry approached the EPA, because it had to supply a product and there was only one place where it was produced, the other case is about EO and PO that were limited due to the freezing of pipes in the production of these materials, which are ingredients for other products such as adjuvants, antifreezes.

It mentions as lessons from these events, what they consider to be the scheme to successfully carry out the activity, having first communication regarding what can happen to inform regulators and give evidence of the possible consequences of shortage of supplies. Then, propose to regulators a pragmatic approach and with the tools available, which does not compromise the regulator, after which, support, assuming that having carried out a risk assessment on the evidence provided, the regulator can communicate to the relevant government hierarchy. The next point is to validate, ask the industry and confirm that the proposal that needs to be made is efficient, and finally, again the communication, that the information is used, and if the regulator does not know how it is used, provide feedback of its function to learn from the continuing need or that it has been finished.



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He commented that notification by batch would be a way to make a large number of compositions efficiently dealt with by means of notifications or to replace substances to meet several requests at the same time. Another option relates to applications with minor composition changes.

Frédéric Bissonnette, PMRA

Frédéric commented that, during the pandemic, the times of approval of the products as disinfectants were reduced, beyond the notification, trying to be flexible, recognizing the situation. Also that the department is actively working with the EPA to see what measures other regulators took, and although progress was slow, there were beneficiaries. They consider the inputs that registrants provide, so that there is a good supply for producers.

Kerry Leifer, EPA

EPA presented on the efforts that occurred at the beginning of the pandemic. During the pandemic, EPA established a list of basic inert ingredients that could come from different suppliers without providing additional information, speeding up the process so that it did not impact the final suppliers. Currently the list of these ingredients on the website, contains 400 products, and more ingredients are continuing to be added at the list is regularly updated.

On the issue raised by the PMRA, the EPA issued measures which provided pesticide manufacturers temporary regulatory flexibility to help address supply shortages.

Concluding Statements for Day 1

As conclusions of the day, Amada Velez mentioned that it is very important to know these approaches and she indicated that for the questions raised by stakeholders, they will be looking to contemplate them at the next meeting.

For his part, Edward Messina thanked the hosts of the meeting, the Mexico team panelists; he also commented on the great day of presentations and all of the good information that was shared. EPA is very excited about the updates of the strategic plan and the talks to strengthen the working group. As the hosts of the next meeting, it is hoped that the meeting will be face-to-face, however considering the pandemic and logistics, there it is possible that the Fall 2022 meeting will be virtual.

Peter adds congratulations and thanks to Mexico, noting that it is not easy to organize these meetings, and Amada Velez and her team have done so successfully. The presentations were also very interesting.



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**DAY 2 (March 23rd, 2022, 8am-10:25am Central Time)
GOVERNMENT – STAKEHOLDERS SESSION: AGRICULTURE/TRADE**

1. Welcome

After welcoming the session back, Amada Velez gave the floor to the speakers to begin her interventions.

- **Farmers' priorities, related to pesticides**

a. México Rogelio García Moreno, Vice President of the Agricultural Sector of the CNA

Mr. Garcia began by taking a tour of the history of pesticide use globally and in Mexico and the importance for activities such as vector control and diseases in crops.

With regard to the proposed changes in legislation, he felt that the sectors involved should agree on a common final goal. With a three-part effort to achieve it. Learn more from each other to work towards a parallel agenda. Ensure sufficient and timely supply of agrochemicals, empathy with the agricultural sector, sensitive and fight day by day for profitable, sustainable and self-sufficient agriculture.

Amada thanks Rogelio for presenting the problem of access to plant protection products by farmers in Mexico.

b. United States. Matt Lantz, Vice President, Global Access, Bryant Christie INC.

This presentation focused on the importance of the hop industry in North America. This industry has lists of permitted and prohibited pesticides, which are updated every year.

The restriction depends on each company, but focuses on MRLs from Japan and Europe, and is now extended to include Korea, UK. Although there are EPA-approved pesticides the industry cannot use them or use them only because of the different MRLs; this represents a huge challenge to continue exporting. In this regard, industry has come together to cooperate, in a group that includes participants from several countries to work on issues related to hops. Hops growers are very appreciative of recent effort to establish new MRLs and harmonized with Canada.

Hops are not grown in Mexico, and there has been no problem with Mexican breweries, since there is no industry here, there are no issues related to MRLs. The US industry supports a risk-based approach to pesticide use.

The main issue is the European Union, where many pesticides are no longer allowed to be used and several MRLs have been removed. Work continues to understand their approach; as other countries



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are using their approaches as well. Industry cannot be 100% organic and thousands of euros are spent to work on these issues and the EU is removing pesticide after pesticide without considering the effects on the agricultural sector.

Amada Velez mentioned that the highlighted points are important, promoting the harmonization of MRLs is vital for commercial exchange, and the decisions that are made regarding the use of pesticides, should be based on risk.

c. Canada Aaron Fowler, Chief Agricultural Negotiator and Director General of Agriculture and Agri-Food Canada

The presenter began his message by commenting on some challenges in the agri-food supply chain, as a background for the dialogue. The pandemic has presented major challenges affecting the global supply chain in different parts of the world, added to the recent war conflict. It is important to work on the sustainable 2030 goals of zero hunger, which could be more difficult to meet in view of the circumstances. Agri-food systems need the tools to maintain global production and food security, for example, Canada continues to support a US-launched Coalition on Sustainable Productivity Growth for Food Security and Resource Conservation coalition to make agricultural systems more resilient and productive.

Countries continue to take different approaches in regulating these issues, they also take different perspectives on the implementation and development of agri-food innovations, including pesticides; so it is important that they are based on science and risk analysis. In North America there have been formal and informal relations in production, supply and government between the three countries. Canada, Mexico, and the US are a good model of cooperation and a strong partnership, And it is important now more than ever to seize the opportunities for collaboration to continue to support trade and the global food chain, and to support farmers and processors.

One of the important aspects of the TMEC has to do with working groups, including that on pesticides, which has produced important results, to achieve better alignment in regulation, while maintaining the highest standards to protect human health and the environment.

Canada has also developed tools, technologies, and improvements, which are key to meeting global food demand and maintaining sustainable resource use. In Canada, responsible use has allowed farmers to carry out and benefit from zero-till practices. The ability of farmers to choose the agricultural practices, products, and technologies that are safe, optimal, and appropriate will also continue to be defended, with innovation being a key driver. The government has invested in programs to drive better agricultural management practices.

The Canadian government is committed to increasing the sustainability of its agriculture and agri-food sector. There is heightened awareness of the need to tackle climate change, and improve environmental protection through a combination of scientific research and investment in new



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technologies. Conditions have also been created for farmers and processors for a more sustainable agricultural process. Within the context of the group, the responsible use of pesticides in commercial agriculture is not inconsistent with sustainable agricultural production, which will help advance sustainability goals. Decisions must be sound based on science, which contributes to this.

In conclusion, the three countries have a mutual commercial relationship of collaboration of agricultural products, which also depends on the contribution that is made. MRL-related decisions should be made responsibly and based on science, ensuring collaboration, sharing technical information and continuing to seek further alignment and harmonization. The trilateral group will then continue to work in this direction.

10. MRL-I Codex Pilot Project and Pilot Project: Import Tolerance Programme

(a) REGULATOR'S PERSPECTIVE

i. Nancy Fitz, EPA

The Import Tolerance Pilot was established after several APEC workshops in 2015 and 2016 to provide flexibility in requesting U.S. import tolerances (import MRLs). In the USA import tolerances are usually based on crop residue data from the exporting countries. Under the pilot program, the EPA relies on a detailed report about the crop residue data from a competent regulatory authority, such as the JMPR and EFSA, rather than reviewing the primary crop residue data itself.

Nancy explained what the process looks like and how the U.S. EPA ultimately establishes a import tolerance level or MRL. In the pilot program, the report of another country or competent authority that has already executed those steps is reviewed. EPA needs the same information as in the normal process, so this report, including the opinion, must be complete. After this, the OECD calculator is used and in consideration of the opinion of the competent authority, if it is JMPR the MRL is harmonized with CODEX, or if it reviewed another country, it is harmonized with that country. It is preferred that the compound has a food use record in the USA, to ensure that toxicology data are already available, although it is not an absolute requirement.

More than 28 MRLs have been established since 2017, the most common being in tea, which constitute the 40%, but they have also been established in a large range of basic products, some are cultivated in the USA, others are primarily imported.

ii. Monique Thomas, PMRA

Project began in 2018, with the aim of exploring and leveraging the use of foreign reviews completed by JMPR or US EPA in reaching a regulatory decision, an initiative that is supported by producers and manufacturers. They support this initiative based on the importance of alignment. With the pandemic, some delays arose, but is targeted for completion by 2024.



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iii. Monique Thomas, PMRA

In July 2021, CCPR 52 approved the working principles of this pilot program, with the proposals and procedures proposed by the electronic Working Group, led by Canada, for JMPR to participate in the parallel review of a new compound.

As a result, the electronic working group chaired by Canada and co-chaired by Costa Rica and Kenya will be re-established, with the mandate to: prepare a discussion paper describing the criteria for selecting a global project manager, inviting to the data sponsors to propose compounds.

For the time being, an electronic working group has been established and a draft document has been prepared to initiate discussion on the proposed criteria for the selection of a global project manager. So the next steps will be to encourage data sponsors to propose compounds for the parallel review pilot project, to test the parallel review procedure in the framework of a pilot project, in order to refine the proposed process taking into account practical and concrete considerations – and to continue to ensure effective use of JMPR resources, to document the concrete results obtained, in order to accelerate the setting of Codex MRLs and harmonisation with international MRLs.

b. FARMER'S PERSPECTIVE

i. Importance of these projects from the perspective of the farmer. Corey Loessin, Chairman of the Board of Directors of Legumes Canada, Airda Farms

Corey Loessin, as producer and president of Pulses in Grains, shared some data about his activity in the field, mentioned that it has taken him several years to plan which products, any, will be applied in the field, and how to rotate them, so that long-term planning is important for all regulatory processes to help recognize that planning or abrupt changes hinder the entire system, unanticipated MRL changes, cause problems in their cultivation system.

Although they are not the largest producer, being India, Canada is the largest exporter of legumes in the world, so the MRLs are very important in most of these markets to continue the trade flow, so the absence of MRLs, causes an interruption of trade. He stressed that there are MRL policies in different export markets, which are not constant, and that there is no possibility of having deferred MRLs, and although several countries are aligned with CODEX, there are still difficulties in establishing them, in particular for minor uses.

This shows that there is a variety of MRL policies in the global market, which can lead to uncertainty and perhaps unnecessary regulatory non-compliance, not only for the producer but for consumers anywhere in the world. He stressed that more solutions were needed in the adoption of MRLs in these small-volume crops.



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He outlines how MRLs limit crop treatment, and the case of those requiring treatment at specific stages of growth, and that very few products are authorised or not accepted in export markets because there are no authorised MRLs.

In conclusion, it is indicated that the missing MRLs affect producers, so a major tolerance programme would allow this use and decrease dependence on other products.

11. Minor Uses Update. Jennifer Ballantine-PMC, Jerry Baron- IR-4

Jennifer and Jerry presented background on how the programs were created, their similarities, including operation and funding, and events held.

The IR-4 Project and the Pest Management Centre (PMC) have been collaborative partners since the creation of PMC in 2003, through a MEMORANDUM OF UNDERSTANDING.

The Regulatory Cooperation Council (RCC), an initiative established by US President Obama and Canadian Prime Minister Harper, formalized processes and data collection, to harmonize them, as well as approaches and reports. As a result, they have been able to harmonize protocols, raw data collection, and reports.

Among the benefits of this collaboration, the following stand out: cooperation through joint projects represents a significant saving of resources, in reducing the number of field tests carried out and laboratory analysis tests, shorter deadlines for the submission and joint regulatory review flow of the EPA and the PMRA, regulatory decisions at approximately the same time, benefiting producers on both sides of the border, harmonized tolerances/maximum residue limits (MRLs) to help eliminate trade barriers.

Each program develops its list of national priorities, if there is a confluence, they work collaboratively to maximize the number of joint projects, which creates efficiencies and optimizes resources. They present results of cooperation over the years and in particular one project concluded in 2021; with several scheduled to be completed in 2022.

They conclude by mentioning some benefits and areas in which joint work can improve and in particular for Mexico to get involved. One benefit is cooperation to save considerable resources, reduced field trials, time to collect information, analysis. Farmers also benefit, decisions are made around the same time for equal access to tools and there is better harmonisation of tolerances and MRLs, to remove trade barriers, to use representative crops for trials whose data can be used for other crops. From Canada's perspective, they recommend that these work approaches be taken for Mexico, through participation in the priority selection process to understand how decisions are made, how applications for registration are submitted, how they are trained, etc.; this has been done in the past



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with avocado producers, so that this can be re-evaluated to seek funding and collaboration opportunities.

12. National Strategy for the Conservation and Sustainable Use of Pollinators (ENCUSP). Sol Ortiz Garcia, Secretariat of Agriculture and Rural Development, SADER – MX

Dr. Sol shared the background of the Strategy, mentioning that it was of the utmost importance to generate an instrument of national public policy, specific to the conservation and sustainable use of pollinators, resulting in a tool to achieve the conservation of key ecological processes, as well as to guarantee food security and sovereignty. Therefore, in 2019, an intersectoral working group of the Federal Government was formed and it was proposed to develop the National Strategy for the Conservation and Sustainable Use of Pollinators (ENCUSP), in order to guide its conservation and achieve the sustainability of the ecosystem service in the long term for the benefit of society and the ecological and evolutionary processes of ecosystems and their species. Highlighting that this is a joint work of over two years. He outlined the structure, with 86 total actions involving all actors, and a coordination group.

The ENCUSP, by its acronym in Spanish, reflects the interministerial work of the Mexican government to contribute to the conservation of bees and other pollinators, thanks to the collaboration of the productive, social, governmental and academic sectors, this strategy was published in the Official Journal of the Federation on June 14, 2021.

It highlights that, although the initiative is at the federal level, it requires the intervention of state and local governments, as well as other actors such as producers, academics, etc., to contribute to its implementation.

Regarding the thematic axes that include activities related to pesticides, one activity seeks to communicate the importance of pollination for food, social and environmental security, and promote the proper and responsible use and management of pesticides in the field; as well as continuously update the applicable regulations to avoid the use of those that cause a negative impact on pollinator populations. Other actions are also mentioned, such as promoting favourable agricultural practices with pollinators, optimising the use of pest control products, raising farmers' awareness of alternatives to use, and reviewing, updating or developing pesticide risk assessment procedures.

Finally, he commented on the initiative at the international level, "Advancing the conservation of pollinators throughout North America", which began in January 2022 and will end in 2024, which seeks to strengthen the regional conversation of pollinating species to ensure their benefits at the local level, with 3 activities in development in collaboration with the three countries.

13. Closure of meeting and next steps. Amada Velez



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Amada Velez stressed that all the comments have been noted, and an attempt will be made to integrate them to address them in the different actions carried out by the Group. As highlights he mentioned the following:

- Part of what has been discussed is decision-making considering the needs of the sectors involved. Producers have mentioned that pesticides are necessary for production, but that it is necessary to consider alternatives that support agricultural production and take care of human health and the environment.
- Another point is the need to consider scientific bases in decision-making, which has been a recurring message in both sessions, so it will be important to have the best scientific information available to make informed decisions for the benefit of all those involved countries.
- Joint work and exchange of information, was also highlighted, it is one of the bases of the working group, so it is necessary to continue working supporting the most appropriate mechanisms for the exchange of information.
- Everyone's participation in international forums is important to learn how these issues are addressed in different latitudes to compare based on type of agriculture, climate, etc., and regionalize some solutions.
- The participation of all in international forums, it is important to know how these issues are addressed in different latitudes to compare based on type of agriculture, climate, etc., and regionalize some solutions.
- The protection of health and the environment are priorities for the three countries, so this group will continue to help in these areas.
- On the subject of new technologies, it is very important to continue promoting research and innovation, for which the impulse from industry and academia is very important.
- Collaboration with international organizations supports the collection of information and analysis from international experts in the field, generating tools that can help modernize the regulatory framework.
- On the issue of joint reviews, it is important that these can be taken up by the regulatory agencies of the three countries. Work has been done as Mexico, and she considers that it must be taken up again and more intensively, since that will allow farmers to have the same tools at the same time in the three countries simultaneously and, where appropriate, have products that are friendlier to health and the environment, as well as make evaluations by the



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authorities more efficient. which represents from the point of view of saving time in the regulation and efficiency of the use of resources.

- In Mexico, it is also required to have a definition and evaluation of highly dangerous pesticides, considering the experience of the US and Canada on the subject, the harmonization of the regulation in North America, and the innovation in methodologies for evaluation of acute toxicity.
- For commercial exchange, the MRL is one of the most important points, although it is necessary to recognize the differences that may exist in the type of agriculture, type of climate, presence of pests, there are also points in common in which it is important focus efforts to have MRLs that do not generate commercial irritants in products of interest.

She asked Peter or Ed to provide feedback on these points so the group can continue the collaboration.

- Peter Brander first congratulates Mexico on the meeting. He comments that many issues that they presented, not necessarily discussed, have generated a lot of participation in questions and answers. Specifically, he says that things are improving, hoping that the pandemic will soon end and we will meet personally in the future, to complete the administrative work related to the terms of reference and the work plan that derives from this meeting, with priorities and capacities.
- Edward Messina also thanks everyone for facilitating the meeting. Commenting on the informative sessions and the underlying message of the importance of collaboration and partnerships.
- Ed Noted that this sense of collaboration is something that we in the U.S. also feel strongly about, and we truly value our close relationships with Mexico and Canada and look forward to continuing to strengthen and share with each other in support of increased harmonization of risk-based processes in the region. We are sensitive to supply chain concerns and the costs that can be involved, and we hope to continue to work closely with our counterparts in Canada and Mexico to provide support, increase efficiencies, and enhance communication on science policy and risk assessments to relieve these pressures wherever possible.
- EPA has a strong and robust science-based approach to risk assessments, and this is something that we look forward to continuing to share with our colleagues in Mexico and Canada for many years to come.
- We are happy to be taking on the role of hosting the next TWG meeting and working with all of you to develop an equally exciting agenda for the next cycle.



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- EPA will communicate with our partners in Mexico and Canada, as well as our IWG contacts as we make our final decisions on the next meeting and are happy to take any feedback you might have.

14. Closing remarks

Chemist Amada Velez, stressed the gratitude for the time and interest in this topic, as already mentioned, it was a pleasure to be able to interact with a wider number of stakeholders, being a pleasure to have had a connection with 210 participants on the first day and 215 today, which motivates us to continue working in a coordinated way between the different instances and countries to strengthen this topic.

Amada Velez stressed that all the comments have been noted, and an attempt will be made to integrate them to address them in the different actions carried out by the Group. As highlights he mentioned the following:

There are many challenges ahead, but we also know that, with the will and work of all the members of this Working Group, progress will be made towards achieving our goals in the region, which will undoubtedly bring benefits to our people.

Mexico, having the Chairmanship of the Executive Committee, will develop the final documents of this meeting, and will coordinate the work so that these are available in the three countries. The Executive Presidency will pass to the United States, which will coordinate the next meeting, as well as the activities of the Working Group to continue developing actions that will address the issues identified.

She stressed the pleasure that it has been to work with Ed, Peter and their respective collaborators, since, without their experience and hard work, this successful meeting could not have taken place. She thanked the task force, representatives of the crop protection industry, farmers and other stakeholders, hoping to have held a forum to help address the concerns. Thanks also to the translation team, thanks for facilitating communication.