



**NAFTA Technical Working Group on Pesticides  
Durham, North Carolina USA  
November 3-5, 2015**

**MEETING SUMMARY**

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The North American Free Trade Agreement (NAFTA) Technical Working Group on Pesticides (TWG) met in Durham, North Carolina USA, from November 3-5, 2015. The meeting was hosted by Jack Housenger, Director of the Office of Pesticide Programs (OPP), United States Environmental Protection Agency (U.S. EPA). Dr. Richard Aucoin, Executive Director of Health Canada's Pest Management Regulatory Agency (PMRA) and Hugo Fragoso, General Director of Safety in Food, Fisheries and Aquaculture from Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria (SENASICA) were also in attendance. The meeting was well attended by other government officials, growers, registrants, and various stakeholders from all three countries.

**PLENARY**

On November 4, Jack Housenger welcomed stakeholders and government participants from the United States, Canada, and Mexico to the meeting and expressed his interest regarding the ensuing discussions on key issues to NAFTA stakeholders. In particular, he mentioned pollinator protection and pointed out that two products have been approved for Varroa mite, one of many stressors that honey bees face, and mentioned how the three countries could work together to improve the decline in Monarch butterfly numbers. Additionally, Jack stated continued efforts to harmonize maximum residue levels (MRLs) were open for discussion. Richard Aucoin and Hugo Fragoso provided an update on key pesticide-related developments in their respective countries. They echoed the continued importance of collaboration to address trade irritants, including the alignment of MRLs where possible between NAFTA countries and at the Codex Alimentarius Forum. Other topics of importance included the reevaluation of the neonicotinoids, farmworker protection in Mexico, and the challenge to ensure correct pesticide use.

**NAFTA TWG 5 YEAR STRATEGIC PLAN 2016-2021**

The NAFTA TWG endorsed a Five-Year Strategy 2016-2021 that focuses on three broad objectives (a workplan will be developed yearly to focus on topics and issues more in depth that the NAFTA TWG would want to collaborate on). The 3 objectives:

1. Identify trade barriers with the goal of promoting equal and simultaneous access for pesticide management tools – this would include MRL alignment, strengthen our position when attending CODEX meetings and crop groupings, etc.
2. Encourage cooperation on joint reviews of new pesticides and uses, and the re-evaluation/re-registration review of pesticides to increase efficiency and quality of decision making.– streamline simultaneous bio-pesticide registration; minor use joint reviews; coordination of registration review and reevaluation
3. Work cooperatively on priority science and regulatory issues and practices including data requirements, science approaches and policies for data interpretation, and risk assessment and communications of regulatory decisions



Overall, the 5 Year Strategic Plan will encompass MRL alignments, pollinator protection, crop groupings, avoiding trade barriers, joint reviews, and global harmonization.

#### Industry Working Group (IWG) (Presenter: John Abbot, Syngenta)

The IWG lead, John Abbott, identified the high interest to grower groups and industry stakeholders for international cooperation on joint review processes. The IWG wants their work to encompass other countries beyond the US and Canada. Industry stakeholder's were very adamant in ensuring knowledge exchange and coordinated process among the three countries. They also wanted clarity on timelines associated with moving projects forward. They proposed promoting global harmonization along with a synchronous introduction of new tools for crop solutions. They also expressed concerns for avoiding trade barriers. Overall they would like to harmonize data requirements and understand the scientific approach towards decision making.

The NAFTA TWG proposal is to take NAFTA approach and expand this to North and South America and to develop framework to identify common goals and a mechanism to encourage other countries to participate.

#### UPDATE ON POLLINATOR PROTECTION

##### USA EPA (Presenter: Rick Keigwin, OPP)

Office of Pesticide Program's (OPP's) Rick Keigwin gave a comprehensive update on EPA's recent actions in response to President Obama's National Pollinator Health Strategy highlighting the proposals to mitigate acute risk to bees, consider monarch butterfly habitat considerations in EPA's regulatory decisions, and the two new registered products for Varroa mite control. Various goals identified included lowering over-wintering loss numbers for honey bees, restoring monarch butterfly populations, increasing forage area, and expediting review of new products to control Varroa mite.

The EPA's proposal on how to manage acute risk to bees was issued for public comment with over 113,000 responses submitted. Elements of strong managed pollinator protection plans would include robust stakeholder engagement, a mechanism for communication between growers, applicators and beekeepers, and the periodic review of the plans with measurement of success. The two new products for Varroa mite control were registered swiftly and have received positive feedback from the beekeeper community

An industry representative articulated their skepticism regarding the lack of bees for food production. OPP's response was the importance of working towards bringing bee populations back so that beekeepers are not continually stressed every year that they will not meet food production goals.

##### Canada, PMRA (Presenter: Scott Kirby PMRA,)

Scott Kirby, PMRA gave an overview on the efforts to protect pollinators in Canada including initial voluntary best management practices (BMP), mandatory initiatives such as low dust seed lubricants, enhanced labeling. He expressed confidence that these BMP have had a positive impact on pollinator protection. He explained that some of the factors being attributed to increasing winter mortality numbers, include pathogens, loss of habitat, bee management, and pesticides..



Canada's Agri-Food Bee Health Roundtable is working with wide variety of stakeholders from industry, agriculture, and academia to research factors affecting pollinators. Additionally, it was made clear that PMRA is not actively involved in monarch butterfly initiative, but rather actively involved in trilateral agreement with the U.S. and Canada on habitat protection, education outreach, monitoring and research.

Mexico, SENASICA/SEMARNAT (Presenters: Alma Tovar Diaz, SEMARNAT; Nelly Pena, National Autonomous University of Mexico)

Mexico announced their work towards pollinator protection such as establishing a Technical Working Group for pesticides. The established working group is comprised of key stakeholders aimed to identify players who can provide information regarding bees and pesticides to ascertain why populations are decreasing, if it's the case. Mexico currently has no data or statistics on bee losses over the past years. The goal of the TWG is to ensure decisions benefit all involved sectors while dually protecting honeybees. Additionally, Mexico hopes to review and adopt the evaluation guidance that the U.S. and Canada plan to implement. They currently do not have specifications for labeling on pesticide products that could be affecting pollinators.

The National Autonomous University of Mexico has begun preliminary projects to determine which regions in the country have honeybee problems. Plans are in order to conduct surveys and hold meetings throughout the country with the beekeepers of various regions.

Update from CropLife Canada (CLC) (Presenter: Maria Trainer, CropLife Canada)

CLC provided an update on their progress at the Canadian Bee Health Roundtable with the Canadian Honey Council and various other stakeholders, highlighting the group's collaborative success and goal to mitigate pollinator losses from pests, pathogens, and pesticides. Their strategic plan centers towards reducing acute exposure of bees from pesticides, and increasing the number of tools that beekeepers have to protect bees from pathogens and pests such as Varroa mite. Additionally, they want to ensure that Canada and the U.S. have the same access to data, and that registration movement forward is simultaneous.

Two recent pollinator developments were completed by CLC including the BeeConnected application and Bees Matter program. BeeConnected facilitates BMPs by locating where hives are to growers and facilitating communication with beekeepers. The application was previously developed and has stirred a lot of interest among beekeepers. The Bees Matter Program is a collaborative effort that brings stakeholders together from across industry. It raises awareness about honey bee health and the importance of habitats.

## **POLLINATOR PROTECTION UPDATE**

Re-Evaluation of Neonicotinoids (Presenters: Donald Brady, OPP and Margherita Conti, PMRA)

US EPA discussed the Regulatory Cooperation Council (RCC) Initiative for the U.S. and Canada to coordinate on the re-evaluation of neonicotinoids with regards to pollinator use. The current set of re-evaluations look at acute and chronic exposure, specifically with pollen and nectar residue data from application specific use patterns. EPA has been working jointly with PMRA (as well as the California Department of Pesticide Regulation) to not only develop the pollinator risk assessment framework but to develop the studies/protocols needed to implement this framework. PMRA has similarly created a new set of data requirements available to the public in support of the pollinator risk assessment framework.



## **MINOR USE PROGRAM DEVELOPMENTS**

### Joint Minor Use (*Presenters: Susan Lewis, OPP and Margherita Conti, PMRA*)

Topics of interest included an update on EPA and PMRA's Minor Use Joint Review Program, an RCC initiative, as well as international collaboration. Update on EPA and PMRA joint reviews with 60 projects completed since 2004, and 16 projects currently on review for 2015-2016. The RCC initiative continues to implement program efficiencies towards harmonization.

The principles of Phase 1 of RCC led to additional work on harmonization with regards to the Joint Review Residue Trial Reduction Project. The US IR-4 and Canada's Pest Management Centre have submitted residue trial reduction proposals to PMRA and EPA for joint projects. A draft guideline for the reduction of residue field trial requirements has been developed, which EPA has shared with stakeholders and PMRA plans to implement in 2015-2016. Overall, the joint residue trial reduction project has been very successful and resulted in up to 50 percent trial reduction for the future Joint Projects.

Under international collaborations, a Global Minor Use Priority Setting Workshop was held in Chicago with a goal to choose priorities for crop/pest issues for three A-priorities in the tropical crop, temperate crop, and protected crop or greenhouse areas and 2 B priorities in each area as backups. The workshop was well attended and very successful. Work continues on crop groupings under the International Crop Group and Consulting Committee (ICGCC) which has saved considerable time and money on the NAFTA and International levels.

### US IR-4 (*Presenters: Dan Kunkel, US IR-4*)

IR-4 provided an overview of the success of Canadian/US cooperation resulting in over 250 joint projects conducted and thousands of uses US and Canadian growers can now enjoy since 2003. A typical review for an IR-4 submission at the US EPA would take 15 months but can be reduced to less than 10 months with the joint review projects. Currently, through the IR-4 Programs, 15 to 20 magnitude of residue cooperative studies are conducted a year, representing more than 25 % of IR-4 workload.

Dan Kunkel acknowledged the success of the RCC program and the support received through the Export Working Group in the OECD and the Codex Committee on Pesticide Residue and the number of activities held with regard to minor uses. An update on the numerous workshops held throughout the year was provided. Canada held a workshop in March, Mexico had their first grower workshop in August, followed by the Global Minor Use Workshop held in September in Chicago, IL.

The Global Minor Use Priority Setting Workshop included over 200 participants from 30 countries. The workshop was an outcome from the previous Global Minor Use Summit to promote data and information sharing. A total of 2,700 data entries were collected as a result of a survey conducted over a year ago to identify grower needs, crops, and pests. The list of priorities and process were narrowed down and three "A" priority projects were selected: 1) aphid control on lettuce grown in the greenhouse; 2) downy mildew on leafy greens in the field for temperate crops; and, 3) fruit flies on tropical fruits. IR-4 is taking the lead on the tropical project working on possible solutions and exploring possibilities to develop a project internationally to address that need.

Issues that have been addressed include working through possible solutions to conduct residue programs in the field, as well as discussions in the margins of sharing data and consideration for other opportunities.



In some cases, the needs have been addressed in one area of the world and hopefully that information can be shared with other areas of the world to meet their needs.

#### Mexico's Update (Presenter: Alma Liliana Tovar Diaz, SEMARNAT)

Ms. Alma Tovar-Diaz presented an update on Mexico's current projects and activities. In an effort to reduce pesticide residues and the use of non-registered products, a meeting was held in August to create awareness of the minor uses challenges faced by Mexico and explain the benefits of creating a national working group and use of existing programs to address those problems. The workshop, endorsed by the IR-4 program, included a group of 50 stakeholders from different groups mainly growers, pesticide producers (avocado, berries, mango, and prickly pear cactus), researchers, and agricultural health and government authorities.

#### MAXIMUM RESIDUE LIMITS / CODEX

##### MRL Alignment Activities Update (Presenters: Susan Lewis, OPP and Yadvinder Bhuller, PMRA)

Similar to a presentation at the last NAFTA TWG meeting, a joint US-EPA presentation was provided on MRLs, which included an update on the number of Codex MRLs (i.e., this year 348 MRLs were set for 32 pesticides, seven of which were new compounds). The benefits of the joint review process for both the NAFTA and OECD submissions in relation to MRL alignment was also discussed and how providing the same data package to CODEX can lead to harmonized MRLs. Joint reviews and a coordinated approach to the nomination process has also helped.

In terms of the proposed pilot that was discussed at last year's meeting, as there has not been a significant level of interest no guidance or tools are being considered. However, Registrants/applicants can use the existing process for joint reviews to discuss their exporting markets with the Regulatory body and how the joint review process timelines can be aligned in order to, for example, allow for a nomination to CODEX.

Registrants were also provided an update on the two, RCC Science-policy projects on proportionality and exchangeability. During RCC consultations, stakeholders had supported both the US EPA and PMRA to incorporate the outcome of the RCC work on these two projects into the OECD guidance document on crop field trials (in lieu of publishing an EPA-PMRA specific document). Stakeholders at this meeting were informed that this work was not only incorporated into the OECD document, but the OECD guidance itself was now open for external comments that were due by November 30, 2015.

Stakeholders were also provided an update on the US EPA and PMRA work the Field Trial Reduction Project whereby this project is aiming at prospectively looking at the number of trials currently required by both countries and whether there could be a reduction in these requirements when the submission is sent jointly to both the US EPA and PMRA. Once the analysis is completed, the intent will be to publish a guidance document for external consultation prior to providing a final decision.

In terms of the data provided based on the number of MRLs that are aligned, a question was asked about why approximately 30% of the MRLs are not aligned. Clarification was provided that this disparity could be due to the transition that occurred in terms of the implementation of the OECD calculator by the countries involved in the joint review process. Once all regulatory bodies shifted to the same calculator and also received the same data package, the MRL should be harmonized. Alignment on Science-Policy approaches, such as Proportionality and exchangeability efforts, will also help.





### Benefits of Harmonized MRLs (Presenter: Gordon Kurbis, Pulse Canada)

The level of engagement in MRLs by growers has increased markedly. MRLs that are not harmonized are a growing problem due to more sensitive testing technology, increased testing and more countries taking country-specific approaches to setting MRLs. The wheat growers in Canada (their largest acreage crop) has made MRLs one of their official priorities as both of these commodities had MRL-related trade issues in exporting markets in 2015.

There are 25,000 pulse growers, and more than 60 exporters in Canada, who export to more than 100 countries. It is difficult to use the latest innovations in pesticides in Canada and the US and keep those markets open when MRLs are not aligned in the exporting countries. The leadership of NAFTA TWG is important for the future.

There are issues that affect trade (Canada has a significant export market in these crops), such as potential for non-compliance with uncertainty with the MRL in the exporting country thereby preventing use of certain pesticides, increasing sensitivity of residue testing, and countries moving to their own national or custom approaches. There are large costs of disruption (\$10-40 million per boat). These trade issues are being addressed through vehicles such as the Canadian industry-government MRL task force.

NAFTA's joint reviews and better synchrony in registrations help reduce the risk and are the key to getting harmonized MRLs. Communication to growers about principles such as the importance of using a product according to the label also help. 2016 is the International Year of Pulse. This is an opportunity to involve growers and commodity traders around the world on the importance of harmonization of MRLs. Trade agreements can help with regulatory cooperation. The OECD forum also provides an opportunity for the NAFTA Regulatory bodies to engage with countries that have a different approach to the setting of MRLs, such as Europe. NAFTA partners need to also continue to make strong representations at CODEX in order to influence CODEX decisions.

### Inadvertent Residues (Craig Hunter, Ontario Fruit and Vegetable Growers' Association)

Craig Hunter discussed concerns about modern pesticides with 3-4 year soil half-lives that cause problems later on, but with action now, perhaps could be averted. The issue of inadvertent residues has been recognized in North America but less so in other areas. Even in North America, there are issues that need to be addressed such as updating lists of pesticides that can lead or have led to inadvertent residues and establish a means to add new crops and pesticides to the current U.S. list. Growers are tracking some of these known issues related to using land for specific crops. However, residue detection improvements is making it more difficult. It was suggested that Industry in collaboration with Grower Associations should create a list of inadvertent residues with related tolerances and this should then be submitted to the NAFTA TWG for further analysis/discussion of this topic. Using NAFTA as a basis for adoption of the list by all three countries was also agreed upon as being an effective and efficient way of using resources. Taking this approach globally would benefit growers who are affected by inadvertent residues, which are a potential trade disruptor.

## **STAKEHOLDER PRESENTATIONS AND DISCUSSIONS**

Industry's Experiences and Perspectives of Joint Reviews (Presenters: Hector Guillén, Association of Growers, Packers and Exporters from Mexico, APEAMAC; Tanya Tocheva, Syngenta Crop Protection Canada; Dan Botts, Minor Crop Farmer Alliance USA; Gordon Kurbis, Pulse Canada)



Hector Guillén, Association of Growers, Packers and Exporters from Mexico, APEAMAC discussed a program with IR-4 that they are working on in Mexico. Most of their production is geared toward the United States, though they have a growing market in other areas of the world. They review MRLs every 30 days to pick up any changes, to update their database, which includes MRLs and all the products registered in Mexico. A current project is using resources from the pesticide industry and from growers to try to work with IR-4 on an MRL for avocado. Another goal is to set an agenda with IR-4 for the next ten years, since these projects take time. They plan to renew and innovate current phyto-sanitary options with the objective of obtaining new MRLs each year, establish this as a model for other crops in Mexico, and officially establish the IR-4 project in Mexico for minor uses.

Tanya Tocheva, Syngenta Crop Protection Canada described industry's perspective on the joint introductions of new technology; accomplishments and positives of joint reviews. She discussed areas of improvement to increase the efficiencies of joint reviews, next steps and what the level of joint reviews should be.

Since 2007, 22 joint reviews have been completed, 12 are underway and 14 are planned through 2018. There is a 76% harmonization of MRLs plus 18% within 0.5 ppm. More countries are participating.

Pre-submission meetings are important to help guide data development. Consistency in regulatory requirements and test guidelines and common data package save time for all. Joint reviews offer cost benefits, potential for cost savings for residue and efficacy trials, facilitating trade, completing reviews more quickly and predictably. Over 10 years, there is an average time of 27 months for joint review products, versus 37 months for Canada-only reviews.

She expressed concern about an apparent increase in the amount of time required to complete a joint review (formerly 16-18 months, now 24-33 months), and given more complicated packages recently. She is interested in how industry can simplify this, perhaps to focus on the basic information to establish an MRL to allow for elimination of trade issues to support global crop trade. Improvement could include more focus on joint review as part of the pre-submission meeting, to better align planning, increased use of common template for reviewers, cross-agency acceptance of reviews, endpoint selection, looking for operational efficiencies, earlier involvement of CODEX.

Dan Botts, Minor Crop Farmer Alliance expressed appreciation for a process that has worked over the past 20 years. He stressed we must get to a point where we are using the same data sets, reviewing for risk in the same way, coming up with a regulatory decision. It would be valuable to find a way to use the joint review process for other actions, such as registration review, label expansion, etc. He asked the NAFTA TWG to encourage the rest of the world to use the TWG model for more global joint reviews. New technologies such as RNAi may be of value in solving some of the problems growers face, such as with citrus greening, but the regulatory process is daunting.

Gordon Kurbis, Pulse Canada, speaking for the Canola Council, presented a case study on what it looks like when things go wrong. Pulse Canada experienced the long-term effects of a noncompliance with the requirements of an exporting country due to a default value that was later raised by 100-fold when the MRL was established. Global joint reviews might not be the perfect tool, but they would be a tool that would take us a couple of giant leaps in the correct direction and would have resolved issues that occurred in these cases. The issues involved timing of MRL establishment versus initial registration of a product and the differing rules for action when there is no tolerance. Export markets are critical for some crops/countries. Sometimes growers are not aware of all the nuances of the status of a new chemical.



There can be effects of a non-compliance situation, even when it is resolved immediately by establishment of an MRL. Synchronizing registrations and MRLs is the solution, which again points to global joint reviews and increasing the number of participating countries, applying joint reviews to actions other than new chemicals, etc. An important need is for NAFTA countries to continue and if possible increase the leadership and support for global joint reviews.

Discussion on Future Collaboration Regarding Joint Reviews (*Presenter: Ray McAllister, CropLife America*)

Ray McAllister, CLA discussed the concept that collaboration can be difficult and requires extra effort, patience and compromise. The resulting synchronous product approvals and harmonized MRLs are of great value to international trade. Without these, delayed access to new crop protection technologies will delay achievement of benefits of improved efficacy and lower risks due to markets being closed to growers who use them. He emphasized overcoming barriers to joint reviews, finding catalysts to keep them moving rather than retreating.

Susan Lewis highlighted the importance of trust and knowledge of each other's countries and the integrity of review processes. This is now routine with NAFTA. All 3 countries have worked closely with some other countries such as Australia, Germany, etc. and are beginning to work with China. The shared scientific integrity is a hurdle as we move beyond the current situation. There are places where the grower and industry communities can participate, in terms of the residue process in setting MRLs, as a starting point.

Other commenters discussed the role of OECD, the ability of governments to trust growers, the role of the marketplace in ensuring that growers follow labels. It was also mentioned that joint projects in minor uses would help ensure availability of data and support confidence among regulators in OECD countries.

**SUMMARY OF DISCUSSIONS AND OPEN FLOOR COMMENTS**

Based on review of the five-year plan, a work plan should be created for each year tailored to work that would be accomplished during that year.

The Industry Working Group (IWG) made a recommendation to combine the NAFTA TWG and RCC into one initiative, with the overarching goal to promote and ensure global harmonization and synchronous introduction of new tools for crop solutions that remove trade barriers, harmonize data requirements, support science-based risk analysis and promote emerging science as a future path and to include Mexico in these efforts.

Stakeholders would like a stronger voice in delegations so that decisions from the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) are more aligned with those made at the national level.

Globally harmonized MRLs are becoming more of a need due to the pressure to maintain open markets in the face of MRLs that are not harmonized. Monitoring data show the MRL value is not the level at which people are exposed to and thus, discussions at the international level on MRL setting should also factor into account the risk, as characterized from the risk assessment. It is also acknowledged that the world is not fully harmonized and some of the organizations (WHO and FAO, for example) can take a more conservative approach in order to manage potential risks of concern, which means that the Regulatory representatives from the NAFTA countries who sit on various panels need to have a stronger voice in order to share and in turn influence these discussions and decisions.





MRLs exclude inadvertent residues, but the older legacy chemicals are still a problem and newer chemicals that have some persistence are building up in soil and crops may result in residues on rotated crops. We need to determine if this is a current problem or one we want to try to be proactive with and try to address now. More information would be helpful.

Mexico could benefit from a program based on establishing a 10-year agenda with IR-4 and working through it to obtain an MRL each year

Residues can disrupt trade and thus affect economics regardless of trade agreements. Therefore, industry, regulators and growers all want to make joint reviews work, to meet our common goals. However, there are areas for improvement. There is a need to set priorities, since it would not be feasible to work on all the possible improvements that were discussed. There is also a need to determine if efforts can now be focused on further aligning MRLs as opposed to exploring the alignment of all endpoints that the US, Canada and Mexico are regulating on.

Consideration should be given to further explore existing processes being used by the governments and whether they can be expanded into a new area of registration such as label expansions. Change will be difficult because the influence at this level is limited. Joint efforts by the three regulatory bodies on how to manage new technologies, such as RNAi, is also considered to be helpful and an efficient use of resources/expertise..

Global joint reviews are primarily being done by the United States and Canada, with limited participation by others. Perhaps a work group could consider how to further expand the scope.

Getting South American countries to join with the NAFTA countries as a voting block at CODEX was discussed, but there is not clarity as to how to accomplish that.

## **FINAL REMARKS**

Hugo Fragoso-Sanchez, SENASICA thought the new five-year plan would help us all work better. He said Mexico understood the need to join their efforts with Canada and the United States and to work on the development, evaluation, and scientific knowledge to support pesticides, MRLs and minor use products. In addition, he expressed working with the countries of South America was important. Together, Mexico, Canada and the USA contribute more than 60% of the food consumed by the world, in terms of grains and fresh products. Mexico will use these discussions and suggestions to create a working program that will offer better results to our three governments, our countries and our consumers.

Dr. Richard Aucoin: Canada appreciates the work that has been done to date by government partners and all stakeholders on MRL alignment and joint reviews. It is important to acknowledge the behind-the-scenes work that make the NAFTA TWG forum work. Dr. Aucoin thanked the US EPA for hosting this year's meeting and looked forward to next year's meeting in Canada, probably in the Province of Quebec.

Jack Housenger, US EPA closed the day's discussions expressing follow through will be important if the NAFTA TWG on Pesticides and IWG are to achieve the items that were discussed, such as having the Americas act as one. He thanked the group for coming and sharing their thoughts.