



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

Accomplishments Report

2008–2013



Introduction

For almost two decades, the North American Free Trade Agreement Technical Working Group on Pesticides has been instrumental in fostering pesticide regulatory cooperation among the North American Free Trade Agreement (NAFTA) countries (the United States, Canada and Mexico). The Technical Working Group (TWG) has achieved measurable success in aligning pesticide regulation in North America while establishing high standards of environmental, ecological and human health protection.

TWG Vision Statement

Canada, the United States and Mexico are striving to make the North American region a world model for common approaches to pesticide regulation and free trade in pesticides and food. Achieving this level of performance, while protecting human and environmental health, will set a global standard and enhance world trade in North American products.

The responsibility for ensuring pesticides do not pose unreasonable risk to human health and the environment is shared by many, including governments, pesticide manufacturing companies, distributors, pest control operators, growers, workers, public interest groups and the general public. The TWG plans to take a holistic approach to pesticide management to create this high standard of excellence.

*Technical Working Group
Five-Year Strategy (November 5, 2003)*

In 2008, the TWG published its third five-year strategy, which identified strategic objectives, priority work areas and indicators that have formed the basis for its activities over this period.

This document provides an overview of the accomplishments achieved by the TWG from 2008-2013 and is a useful platform for developing the next five-year strategy.

Objective 1:

Provide the growers and other pesticide users in the United States, Canada and Mexico with equal access to and same time introduction of pest management tools, including safer alternatives.

Key Indicators

1. *Number of new pest control product registrations following joint reviews and work share reviews*
 - The joint review process and work sharing for new pesticides have been well established among and beyond NAFTA countries and are now considered to be normal business program among governments and stakeholders.
 - The programs enhanced access to pest management tools in NAFTA countries, avoided potential disparities in maximum residue limits (MRLs) or tolerances, and reduced technology gaps. This resulted in increased levels of shared scientific knowledge and an increased understanding of each country's risk assessment and risk management processes.
 - Working together has resulted in the registration of 20 new pesticides including 15 conventional active ingredients (Table 1), one safener (Cyprosulfamide, 2008) via joint reviews, and four conventional active ingredients (Mandipropamid, 2008; Metrafenone, 2010; Ethaboxam, 2013; and Kasugamycin, 2013) via work sharing over the five-year period in at least two NAFTA countries. There are also several joint reviews of conventional pesticides that have been initiated over this period and are in progress.

2. *Number of biopesticides registered following joint and work share reviews*
 - Canada and the United States established a process for the joint and work share reviews of biopesticides in 1997.
 - Seven biopesticides were registered via joint reviews over the five-year period (Table 2). In addition, four other joint reviews of biopesticides, which are in progress were initiated.
 - A NAFTA biopesticide workshop was held in 2009 to discuss key issues in North America with regulators, growers, researchers and industry to explore ways to improve pesticide research.
 - A three-day NAFTA biopesticide registration improvement course was held in 2011 to promote common approaches between the NAFTA countries and increase joint review applications to all three countries.

Table 1 Conventional Pesticides Registered Over a Five-Year Period via Joint Review

- Pyroxsulam (2008)**
- Thien carbazonemethyl (2008)**
- Chlorantraniliprole (2008)**
- Spirotetramat (2008)**
- Saflufenacil (2010)**
- Ametoctradin (2012)**
- Sedaxane (2012)**
- Picoxystrobin (2012)*
- Fluopyram (2012)**
- Pyroxasulfone (2012)**
- Fluxapyroxad (2012)**
- Penthiopyrad (2012)**
- Penflufen (2012)**
- Sulfoxaflor (2013)**
- Cyantraniliprole (2013)**

* indicates NAFTA.

** indicates global.

3. *Number of minor uses registered*

- Minor use joint reviews are now an established collaborative process between Canada and the United States involving the Pest Management Regulatory Agency (PMRA), the United States Environmental Protection Agency (USEPA), Agriculture and Agri-Food Canada, Pest Management Centre (AAFC-PMC), and United States Interregional Research Project Number 4 (IR-4).
- Minor Use Research: From 2008 to 2013, a total of 100 projects, supported by 344 Canadian field trials and 701 United States field trials were conducted jointly by AAFC-PMC and IR-4. These cooperative projects included full NAFTA field trial requirements and appropriate product performance/crop tolerance data to support new NAFTA pest control tools for commodity growers.
- A new process to simultaneously register minor uses in Canada and the United States was implemented in 2004. The process was revised in November 2008. This process was described in the 2010 USEPA/PMRA Standard Operating Procedures for the NAFTA Minor Use Joint Review Submission.¹
- Between 2008 and 2013, 45 joint minor use reviews were completed, providing 307 new uses. Nineteen work shares were completed, providing 17 new uses. Work under Regulatory Cooperation Council (RCC) in 2012-2014 further refined this process to allow even greater alignment of product approvals and simultaneous access of growers to pesticide management tools.

¹ <http://www2.epa.gov/pesticide-registration/minor-uses-and-grower-resources#nafta>

Table 2 Biopesticides Registered Over a Five-year Period via Joint Reviews

- *Typhula phacorrhiza* (strain 94671) (2011)
- *Paecilomyces fumosoroseus* (strain FE 9901) (No Fly) (2011)
- *Phoma macrostoma* (Scott's Ecosense) (2011)
- *Clavibacter michiganensis* bacteriophage (Agriphage) (2012)
- *Trichoderma virens* (strain G-41) (Rootshield) (TDG) (2012)
- Tea tree oil (2013)
- 3-decen-2-one (AMV-1018)(DCO) (2013)

United States–Canada Grower Priority Databases

- The identification and elimination of trade barriers is critical work for the TWG. The Grower Priority Databases were designed as a way for growers to identify their priorities for harmonization of MRLs and pesticide registrations. The databases have provided a tool for tracking grower priorities and progress towards addressing the technology gap between the United States and Canada for both governments and pesticide manufacturers. Between the time the database was created in 2011 and April 2014, more than 787 grower priorities in Canada and hundreds of grower priorities in the United States have been addressed through registration.

Aligning Maximum Residue Limits/Tolerances

- USEPA and PMRA have established an internal process to help facilitate regular discussions designed to prospectively resolve any potential discrepancies in tolerances/MRLs before these are legally established.
- Creation of the NAFTA MRL Calculator in 2008 and subsequent implementation of the OECD MRL Calculator on 1 April 2011 contributed significantly to addressing MRL/tolerances issues. The OECD Calculator, which replaces and supersedes the NAFTA MRL Calculator, provides statistically robust and scientifically defensible MRLs.

Objective 2:

Work cooperatively on the re-evaluation/re-registration review of older pesticides using each country's evaluation program to the fullest to increase efficiency.

Key Indicators

1. Number of older pesticides re-evaluated using cooperative reviews

- Registered products are periodically re-evaluated to ensure that their acceptability for continued use is examined using current scientific approaches.
- During 2008-2013, Canada and the United States developed a joint work plan for the re-evaluation/re-registration of the heavy duty wood preservatives (pentachlorophenol, creosote and chromated copper arsenate). As a result of this work plan, the assessment of heavy duty wood preservatives was completed.
- Current ongoing work sharing arrangements between Canada and the United States include Clofentezine, glyphosate and neonicotinoids (imidacloprid, clothianidin and thiamethoxam).

2. Transition Strategies for Older Pesticides

- The TWG, based on assessment of azinphos-methyl (AZM) in Canada and the United States, agreed to coordinate and align North American regulatory activities pertaining to the transition of the agricultural industry from the use of AZM to lower-risk pest management strategies. The goal of the initiative was to phase out uses of AZM, develop alternative pest control strategies and help to provide a level playing field for North American trade of commodities affected by the phase-out of AZM.
- Canadian and American phase-outs of AZM were completed in 2012 and 2013, respectively.
- Canada and the United States worked collaboratively to identify the potential alternatives. Through joint reviews and work shares, coupled with our cooperation at the Codex Alimentarius Commission, efficacious alternatives are now available for all previously registered uses of AZM.

Objective 3:

Integrate smart business approaches and practices into NAFTA TWG work.

Key Indicators

1. *Harmonization of remaining technical data requirements and development of new scientific tools and methodologies*

Working together has resulted in the harmonization of the following technical data requirements and development of new tools and methodologies between at least two of the NAFTA countries over the five-year period:

- **Guidelines for voluntary pesticide resistance-management labelling (Canada and the United States).** Guidelines for voluntary pesticide-resistance management labelling were developed. The goal of a uniform North American approach is to delay the development of resistance to pesticides and to provide consistency in labelling. The PMRA published its regulatory directive on pesticide resistance management labelling in 2013 (DIR2013-04, *Pesticide Resistance Management Labelling Based on Target Site/Mode of Action*, 17 December 2013).² The USEPA document is in the final stages of approval.
- **Crop grouping.** One way in which USEPA and PMRA have eased the regulatory burden of pesticide registration on all food crops is through a collaborative effort with the United States Department of Agriculture's IR-4 Project. Similar crops that could be expected to have the same levels of pesticides on them following treatment are grouped together. This is a process known as crop grouping. The current update to crop groups started in 2002. It has resulted in nine crop groups being updated with nearly 200 commodities being added to the crop groupings. This has provided many opportunities for growers to produce these high value profitable crops and facilitate trade. It is expected that over the next five years the process will be completed with a total of 24 crop groups and over 1000 crops being added, with simultaneous updates in the Codex Alimentarius system.
- **Data requirements for pollinator risk assessment (the United States and Canada).** Data requirements for pollinator risk assessment were aligned (*White Paper in Support of the Proposed Risk Assessment Process for Bees*, September 11-14, 2012).³
- **Guidance for assessing pesticide risks to bees.** A pollinator risk assessment framework, which describes the basics of the risk assessment process and the data requirements, was developed collaboratively by the USEPA Office of Pesticide Programs, PMRA and the California Department of Pesticide Regulation. In September 2012 the framework was presented to the USEPA Science Advisory Panel (SAP) and it is currently implemented in both countries. A risk assessment guidance document incorporating comments received from SAP was published in June 2014. The guidance

² http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_pol-guide/index-eng.php

³ <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2012-0543-0004>

enables all three regulatory agencies to have a common, harmonized approach to evaluating the potential risks of pesticides to bees.⁴

- **Modelling pesticide transport to groundwater (Canada and the United States).** An aligned approach to groundwater modelling for estimating pesticide concentrations in groundwater was developed and published in January 2013. The document is available on request from PMRA (RC11-05-0809 and 0909 – *Modelling Pesticide Transport to Ground Water*).⁵
- **Degradation kinetics in environmental media.** An alignment approach for evaluating and calculating degradation kinetics (half-lives) in environmental media was developed and published in November 2011. The document is available on request from PMRA (RC12-06-0808 – *Development of Guidance for Evaluating and Calculating Degradation Kinetics in Environmental Media*).⁶
- **Assessment of bioaccumulation of pesticides in aquatic systems.** Work on aligning methods for assessing bioaccumulation of pesticides in aquatic systems was initiated. On 17 April 2013, a workshop in Ottawa was held to discuss and compare current methods used by USEPA, PMRA and Environment Canada, and to identify the future directions.
- **Assessment of dermal absorption.** In 2008, a position paper *Use of In Vitro Dermal Absorption Data in Risk Assessment* was finalized that outlined the Triple Pack approach. Before this aligned approach, none of the NAFTA agencies had a formal policy or position on the use of in vitro dermal absorption studies in pesticide risk assessment. In 2011, a streamlined in vivo dermal absorption test guideline was developed. The goal of this guideline was to detail how to reduce animal use and cost, while maintaining scientific integrity and utility for risk assessment purposes.
- **Protocol on conducting of in vitro dermal absorption studies.** In 2012, NAFTA countries participated in a workshop, hosted by the Institute for In Vitro Sciences, a non-profit organization. The objective of the workshop was to review and discuss best practices for the conduct of in vitro dermal absorption studies. A number of protocol parameters were agreed upon, which will be captured by the workshop coordinators in a draft report and protocol (still pending).
- **NAFTA TWG Project on 21st Century Toxicology: Integrated Approaches to Testing and Assessment (IATA).** PMRA and the United States Office of Pesticide Programs have cooperated on the development of a guidance document on the use of quantitative structure activity relationships for pesticide risk assessors. The guidance document is available from the PMRA website via a link to the USEPA website.⁷

⁴ <http://www2.epa.gov/pollinator-protection/pollinator-risk-assessment-guidance>

⁵ http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_corp-plan/index-eng.php

⁶ http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_corp-plan/index-eng.php

⁷ http://www.hc-sc.gc.ca/cps-spc/pest/part/int/_nafta-alena/quantitative-relation-eng.php

- **Workshops on Developmental Neurotoxicity (DNT).** NAFTA countries successfully completed two technical workshops on DNT and one focused technical discussion on brain morphometric. The workshops and focused technical discussions were used as a means to ascertain expert input required for the development of guidance for risk assessors responsible for reviewing these studies. A template, using motor activity as an example, was finalized and both agencies are in the process of completing the remaining chapters using the agreed-upon format.
- **Estimating exposure from non-occupational pesticide uses (the United States and Canada).** Approaches for estimating exposure from residential scenarios (non-occupational pesticide uses including lawn and garden care, foggers and pet treatments) were aligned in 2012, using USEPA updated Residential Standard Operating Procedures.

2. *Harmonization of Risk Assessments*

In general, the data requirements for conducting risk assessments are aligned between at least two of the NAFTA countries, where possible. For example, NAFTA TWG published a document outlining *Updated Procedures for the Joint Review of Biopesticides (i.e., Microbials and Biochemicals)* in November 2010. This document informs applicants and other interested groups about the process for joint review of proposed biopesticides, leading to simultaneous registration decisions in both Canada and the United States. Moreover, USEPA and PMRA have established processes to help facilitate regular discussions designed to prospectively resolve any potential discrepancies, which might affect both agencies.

3. *Information on TWG activities and accomplishments provided to public and stakeholders via different mechanisms (for example, the website, and progress and accomplishments reports and meetings)*

- Public and stakeholders have access to information concerning NAFTA TWG activities. For example, meeting reports and five-year NAFTA strategy and accomplishment reports are available to the public and stakeholders on the PMRA and USEPA websites. Stakeholders have the opportunity to attend NAFTA TWG meetings, to be consulted on meeting agendas ahead of each meeting, and to have their topics of interest considered during development of the agendas.

4. *Number of NAFTA TWG projects advanced at the Organisation for Economic Cooperation and Development*

NAFTA countries strive to participate and maintain strong representation for North Americans at international forums. Some examples follow.

- PMRA and USEPA are members of the Organisation for Economic Cooperation and Development (OECD) Persistent, Bioaccumulative and Toxic (PBT) expert group for pesticides. The working group is developing and implementing risk assessment/management approaches for PBT chemicals.
- PMRA and USEPA are members of the International Crop Grouping Consulting Committee (ICGCC). Mechanism for harmonizing crop groups has been established and the process for developing new/additional crop groups is ongoing. As new scientific information becomes available, existing guidance documents will be revisited.
- Some members of the NAFTA MRL working group are also members of the OECD MRL working group, liaising with representatives from other international agencies responsible for regulating pesticides and OECD stakeholders on issues related to global MRLs.

The following NAFTA TWG projects have been advanced at the OECD:

- Implementation of the OECD MRL Calculator on 1 April 2011 contributed significantly in addressing MRL/tolerances issues. The OECD MRL Calculator, influenced by the NAFTA MRL Calculator, provides a statistically based method for calculating maximum residue limits.
- NAFTA countries led development of the OECD regulatory test guideline, the extended One-Generation Reproductive Toxicity Study guideline (OECD Test Guideline 443). The development of this guideline took into account the dialogue that occurred at the NAFTA level.
- *NAFTA TWG (Quantitative) Structure Activity Relationship [(Q)SAR] Guidance Document*, a key document developed under the NAFTA TWG joint project, was also well received at the OECD level. It will serve as a key reference source in the development of the OECD Guidance Document on (Q)SARs.
- In 2013, the OECD also accepted the USEPA/PMRA proposal to develop an OECD guidance document that would build upon existing U.S. and Canadian guidelines on waiving/bridging acute toxicity studies.
- Ecological Crosswalk Tool (Guidance for Evaluating the Acceptability of Environmental Fate Studies Conducted on Foreign Soils [NAFTA/International Soils X-Walk]) has been incorporated into the OECD ecoregion crosswalk project. PMRA, in collaboration with

Agriculture and Agri-Food Canada, the USEPA and European Union organizations such as the European Food Safety Organization and the European Union Joint Research Centre, is developing a method to identify comparable ecoregions between North America and Europe. This Geographic Information System-based model allows a terrestrial field dissipation study conducted in Europe to be used by North American regulators and vice versa for their respective regulatory reviews. This will facilitate use of environmental field studies and decrease regulatory burdens for both regulators and industry. The PMRA and USEPA are also developing harmonized terrestrial field dissipation study guidance acceptable to all organizations.