North American Free Trade Agreement

Technical Working Group on Pesticides

Accomplishments Report

For the period of 2003–2008

Cat.: H114-18/2008E (H114-18/2008E-PDF)
ISBN: 978-1-100-11928-1 (978-1-100-11929-8)

Table of Contents

List of Acronyms i

Introduction 1

Technical Working Group Accomplishments for 2003–2008 2

Objective 1: Full North American Collaboration in Pesticide Regulation, Including Re-assessment 2

- Re-registration and Tolerance Re-assessment 2
- Commodity Pilots 4
- Grower Priority List Database 4
- Transition Strategies for Older Pesticides 4

Objective 2: Equal and Timely Access to New Pest Management Tools 5

- Protection of Human Health and the Environment 5
- Train-the-Trainer 5
- Work Sharing Arrangements: Joint Reviews, Workshare Reviews and Cooperative Reviews 6
  - Joint Reviews 6
  - Workshare Reviews 6
  - Cooperative Reviews 6
  - Reduced Risk Pesticide Joint Reviews 8
  - Minor Use 8
- NAFTA Label Task Force 9

Objective 3: Robust Stakeholder Participation 10

Additional Accomplishments of the Subcommittees 11

- Information Technology, Electronic Submission and Review Tools 11

Highlighted Achievements 13

Looking Ahead 15

List of Acronyms

AAFC	Agriculture and Agri-Food Canada
CDN	Canada
CEC	Commission for Environmental Cooperation
CEC SMOC	CEC Sound Management of Chemicals
CICOPLAFEST	Comisión Intersecretarial para el Control del Proceso y Uso de Plaguicidas y Sustancias Tóxicas (México)
EPA	Environmental Protection Agency (U.S.)
EPA OPP	EPA Office of Pesticide Programs (U.S.)
GHS	Globally Harmonized System
IPM	Integrated Pest Management
IWG	Industry Working Group
MRL	Maximum Residue Limit
NAFTA	North American Free Trade Agreement
NAFTA TWG	NAFTA Technical Working Group on Pesticides
OECD	Organisation for Economic Co-operation and Development
PMC	Pest Management Centre (Canada)
PMRA	Pest Management Regulatory Agency (Canada)
TWG	Technical Working Group on Pesticides
SOP	Standard Operating Procedure
U.S.	United States
USDA	U.S. Department of Agriculture
US IR-4	U.S. Interregional Research Project Number 4
SENASICA	Servicio Nacional de sanidad, Inocuidad y Calidad Agroalimentaria (Mexico)

Introduction

The North American Free Trade Agreement (NAFTA) initiated a new level of trilateral regional regulatory cooperation on pesticides in 1997 with the establishment of the Technical Working Group (TWG) on Pesticides. Since its creation, the TWG has focused on facilitation of cost-effective pesticide regulation among Canada, Mexico and the United States through collaboration and work sharing, while achieving a high level of environmental, ecological and human health protection.

In 2003, the TWG published its second five-year strategy supported by all three governments, which identified a vision, goals and objectives that have formed the basis for the TWG's activities from 2003 to 2008.

The 2003 Strategy included two broad goal statements:

- ***Work sharing is the way to do business:*** this goal emphasized the importance of creating a culture for collaboration and openness among governments and stakeholders that would allow information to be shared and collectively worked on as a means of easing regulatory burdens, consistent with the goals and intent of NAFTA.
- ***A North American market for pesticides:*** this goal identified the need for a mechanism to facilitate cost-effective pesticide regulation among the three countries, continuing the previous success of eliminating trade barriers and increasing access to pesticides in all three markets.

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)

The goals were further defined by three objectives, which included:

1) full North American collaboration in pesticide regulation, including re-assessment;
2) equal and timely access to new pest management tools; and
3) robust stakeholder participation.

Specific projects to meet these objectives were administered through one of four subcommittees: Joint Review, Food Residue, Risk Reduction and Regulatory Capacity Building.

Technical Working Group Accomplishments for 2003–2008

The TWG wanted to evaluate its performance and success in the implementation of the 2003 strategy to better inform the design and implementation of a strategy for the next five years. The assessment of how well the objectives of the TWG were met was accomplished by interviewing the TWG members and stakeholders as well as reviewing the TWG reference materials. The preparation of this report also gave the TWG an opportunity to reflect on lessons learned to improve on its future performance and identify where adjustments were needed.

The accomplishments that are presented below are organized by the three above-mentioned objectives. An overview of the TWG's key accomplishments and the relevance to future planning efforts of the TWG is provided in the final section.

Objective 1: Full North American Collaboration in Pesticide Regulation, Including Re-assessment

Re-registration and Tolerance Re-assessment

- Registered products are periodically re-evaluated to ensure that their acceptability for continued use is examined using current scientific approaches.
- Canada is currently re-evaluating about 400 active ingredients that were registered prior to 1995.
- Collaboration through NAFTA TWG, has enhanced Canada's capacity in the area of re evaluation of existing pesticides. The U.S. has been re-registering older pesticides since 1985. Canada created a similar program, maximizing the use of the EPA reviews.
- Now, all pesticides must be re-evaluated on a 15-year cycle under Canada's new Pest Control Products Act and U.S. *Food Quality Protection Act*.
- The U.S. and Canada have successfully undertaken several cooperative reviews (worksharing and joint reviews) of existing pesticides under re-evaluation program and there is a strong support among NAFTA countries that worksharing and joint reviews should be adopted as the normal business practice, which is common for the registration of new pesticides.

- In a cooperative effort to re-evaluate/reregister older pesticides, utilizing each country's re-evaluation programs to the fullest (including communication, schedule, work/information sharing), Canada and U.S. developed a joint workplan for the re evaluation/re-registration of the heavy duty wood preservatives (i.e., pentachlorophenol, creosote and chromated copper arsenate).
- Re-evaluation/re-registration of pesticides may result in changes in the uses and associated MRLs or tolerances of these pesticides. This could affect trade among NAFTA partners. It is important that cooperation of the regulatory agencies increases in terms of joint reviews, worksharing reviews and information dissemination to ensure that the best possible information is used in making decisions throughout the reevaluation/ re-registration process. Over the years, the TWG has been collaborating with affected stakeholders to prevent and resolve trade irritants. Prospectively, some registrants have taken advantage of the TWG's joint review program to obtain product registrations and comparable MRLs in all three countries.
- Many of the MRLs and tolerance issues among the NAFTA countries have been resolved, and the NAFTA TWG will continue to work toward resolving remaining differences. For example, NAFTA governments developed and implemented a NAFTA guidance to set tolerances/MRLs through a statistics-based methodology (MRL calculator). This standard methodology can be used by governments as part of the joint review program so that the same or similar data sets will result in the same recommendation for tolerance/MRL levels.
- The development of the MRL calculator and the guidance document on residue trial efficiencies Contributed significantly to addressing MRL/tolerances issues.
- The TWG member countries participated in the International Crop Grouping Consulting Committee (ICGCC) efforts to develop a mechanism for establishing residue data using representative crops. This initiative included the standardization of commodity terminology and the adoption of Codex MRLs representative of the ICGCC Crop Groups.

The MRL Calculator

Pesticide Maximum Residue Limits (MRL) or pesticide tolerances are an important means of ensuring that food crops being imported into a country do not contain quantities of pesticides above the amount allowed by regulations. MRLs/tolerances are determined based on pesticide levels resulting from field trials of pesticide applications to crops.

Creating MRLs which are common between countries is an important means of reducing trade irritants that can prevent the trade in fruits and vegetables. Two important achievements of the TWG have facilitated the likelihood of common MRLs in the future;

- The development of a SOP for determining pesticide MRLs (or tolerances) which will help ensure that the same or similar data sets will result in the same or similar recommendation for MRL levels in each regulatory program; and
- The development of a "NAFTA MRL spreadsheet," (MRL Calculator) which is a spreadsheet that incorporates the decision algorithm and automates the statistical calculations that are outlined by the SOP.

The draft SOP and calculator are intended for use by residue chemistry reviewers in the U.S. and Canada as part of the joint review program. The SOP and accompanying spreadsheet are intended to reduce reviewer bias and enhance the reproducibility of MRL/tolerance determination through adherence to agreed upon methods and assumptions. Through development and use of the SOP and the MRL calculator the regulatory communities in both Canada and the U.S. have made a great advancement toward establishing harmonized MRLs between the two regulatory programs. The calculator and related methodology are also being considered for use in other regulatory jurisdictions (i.e., Europe) which could further reduce trade barriers with other markets.

Commodity Pilots

- The Risk Reduction Working Group focused on a commodity-based approach to identify registration priorities and address trade irritants. Several commodity-based integrated pest management (IPM) initiatives have been completed, including one for cranberry and one for canola.
- Growers in the NAFTA countries were highly supportive of this initiative. For example, tomato, potato, pulse, and avocado grower groups cooperated significantly in these commodity-based activities. In an effort to develop a commodity/pest-based strategy for potatoes, the U.S. and Canadian project stakeholders agreed to develop recommendations and identify priorities for harmonizing pest control tools for potatoes.
- To develop and implement a North American strategy to address trade irritants/barriers and achieve risk reduction for pulse crops (dry lentils, beans, chickpeas and peas, excluding soybeans), the pulse growers in Canada and the U.S. increased their cooperation level with the TWG.
- Currently, Mexico, Canada and the U.S. are working in cooperation on avocado trade irritants.

Grower Priority List Database

The identification and elimination of trade barriers is critical work for the TWG. One group of stakeholders, U.S. growers of specialty crops, worked in cooperation with government officials to develop a process to identify trade irritants on the internet that could be expanded to include growers of other crops and from other countries. The first phase of the online database, completed April 2008, can lead to increased collaboration between stakeholders in different countries by providing a single collection point for information. Having a more comprehensive source of information on irritants may also facilitate efforts to establish priorities and ultimately pinpoint high priority issues to be addressed by the TWG. The database is an excellent example of an effort that is innovative and that will contribute to multiple objectives of enhanced communication and the elimination of trade barriers.

Transition Strategies for Older Pesticides

The TWG, based on assessment of azinphos-methyl (AZM) in Canada and the U.S., 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 is to phase out the remaining uses of the AZM by 2012, while developing alternative pest control strategies that will support regulatory implementation and help to provide a level playing field for North American trade of commodities affected by the phase-out of AZM.

Objective 2: Equal and Timely Access to New Pest Management Tools

This objective focuses on a North American market for pesticides and commodities treated with pesticides through equal and timely access to new pest management tools, including lower risk alternatives for growers in NAFTA countries, and minimization of trade barriers caused by differences in regulatory requirements, while protecting human health and environment throughout North America.

Protection of Human Health and the Environment

The TWG identified within its mandate the need to address the objectives of Chapter Seven, Subchapter B of NAFTA to ensure the protection of human, animal and plant life, and health in North America. Activities of the TWG to address this mandate include:

- enhancing the introduction of reduced-risk products, and
- special projects on children's health and worker safety.

Train-the-Trainer

- Mexico took the lead in this bilateral effort with the U.S. on a number of worker safety issues. The 2004 National Program to Prevent Risks Derived from Pesticides included a number of programs, such as "Training the Trainer", health promoters training, training for distribution facilities, and health professional training.
- Canada and the U.S. developed a pesticide applicator certification and training program with the goal of protection of human health and the environment. This program includes a standard examination to verify an applicator competency to apply pest control products in a safe and effective manner.

Training the Trainer – Worker Safety for Migrant Workers

Between December 2005 and 2007, Mexico completed a program aimed at reducing the direct and indirect pesticide exposure to migrant agricultural workers and their families. The "Training the Trainer" Program developed under the framework of the National Program Against Risk Derived from Pesticide Use created a trainer's network across 20 states of the Mexican Republic. By the end of the project, the program had delivered more than 1,100 courses which developed 1,292 trainers and 22,278 trainees including health promoters, field technicians, doctors, traders, airplane and land fumigators as well as agricultural workers and their families. These outcomes were made possible through the bilateral efforts between Mexico and the United States.

Work Sharing Arrangements: Joint Reviews, Workshare Reviews and Cooperative Reviews

Joint Reviews

Joint Reviews are completed reviews of new data packages submitted at the same time to two or more countries, where the workload is split and reviews are exchanged/peer reviewed. This includes new active ingredients and second entry reviews, which include new uses (minor and major) and new sources of active ingredients of currently registered pesticides. The goal is to reach harmonized registration decisions within the same general timeframe.

Workshare Reviews

This category is similar to joint reviews accept that new data packages are submitted at different times to two or more countries and the reviews are shared as they become available. The goal is to reach harmonized registration decisions, but possibly following different timeframes.

Cooperative Reviews

This category is limited to reassessments of currently registered pesticides. It includes completed reviews of data supporting existing older pesticides within the same general timeframe, where the workload is split between two or more countries and reviews are exchanged/peer reviews. The goal is to reach harmonized registration decisions for older active ingredients using modern data and evaluation methods within the same general timeframe.

- Each of these reviews involves collaboration among governments and stakeholders, through the TWG, sharing the work of pesticide regulation, set priorities and accelerate the registration decision process. Joint reviews have established compatible review procedures for conventional pesticides and biopesticides. These collaborative efforts increase the efficiency of the registration processes, facilitate registration as close to the same time as possible as well as increase access to new and lower-risk pest management tools in participating countries.
- The joint review and workshare review programs have resulted in the registration of a significant number of pesticide products in the U.S. and Canada over the five-year period of the 2003–2008 strategy. Therefore, these programs provided more equal access to pest management tools, avoided potential disparities in MRLs or tolerances, and improved available technologies. This accomplishment has also resulted in increased levels of shared scientific knowledge and in increased understanding of each country's risk assessment and risk management processes. Consequently, regulatory governments have gained trust in their counterparts decision-making.

- There is a strong sense among NAFTA countries that collaboration in the areas of science and policy will contribute to better science, decision-making and capacity building in all three countries.
- The joint review process for new pesticides has been well established and is now considered to be 'normal business practice' among governments and stakeholders. Governments now routinely prompt registrants to register new products in all three countries simultaneously, which facilitates the joint review process.
- The joint review and workshare review process is now considered a model for international collaboration on product review and multiple registrations by other non NAFTA countries. While decisions on the adoption of the TWG's process are still pending, this development was considered by many to be one of the most significant accomplishments of NAFTA TWG.
- The joint reviews have provided substantive 'real world' examples that have enabled government regulators to work through risk assessment and risk management issues. This practical approach has meant that regulatory cooperation has been advanced in a pragmatic way that is meaningful to the day-to-day activities of regulatory communities in each country. This approach has enabled regulators to advance their own core tasks while contributing to the joint review process. Joint reviews stretch resources by addressing common areas of interest, as opposed to treating NAFTA activities as tasks in addition to each country's core activities.
- Joint reviews and workshare activities have been successful at leveraging intellectual capacity, which has contributed additional resources to resolving common challenges. Thus, the regulatory community has been able to bring more minds to bear on solutions that have extended, rather than expended, resources. For example, a project to identify areas where Canadian regulators can assist Mexican regulators in the evaluation of efficacy data was helpful in supporting the trilateral joint review of Aminopyralid.

Since 2003, there have been joint reviews for the following pesticides which have involved at least two NAFTA countries:

- Pyroxsulam (2007)
- Chlorantraniliprole (2008)***, ****
- Spirotetramat (2008)***
- Clothianidin (2003)
- Famoxadone(2003)
- Boscalid (2003)****
- Spirodiclofen (2005)
- Pinoxaden(2005)
- Aminopyralid (2005)*, ****
- Topramezone (2005)
- Prothioconazole (2007)
- Spinetoram (2007)
- Pyrasulfotole (2006)**
- Chondrostereum purpureum (2004) ****
- Pantoea agglomerans strain E325 (2006)
- Pantoea agglomerans strain C9-1 (2006)
- Poly B ****
- Fungitrole ****
- Thiencarbazone*** (2008)

* included Mexico
** trilateral w/Australia
*** global joint review
**** include non-agricultural uses

- The joint review process has been facilitated by the development of a number of standard operating procedures (e.g., minor use joint review, conducting joint minor use residue trials, etc.), which have increased the efficiency and consistency of the review process while minimizing differences that have negative impact on the delivery of review decisions. The U.S. EPA noted that the record for the quickest review and approval now stands with a joint review. Consequently, the joint review process has increased the speed of the review process, which has benefited the regulators, registrants and growers.
- The TWG completed a mapping and review of the submission process for joint reviews.
- The PMRA and the U.S. EPA have also established a process for the joint review of microbial and arthropod semiochemical (including pheromones) pest control products.
- The objective of this program is to remove regulatory barriers for the registration of biopesticides and increase equal market access to new biopesticide products for Canada and the U.S.
- Alignment of the evaluation of antimicrobial pesticides (e.g., data requirements and risk assessment practices) has been initiated and is making progress towards the goal of work sharing.

Since 2003, there have been NAFTA work shares for the following pesticides:

- Clothianidin (2003, second product)
- Cyazofamid (2004 U.S./2005 CDN)
- Paraquat (2005) (with Mexico)
- Iprovalicarb (2001 import MRL with CDN; 2005 with Mexico)
- Novaluron (2004 U.S./2006 CDN)
- Mandipropamid (2008)
- Foramsulfuron (2003)
- Iodosulfuron-methyl (2003)
- Florasulam (2007)

Reduced-Risk Pesticide Joint Reviews

- The TWG has contributed to the reduction of risks to human and environmental health by increasing timely access to new lower-risk pest control tools in NAFTA countries over time. For example the TWG policy decision to expedite the coordinated review of the low risk pest control products created significant risk reduction opportunities.
- Continuing the emphasis of TWG on the joint registration of biopesticides will increase the access to lower risk alternatives to conventional pesticides.
- Mexico has undertaken activities to expand access to reduced risk products (biopesticides), including projects to increase the registration and use of pheromones in Mexico, and resolving trade barriers and issues related to these products.

In 2005, two new active ingredients (both reduced risk) were registered in record time (14 and 16 months)

Minor Use

- Many products are registered in the U.S., but not in Canada, because of the small Canadian market size. It is important to have targeted registration programs to increase submissions to register products in Canada so that Canadian growers are not at a competitive disadvantage with their U.S. counterparts.

- In response to stakeholder concerns, The Pest Management Centre (PMC) was established under the jurisdiction of Agriculture and Agri-Food Canada (AAFC) to address domestic needs for minor use pest control products and risk reduction. The U.S. Interregional Research Project Number 4 (IR-4) was identified as a potential model for collaboration among grower groups for prioritizing work across commodity groups. The PMC has benefited from collaboration with the IR-4 to facilitate registration of pesticides needed by minor use crop producers. The IR-4 and PMC programs work in collaboration with the industry to promote simultaneous registration of new uses under the NAFTA Minor Use Joint Review process to facilitate equal access in both countries.
- The active ingredient approach in minor use applications has generated a substantial number of MRLs for minor use crops. The reviewing of Carfentrazone, Spiromesifen and Bacillus subtilis resulted in over 450 new minor use registrations.
- There is increased attention to minor use issues in Canada. For example, Canadian projects are prioritized annually in March, and the U.S. IR-4 and AAFC's PMC meet each September to discuss projects for joint efforts.
- The IR-4 and PMC regulatory programs assist the industry with pre-registration consultations with the agencies for new active ingredients. During the pre-registration consultations, data requirements are clearly outlined in order to prevent delays during the submission review process.
- A minor use joint review standard operating procedure (SOP) was approved by the NAFTA Executive Board in December 2005, providing minor use growers in both countries with concurrent access to the products. The SOP enables regulators to reach a simultaneous regulatory decision in eight months for joint minor use submissions.

Examples of Pesticide MRLs created for Minor Use Crops
Fiscal Year 2006: fenhexamid—ginseng (Minor Use Pilot Project) and raspberry; s-metolachlor—pumpkin and winter squash.

Fiscal Year 2007: imidacloprid—caneberry; cymoxanil/famoxadone—caneberry; fenamidone—carrot; fluazinam - broccoli, blueberry, snap bean, mustard greens and cabbage.

NAFTA Label Task Force

- All three governments collaborated to develop a Globally Harmonized System (GHS) of Classification and Labeling of Chemicals. The NAFTA partners are supporting the use of GHS for the future NAFTA label projects. Three benefits noted from this initiative were: enhanced protection of human health and the environment, eliminating the duplicate evaluation of pesticide tests and facilitation of international trade.

- Another example of a collaborative effort on labeling is the development of guidelines to encourage the standardization and adoption of pesticide resistance management information on labels.
- Stakeholders and non-government organization have played a critical role in the development of NAFTA labels. Several government officials noted that great accomplishments such as development of the NAFTA labels are due to the substantive involvement of growers in the NAFTA countries.
- In the non-agricultural pesticides area, a process was also developed for NAFTA labels. The NAFTA label pilot project for hard surface disinfectants (HSD) resulted in a new NAFTA label using Global Harmonization System (GHS) symbols, a HSD NAFTA label guidance document, and the development of a registration data requirements matrix.

Objective 3: Robust Stakeholder Participation

- Stakeholders noted that the level of the dialogue with non-governmental organizations had improved significantly over the last five years.
- There are numerous examples of how participating governments have increased the opportunity for stakeholders to provide input by teleconference prior to and following meetings (i.e., annual meetings and subcommittees).
- Another example of increased access for stakeholders is the annual joint meeting held with regulators and registrants.
- The inclusion of additional interaction hours at the Annual NAFTA Stakeholder meeting has built relationships and trust among stakeholders and government.
- The inclusion of breakout groups at the annual stakeholder meeting has led to significant improvements in the dialogue with stakeholders. The efficiency of the annual stakeholder event is very high and has a good value for industry and grower stakeholders.
- The non-agricultural pesticide stakeholders noted that the opportunity to participate in the TWG has been a major accomplishment from their perspective.
- Stakeholders have gained an increased knowledge through their interaction with governments and each other, including:
  - increased knowledge of environmental issues; and
  - knowledge of the use of submitted data in the risk assessment and risk management processes.
- The commodity pilot projects have increased stakeholder engagement (e.g., pulse growers).

Approved NAFTA Labelled Products

Sporodex WP biological fungicide (Pseudozyma flocculosa), 2002 *

Simplicity Herbicide (Pyroxulam), January 2008

Reflex Liquid Herbicide (Fomesafen), October 2007

Gavel 75 DF Fungicide (Mancozeb, Zoxamide), May 2007

Avadex Microactiv Herbicide (Triallate), January 2007

Asepticare Aerosol Disinfectant Virucide, March 2008 *

Axial TBC (U.S.)/Broadband Herbicide (CDN), November 2008

Revus Fungicide, August 2008

Discover (U.S.)/Horizon 60 NG Herbicide (CDN), October 2008

* Includes non-agricultural use

- The transparency of the TWG has improved over time. Meeting minutes are now posted on the web site and it is relatively easy for the general public to get information.
- The level and quality of coordination amongst the Secretariats has improved over time, which subsequently lead to further opportunities for collaboration among the governments.
- The resolution of trade irritants among the NAFTA governments is an accomplishment stemming from significant collaborations between governments and stakeholders.
- The communication between government and industry is excellent. The information that flows from the TWG is disseminated by industry to a broad community, keeping many companies apprised of government activities and future directions

Additional Accomplishments of the Subcommittees

The Four Subcommittees worked on numerous projects to facilitate work sharing activities. The alignment of assessment methodologies and development of electronic submission and review tools facilitate collaborative work processes and ultimately will save time and money. Stakeholders were highly complementary of the work achieved to date in these areas and encouraged the further development of such Smart Business Practices.

Information Technology, Electronic Submission and Review Tools

- Efficiencies for the registrants have been improved through the promotion, facilitation and international harmonization of the electronic submission process, including data delivery, review, exchange, storage and visibility. Electronic submissions created a means to exchange data within a secure non-paper environment.
- Standardized electronic review templates have been developed for all study types (e.g., Chemistry, Efficacy, Environmental Toxicology and Fate, Food Residues, Occupational/Bystander Exposure, and Toxicology) within a pesticide submission.
- An electronic index tool was introduced that permits governments to locate any document within a submission without reliance on a hierarchy of folders and sub-folders or on hyperlinks from a transmittal document. The e-index has simplified the transmittal document and makes it compatible with OECD's dossier guidance, thus increasing the efficiency of the submission process.

- Canada and the U.S. have adopted similar approaches for segregating confidential business information and making confidentiality claims, eliminating another barrier to assembling a single NAFTA data submission.

Significant progress and experience has been gained towards single dossier, single format for data reviews and generation of the single monograph.

- Efforts to further standardize electronic submission data are continuing. New software, the PRISM e-Submission module, went into production in mid-July 2008. The new capability allows registrants to submit applications for new or amended Section 3 Registrations, Experimental Use permits, Tolerance Petitions, and Supplemental Distributor products in an electronic format based on the Canadian PMRA's e-Index Builder. When registrants submit electronically, they do not need to submit paper thus reducing the burden on them. Future efforts will look into the feasibility of harmonizing the electronic submission methodology across all OECD member countries.
- Regulatory cooperation has been an important focus of project activity over the course of the five-year strategy. This has resulted in common approaches (standard operating procedures) and the development of guidance documents to facilitate regulatory cooperation during the last five years. Some of the following projects have not yet been completed:
  - Guidance for harmonization of the approaches used in the United States and in Canada for the selection of doses in carcinogenic bioassays.
  - Guidance to harmonize evaluation and interpretation of developmental neurotoxicity studies.
  - Harmonized derivation of dermal absorption values and analysis for use in occupational and residential risk assessments.
  - Guidelines for conducting pesticide terrestrial field dissipation studies in Canada and the United States.
  - Common modeling procedures for estimating pesticide concentrations in groundwater (ongoing).
  - Guidance for the evaluation and calculation of pesticide degradation kinetics (ongoing).
  - Guidance to accept environmental fate and transport studies conducted on foreign soils (i.e., NAFTA/international soils cross-walk) for use in country specific environmental risk assessment (ongoing).
- An area of science collaboration that has been very fruitful is the identification and documentation of uncertainty factors. This activity has focused on additional research to support advancements in methodologies that address uncertainty and improve joint decision-making procedures.

- Common dossiers have significantly enhanced efficiencies for registrants and regulators who are active in work shares and joint reviews. Common formats have also assisted research efforts. When information requirements are similar, the sharing of information is significantly enhanced. Some of the accomplishments that have contributed to harmonization efforts include:
  - Information formats, (e.g., maximum tolerated dose, labeling).
  - Methodologies (e.g., risk assessment methods such as dietary exposure assessments).
  - Interpretation of scientific data (e.g., standardized methodology for the development of MRL/tolerances).
- *Residue Proportionality (residue zone map):* The AAFC's PMC has established a number of joint field projects with the U.S. IR-4 to address residue proportionality, and is actively pursuing the sharing of data and information on growing zones and crop applications. IR-4 may extend this work to Mexico in the future.
- *Terrestrial Field Dissipation Guidelines:* Canada and the U.S. developed a guidance document to increase the comparability of pesticide environmental fate and transport data requirements, which will ensure registrants conduct terrestrial field dissipation studies that will satisfy requirements in both the United States and Canada. Thus, the opportunities for successful work sharing are enhanced.
- *Percent Crop Treated:* The TWG initiated a detailed review of procedures and statistical methods for estimating percent of crop treated (PCT) and projected percent of a crop treated (PPCT) with a pesticide. The objective of this initiative is to investigate the potential to harmonize these procedures based on the existing similarities in the PMRA and EPA approaches. Similar methods and procedures will contribute further to work sharing opportunities (ongoing).

Highlighted Achievements

The analysis of the input collected from the interviews illustrates that significant achievements in line of the goals and objectives of the TWG five year have been obtained.

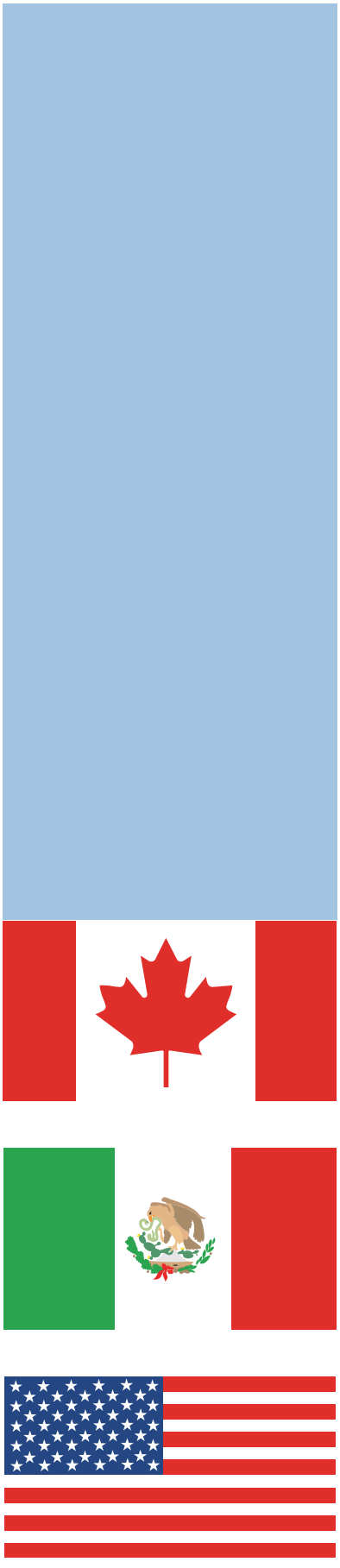
Observations from TWG members and stakeholders provided a varied and substantive list of noteworthy accomplishments that have been achieved over the last five years. The NAFTA TWG members and stakeholders identified numerous accomplishments; however, the following accomplishments were considered the highlights.

1) **Achieving international recognition for the TWG's joint review process:** Joint reviews with other non-NAFTA countries have now been completed and lessens learned are being used to support what is now a developing OECD global joint review process. It is anticipated that the objective of North American market will even be expanded further to include a broader global market.

2) **A higher level of collaboration:** Some examples of the higher level of collaboration were identified as:
   - The establishment of joint reviews as the 'every day normal business' practice;
   - The development of a statistics-based tool for setting MRL/tolerance; and
   - The establishment of record-setting review periods for new products.

3) **A better understanding of each country's decision-making process:** Many respondents were pleased with current levels of understanding and anticipated further cooperation would develop over the period of next five year strategy. Mexico noted that the nature of the information flowing out of the TWG process was allowing their regulators to enhance their capacity in important areas of regulatory review and decision-making.

4) **Communication which assisted the TWG to fulfill its objectives:** From 2003–2008, there were different efforts and venues to keep stakeholders informed of the activities of NAFTA TWG and to increase their engagement. The stakeholder participation was needed:
   - To identify issues concerning the pest control products;
   - To identify trade irritants;
   - To set priorities;
   - To provide focus for research needs;
   - To create NAFTA labels; and,
   - To develop tools that facilitates work sharing and joint reviews. Some examples are the statistics-based MRL calculator and the grower priority MRL database.



Looking Ahead

The accomplishments described in this report point to activities that could be leveraged in the next five-year strategy. The preparation of this report also gave the TWG an opportunity to reflect on lessons learned to improve upon its future performance and identify where adjustments were needed.
The respondents were collectively supportive of future improvements in the areas of equal access to pest control tools by all three NAFTA countries and consideration of joint reviews as an every-day business practice for re-evaluation program. They also requested closer tracking of the achievements related to safety, sustainability and access to reduced-risk products in order to maintain current high levels of protection of human health and the environment and support the principle of sustainable pest management. The enthusiasm for the future of the TWG's activities is perhaps one of the most important assets that the TWG has available as it looks to the future.