



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

## PROJECT COMPLETION SHEET

**SUBCOMMITTEE:** Regulatory Capacity Building

**PROJECT TITLE:** Electronic Submissions  
- Electronic Review Templates for Data Evaluation Reports  
- Electronic Submissions and Review  
- Harmonize Assembly of Electronic Submissions

**PROJECT ID:** RC06-96-1205

**PROJECT LEADS:** Canada: Aaron Carswell (PMRA)  
United States: Oscar Morales, Quentin Jones (EPA)

**PROJECT DATES:** Initiation: Summer 1996  
Completion: February 2008

### GOAL:

To achieve operating efficiencies in pesticide regulation through the promotion, facilitation and international harmonization of the electronic submission process, including data delivery, review, exchange, storage and visibility. To harmonize and implement the standard templates using the Extensible Markup Language (XML) schemas proposed to improve our review of study data.

### PROJECT DESCRIPTION:

To establish a process for accepting and reviewing submissions electronically with the capacity to exchange data with stakeholders involved in the regulatory process.

### BACKGROUND/RATIONALE:

Various initiatives in the use of information technologies are undertaken to achieve operating efficiencies in the regulation of pesticides. The majority of these initiatives are conducted by individual countries that share the results with NAFTA partners in both government and industry. The initial NAFTA efforts were to consolidate and standardize study submission formats. Health Canada's Pest Management Regulatory Agency (PMRA) and the United States Environmental Protection Agency (EPA) Office of Pesticide Programs (OPP) collaborated on other electronic submission efforts outside the scope of NAFTA. These efforts include the submission of electronic registration applications, full study data and other similar initiatives.

In September 2004, the EPA and Mexico attended a two-day technical work share session in Ottawa, hosted by the PMRA to exchange opportunities to leverage IT best practices. The PMRA and the EPA received three pilot joint review e-submissions in March–April 2004 indexed with the e-index tool announced in December 2003. For the PMRA, the benefits were immediate: the e-index has enabled the automation of the principal data entry process, which previously took three weeks of manual labour, and now, if properly populated, this process takes 1.5 hours. The PMRA will continue to encourage registrants to submit e-submissions using this method and share results with the EPA.

In November 2005, the EPA visited the PMRA to investigate ways in which the EPA can leverage the PMRA's experience related to electronic submission and data standardization. This included the review of lessons learned in the development of the e-Index tool, PMRA's plans for future enhancements and the assessment of emerging international standards (such as the NAFTA and Organisation for Economic Cooperation and Development [OECD] study evaluation templates). To the extent possible, the EPA will design its own solutions based on similar concepts and technology to the PMRA, with the goal of facilitating information exchange between the two agencies and increasing the registrants' efficiency in managing their submissions.

In June 2006, representatives from the EPA (Quentin Jones) and the PMRA (Aaron Carswell) traveled to Ispra (Italy) for an Information Technology Conference to promote international harmonization. The conference focused on the templates developed by the OECD that describe the composition of a study profile. In 2005, 86 OECD templates were constructed and published with input from several regulatory agencies (including the EPA and PMRA) and leading registrants. The conference discussions focused on the implementation of the templates. The regulatory authorities and CropLife representatives gave presentations in which they explained their respective approaches. Additional presentations were delivered on particular IT solutions that have been specifically developed to support the OECD templates. The remaining time was spent in general discussion and in developing a strategy moving forward.

In September 2006, the PMRA (Aaron Carswell) visited the EPA to take part in the annual retreat of their OPP-IT Division. The PMRA presented an overview of ongoing project work related to their **Electronic Pesticide Registration System** (e-PRS), with particular emphasis on tools the PMRA developed to meet the information management requirements of electronic pesticide submissions. The PMRA attended a number of EPA overview presentations on projects related to IT strategies to support the information management objectives of the OPP. The PMRA and the EPA discussed and shared ongoing IT tools and strategies that each is using to provide business application support to each of their respective clients.

In April 2007, OPP started a e-Submission Pilot with 5 industry members: Bayer, BASF, Keller & Heckman, Syngenta, Valent. The system allows OPP users to upload zip files containing digitized versions of their submission documents, such as studies, labels, and forms. The zip files also contain XML (eXtensible Markup Language) files that describe the submission documents using a prescribed schema adopted from Canada's Pest Management Regulatory Agency (PMRA) in an effort to promote international harmonization. The e-Submission system unzips the files, parses the XML, performs a variety of validation checks, and stores the "package" and document records in the database. The pilot was successfully completed in August of 2007.

In October 2007, a team of four traveled to PMRA for meetings that consisted of follow-up discussions on several pesticide regulation topics that had previously been addressed during earlier visits. The EPA views harmonization with the PMRA and other regulatory agencies around the world as one of its most critical initiatives. In an effort to reach its goals, the OPP benefits from first finding common ground with Canada. The two agencies have been working together since 2005 to establish a unified approach to information exchange between regulators and registrants. Once this joint methodology is established,

EPA and PMRA can co-sponsor its adoption by other international pesticide producing and regulating organizations in the upcoming harmonization conferences. To this point, the discussions had focused on two items: 1) establishment of an XML standard that companies can use to describe the contents of their submission packages; and 2) determination of an approach for handling incoming Study Profiles in the XML format prescribed by the OECD. During the three days of meetings, the OPP-PMRA workgroup continued to share information about these topics and refine their joint approach. In addition, the group addressed two new topics: 3) the capturing of label data, including the potential creation of a standard to describe label components; and 4) methodologies for tracking company contact information. The purpose of these latter discussions was to gain an understanding of the other agency's approach to handling two common problems.

The OPP's PRISM e-Submission System will be in production May 2008 and we will provide industry with an Application Support Help Desk.

The initial objectives of this project have been fulfilled. The PMRA and the EPA will continue to collaborate on an ongoing basis in this area.