



NAFTA Technical Working Group on Pesticides
Grupo de Trabajo Técnico del TLC sobre plaguicidas
Groupe de travail technique sur les pesticides d'ALENA

Joint EPA–PMRA Status Report on Electronic Submissions and Review

January 2001

Under the North American Free Trade Agreement Technical Working Group on Pesticides, the Pest Management Regulatory Agency (PMRA) and the Office of Pesticide Programs (OPP) in the United States Environmental Protection Agency (EPA) are working together to examine electronic submissions and review capability.

A series of pilots have been undertaken in cooperation with the pesticide industry to investigate approaches to electronic data submission (EDS) and review. The pilots have resulted in the following:

- The EPA/OPP and the PMRA participated on the Computer Aided Dossier and Data Supply (CADDY) Steering Group. CADDY was first initiated to assist in submitting data to all European Union countries in a manageable way. Under CADDY, TIFF images of studies are stored on compact disks along with an index and software to navigate throughout the submission. The Steering Group collaborated on a number of areas including specification of requirements, development and testing of CADDY software, and developing procedures for registrants and regulatory staff on preparation and in-processing of CADDY submissions. While CADDY is a useful tool for European industry and regulatory authorities, it was not embraced by the OPP, the PMRA or North American industry because of its limitations as an aid to study review by regulatory staff. As a result, the PMRA and the OPP have both undertaken joint agency–industry pilot projects to assess the use of Portable Document Format (PDF), Adobe Acrobat and other tools that facilitate the evaluation process.
- Cooperative effort within the PMRA involving submissions provided by Bayer and Dupont compared three formats for electronic submission and review against a paper standard. The electronic formats included CADDY, a submission format using Adobe Acrobat's PDF and a submission format that combined PDF with a web browser interface (PDF/web browser). The purpose of these pilot projects was to evaluate and compare the data evaluation capabilities of the electronic formats in support of achieving operating efficiencies in the registration process.

PMRA evaluators determined that a 23% gain in efficiency (in evaluator time) occurred in this pilot project with the use of the PDF/browser format. CADDY (designed to archive and reduce paper) did not support evaluator electronic review needs.

- The American Crop Protection Association (ACPA) and the OPP organized a workshop on the use of electronic data submissions for pesticide registration applications in March 2000. The workshop was attended by representatives from the Canadian industry, and the PMRA, the U.S. Food and Drug Administration (FDA), the EPA's Office of Pollution Prevention and Toxics. The purpose of the workshop was to jointly identify future steps needed in making electronic submissions a viable tool for both the EPA and the PMRA and registrants. Break out sessions provided forums to discuss options for formatting data to supplement studies as well as study reports and overall submissions. A report of the workshop and proposed next steps is available on the OPP's web page on electronic submission (www.epa.gov/oppfead1/edsgoals.htm). It is expected that a further work shop involving the PMRA, the EPA and industry will be scheduled in 2001.
- The PMRA and the OPP are undertaking further pilots with registrants involving PDF formats and supplemental files as tools to facilitate data submission and review. Consultation with the ACPA, Crop Protection Institute of Canada, other interested industry associations, and individual registrants interested in electronic submission is occurring. An operating principle is to build on the lessons learned by others, particularly the FDA and the CADDY group, as well as U.S. registrants' electronic document management efforts.
- At present, three interim guidance documents have been developed by the PMRA on Electronic Dossier, Delivery, and Evaluation (EDDE), which provide extensive information based on experiences to date. They are available on the PMRA web site, www.hc-sc.gc.ca/pmra-arla.
 - Guidance on how to create a document to facilitate electronic exchange
 - A preliminary statement of evaluator needs
 - Guidance to industry on how to provide an electronic dossier to Canada
- The OPP has developed interim guidance for the electronic submission and review pilots, which is available on the OPP electronic submission web page, www.epa.gov/oppfead1/edsgoals.htm. Additional guidance will be developed as the pilot efforts evolve. The guidance developed by the EPA and the PMRA are consistent with each other and reflect country specific experience to date. Current guidance includes:
 - specifications for creating electronic submissions in Adobe Acrobat version 4;
 - suggested format for reporting toxicology studies;
 - certification with respect to data integrity;
 - in-processing and storage of studies submitted in PDF format; and
 - draft guidance for submitting data in several supplemental file formats.
- The OPP and the PMRA look forward to a continuing dialogue with the European Commission (EC) and European countries on our joint experiences with EDS and how to work toward convergence of EDS approaches as we both gain greater experience. This was a topic of discussion at the November 2000 meeting of the Organisation for Economic Co-operation and Development's (OECD) Working Group on Pesticides. There was also an opportunity to share information on EDS activities at the trilateral EC/U.S./Canada meeting in advance of the OECD meeting.

Summary

The pilots are demonstrating positive results. Outcomes expected from the pilots are the establishment of an electronic submission formatting standard that strikes a good balance between registrants and reviewers. The standard must be cost effective and easy for the wide range of North American registrants to implement. It must provide reviewers with easily learned functionality that makes their work more efficient and effective. The PMRA and the OPP will share results of pilot efforts with all interested parties on request and through regular updates on their respective web sites.