



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

File name: RC0300FE

PROJECT SHEET

SUBCOMMITTEE: Regulatory Capacity Building

PROJECT TITLE: **Electronic Submissions and Review**

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INITIATION: Summer 1996

UPDATE: November 2003

GOAL: To achieve operating efficiencies in the regulation of pesticides through the promotion, facilitation and international harmonization of the electronic submission process, including the delivery, review, data interchange capability and archiving

PROJECT DESCRIPTION:

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

MILESTONES:

The Pest Management Regulatory Agency (PMRA) and the U.S. Environmental Protection Agency (EPA) Office of Pesticide Programs (OPP) have set standards for electronic submission of studies and their evaluation. They continue to conduct pilot projects and share the results among regulators and industry. The pilots explore a variety of electronic submission and review opportunities involving product label text, computer assisted in-processing and screening, full studies, and statistical analyses and raw animal data that supplement studies.

- Based on the EPA/PMRA agreement to adopt PDF as the standard format for electronic data submission, EPA has published a series of guidance documents for electronic submissions using PDF. PMRA will be updating the EDDE guidance series in 2004 and will be looking to leverage and adopt where applicable current EPA technical PDF specifications.
- PMRA and EPA are working towards a better understanding of each others internal screening procedures and have initiated a process mapping activity to address any potential areas for harmonization.
- PMRA and EPA are piloting an electronic index tool to simplify and facilitate the assembly of electronic submissions using the OECD crosswalk.

- The OECD Workshop on Electronic Tools for Data Submission, Evaluation, and Exchange for the Regulation of New and Existing Industrial Chemicals, Agricultural Pesticides and Biocides was held in Ottawa, Canada October 2-4, 2002. Its purpose was to exchange information and share experiences in the use of electronic tools, discuss current approaches with the view of sharing information between programmes and to identify potential OECD activities for future work.

BACKGROUND:

Various initiatives in the use of information technologies have been undertaken to achieve operating efficiencies in the regulation of pesticides. The majority of these have been conducted by individual countries that share the results with NAFTA partners in both government and industry. Under this project, the NAFTA countries strive to harmonize efforts among themselves and to work in close coordination within larger international forums such as the European community (EC) and the OECD.

NEXT STEPS:

- Continue to strengthen opportunities for industry and other stakeholder input on Electronic Data Submission (EDS) guidance development to ensure effective implementation.
- Undertake new pilots that build on past experience and are consistent with EPA and PMRA review schedules and priorities.
- Complete pilot and established projects; evaluate and share results with NAFTA stakeholders.
- Encourage industry to routinely submit data in electronic format and ensure that reviewers are adequately trained to use tools that take advantage of EDS.

WORK PLAN

SUBCOMMITTEE: Regulatory Capacity Building

PROJECT TITLE: Electronic Submission and Review Project

UPDATE: November 2003

I. Pilot Electronic Submission and Review Formats and Tools

The OPP and the PMRA continue with a series of pilots with registrants and reviewers using Adobe Acrobat's PDF and its related tools to assemble large data submissions and to review the studies. The objective is to establish an electronic data formatting standard that is practical and achievable for registrants and that meets the functional requirements of agency staff that analyze studies and prepare review documents. Initially, data submitted for applications included on the current registration work plan were selected as candidates for the pilots. The EPA and the PMRA now encourage industry to submit any data electronically. The pilots involve studies and reviewers in a variety of disciplines.

A. PMRA Activities

- PMRA's EDDE system is transitioning from primarily a pilot site to a new channel for PMRA stakeholders to conduct business with the Agency. In Fall 2004 PMRA will be launching the On-line PMRA Regulatory System (OPRS) that will leverage years of collaboration with the CropLife and other industry participants, to deliver secure on-line filling of electronic submissions including, forms, labels and submission data. The OPRS will also facilitate PMRA's commitments for transparency given the new legislation.
- PMRA has seen a significant increase in the receipt of electronic data with 2678 partial and full electronic submissions received in 2002-2003. The numbers were extremely high for Category As and Category Cs were roughly 95% were received with e-components.
- Electronic evaluation templates continue to be developed and approved under a NAFTA project. These are made available to industry to use during dossier assembly. PMRA continues to promote the use of these templates as it facilitates the evaluation process. Templates are now integrated into PMRA's internal document management tool, the Workbook.
- PMRA is assessing approaches to establishing performance measurements for determining the benefits/efficiency levels of using electronic tools throughout the submission life cycle.
- Update PMRA electronic submission guidelines.

B. OPP Activities:

OPP has received nearly 2,200 studies in full and partial electronic submissions. Work products include specifications and formatting guidance for data and supplemental files that are posted on an OPP Web site.

- Notify registrant community that electronic submission of studies and supplemental files is encouraged but not mandatory. Provide submitters guidance on as they prepare electronic submissions. Ongoing

- Train OPP reviewers in the use of Adobe Acrobat and other automated tools as aids to their evaluation of electronic versions of the study and to develop the review and decision document. Ongoing
- Develop and refine technical specifications for submissions as well as guidance on formatting study reports, full submissions, supplemental files and review aids, and in-processing steps. Design study formatting guidance that parallels templates for review documents. Post on OPP Web site dedicated to electronic submission and review efforts. Ongoing
- Pilot electronic submission and review of supplemental data files that support chronic toxicology studies. Work with Bayer to develop specifications for animal data to be submitted in SAS Transport and post on the Web. Train staff in use of JMP software (by SAS) to evaluate supplemental files. August 2000 - on-going.
- Pilot electronic submission of label text in PDF for label amendment submissions. Train label reviewers in use of Adobe Acrobat 'compare' function to improve efficiency and effectiveness of label review process.
- Work with the CropLife America (formerly American Crop Protection Association)EDI Committee and the PMRA to plan and conduct second joint Electronic Submission Workshop as an opportunity to share experiences and plans since the first workshop in March 2000. January 2003
- Continuously evaluate electronic data submission and review efforts; building on experiences to refine. Share results with the PMRA and industry. Ongoing

II. Share North American Experiences with Electronic Submission and Review with the E.C. and the OECD

- Share results of process and standards harmonization Spring 2004

III. Explore Other Electronic Submission and Review Opportunities

- The PMRA and the OPP have formed work teams to explore other uses of information technology to share experiences. The potential for the use of Extensible Markup Language (XML) as a data submission format is being explored. The PMRA and the OPP work teams will share the results of these efforts to promote further harmonization of processes and work sharing. Ongoing
- The PMRA and the EPA to share information on secure data transmission technologies and leverage lessons learned. Ongoing

IV. Increase Involvement of Industry in Electronic Submission and Review Project

The NAFTA Industry Technical Working Group (IWG) was formed in June 1998 to represent the pesticide industry in Canada, the U.S. and Mexico in NAFTA matters. In August 1998, it identified projects in which it wanted to participate because of the high level of interest among its members. Among them is the Electronic Submission and Review Project. The NAFTA TWG, the co-chairs of the Regulatory Capacity Building Subcommittee and the co-leads on the Electronic Submission and Review Project welcome industry participation on this project. In addition, frequent communication with trade associations and individual companies increases the understanding of and participation in electronic submission and review efforts.

- Establish and maintain process for communications of activities among the PMRA, the EPA and industry as represented by the I.G. Ongoing

In an exchange of letters, the Electronic Submission and Review Project co-leads and the I.G. established basic operating principles, designated key contacts and agreed to communicate on the various pilot efforts.

- Continue to explore the use of technologies for forms and labels. 2004