


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: **Evaluation Guidance for Developmental Neurotoxicity (DNT) Testing**

PROJECT ID: RC03-98-1205

PROJECT LEADS: Canada: Connie Moase
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PROJECT DATES: Initiated June 1998. Completed December 2005.

GOAL/OBJECTIVE: Development of guidance to harmonize evaluation and interpretation of developmental neurotoxicity (DNT) studies

BACKGROUND:

Developing a common guidance document was considered to be important to both regulatory agencies, the United States Environmental Protection Agency (EPA) and Health Canada's Pest Management Regulatory Agency (PMRA), as well as to the pesticide registrants. The health evaluation divisions at the EPA and the PMRA conduct joint reviews and risk assessments; the registrants must satisfy the regulatory requirements of both countries. Having harmonized approaches the evaluation of these studies is beneficial to all as the two governmental bodies will be interpreting the DNT data using the same standard.

OUTPUT/RESULTS:

As part of the effort to harmonize the EPA's and PMRA's approaches, guidance was jointly developed for the evaluation of DNT studies. This guidance was incorporated into the DNT Data Evaluation Report (DER) format, thus providing toxicology reviewers with readily available information to utilize in the completion of DNT study reviews. The guidance was developed jointly by the EPA's and PMRA's health evaluation divisions. The guidance addresses the methods and results for all endpoints assessed in the DNT study and provides example language, instructions for customizing the DER to the study being reviewed, descriptions of important aspects of typical study conduct that should be included in the DER, descriptions of common methodological variants and their potential impact on the study results, helpful hints on data presentation, and background information on the typical ontogeny of functional endpoints assessed in the DNT study.

This project was moved under the auspices of the International Life Science Institute in Spring 2004 to facilitate broader participation from industry and academia as well as to facilitate a guidance document that would also be useful to regulators and the industry.