

## PROJECT SHEET

**SUBCOMMITTEE:** Regulatory Capacity Building

**PROJECT TITLE:** Harmonization of Approaches for Dermal Absorption

**PROJECT ID:** RC10-04-1205

**PROJECT TEAM:** PMRA: Stephen Croteau, Cindy Barnes, Angelika Zidek,  
EPA: Rebecca Daiss, Jess Rowland, PV Shah, Jeff Evans, Larry Chitlik  
CDPR: Joe Frank, Tom Thongsinthusak

**PROJECT DATES:** Initiated in 2004; updated in May 2006.

**UPDATE:** The NAFTA Project Team held conference calls in July, September, and December, 2005. The Team began meeting monthly after January, 2006. Each group is developing a paper outlining their position on, and assigning priority to, issues identified with five groups of technical items. Issues and priorities are to be discussed at the June 2006 meeting.

**GOAL/OBJECTIVE:** The goal of this project is to ensure continued harmonization among the EPA, PMRA and CDPR with regard to analysis of dermal absorption data and derivation of dermal absorption values for use in occupational and residential risk assessment. Specifically, the intent is to revisit and update the harmonized position on derivation of dermal absorption values for use in occupational and residential risk assessments, as established in a previous NAFTA project: Harmonized Approaches to Occupational and Residential Exposure Assessment. This will facilitate work sharing and joint reviews among the EPA, CDPR and PMRA.

### PROJECT DESCRIPTION:

Five key steps have been identified.

Step 1: Identify project participants. Consider inclusion of the California Department of Pesticide Regulation.

Step 2: Review harmonized position established in 1998 and identify priority issues for re-examination.

Step 3: For priority issues, each Agency to develop a document outlining its policy, with illustrative examples of application to occupational and residential risk assessment.

Step 4: Analysis of differences; cross-walk to compare/contrast and define areas where differences exist.

Step 5: Differences in approaches will be highlighted, and process for resolving differences will be initiated.

**BACKGROUND/RATIONALE:**

In 1995, the NAFTA Subworking Group on Pesticide Occupational and Bystander Exposure identified several issues needing harmonization, including approaches to dermal absorption.

A harmonized position on several technical issues related to dermal absorption (e.g., default values, use of in vitro data, approaches to assessment of skin bound residues) was reached. These issues are documented in *International Harmonization Position Paper on Methodology Issues* (January 18, 1998). Since then, approaches in practice have diverged. Furthermore, scientific advances in the field, together with international regulatory activity in this area, have taken place. As such, there is merit in revisiting and updating the harmonized position.

**WORK PLAN**

**SUBCOMMITTEE:** Regulatory Capacity Building

**PROJECT TITLE:** Harmonization of Approaches to Dermal Absorption

GOAL	ACTIVITIES	TIMEFRAME
Initiate Harmonization of Approaches to Dermal Absorption	Agreement by NAFTA partners to devote resources to project activities in various areas.	June 2004
Identify project participants. Consider inclusion of California Department of Pesticide Regulation.	Plan a conference call with participants to introduce members as well as project goal and description.	March 2005
Review harmonized position established in 1998 and identify priority issues for re-examination.	A conference call was held on September 22. Reviewed the project sheet; reasserted the goal of the project; identified the project description with its five key steps as a workable framework. A conference call was held on December 8. Each group reviewed technical items as presented in 1998 and proposed and agreed upon revisions of the technical items. Issues for discussion were identified within each technical item.	June–December 2005
	The agencies are still identifying priority issues for reexamination and assigning priorities to the identified issues.	March-June 2006
For priority issues, each Agency to develop a document outlining its policy, with illustrative examples of application to occupational risk assessment.	Agencies to write up their policies on priority issues.	June 2006
Analysis of differences: cross-walk to compare/contrast and define areas where differences exist.	Conference calls to continue every third Wednesday of the month to review and discuss issues needing harmonization.	September 2006
Differences in approaches will be highlighted, and a process for resolving differences will be initiated	Conference calls to continue every third Wednesday of the month to review and discuss issues needing harmonization.	December 2006

**Project Leads:**

Canada: Connie Moase, Director, HED;

USEPA: Jeff Herndon, Associate Director, HED;

Science Leads	Canada	United States
	PMRA Stephen Croteau, Exposure Re-evaluation Section	USEPA Rebecca Daiss Health Effects Division  CDPR Joseph Frank Worker Health and Safety Branch