



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 SHEET

SUBCOMMITTEE: Regulatory Capacity Building

PROJECT TITLE: Detailed Review and Harmonization of Dermal Absorption Practices

PROJECT ID: RC14-07-0908

PROJECT LEADS: PMRA: Stephen Croteau, Mark Baker, Kim Irwin
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PROJECT DATES: Initiated May 2007. Updated September 2008.

GOAL/OBJECTIVE:

The goal of this project is to develop a detailed review of EPA, PMRA and CDPR positions on specific issues regarding analysis of dermal absorption data and derivation of dermal absorption values for use in occupational and residential risk assessment of pesticide compounds. The objective is to discuss and determine NAFTA agency approaches, practices and positions on a detailed, prioritized list of specific dermal absorption issues identified by NAFTA Agencies in previous workgroup efforts. The list of issues provides a basis for continued discussion and efforts to further delineate/harmonize NAFTA Agency positions regarding dermal absorption. The primary goals and objectives of this effort are four-fold: 1) to review agency practices/positions on specific issues and develop a more detailed harmonized approach to derivation of dermal absorption values; 2) to maintain awareness of dermal absorption approaches/practices and enhance consistency among NAFTA Agencies; 3) to facilitate work sharing and joint reviews among the USEPA, CDPR and PMRA and 4) to develop a new International Harmonization Position Paper on Dermal Absorption Practices.

PROJECT UPDATE:

The NAFTA Dermal Absorption Group has finalized a consensus "Position Paper on Use of *In Vitro* Dermal Absorption Data in Risk Assessment." The number of *in vitro* studies submitted to NAFTA agencies has increased in recent years and is expected to continue to increase based in part on OECD policies. None of the NAFTA agencies has a detailed formal policy/position on the use of *in vitro* dermal absorption studies in pesticide risk assessment. Therefore, the NAFTA dermal absorption group selected use of *in vitro* data as a high priority issue to address as part of our ongoing coordination and harmonization efforts. NAFTA Dermal Absorption Group members have reached consensus on the final position paper and it has been approved by management of the NAFTA group agencies (OPP, PMRA and CDPR). The position paper has also been provided to the OECD workgroup on dermal absorption as part of the NAFTA group's joint US/Canada comments on OECD's Draft Dermal Absorption Guidance. The NAFTA dermal absorption group will continue to work with OECD on its development of dermal

absorption guidance. Ongoing interaction with OECD has been added to the work plan for this NAFTA Project.

PROJECT DESCRIPTION:

Five key steps have been identified.

Step 1: Review the current prioritized list of outstanding issues identified under each of the five overarching dermal absorption technical items.

Step 2: Each Agency will provide a summary of their current policy/existing approaches regarding each of the outstanding issues.

Step 3: Analyze differences; cross-walk to compare, contrast, and define areas where differences exist.

Step 4: Highlight differences in current practices/positions and discuss approaches for harmonization.

Step 5: Develop a new International Harmonization Position Paper on Dermal Absorption Approaches and Practices.

BACKGROUND/RATIONALE:

In 1995, the NAFTA Subworking Group on Pesticide Occupational and Bystander Exposure identified several issues needing harmonization, including approaches to dermal absorption. In 1998 a harmonized position on several technical issues was documented in the International Harmonization Position Paper on Methodology Issues (January 18, 1998). In 2005, a new NAFTA Dermal Absorption Working Group was formed to revisit and update the 1998 position paper. In 2006, the NAFTA Group developed a list of five technical items that encapsulate key components in the process of conducting, interpreting, and using dermal absorption studies for risk assessment. The NAFTA Group developed general descriptions of each Agency's current approach regarding each of the five technical items, summarized the harmonization status of the NAFTA Agencies for each technical item, and identified areas for continued progress. Based on the most recent review, NAFTA Agencies are currently harmonized on their general approach to dermal absorption as defined by the five overarching technical items. Current Agency approaches and harmonization status are documented in an updated NAFTA position paper on dermal absorption. The Working Group also developed and prioritized a detailed list of outstanding dermal absorption issues as a basis for continued efforts to clarify and harmonize specific NAFTA Agency positions regarding dermal absorption.

WORK PLAN

SUBCOMMITTEE: Regulatory Capacity Building

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GOAL	ACTIVITIES	TIMEFRAME
Finalize new project sheet for the next phase of the dermal absorption harmonization project	Comment on, review, revise Draft Project Sheet	April, 2007
Review current prioritized list of outstanding issues identified under each of the five overarching dermal absorption technical items.	Review, revise current list of prioritized issues	May/June, 2007
Document each Agency's current policy/existing approaches regarding each of the outstanding issues.	Discuss, develop summaries of current policy/existing approaches regarding each of the outstanding issues.	December, 2007/January, 2008
Cross-walk to compare, contrast, and define areas where differences exist.	Analyze and document conformity and differences in approach/procedures; highlight differences	February/March, 2008
<p>Harmonize approaches/procedures to the extent possible</p> <p>Produce a new International Harmonization Position Paper on Dermal Absorption Approaches and Practices</p> <p>Interact with OECD Expert Group on Dermal Absorption. Provide NAFTA (US and Canada) input on OECD dermal absorption document</p>	<p>Discuss, identify approaches for harmonization.</p> <p>Develop a position paper documenting Agency positions/approaches on primary technical items and detailed issues/procedures</p> <p>Provide review and comment on OECD Dermal Absorption Draft Guidance Notes</p>	<p>May/June, 2008 July 2008 – Developed a harmonized approach to use of <i>in vitro</i> dermal absorption data in risk assessment.</p> <p>October/November, 2008 July 2008 – Completed NAFTA Position Paper On Use of <i>In Vitro</i> Dermal Absorption Data in Risk Assessment</p> <p>June 2009 July/August 2008 – Provided preliminary and detailed comments on OECD draft dermal absorption guidance.</p>