



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: Terrestrial Field Dissipation Study Guideline Harmonization and Ecoregion Crosswalk

PROJECT ID: RC16-07-0808

PROJECT LEADS: U.S.:
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PROJECT DATES: Initiated Fall 2007. Updated August 2008.

GOAL/OBJECTIVE: To develop a crosswalk for North American and European ecoregions and harmonized international guidelines for terrestrial field dissipation studies

PROJECT DESCRIPTION:

Recently, a soil crosswalk incorporating the USDA, Canadian and FAO systems of soil classification (i.e., soil taxonomy) was jointly developed by EPA, PMRA and Mexico to assess the relevance of foreign soils used in laboratory studies of pesticide fate to their respective native soils in regulatory assessments.

Recent advances in global harmonization of regulatory review and registration of new pesticides has resulted in a desire by registrants and regulatory agencies to develop an analogous crosswalk for foreign field study sites (initially focussing on North America and Europe, but this could be extended to other areas in the future).

BACKGROUND /RATIONALE:

In order to address the evolving nature of pesticide risk assessments, and to develop harmonized guidance for terrestrial field dissipation studies, a joint NAFTA workgroup was formed in April 2000 under the auspices of the North American Free Trade Agreement (NAFTA). In March 2006, the NAFTA-harmonized guidance for conducting terrestrial field dissipation studies was published in the U.S. and Canada. Following up on this success, the next step being proposed is to extend the harmonization beyond North America, both in terms of guidance for conducting terrestrial field dissipation studies, as well as developing criteria that can be used to assist in site selection across international borders.

Environmental conditions, such as climatic (temperature and precipitation) and soil characteristics (pH, texture, organic carbon content), are important factors affecting the dissipation of pesticides under field conditions. Prior to the harmonization of the NAFTA guidance for terrestrial field dissipation studies, the Ecological Regions of North America Level 3 Map produced by the Commission for Environmental Cooperation (1998) was adopted as the standard for site selection. Visual comparison with soil temperature, moisture and classification maps reveals the strong influence of these factors on the North American ecological regions. Only those U.S. field studies conducted in ecoregions that are common to Canada are considered to be relevant to Canadian conditions.

It is proposed that a similar ecoregion approach be adopted in the development of crosswalks for terrestrial field dissipation studies initially between North America and Europe (with the possibility of extension to include other areas at a later date).

WORK PLAN

SUBCOMMITTEE: Regulatory Capacity Building

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UPDATE: August 2008

COMPONENT A: Terrestrial Field Dissipation Study Guideline Comparison and Harmonization (EPA lead)

GOAL	ACTIVITY	TIME FRAME
Seek interest from the OECD member countries.	Present the project sheet at the OECD meeting in June 2008 to seek interest from member countries.	June 2008 (completed)
	Report back to the Executive Board on the outcome of the OECD meeting.	November 2008
Develop OECD work plan	Share draft with OECD when complete	October 2008
	OECD to identify interested member states and points of contact	ongoing

GOAL	ACTIVITY	TIME FRAME
OECD to identify current European guidance of field dissipation studies	Identify existing international guidance on terrestrial field dissipation studies	November - December 2008
Determine similarity European/other guidelines to North American guidelines	Establish criteria for determining similarity or identify experts who can do this	
Review and compare the existing international guidance for conducting terrestrial field dissipation studies	<p>Collect and evaluate the purpose and design of available terrestrial field dissipation study guidelines and guidance documents</p> <p>Develop summary document along with case studies of examples available to EPA/PMRA</p> <p>Evaluate studies conducted according to the NAFTA harmonized guidance to ensure that the conceptual model approach gives the desired results</p>	
Develop and publish comparison document on international field dissipation study guidelines	Draft comparison document.	
	Workshop for OECD/NAFTA member states only	
	Solicit stakeholder review of draft comparison document	
	Finalize comparison document	
Draft harmonized guidance document on international field dissipation study guidelines	Draft guidance document on harmonized international field dissipation study guidelines incorporating results from Ecoregion crosswalk map	
	Workshop for OECD/NAFTA member states and external stakeholders	
	Solicit stakeholder review of draft guidance document on harmonized international field dissipation study guidelines	
	Finalize guidance document on international harmonized field dissipation study guidelines	

COMPONENT B: Ecoregion Crosswalk Map (PMRA lead)

GOAL	ACTIVITY	TIME FRAME
Preliminary		
Seek interest from the OECD member countries.	Present the project at the OECD meeting in June 2008 to seek interest from member countries.	June 2008 (completed)
	Report back to the Executive Board on the outcome of the OECD meeting.	November 2008
	OECD to identify interested member states and points of contact.	Ongoing
Phase I - Pilot		
Pilot analysis of two case studies (one where European site is acceptable and one where it's not).	Finalize and sign Interdepartmental Letter of Agreement between PMRA and Agriculture and Agri-Food Canada (AAFC).	July 2008 (completed)
Identify European ecoregions (climate and soils).	AAFC to identify European experts and obtain existing European ecoregion, soil and climate maps.	July - August 2008
Determine similarity of European ecoregion(s) to North American ecoregion(s)	AAFC to assemble all relevant data layers, documentation and metadata for the evaluation area (Canada and the European Union).	July - September 2008
	AAFC to develop methodology for pilot geospatial analysis of ecological and other layers.	
	AAFC to conduct pilot analysis of climatic and soils data based on the "NAFTA Soils Crosswalk".	
Prepare reports and maps and develop Phase II workplan for presentation to OECD.	AAFC to prepare preliminary report with digital and PDF maps and Phase II planning for OECD meeting in November 2008.	October 2008
	AAFC to prepare final reports, maps and Phase II planning for OECD meeting in November 2008.	
Phase II – OECD Workplan (To be finalized after completion of Phase I)		
Identify European ecoregions (climate and soils).	Identify European experts and obtain existing European ecoregion, soil and climate maps.	
Determine similarity of European ecoregions to North American ecoregions and create crosswalk.	Establish criteria for determining similarity of ecoregions.	
	Create draft ecoregion crosswalk for North American and European terrestrial field study sites.	
	Workshop for OECD/NAFTA	

GOAL	ACTIVITY	TIME FRAME
	member states only.	
	Solicit stakeholder review of draft ecoregion crosswalk.	
	Finalize ecoregion crosswalk.	
Develop and publish harmonized ecoregion crosswalk guidance document.	Draft ecoregion crosswalk guidance document.	
	Workshop for OECD/NAFTA member states and external stakeholders.	
	Solicit stakeholder review of draft harmonized ecoregion crosswalk guidance document.	
	Finalize harmonized ecoregion crosswalk guidance document.	
Incorporate harmonized ecoregion crosswalk guidance into harmonized international field dissipation study guidelines.	Merge harmonized ecoregion crosswalk guidance with harmonized international field dissipation study guidelines.	