



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

Filename: JR0500FE

PROJECT SHEET

SUBCOMMITTEE: Joint Review of Chemical Pesticides

PROJECT TITLE: **Harmonization of the Evaluation of Antimicrobial Pesticides**

PROJECT TEAM: Lead contacts: Pierre Beauchamp, PMRA
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INITIATION: Fall 1995

UPDATE: September 2002

GOAL: To harmonize data requirements and risk assessment practices for antimicrobial pesticides to facilitate work sharing

PROJECT DESCRIPTION:

As part of the North American Initiative (NAI), the project will review the current data requirements, testing strategies and risk assessment practices for antimicrobial pesticides in Canada and the U.S. and identify those areas where data requirements are similar or identical. Specific activities included a review of the toxicology data requirements in Tier 1 of the U.S. Environmental Protection Agency (EPA) testing strategy and a U.S. proposal for environmental data requirements.

Initial efforts focussed on clarification of current regulatory practices and terminology through case studies on wood protection product, material preservatives and slimicides. The objective of this project and its activities are linked to other NAFTA projects on the re-evaluation of heavy duty wood preservatives (Joint Review of Chemical Pesticides Subcommittee); the development of guidance on the conduct and evaluation of post application exposure to pest control products (Regulatory Capacity Building Subcommittee); and identifying priorities for the development of Organisation for Economic Co-operation and Development (OECD) test protocols and guidelines (Regulatory Capacity Building Subcommittee).

MILESTONES:

September 1997 Pest Management Regulatory Agency (PMRA) comments on EPA environmental data requirements

December 1997 Conclusion of case study building and refining cross walk for wood preservative uses

February 1998	Completed preliminary comparative matrix of U.S. and Canadian wood preservative data requirements (via OECD Biocide Survey results), tabled at Pesticide Forum
June 1998	Proposals on priorities for further work for the consideration of the NAFTA TWG
June 1998	The EPA and the PMRA participated in first OECD Biocide Project Steering Group (SG) meeting to outline harmonization work plan. In line with this NAFTA project
July 1998	Joint Canada–U.S. guidance document on post-application exposure assessment is to be available
November 1998	OECD agreed to work plan (developed in June 1998) harmonization activities in the following areas: data requirements; product efficacy; exchanging and sharing of reviews; risk assessment
Summer 1999	The EPA revised 40 Code of Federal Regulations (CFR) Part 158, Subpart W, to be published. (Publication date to be determined)
February 1999	Canada and the U.S. participated in second OECD Biocides SG meetings, which have developed further details that will lay the basis for international harmonization of data requirements and risk assessments. Specifically, Canada and the U.S. have agreed to work closely in an OECD workshop hosted by Canada on human exposure assessment scheduled for early summer 2000.
October 1999	Canada and the U.S. attended the first meeting of the Organizing Committee for the OECD Workshop on Human Exposure Assessment of Wood Preservatives in Ottawa, Canada. This committee is drafting the structure, organization, agenda and identifying speakers for the planned OECD Workshop in Ottawa, Canada, in June 2000 (June 19–20). Discussion focussed on identification of primary (e.g., occupational: wood treatment plant) and secondary (e.g., handling of treated wood) exposure scenarios as well as the format of this workshop.
October 1999	Canada and the U.S. participated in the third OECD Biocides SG in Ottawa, Canada. Discussion areas included: examination of the progress of the organizing committees for the two planned OECD workshops for wood preservatives (human exposure workshop: Ottawa, Canada, June 19–21, 2000; environmental exposure workshop: Arona, Italy, April 10–12, 2000); planned review of new European Union (EU) guidance documents concerning biocide risk assessment procedures; proposed comparison of existing “core data requirements” between the U.S., Canada and the EU; development of use pattern and task description scenarios for slimicides to better determine conditionally required data; strategies for interfacing with the International Maritime Organization on tributyltin (TBT) alternative antifoulants; electronic document initiatives; and proposed approaches for dealing with efficacy (product performance) issues.

April 2000	Canada and US participated in environmental exposure workshop in Italy representing North American views on regulation of wood preservative products and science approaches for assessing environmental exposures.
June 2000	Canada and US participated in human exposure workshop in Canada representing North American views on regulation of wood preservative products and science approaches for assessing human exposures. Canada is assisting OECD in sponsoring the workshop.
December 2000	EPA and PMRA conference call with agreement to defer publication of document with detailed comparison of data requirements pending publication of 40 CFR Part 158W
February 2001	At OECD Working Group on Pesticides meeting, agreement that EPA proposal that antimicrobial data requirements to be published in 40 CFR Part 158W could serve as basis for OECD Biocide Work on harmonized data requirements
Spring 2001	NAFTA Executive Board support proposal to publish a PMRA document outlining progress on harmonization of data requirements
April 2002	Canada and US attended the first OECD Workshop on Efficacy Testing in Washington, DC. US and Canada represented North American views on regulation of antimicrobial efficacy products and science approaches for assessing efficacy methodologies. US and Canada assisted OECD in sponsoring the workshop. A final report is expected with recommendations to OECD countries on label claims, performance standards & test methods and recommendations for future OECD work.

BACKGROUND/RATIONALE:

At present, the U.S. EPA uses a tiered testing strategy in the assessment of antimicrobial pesticides. Canada has defined use pattern based data requirements. Products may be eligible for an exemption of specific studies on the basis of a data waiver/rationale prepared by the manufacturer. These differences in approach to the assessment of antimicrobial pesticides preclude effective work sharing.

The harmonization of assessment practices between Canada and the U.S. will result in a reduction in the ambiguity of current of data requirements by providing an ‘up-front’, ‘use-based’ description of these requirements. This and other related activities will increase efficiencies in the review of applications for registration and reregistration through increased opportunities for work sharing.

Linkage to OECD Biocide (non-agricultural pesticide) Project:

In 1996, the OECD Pesticides Forum concluded a survey on countries data requirements and approaches to the regulation of biocides (non-agricultural pesticides) which include antimicrobial products. The results of the survey were presented at the February 1998 meeting for discussion

and as a basis for identifying further work that might be initiated within the Forum. As part of the result of the survey, a comparison of data requirements from 17 countries has been documented. The results of this project should facilitate a coordinated Canada and U.S. position in the OECD Forum activity.

Both Canada and the U.S., as members of a SG for this project, will continue to plan activities that will lead to harmonization of regulatory approaches to data requirements and risk assessment. Work is presently focussed on wood preservatives and slimicides, as case studies, in developing a standard approach to identifying additional data requirements.

WORK PLAN

SUBCOMMITTEE: Joint Review of Chemical Pesticides

PROJECT TITLE: Harmonization of Antimicrobial Pesticides

UPDATE: August 14, 2001

GOAL	ACTIVITY	TIME FRAME
Exchange of data reviews to facilitate work sharing	The EPA to provide the PMRA with DERs ¹ for six active ingredients not yet registered in Canada. The EPA seeking industry consent to forward reviews. Note: Timing of industry consent may affect feasibility of July target date. The PMRA will consider these assessments in their review of these actives.	July 1997 completed
	The EPA and the PMRA to identify and inventory additional reviews (either re-evaluations or new registrations) of active ingredients that could be exchanged	ongoing
Harmonization of data requirements: common use descriptions and criteria for identifying use pattern specific data requirements	Develop coordinated EPA and PMRA input into Use Descriptions (UD) documents for wood preservatives and slimicides containing sufficient detail to identify expected environmental and human exposure and risk.	summer 1999
	Using UD documents and OECD SG criteria, provide the EPA and the PMRA coordinated input in the identification of broad end points for additional data requirements, revise criteria and develop list of additional data for slimicides and wood preservatives.	starting fall 1999
	Provide ongoing coordinated EPA and PMRA input into OECD project as harmonized data requirements are developed by 2002 Note: this activity is consistent with the NAFTA NAI in terms of its objectives and target date for completion	Ongoing
Harmonization of data requirements: Toxicology data – Reproductive toxicity: Assessment for non-food chemicals based on Tier 1	The PMRA provided the EPA with preliminary results of a retrospective analysis of 90 chemicals indicating that the lack of a reproductive study in the EPA first tier may hamper the ability to identify reproductive end points for non-food chemicals.	June 1997 completed
	The PMRA provided an overview of the preliminary results comments at June 1997 EPA Science Advisory Panel (SAP) meeting.	June 1997 completed

¹DER, Data Evaluation Report/Review

GOAL	ACTIVITY	TIME FRAME
	The PMRA provided the EPA with documentation ² on possible approaches to address reproductive toxicity	November 1997 completed
	The EPA added reference to harmonization considerations in preamble of proposed 40 CFR 158, for stakeholder comment. Timing for publication of proposed rule t.b.d.	Pending Part 158
Harmonization of data requirements: Toxicology data – Chronic toxicity: Use pattern involving chronic exposure	The PMRA to organize discussions with the Health Evaluation Division and the EPA regarding toxicology data requirements for use pattern involving chronic exposure (Linked to OECD human exposure workshop of summer 2000)	Summer 2000 completed
Harmonization of data requirements: environmental chemistry, environmental toxicology	The PMRA to provide comments on the EPA's environmental data requirements ³ . If comments available soon enough, the EPA to consider them along with the SAP and public comments. Send SAP comments to the PMRA.	October 1997 completed
	The EPA will incorporate PMRA comments into preamble of proposed 40 CFR 158, subpart W, for stakeholder comment. Publication of proposed rule was targeted for summer–fall 2000.	Pending Part 158
Comparison of data requirements	The PMRA and the EPA will develop comparative table of health and environmental, and value data requirements to clearly identify common data requirements. Comparison document will be limited to antimicrobial pesticides.	Summer 1998 completed
	Environmental component of comparative table is completed (as part of reference document)	October 1997 completed
	Additional comparison of health, environment, efficacy and chemistry requirements has been completed via OECD Biocide Survey. This will provide the basis for preliminary analysis of comparative EPA–PMRA data requirements.	June 1998 completed

²Draft 'The Assessment of Reproductive Toxicity for Antimicrobial Pesticides: The tiered approach of the U.S. EPA and Proposals for Change,' November 1997.

³Reference document: 'PMRA and EPA Antimicrobial Use Categories and Environmental Data Requirements' by Ian Nicholson, PMRA, October 15, 1997.

GOAL	ACTIVITY	TIME FRAME
	<p>The U.S. and Canada to participate at OECD biocides project SG meetings to discuss work plan elements that would be consistent with objective of this project Note: This project is seen by both the U.S. and Canada to offer an opportunity to work with other antimicrobial regulators in addressing NAFTA harmonization issues.</p>	<p>June 1998 completed</p>
	<p>Publish document on the Status of NAFTA Harmonization of Data Requirements for Antimicrobial pesticides <i>This activity has been postponed pending the publication of 40 CFR part 158 W.</i></p>	<p>Pending Part 158</p>
	<p>As part of the NAI, the EPA and the PMRA to develop document identifying current areas where data requirements are or are not harmonized, with explanations for absence of harmonization <i>This activity has been postponed pending the publication of 40 CFR part 158 W.</i></p>	<p>Pending Part 158</p>
	<p>Publish PMRA document as status report on areas of harmonization that have been achieved</p>	<p>December 2002</p>
<p>Risk assessment practices: Human exposure</p>	<p>Workshop on Post application Exposure Assessment Guideline document, including a session on antimicrobial pesticides</p>	<p>October 1997 completed</p>
	<p>The EPA, CalEPA and PMRA to develop joint guidance on conduct and evaluation of post-application exposure Note: applicator exposure is not included</p>	<p>July 1998 (see project “Harmonization of Occupational/ Bystander/ Residential Exposure Assessment”)</p>
	<p>The PMRA and the EPA to participate as part of organizing committee for OECD workshop on human exposure (focussed on wood preservatives) workshop was hosted by PMRA</p>	<p>Summer 2000 completed</p>
<p>Risk assessment practices: Environmental exposure</p>	<p>The PMRA and the EPA participated in a spring 2000 OECD environmental exposure workshop focussed on wood preservatives</p>	<p>Spring 2000 completed</p>
<p>Efficacy Methodologies</p>	<p>PMRA and EPA participated in a spring 2002 OECD efficacy methodology workshop focused on antimicrobial pesticides (biocides).</p>	<p>Spring 2002 Completed</p>