Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Regulatory Proposal

PRO2001-02

Harmonization of environmental chemistry and fate data requirements under NAFTA

The purpose of this document is to provide information on proposed changes to the Pest Management Regulatory Agency's environmental chemistry and fate data requirements for conventional chemical pesticides on terrestrial food crops (PMRA Use–Site Category 14). These proposed changes implement the agreements reached with the United States Environmental Protection Agency under the North American Free Trade Agreement Technical Working Group on Pesticides. It is proposed that these changes will come into effect on January 1, 2003.

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(publié aussi en français)

October 5, 2001

This document is published by the Submission Coordination and Documentation Division, Pest Management Regulatory Agency. For further information, please contact:

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ISBN: 0-662-31114-0
Catalogue number: H113-8/2001-2E-IN

The harmonization of pesticide regulatory requirements being carried out under the auspices of the North American Free Trade Agreement (NAFTA) Technical Working Group (TWG) on Pesticides is important for achieving the goal of one North American market for pesticides. This goal is articulated in the document known as the *North American Initiative* (NAI). The NAI commits Canada's Pest Management Regulatory Agency (PMRA) and the U.S. Environmental Protection Agency (EPA) to harmonize pesticide regulatory tools so that work sharing and joint review activities become routine.

Changes to the PMRA environmental chemistry and fate data requirements for conventional chemical pesticides used in Use–Site Category (USC) 14 (Terrestrial Food Crops) are being proposed to implement the agreements[1] reached with the U.S. EPA under the NAFTA. These changes are reflected in the attached USC 14 data code (DACO) table for the combined technical grade active ingredient (TGAI) and end-use product (EP) (Appendix 1). Identical changes will be made for corresponding data codes in the USC 14 TGAI and EP DACO Tables. The proposed changes do not jeopardize the stringency of the environmental data requirements nor the interpretation of the data with respect to environmental protection. It is proposed that these changes will come into effect on January 1, 2003. Applicants, however, are encouraged to accommodate these changes as soon as possible. Combinations of old and revised data requirements will not be acceptable. The EPA will be implementing these agreements on the same schedule through its normal processes until Code of Federal Regulations 40 Part 158 is revised. Highlights of the changes to the environmental chemistry and fate data requirements appear in the following summary tables.

Proposed revisions to USC 14 environmental chemistry data requirements for the TGAI

Data code	Title	Existing		Proposed	
		Data required	Conditions	Data required	Conditions
8.2	**Laboratory Studies**				
8.2.3.4	Biotransformation in Soil (TGAI)				
8.2.3.4.4	Anaerobic Soil 20–30EC	CR	Can be satisfied by 8.2.3.5.6	R	Can be satisfied by 8.2.3.5.6
8.2.3.5	Biotransformation in Aquatic Systems (TGAI)				
8.2.3.5.2	Aerobic Water 20–30EC	R	Preferred over part 8.2.3.5.4	R	
8.2.3.5.4	Aerobic Water–Sediment 20–30EC	CR	If partitioning into sediment is expected	R	

[1] See *Status of Harmonization of Data Requirements and Test Protocols for Pesticide Registration, Environmental Fate*, NAFTA Technical Working Group on Pesticides, June 5, 2000.

Data code	Title	Existing		Proposed	
		Data required	Conditions	Data required	Conditions
8.2.3.5.6	Anaerobic Sediment–Water 20–30EC	R		CR	If partitioning into sediment is expected; likely to be upgraded to required (R) in the future for the purposes of model input
8.2.4	Laboratory Studies of Mobility (TGAI)				
8.2.4.2	Adsorption or Desorption	CR	One of 8.2.4.2, 8.2.4.3.1, 8.2.4.3.2 or 8.2.4.4 is required (R)	R	
8.2.4.3	Soil Column Leaching			R	
8.2.4.3.1	Unaged Soil	CR	See 8.2.4.2		
8.2.4.3.2	Aged Soil	CR	See 8.2.4.2		
8.2.4.4	Soil Thin Layer Chromatography (TLC) Leaching	CR	See 8.2.4.2		

R = required; CR = conditionally required; blank = not required.

With respect to the data requirements for laboratory studies of mobility, adsorption or desorption (8.2.4.2) and soil column leaching data (8.2.4.3) will now be required. The differentiation between unaged soil and aged soil column leaching (8.2.4.3.1 and 8.2.4.3.2, respectively) has been removed, as well as the requirement for soil TLC (8.2.4.4).

Proposed revisions to USC 14 environmental chemistry data requirements for the EP

Data code	Title	Existing		Proposed	
		Data required	Conditions	Data required	Conditions
8.3	**Field Studies of Dissipation or Accumulation [May be Small or Large Scale] EP**				
8.3.2	Terrestrial			R	U.S. field studies are acceptable, if conducted at appropriate sites in relevant ecoregions
8.3.2.1	Canada	R			
8.3.2.2	Northern U.S.	CR	Can substitute for some Canadian studies		

Data code	Title	Existing		Proposed	
		Data required	Conditions	Data required	Conditions
8.3.3	Aquatic			CR	Based on potential for aquatic exposure and if pesticide residues have the potential for persistence, mobility, non-target aquatic toxicity or bioaccumulation; U.S. field studies are acceptable, if conducted at appropriate sites in relevant ecoregions
8.3.3.1	Canada	CR	Based on potential for aquatic exposure and if pesticide residues have the potential for persistence, mobility, nontarget aquatic toxicity or bioaccumulation		
8.3.3.2	Northern U.S.	CR	Can augment Canadian studies		

R = required; CR = conditionally required; blank = not required.

The changes to the environmental field study data requirements reflect the removal of the differentiation between Canadian and northern U.S. study sites. For the terrestrial field studies, the subsections 8.3.2.1 and 8.3.2.2 have been collapsed into 8.3.2. This does not affect the overall data requirements, as terrestrial field studies (Canadian or northern U.S.) remain required. Previously, available northern U.S. terrestrial field studies could substitute for some Canadian studies and consequently were denoted as “CR.” Similarly, 8.3.3.1 and 8.3.3.2 have been combined into 8.3.3 for the aquatic field studies, which remain conditionally required.

Similar changes to several other outdoor USCs (4,7,13,16, 25, 27 and 30) will be addressed in a separate regulatory proposal.

List of abbreviations

CR	conditionally required
DACO	data code
EP	end-use product
EPA	Environmental Protection Agency
NAFTA	North American Free Trade Agreement
NAI	North American Initiative
PMRA	Pest Management Regulatory Agency
R	required
TGAI	technical grade active ingredient
TLC	thin layer chromatography
TWG	Technical Working Group
U.S.	United States
USC	Use–Site Category

Appendix I Proposed USC 14 DACO requirements for the combined TGAI and EP

Data code	Title	Data required	Conditions	Volume no. and pages
8	Environmental Chemistry and Fate			
8.1	Summaries	R		
8.2	Laboratory Studies			
8.2.1	Summary of Physicochemical Properties to include Solubility in Water, Vapour Pressure, Octanol–Water Partition Coefficient, Dissociation Constant and UV–Visible Absorption (See Part 2) (TGAI)	R	Data submitted under 2.14.7, 2.14.9, 2.14.10, 2.14.11 and 2.14.12	
8.2.2	Analytical Methodology (parent compound and transformation products)			
8.2.2.1	Soil	R		
8.2.2.2	Sediment	R		
8.2.2.3	Water	R		
8.2.2.4	Biota	R		
8.2.3	Laboratory Studies of Transformation (TGAI)			
8.2.3.1	Summary	R		
8.2.3.2	Hydrolysis	R		
8.2.3.3	Phototransformation			
8.2.3.3.1	Soil	R		
8.2.3.3.2	Water	R		
8.2.3.3.3	Air	CR	If volatilization is indicated by vapour pressure or Henry's Law Constant	
8.2.3.4	Biotransformation in Soil (TGAI)			
8.2.3.4.2	Aerobic Soil 20–30EC	R		
8.2.3.4.4	Anaerobic Soil (Flooded) 20–30EC	R	Can be satisfied by 8.2.3.5.6	
8.2.3.5	Biotransformation in Aquatic Systems (TGAI)			
8.2.3.5.2	Aerobic Water 20–30EC	R		
8.2.3.5.4	Aerobic Water–Sediment 20–30EC	R		

Data code	Title	Data required	Conditions	Volume no. and pages
8.2.3.5.6	Anaerobic Sediment–Water 20–30EC	CR	If partitioning into sediment is expected; likely to be upgraded to required (R) for the purposes of model input	
8.2.3.6	Special Studies Related to Use Pattern or Formulation (EP)	CR		
8.2.4	Laboratory Studies of Mobility (TGAI)			
8.2.4.1	Summary	R		
8.2.4.2	Adsorption or Desorption	R		
8.2.4.3	Soil Column Leaching	R		
8.2.4.5	Volatilization	CR	If volatilization is indicated by vapour pressure or Henry's Law Constant	
8.2.4.6	Special Studies Related to Use Pattern or Formulation (EP)	CR		
8.3	Field Studies of Dissipation and Accumulation [may be small or large scale] (EP)			
8.3.1	Summary	R		
8.3.2	Terrestrial	R	U.S. field studies are acceptable, if conducted at appropriate sites in relevant ecoregions	
8.3.3	Aquatic	CR	Based on potential for aquatic exposure and if pesticide residues have the potential for persistence, mobility, non-target aquatic toxicity or bioaccumulation; U.S. field studies are acceptable, if conducted at appropriate sites in relevant ecoregions	
8.3.4	Special Studies Related to Intended Use Pattern	CR	Based on concerns arising from results of other studies	
8.4	Storage, Disposal and Decontamination (TGAI and EP)			
8.4.1	Summary	R		
8.5	Other Environmental Fate Studies (TGAI and EP)			
8.5.1	Summary	CR	Based on concerns arising from results of other studies	
8.6	Other Studies, Data and Reports	CR	If available	