Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Regulatory Directive DIR2003-03

Harmonization of environmental chemistry and fate data requirements for chemical pesticides under NAFTA

The purpose of this document is to provide information on 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). The registration data requirements and test guidelines for environmental chemistry and fate are now essentially harmonized between Canada and the United States. This document replaces Regulatory Proposal PRO2001-02 published for public comment in October 2001. Comments received were taken into consideration. These changes will come into effect six months after publication of this document.

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Foreword

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 United States Environmental Protection Agency (USEPA) 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) have been made to implement the agreements[1] reached with the USEPA under NAFTA. In October 2001, the PMRA announced proposed changes[2] and since then revision has been made in light of respondents' comments and further PMRA and USEPA harmonization efforts. The changes are discussed within the body of this document and are summarized in Tables 3 and 4 for the technical grade active ingredient (TGAI) and end-use product (EP), respectively. They are also reflected in the attached combined USC 14 data code (DACO) table for the TGAI and EP (Appendix I). Identical changes will be made for corresponding data codes in the USC 14 TGAI and EP DACO Tables. The changes maintain the stringency of the environmental data requirements and do not affect the interpretation of the data with respect to environmental protection. These changes will come into effect six months after publication of this document. Applicants are, however, encouraged to accommodate these changes as soon as possible. Combinations of old and revised data requirements to achieve a minimum data set will not be acceptable. To facilitate data screening by the PMRA, applicants should indicate in their submissions which set of data requirements they are following.

For convenience, the corresponding USEPA OPP and OPPTS Guideline numbers have been included in the revised USC 14 DACO Table for the TGAI and EP that appears in Appendix I. In the past, the PMRA has accepted studies conducted in accordance with USEPA guidelines and will continue to do so. The PMRA and the USEPA are currently developing a harmonized protocol for Terrestrial Field Studies. The OECD is also developing pesticide guidelines for several of these data requirements. As these guidelines are in various stages of completion or revision, however, further reference to them has been omitted from this document. In the past, the PMRA has accepted studies conducted in accordance with OECD guidelines and will continue to do so.

The registration data requirements and test guidelines for environmental chemistry and fate are now essentially harmonized between Canada and the United States.

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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.

2 Regulatory Proposal PRO2001-02, *Harmonization of environmental chemistry and fate data requirements under NAFTA.* October 5, 2001.

1.0 Previously harmonized requirements

Some of the PMRA environmental chemistry and fate data requirements for the TGAI were already harmonized with those of the USEPA and these requirements have not changed. These requirements are summarized in Table 1.

Table 1 Previously harmonized USC 14 environmental chemistry data requirements for the TGAI

Data code	Title	Data required	Conditions
8.2.3.2	Hydrolysis	R	
8.2.3.3.2	(*Phototransformation in*) Water	R	
8.2.3.3.3	(*Phototransformation in*) Air	CR	If volatilization is indicated by vapour pressure or Henry's Law constant
8.2.3.4.2	(*Biotransformation in*) Aerobic Soil 20–30°C	R	

R = required; CR = conditionally required

2.0 Results of current harmonization activities

The USEPA now requires the data summarized in Table 2, which has resulted in harmonization with the PMRA USC 14 data requirements.

Table 2 Harmonization of USC 14 environmental chemistry data requirements from revisions by the USEPA

Data code	Title	Data required	Conditions
8.2.3.3.1	(*Phototransformation on*) Soil	R	Not required if application is only by soil injection or soil incorporation
8.2.3.5.6	(*Biotransformation in*) Anaerobic Aquatic Sediment 20–30°C	R	

R = required

The PMRA has further harmonized the requirement for phototransformation on soil (8.2.3.3.1) by indicating that it is not required if application is only by soil injection or soil incorporation. Also, the PMRA has changed the title of the anaerobic sediment / water data requirement to “Anaerobic Aquatic Sediment 20–30°C”.

Additional changes to the PMRA USC 14 environmental chemistry and fate data requirements that were made to harmonize with the USEPA requirements appear in Tables 3 and 4 for the TGAI and EP, respectively.

Table 3 Revisions to USC 14 environmental chemistry data requirements for the TGAI

Data code	Title	Previous		Revised	
		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 (Flooded) 20–30°C	CR	Can be satisfied by 8.2.3.5.6	R	
8.2.3.5	Biotransformation in Aquatic Systems (TGAI)				
8.2.3.5.2	Aerobic Water 20–30°C	R	Preferred over part 8.2.3.5.4		
8.2.3.5.4	Aerobic Water–Sediment 20–30°C	CR	If partitioning into sediment is expected	R	
8.2.4	Laboratory Studies of Mobility (TGAI)				

Data code	Title	Previous		Revised	
		Data required	Conditions	Data required	Conditions
8.2.4.2	Adsorption and 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	Adsorption and desorption (8.2.4.2) is preferred, however in some cases, soil column leaching (8.2.4.3) with unaged or aged columns may be necessary to fully characterize the potential mobility of the parent compound and major transformation products
8.2.4.3	Soil Column Leaching (unaged or aged)				
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		
8.2.4.5	Volatilization	CR	If volatilization is indicated by vapour pressure or Henry's Law constant	CR	If volatilization is indicated by vapour pressure or Henry's Law constant; studies conducted with a typical EP are acceptable and should be submitted under 8.2.4.6

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

Biotransformation data are now required for anaerobic soil (8.2.3.4.4). The data requirements for aquatic biotransformation in aerobic water and aerobic water–sediment

(8.2.3.5.2 and 8.2.3.5.4, respectively) have been amalgamated under the heading "Aerobic Water–Sediment 20–30°C" (8.2.3.5.4) for which data are required.

With respect to data requirements for laboratory studies of mobility, 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). Adsorption and desorption (8.2.4.2) and soil column leaching (8.2.4.3) are now the remaining data requirements. Laboratory data characterizing the potential mobility of the parent compound and the major transformation products are required. Column leaching studies can be with unaged or aged soil, or both. The column leaching of non-persistent parent compounds is best addressed with unaged soil, while aged soil is more appropriate for transformation products. As indicated under "conditions" for 8.2.4.2 and 8.2.4.3, however, characterization of the potential mobility of the parent compound and major transformation products by batch equilibrium adsorption and desorption is preferred over soil column leaching.

Previously, the PMRA and USEPA both conditionally required data for volatilization (8.2.4.5), but differed in specification of the test substance (i.e., the PMRA indicated TGAI, whereas the USEPA indicated a typical EP). The PMRA has augmented the conditions for this data requirement to include studies conducted with a typical EP. They should be submitted under 8.2.4.6 (Special Studies Related to Use Pattern or Formulation (EP)).

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, DACOs 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 relevant 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, DACOs 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. The authority for the determination of the acceptability of U.S. field sites in support of Canadian pesticide registration is the *Ecological Regions of North America, Level II Map*[3].

Similar changes to several other outdoor USCs (4, 7, 13, 16, 25, 27 and 30) will be separately addressed.

3.0 Conclusions

The registration data requirements and test guidelines for environmental chemistry and fate are now essentially harmonized between Canada and the United States.

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[3] Commission for Environmental Cooperation (CEC). 1997. Ecological Regions of North America: Toward a Common Perspective. Secretariat of the Commission for Environmental Cooperation. Montreal, Quebec, Canada, p. 60.

Table 4 Revisions to USC 14 environmental chemistry data requirements for the EP

Data code	Title	Previous		Revised	
		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 (see Ecological Regions of North America, Level II)
8.3.2.1	Canada	R			
8.3.2.2	Northern U.S.	CR	Can substitute for some Canadian studies		
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 (see Ecological Regions of North America, Level II)

Data code	Title	Previous		Revised	
		Data required	Conditions	Data required	Conditions
8.3.3.1	Canada	CR	Based on potential for aquatic exposure and if pesticide residues have the potential for persistence, mobility, non-target aquatic toxicity or bioaccumulation		
8.3.3.2	Northern U.S.	CR	Can augment Canadian studies		

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

List of abbreviations

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

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

Data code	Title	Data required	Conditions	USEPA OPP Guideline	USEPA OPPTS Guideline
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		164-1 reporting requirement	835.6100 reporting requirement
8.2.2.2	Sediment	R		164-2 reporting requirement	835.6200 reporting requirement
8.2.2.3	Water	R		166-1 reporting requirement	835.7100 reporting requirement
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		161-1	835.2120
8.2.3.3	Phototransformation				
8.2.3.3.1	Soil	R	Not required if application is only by soil injection or soil incorporation	161-3	835.2410

Data code	Title	Data required	Conditions	USEPA OPP Guideline	USEPA OPPTS Guideline
8.2.3.3.2	Water	R		161-2	835.2240
8.2.3.3.3	Air	CR	If volatilization is indicated by vapour pressure or Henry's Law constant	161-4	835.2370
8.2.3.4	Biotransformation in Soil (TGAI)				
8.2.3.4.2	Aerobic Soil 20–30°C	R		162-1	835.4100
8.2.3.4.4	Anaerobic Soil (Flooded) 20–30°C	R		162-2	835.4200
8.2.3.5	Biotransformation in Aquatic Systems (TGAI)				
8.2.3.5.4	Aerobic Water–Sediment 20–30°C	R		162-4	835.4300
8.2.3.5.6	Anaerobic Aquatic Sediment 20–30°C	R		162-3	835.4400
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 and Desorption	R	Adsorption and desorption (8.2.4.2) is preferred, however in some cases, soil column leaching (8.2.4.3) with unaged or aged columns may be necessary to fully characterize the potential mobility of the parent compound and major transformation products	163-1	835.1230
8.2.4.3	Soil Column Leaching (unaged or aged)				835.1240

Data code	Title	Data required	Conditions	USEPA OPP Guideline	USEPA OPPTS Guideline
8.2.4.5	Volatilization	CR	If volatilization is indicated by vapour pressure or Henry's Law constant; studies conducted with a typical EP are acceptable and should be submitted under 8.2.4.6	163-2	835.1410
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 (see Ecological Regions of North America, Level II)	164-1	835.6100
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 bioaccumula-tion; U.S. field studies are acceptable, if conducted at appropriate sites in relevant ecoregions (see Ecological Regions of North America, Level II)	164-2	835.6200
8.3.4	Special Studies Related to Intended Use Pattern	CR	Based on concerns arising from results of other studies		

Data code	Title	Data required	Conditions	USEPA OPP Guideline	USEPA OPPTS Guideline
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		