



NAFTA Technical Working Group on Pesticides
Grupo de Trabajo Técnico del TLC sobre plaguicidas
Groupe de travail technique sur les pesticides d'ALENA

Status of Harmonization of Data Requirements and Test Protocols for Pesticide Registration

Environmental Fate

The harmonization of pesticide regulatory requirements being carried out under the auspices of the 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. It is also an objective of the TWG to clearly communicate the status of the harmonization process.

The attached chart demonstrates the status of harmonization between Canada and the U.S. for pesticide registration data requirements and test protocols related to environmental fate. In general, there are substantial areas of agreement between the two countries, and few differences.

This comparison has been approved by the lead disciplinary scientists in the U.S. and Canada. It has not been granted official status through each country's respective regulatory process, nor is it yet reflected in the official regulatory documents of each country.

A submission prepared according to these guidelines would be accepted for review by the PMRA and the EPA. In some instances, differences in climate, pest complexes, application methods or environmental concerns in one country will warrant different data for certain products or product uses. These issues must be addressed by the applicant as is appropriate for each country. Prior to the use of this table in developing a submission, it is strongly recommended that applicants schedule a consultation with regulatory officials at an early stage in the process.

For the U.S., some of the agreement reflected here indicates that changes to the U.S. 40 Code of Federal Regulations Part 158 (40 CFR 158) will be necessary. The U.S. is in the process of developing a regulatory proposal for all Part 158 data requirements. Thus, the changes reflected in this table will be incorporated into that regulatory development process. Canada will be formalizing these requirements through its normal processes.

The following tables apply to conventional chemical pesticides proposed for use on terrestrial food crops (PMRA Use Site Category 14).

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Harmonized environmental fate data requirements

Fully harmonized data requirements and protocols for the technical grade active ingredient (TGAI)

| Study Title | Harmonized Requirement | PMRA Data Code | EPA OPP Guideline |
|---|------------------------|----------------|-------------------|
| Hydrolysis | R | 8.2.3.2 | 161-1 |
| Phototransformation in Water | R | 8.2.3.3.2 | 161-2 |
| Phototransformation in Air | CR | 8.2.3.3.3 | 161-4 |
| Biotransformation in Aerobic Soil 20–30°C | R | 8.2.3.4.2 | 162-1 |

Agreement at the working level in the EPA and the PMRA on aquatic biotransformation (metabolism) data requirements and protocols

The following requirements have been agreed to at the working level, but are not reflected in the U.S. 40 CFR 158 or in a PMRA Regulatory Directive.

| Study Title | Harmonized Requirement | PMRA Data Code | EPA OPP Guideline |
|---|------------------------|----------------|-------------------|
| TGAI (Requirements and protocols) | | | |
| Biotransformation in Anaerobic Soil (Flooded) 20–30°C | R | 8.2.3.4.4 | 162-2 |
| Biotransformation in Aerobic Water 20–30°C | R | 8.2.3.5.2 | 162-4 |
| Biotransformation in Aerobic Water/Sediment 20–30°C | R | 8.2.3.5.4 | 162-4 |
| Biotransformation in Anaerobic Sediment/Water 20–30°C | CR ¹ | 8.2.3.5.6 | 162-3 |
| End-use Product (EP) (Requirements) | | | |
| Aquatic Field Studies of Dissipation | CR ² | 8.3.3 | 164-2 |

¹ Likely to be upgraded in both the EPA and the PMRA from conditional (CR) to required (R) for the purposes of model input.

² The PMRA will accept U.S. field studies, if conducted at appropriate sites in relevant ecoregions.

Agreement at the working level in the EPA and the PMRA on soil mobility data requirements and protocols for the TGAI

The following requirements have been agreed to at the working level, but are not reflected in a PMRA Regulatory Directive.

| Study Title | Harmonized Requirement | PMRA Data Code | EPA OPP Guideline |
|-----------------------|------------------------|----------------|-------------------|
| Adsorption/Desorption | R | 8.2.4.2 | 163-1 |
| Soil Column Leaching | R | 8.2.4.3 | 163-1 |

Essentially harmonized environmental fate data requirements and protocols

The PMRA will accept data required and accepted by the EPA.

For the TGAI

| Study Title | PMRA Requirement | EPA Requirement | PMRA Data Code | EPA OPP Guideline |
|-----------------------------|------------------|-----------------|----------------|-------------------|
| Phototransformation on Soil | R ³ | CR ³ | 8.2.3.3.1 | 161-3 |
| Volatilization | CR ⁴ | CR ⁴ | 8.2.4.5 | 163-2 |

³ In reality, both the PMRA and the EPA would require the study for surface applications and would waive the requirement for application solely by injection or incorporation.

⁴ The PMRA conditional requirement is with the TGAI if volatilization is indicated by vapour pressure or Henry's Law Constant, whereas the EPA conditional requirement is with the EP on a case-by-case basis, depending on use pattern and other pertinent factors, including vapour pressure and Henry's Law Constant. A waiver of a TGAI volatilization study, on the basis of the submission of an EP study, would be accepted by the PMRA.

For the EP

Both countries require terrestrial field dissipation studies, although there is not yet agreement on the protocol or the number of sites.

| Study Title | PMRA Requirement | EPA Requirement | PMRA Data Code | EPA OPP Guideline |
|--|------------------|-----------------|----------------|-------------------|
| Terrestrial Field Studies of Dissipation | R ⁵ | R | 8.3.2 | 164-1 |

⁵ The PMRA will accept U.S. field studies, if conducted at appropriate sites in relevant ecoregions.

For the Parent Compound and Transformation Products

| Study Title | PMRA Requirement | EPA Requirement | PMRA Data Code | EPA OPP Guideline |
|-------------------------------------|------------------|-----------------|----------------|-------------------|
| Analytical Methodology for Soil | R | R | 8.2.2.1 | 164-1 |
| Analytical Methodology for Sediment | R | CR | 8.2.2.2 | 164-2 |
| Analytical Methodology for Water | R | R | 8.2.2.3 | 166-1 |
| Analytical Methodology for Biota | R | CR | 8.2.2.4 | 164-1 |

In addition, it is recognized that each country can require special studies depending on the circumstances.