Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

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Backgrounder

Harmonization of Environmental Data Requirements under NAFTA for Registration of Chemical Pesticides[1]

The Pest Management Regulatory Agency (PMRA) and the United States Environmental Protection Agency (EPA) are committed to establishing a process that will enable joint reviews or worksharing of pesticide evaluations on a regular basis. For efficient worksharing, harmonization is necessary in a number of areas including data requirements, test guidelines for the generation of data, and evaluation methodologies.

[1] Major agricultural and forestry uses of chemical pesticides.

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The Achievement

The Pest Management Regulatory Agency (PMRA) and the United States Environmental Protection Agency (EPA) are committed to establishing a process that will enable joint reviews or worksharing of pesticide evaluations on a regular basis. For efficient worksharing, harmonization is necessary in a number of areas including data requirements, test guidelines for the generation of data, and evaluation methodologies. The achievement of harmonizing environmental data requirements for the registration of the major agricultural and forestry uses of chemical pesticides in Canada and the United States is one more positive step on the road toward harmonization. Harmonization reduces costs to applicants and facilitates simultaneous registration of pesticides in Canada and the United States.

Impediments still remain, however, to optimum worksharing of environmental reviews, i.e., requirements for field dissipation studies, test guidelines and exposure and risk assessment methodologies. These are currently being addressed under the North American Free Trade Agreement (NAFTA) Technical Working Group on Pesticides.

Announced at the March 1996 meeting of the NAFTA Technical Working Group on Pesticides in Washington, D.C., the environmental data requirements for the registration of the major agricultural and forestry uses of chemical pesticides in Canada and the United States have, essentially, now been harmonized. This paper explains the process and rationales by which this important harmonization step was achieved.

The Process

Canadian data requirements for environmental chemistry and fate of chemical pesticides, as specified in Trade Memorandum T-1-255, were compared with those proposed by the U.S. EPA in 40 Code of Federal Regulations Part 158 Subparts D and N. Differing requirements were then examined in terms of their importance to the determination of environmental risk based on the experience of evaluating numerous chemical pesticides over more than a decade.

Bioaccumulation in Earthworms

Decision: The Pest Management Regulatory Agency (PMRA) has deleted the requirement for an earthworm bioaccumulation study.

The PMRA did not frequently request data on bioaccumulation in earthworms, except for terrestrial and forestry uses for pesticides with a potential to bioaccumulate. The triggers for this requirement were based on the potential for exposure, the log of the octanol/water partition coefficient (log K_{ow})$3, accumulation in non-target aquatic organisms, and persistence in soil. The EPA did not have this requirement. For the majority of cases, the PMRA will use the log K_{ow} $3, the bioconcentration/bioaccumulation in fish, and the metabolism data in plants, rats, cows, goats and chickens to assess potential for bioaccumulation in other organisms.

Sorption/Soil Column Leaching Data

Decision: The PMRA will accept either adsorption/desorption studies or soil column leaching studies or soil thin layer chromatography studies for all relevant non-aquatic uses.

The PMRA required adsorption/desorption and either soil-column leaching or soil thin layer chromatography (TLC) data for terrestrial, seed treatment, and forestry uses, but one of either adsorption/desorption or soil-column leaching or soil TLC data for greenhouse and domestic (residential) uses, and only adsorption/desorption data for aquatic uses. The EPA required either adsorption/desorption or soil-column leaching data for all of these uses. In most cases, experience has shown that either adsorption/desorption or soil-column leaching data would suffice to assess potential mobility in soil. The PMRA will continue to accept soil TLC data where these data are generated using internal standards. The PMRA will continue to require only adsorption/desorption data for aquatic uses because leaching data are not relevant to the aquatic use pattern.

Aquatic Biotransformation Data

Decision: The EPA has extended the requirements for aquatic biotransformation from aquatic to terrestrial uses where runoff to aquatic sites is of concern.

The new EPA requirements will allow the Agency to predict the impact of pesticides on aquatic environments (including sediment) due to runoff from terrestrial use. These requirements are closer to the PMRA's requirements for aquatic biotransformation for all terrestrial, aquatic and forestry uses.

Biotransformation Data at Two Temperatures

Decision: The PMRA has deleted the low temperature requirement for aerobic and anaerobic soil and aerobic aquatic studies.

The PMRA required data on aerobic and anaerobic biotransformation at two temperatures (3-8EC and 20-30EC) in soil for terrestrial and forestry uses and in natural water/sediment systems for terrestrial, aquatic and forestry uses, while the EPA required these data at one temperature in the higher range (18-30EC). In most cases, biotransformation data from only a higher temperature will permit an adequate assessment of pesticide behaviour in soil and natural water. Past evaluation of data generated at low and high temperatures has shown that there is generally a two-to-threefold decrease in transformation rate for a 10°C decrease in temperature. The PMRA will, however, continue to require low-temperature anaerobic aquatic biotransformation data on a case-by-case basis for pesticides that may contaminate groundwater or bottom sediments. This issue will be discussed further through the OECD Test Guideline development process.

Environmental Toxicology - Soil Microorganism Toxicity Studies

Decision: The PMRA has deleted the requirement to conduct toxicity studies on soil microorganisms.

Over the years, the results of studies on toxicity to soil microorganisms were never pivotal in reaching a decision on whether to register a pesticide. Most data generally indicated no effect on the endpoint tested or transient short-term effects.

Use-pattern Index - Seed Treatments

Decision: The EPA has changed the use-pattern classification of seed treatments from an indoor use to a terrestrial food/feed crop use category which results in a change in data requirements.

With the exception of seed treatments, the broad use patterns designated by the EPA and the PMRA were compatible. The PMRA regarded seed treatments as a special terrestrial, i.e., agricultural use pattern requiring a reduced dataset, whereas the EPA considered them an indoor use. After reviewing the toxicity and persistence data of pesticides on seeds, the EPA concluded that they needed additional data to estimate exposure of these pesticides to the environment. EPA's reclassification of seed treatments to a terrestrial food/feed crop use category will provide additional data for more accurately estimating exposure and will achieve harmonization with both Canada and the United Kingdom.