Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Dir96-05

Regulatory Directive

Comprehensive Data Summaries

In pursuing a more streamlined and efficient regulatory process, the Pest Management Regulatory Agency (PMRA) will implement a number of changes to the current submission requirements outlined in Regulatory Directives Dir93-01, *Organization of Data for Technical Active Ingredients*, and Dir93-03, *Organization of Data for End-Use Products*. One of the changes is the requirement of comprehensive data summaries in registration submissions involving major new uses and new active ingredients. This Regulatory Directive outlines the requirements and format of such comprehensive data summaries. To reduce the regulatory burden on applicants, the PMRA is planning to use the format adopted by the European Union (EU) while at the same time working with the Organisation for Economic Cooperation and Development (OECD) to make the EU Format acceptable to all OECD countries.

This document serves as an addendum to Dir93-01 and Dir93-03 while these Regulatory Directives are being updated.

(publié aussi en français)

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Canada

The Pest Management Regulatory Agency (PMRA), in conjunction with stakeholders, is actively pursuing a more streamlined and efficient regulatory process. The Agency is committed to cost avoidance and timely regulatory decisions. To meet these objectives, the PMRA will implement a number of changes to the current submission requirements outlined in Regulatory Directives Dir93-01, *Organization of Data for Technical Active Ingredients,* and Dir93-03, *Organization of Data for End-Use Products.*

The PMRA continues to work toward international harmonization of all aspects of pesticide registration to the extent possible. Our international harmonization activities have led to the inclusion of comprehensive data summaries in submission requirements and the decision that these summary reports should be prepared according to the European Commission (EC) guidelines. This requirement is designed to speed up the review process, by providing decision-makers in the PMRA with a clear, comprehensive summary of the characteristics of the product, its risks and value. The summaries will also expedite the production of the Proposed Regulatory Decision Documents (PRDDs).

Effective January 1, 1997, applications for registration of a major new use or new active ingredient must include comprehensive data summaries based on the EC Directive[1] Annex II, Tier II format. The summary should be in such detail that it is apparent that the submitter has performed a thorough evaluation of each study and reported the full detail of this evaluation. These summaries must be certified by the applicant company's Chief Executive Officer. In addition, submissions must include a document based on the EC Annex II, Tier IV model. The nomenclature of the various tiers within the EC model is currently undergoing some changes. Certain key elements are currently not addressed at all in the EC Document. These are efficacy, effects on nontarget plants, occupational exposure and studies on pest control agents other than chemicals. The PMRA will work with the industry to develop these sections. Discussion with the PMRA prior to presentation of summaries is, therefore, recommended. Between July 1, 1996 and December 31, 1996 the PMRA will continue to accept submissions not accompanied by comprehensive data summaries. In order for the PMRA to process these submissions, however, the applicant will be required to submit comprehensive data summaries by January 1, 1997. Non-compliance will result in the return of the submission to the applicant.

Before the PMRA was established, Discussion Documents, similar to PRDDs, were issued to provide the basis for informed comment on proposed registration decision where particular health, environmental or other considerations warranted public discussion before final decisions were made. This policy will be maintained for registration submissions received before April 1, 1995, but these Discussion Documents issued as a basis for public discussion will now be called PRDDs.

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1 Guidelines and Criteria for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for the Inclusion of Active Substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2) (EC-Document 1663.VI/94).

As of April 1, 1995, the PMRA's policy has been to issue PRDDs for regulatory decisions relating to registration submissions involving new active ingredient or major new uses. This policy reflects the government's commitment to issue PRDDs, as outlined in the October 1994 *Government Proposal for the Pest Management Regulatory System*. Although the present Regulatory Directive does not *require* the submission of comprehensive summaries for registration applications received before July 1, 1996, their availability to the Agency will reduce the time needed to complete the review process and to produce PRDDs.

The Organisation for Economic Cooperation and Development (OECD) is currently developing guidance documents on reporting data reviews based on the EC Directive. Canada is actively involved in this initiative. It is anticipated that this will result in a world wide acceptance of a common guidance document for the preparation of comprehensive summaries.

The decision to include comprehensive summaries as part of the original submission package has been under consideration for some time and is now appropriate as the EU has made it a mandatory requirement and proved its value in the registration process. Our intention is to ensure that only complete submissions are allowed into the review process so that the PMRA can process registration reviews in a timely and efficient manner.

If you are planning to submit in the near future, we can make the EU document available to you. If you have any questions regarding this Regulatory Directive, please contact an Information Officer at 1-800-267-6315 or (613) 736-3799.