



Regulatory Directive

Comprehensive Data Summaries

On October 11, 1996, the Pest Management Regulatory Agency (PMRA) published Regulatory Directive Dir96-05, *Comprehensive Data Summaries*, introducing the requirement that comprehensive data summaries be included with applications to register major new uses and new active ingredients.

This document serves as an update to Dir96-05.

(publié aussi en français)

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The pesticide industry remains supportive of the comprehensive data summary initiative but has expressed concern regarding the implementation time frame and the need for clearer guidance on the structure, format and content of these documents.

The Agency recognizes these concerns and is addressing them by:

- continuing to offer applicants the opportunity for consultation and specific guidance on preparing comprehensive data summaries for individual compounds;
- offering generic information and training at industry meetings, workshops and other similar opportunities; and
- extending the implementation date to January 1, 1998; upon and after which, comprehensive data summaries must be included with applications to register major new uses or new active ingredients.

Until January 1, 1998, the PMRA will accept applications for registration that are not accompanied by comprehensive data summaries and will advance these applications through the screening process. These applications will not, however, advance to the product evaluation stage until comprehensive data summaries, including the electronic format, have been received by the PMRA.

Applications already received that have not met the requirement for comprehensive summaries, as per Regulatory Directive Dir96-05, will proceed through the screening process. However, they will not advance through the evaluation stage until the required summaries have been received by the PMRA.