



## Delay on Helix Registration Decision

Helix is the trade name for a new seed treatment produced by Novartis Crop Protection Canada Inc. proposed for use on canola and mustard for control of flea beetles, seed-borne blackleg and seedling diseases. It is a potential lindane replacement product and as such has been a work sharing project between the Canadian Pest Management Regulatory Agency (PMRA) and the US Environmental Protection Agency (EPA).

After careful consideration, the Agencies have determined that a study is required to fully characterize worker exposure to Helix in commercial seed treatment plants. This will ensure the long-term safety of workers in these plants.

The necessary in-plant worker exposure information can only be generated via limited operational-scale research in commercial seed treatment facilities. Agreement in principle has been established to carry out the further testing required in Canadian facilities under the Research Permit authority of the Pest Control Products Regulations.

*(publié aussi en français)*

**February 16, 2000**

**This document is published by the Submission Management and Information Division,  
Pest Management Regulatory Agency. For further information, please contact:**

**Publications Coordinator  
Pest Management Regulatory Agency  
Health Canada  
2250 Riverside Drive  
A.L. 6606D1  
Ottawa, Ontario  
K1A 0K9**

**Internet: [pmra\\_publications@hc-sc.gc.ca](mailto:pmra_publications@hc-sc.gc.ca)  
[www.hc-sc.gc.ca/pmra-arla/](http://www.hc-sc.gc.ca/pmra-arla/)  
Information Service:  
1-800-267-6315 or (613) 736-3799  
Facsimile: (613) 736-3798**

Helix is the trade name for a new seed treatment produced by Novartis Crop Protection Canada Inc. proposed for use on canola and mustard for control of flea beetles, seed-borne blackleg and seedling diseases. It contains a new insecticide (thiamethoxam) and three fungicide (difenoconazole, metalaxyl-M, fludioxonil) active ingredients. It is a potential lindane replacement product and, as such, has been a work sharing project between the Canadian Pest Management Regulatory Agency (PMRA) and the United States Environmental Protection Agency (EPA).

The EPA and the PMRA have been expediting the review of Helix, endeavouring to coordinate a registration decision to facilitate access to a lindane replacement product. A harmonized registration would avoid potential trade irritant problems. The Agencies have continued to work together in evaluating additional information recently supplied by Novartis Crop Protection Canada Inc. and have taken it into account in the risk assessment process.

After careful consideration, the Agencies have determined that a study is required to fully characterize worker exposure to Helix in commercial seed treatment plants. This will ensure the long-term safety of workers in these plants. A health assessment has been done that shows farmers can safely plant Helix-treated seed.

The necessary actual in-plant worker exposure information can only be generated via limited operational-scale research in commercial seed treatment facilities. Agreement in principle has been established to carry out the further testing required in Canadian facilities under the research permit authority of the Pest Control Products Regulations. Relevant details and appropriate test protocols are currently being developed cooperatively between the Agencies and Novartis Crop Protection Canada Inc.

The research permit provides for the sale of Helix to treatment facilities, as well as the distribution of treated seed and harvested crop through normal commercial channels. Extensive field trials in Canada and the United States have confirmed that there are no detectable residues in the harvested crop.

The results of this research will be useful to both Agencies. The test data, however, will not be available in time to allow consideration of Helix registration for the 2000 growing season.

It is important to note that Helix is not registered for use on canola in the United States and no import maximum residue limit (MRL) (tolerance) has yet been established in the United States. In addition to information provided via commercial channels, this type of background and other pertinent details will be communicated to growers via the tag that is required to accompany all treated seed.

The United States is currently evaluating emergency use of Helix treated canola. The EPA expects to be able to establish an import MRL to accommodate importation of seed and Canada's 2000 crop grown from seed treated with Helix under this research program.

The Agencies will continue to cooperate in their review of Helix and related files, in the interests of providing pest management tools needed by growers while ensuring the protection of human health and the environment in both countries.