



## Re-evaluation Note

REV2001-03

### Discontinuation of the Organophosphate Insecticide Ethion

Ethion is one of the 27 organophosphate pesticides to be re-evaluated by the Pest Management Regulatory Agency (PMRA), as announced on June 29, 1999, in the Agency's publication REV99-01, *Re-evaluation of Organophosphate Pesticides*.

The purpose of this note is to notify registrants, pesticide regulatory officials, and the Canadian public that, in response to the re-evaluation announcement, Cheminova Inc., manufacturer and registrant of ethion technical active ingredient, has informed the Agency that they do not intend to support the continued registration of ethion products in Canada and have stopped supplying technical ethion to formulators and registrants of the end-use products in Canada. Information on the phase-out of the sale and use of this pesticide in Canada and the possible need for maximum residue limits (MRLs) to accommodate imports is provided in this note.

In Canada, commercial class products containing ethion have been registered for use on the following crops:

apple, cherry, grape, onion, peach, pear, plum, strawberry, and a variety of ornamental trees and shrubs.

Domestic class products containing ethion have been registered for use as soil-incorporated insecticide to control the following:

onion maggot in onion.

In the U.S., registration of ethion is being supported by the registrant, Cheminova, for use on citrus in Florida and Texas and as a cattle eartag. The commodities for which registration appears likely to continue in the U.S. are those that are imported into Canada, i.e. citrus and livestock products.

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## **1.0 Re-evaluation of organophosphate pesticides**

Organophosphate (OP) pesticides, which are mainly insecticides, are used in a broad range of use-site categories, such as forests and woodlands, greenhouse food and nonfood crops, livestock, seed treatments, oilseed and fibre crops, stored food and feed, terrestrial feed and food crops, structural uses, outdoor ornamentals and indoor plants, plant scapes and turf.

The re-evaluation of organophosphate pesticides was announced on June 29, 1999, in REV99-01. Under the re-evaluation program, the PMRA uses a modern scientific approach to re-examining older active ingredients and their end-use products to determine their continuing acceptability in relation to human health and the environment.

## **2.0 Uses of ethion to be discontinued**

Ethion (*O,O,Oll,Oll*-tetraethyl *S,S*-methylene bisphosphorodithioate) Commercial Class products have been registered for the following pest-crop combinations:

several foliar-feeding insects in apple, cherry, grape, hazelnut, onion, strawberry, peach, pear, plum and a variety of ornamental trees and shrubs.

Domestic class products have been registered as soil-incorporated insecticide for the following use:

onion maggot in onion.

## **3.0 Alternatives for ethion**

A variety of other products are registered for discontinued ethion uses: other organophosphates, carbamates, pyrethroids, organochlorines, imidacloprid, abamectin, formetanate, propargite, pyridaben, chinomethionat, lime-sulphur and insecticidal soap.

## **4.0 Extent of use and usage**

The *Survey of Organophosphate Uses in Canada* conducted in 1998 indicated only limited use of ethion for the control of onion maggot on green onions. The Commercial Class product that was labelled for this use has been discontinued by the registrant.

## 5.0 U.S. Environmental Protection Agency status of ethion

According to an Environmental Protection Agency (EPA) *Ethion Summary*, released July 14, 1999, ethion is registered in the U.S. for use on citrus in Florida and Texas and as a cattle eartag. The summary document indicated that dietary risk was below the level of concern. Acute drinking water level of concern was slightly exceeded based on a conservative model and chronic drinking water level of concern was not exceeded. Occupational exposure generally exceeded the level of concern for most exposure scenarios. Amongst the ecological risks of concern, aquatic risks would be the highest priority in the U.S. and especially in Florida. A final position on ethion has not yet been released in the U.S.

## 6.0 The PMRA's regulatory position

### 6.1 Registration

In response to the PMRA's announcement of the re-evaluation of organophosphate products, Cheminova Inc., the technical manufacturer, indicated it would not support the continued registration of products containing ethion in Canada and is no longer selling its technical product to formulators for the Canadian market. All commercial class products containing ethion have been discontinued by registrants and the registrations for these products expired on December 31, 2000.

The registrant of the only remaining registered product containing ethion, Later's Onion Maggot Control (Registration No. 12886), will discontinue the sale of the product December 31, 2001. Under authority of section 16 of the PCP Regulations, distribution and sale of this product by other than the registrant is permitted until December 31, 2002, and use of the product is to end on December 31, 2003, when the registration will be cancelled. This will allow for any remaining product in the hands of users to be used legally. It is expected that there will be very little product use after the 2001 use season.

### 6.2 MRLs

The following are the current Canadian MRLs:

**Table II, Division 15, Food and Drug Regulations**

<b>Chemical</b>	<b>MRL</b>	<b>Foods</b>
<b>ethion</b>	<b>2.5</b>	meat, meat by-products, fat of cattle (calculated on the fat content)
	<b>2.0</b>	apples, citrus fruits, grapes, pears
	<b>1.0</b>	beans, peaches, plums, strawberries
	<b>0.5</b>	tomatoes

A reassessment of the definition of the residue of concern (ROC), based on plant and metabolism studies, indicates that the ROC should be redefined from ethion to ethion and ethion oxon. This ROC will be harmonized with that used in the U.S. by the EPA and the U.S. Food and Drug Administration. This change in the ROC will be communicated to the Canadian Food Inspection Agency (Agriculture and Agri-Food Canada) to ensure the monitoring for these residues in imported foods.

As indicated, the registrant of technical grade ethion has voluntarily discontinued sale of the product in Canada and indicated that they have no further interest in providing data in support of this pesticide in Canada. The PMRA therefore has no plan to schedule this pesticide for an updated risk assessment under the re-evaluation program.

The *Food and Drugs Act* prohibits the sale of food containing pesticide residues at levels in excess of the MRLs established in the Regulations under that Act. The decision to establish, maintain or modify an MRL must be based on an assessment of information that is sufficient to determine the safety of the permitted level of residues.

Because ethion is not being scheduled for an updated risk assessment, the PMRA will recommend the revocation of all ethion MRLs established in Table II, Division 15 of the Food and Drug Regulations, including those that were originally established to cover both domestic uses and imports, and those that were established to cover imports only.

The PMRA will consider requests to modify or maintain the MRLs established for ethion to cover imports from other countries. Interested parties should petition the PMRA for the establishment of MRLs to cover ethion and ethion oxon residues in treated imported raw agricultural commodities and their processed products. The interested party may identify or provide existing domestic or foreign data and the PMRA will determine whether they are sufficient.

In cases such as this, where there is no remaining domestic use for the product and there is interest in import MRLs, the toxicology data would be reviewed (as per the process currently in place, i.e. a peer review of the EPA and other international data evaluations where available and suitable). Any necessary use information, and chemistry and residue data would also be reviewed. The PMRA may request additional data. Data requirements will be similar to those required for establishing an MRL to cover domestic use of the pesticide (see Regulatory Directive DIR98-02, *Residue Chemistry Guidelines*).

The PMRA is also considering adopting the proposals that the EPA has under consideration for import tolerances that are outlined in their document *Pesticides: Guidance on Pesticide Import Tolerances and Residue Data for Imported Food; Request for Comment* (Federal Register, Vol. 65, No. 106, Thursday, June 1, 2000). These proposals include a possible reduction to the standard data requirements, depending on the conditions described.

### **6.3 Conclusion of Re-evaluation**

The decisions and actions outlined in this Re-evaluation Note conclude the re-evaluation of ethion by the PMRA.