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Re-evaluation Note

REV2017-15

# Re-evaluation Project Plan for Isoxaflutole

*(publié aussi en français)*

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## **Background**

In Canada, isoxaflutole is under re-evaluation by Health Canada's Pest Management Regulatory Agency (PMRA). PMRA re-evaluates registered pesticides to determine whether the use of these products continues to be acceptable in terms of value, human health and the environment according to current standards.

Isoxaflutole is a broad spectrum herbicide. It is registered for use in field corn and isoxaflutole-tolerant soybean in Eastern Canada and British Columbia, and for use in seed corn in Eastern Canada, for the control of broadleaf and annual grass weeds. As of 4 May 2017, five products containing isoxaflutole are registered in Canada, including one technical grade active ingredient and four end-use products.

Under the authority of section 16 of the *Pest Control Products Act*, the registrant of isoxaflutole in Canada was notified of the initiation of this re-evaluation. Following this, the registrant indicated support of all uses included on the labels of end use products in Canada.

The re-evaluation project plan below outlines the timeline, the anticipated areas of focus for the risk assessments, and the data requirements for the re-evaluation of isoxaflutole.

## **Re-evaluation Project Plan**

### **Anticipated Re-evaluation Timeline**

The re-evaluation of isoxaflutole is defined as a Category 1 as described in Regulatory Directive DIR2016-04, *Management of Pesticides Re-evaluation Policy*, which was adopted on 1 December 2016. However, because this re-evaluation was initiated prior to the publication of DIR2016-04, the proposed re-evaluation decision for isoxaflutole is anticipated to be published for consultation by May 2019. The re-evaluation timeline may be updated if, during the risk assessment, PMRA identifies additional areas of focus that should be considered.

### **Human Health Risk Assessment**

New assessments will be conducted for toxicology and postapplication exposure. Existing assessments with minor updates are considered to be adequate to support the re-evaluation of isoxaflutole for the other aspects of human health assessment.

### **Environmental Risk Assessment**

New assessments will be conducted for environmental fate, water modelling and environmental exposure.

### **Value**

The value of isoxaflutole will be considered. The viability of alternatives will be examined for certain uses if risks of concern requiring mitigation are identified.

## **Data Requirements**

PMRA has identified the need for the technical registrant to provide data for isoxaflutole related to toxicology and environmental toxicology. Relevant data/studies have been requested from the technical registrant. A summary of the data call-in is found PMRA's Public Registry, found online at <http://www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#ppid>. For a list of data categories that have been required, see Appendix I. In addition, information regarding the registered use pattern has been requested from the registrants, to inform the risk assessments.

## **Additional Information**

PMRA documents can be found in the Pesticides and Pest Management section of Health Canada's website at [healthcanada.gc.ca/pmra](http://healthcanada.gc.ca/pmra). PMRA documents are also available through the Pest Management Information Service:

Phone:           1-800-267-6315           within Canada or  
                  1-613-736-3799           outside Canada (long distance charges apply)  
Fax:             1-613-736-3798  
E-mail:          pmra.infoserv@hc-sc.gc.ca

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## **Appendix I      Data Required Under Subsection 19(1) of the *Pest Control Products Act* for the Re-evaluation of Isoxaflutole**

### **I      Toxicology Data**

- 4.4            Long-term Studies - TGAI
- 4.5.1        Multigeneration Reproduction (rodent)
- 4.5.8        Other Genotoxicity Studies
- 4.5.9        Metabolism/Toxicokinetics in Mammals (laboratory animals)
- 4.5.12      Acute Neurotoxicity (rat)
- 4.5.13      90-day Neurotoxicity (rat)
- 4.5.14      Developmental Neurotoxicity
- 4.5.15      Immunotoxicity
- 4.8           Other Studies /Data / Reports

### **II      Environmental Toxicology Data**

- 9.2.3.1      Acute Toxicity (Earthworms)
- 9.2.4.3      Hive Study (including Brood)
- 9.2.8        Laboratory studies on Non-Target Terrestrial Invertebrates
- 9.3.2        *Daphnia* sp. Acute
- 9.3.4        Laboratory Studies with Other Species (Non-Target Freshwater Invertebrates)
- 9.4.2        Acute (Crustacean)
- 9.5.2.4      Marine/Estuarine Fish (Acute Studies)
- 9.5.3.1      Fish, Early Life Cycle Toxicity Test
- 9.6.2.4      Dietary (LC<sub>50</sub>) Bobwhite Quail
- 9.6.3.1      Avian Reproduction Bobwhite Quail
- 9.8.2        Fresh Water Algae
- 9.8.5        Aquatic Vascular Plants