



Re-evaluation Decision

RVD2022-04

# Isoxaflutole and Its Associated End-use Products

*Final Decision*

*(publié aussi en français)*

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## Re-evaluation decision for isoxaflutole and associated end-use products

Under the authority of the *Pest Control Products Act*, all registered pesticides must be re-evaluated by Health Canada's Pest Management Regulatory Agency (PMRA) to ensure that they continue to meet current health and environmental standards and continue to have value. The re-evaluation considers data and information from pesticide manufacturers, published scientific reports and other regulatory agencies, as well as comments received during public consultations. Health Canada applies internationally accepted risk assessment methods as well as current risk management approaches and policies.

Isoxaflutole is a broad spectrum herbicide registered for use in field corn and soybeans in Eastern Canada and British Columbia and for use in seed corn in Eastern Canada only. Currently registered products containing isoxaflutole can be found in the [Pesticide Label Search](#) and in Appendix I. The Proposed Re-evaluation Decision PRVD2021-02 isoxaflutole<sup>1</sup> containing the evaluation of isoxaflutole and proposed decision, underwent a 90 day consultation period ending on 29 April 2021. PRVD2021-02 proposed continued registration of all uses of isoxaflutole and associated end-use products registered for sale and use in Canada.

Health Canada received comments (and information) relating to the health and value assessments. Commenters are listed in Appendix II. These comments are summarized in Appendix III along with the responses by Health Canada. The assessment of comments resulted in the reassessment of the proposed value-related label improvements but did not result in any other revisions to the value assessment, and did not result in changes to the proposed re-evaluation decision as described in PRVD2021-02.

A reference list of information used as the basis for the proposed re-evaluation decision was included in PRVD2021-02. There was no further information used in the re-evaluation decision of this RVD. Therefore, the reference list of all information used in the proposed re-evaluation decision, set out in PRVD2021-02, represents the complete reference of information used in this final re-evaluation decision.

This document presents the final re-evaluation decision<sup>2</sup> for the re-evaluation of isoxaflutole, including the required amendments (risk mitigation measures) to protect human health and the environment. All products containing isoxaflutole that are registered in Canada are subject to this re-evaluation decision.

### Re-evaluation decision for isoxaflutole

Health Canada has completed the re-evaluation of isoxaflutole. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of products containing isoxaflutole is acceptable. An evaluation of available scientific information found that

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<sup>1</sup> "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

<sup>2</sup> "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

uses of isoxaflutole products meet current standards for protection of human health and the environment and have acceptable value when used according to revised conditions of registration which includes new mitigation measures.

## **Risk mitigation measures**

Registered pesticide product labels include specific directions for use. Directions include risk mitigation measures to protect human health and the environment and must be followed by law. The required amendments, including any revised/updated label statements and/or mitigation measures, as a result of the re-evaluation of isoxaflutole, are summarized below. Refer to Appendix IV for details.

### **Human health**

Label improvements to meet current standards:

As a result of the re-evaluation of isoxaflutole, Health Canada is proposing additional revisions to the isoxaflutole labels to update label statements to current policies and language.

- To protect bystanders, a statement is required indicating to apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools and recreational areas is minimal.

Risk mitigation:

To protect workers entering treated sites, a restricted-entry interval (REI) of 12 hours is required.

### **Environment**

Risk mitigation:

To protect the environment, the following risk-reduction measures are required:

- Standard label statements to inform users of the potential toxic effects of isoxaflutole to aquatic organisms and terrestrial plants.
- Spray buffer zones for the protection of aquatic and terrestrial habitats.
- A leaching advisory statement.
- Precautionary label statements to reduce the potential for runoff of isoxaflutole to adjacent aquatic habitats for sites with characteristics that may be conducive to runoff and when heavy rain is forecast.

## **Next steps**

To comply with this decision, the required amendments (mitigation measures and label updates) must be implemented on all product labels no later than 24 months after the publication date of this decision document. Accordingly, both registrants and retailers will have up to 24 months

from the date of this decision document to transition to selling the product with the newly amended labels. Similarly, users will also have the same 24-month period from the date of this decision document to transition to using the newly amended labels, which will be available on the Public Registry.

Refer to Appendix I for details on specific products impacted by this decision.

## **Other information**

Any person may file a notice of objection<sup>3</sup> regarding this decision on isoxaflutole and its associated end-use products within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides section of the Canada.ca website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

The relevant confidential test data on which the decision is based (as referenced in PRVD2021-02) are available for public inspection, upon application, in the PMRA's Reading Room. For more information, please contact the PMRA's [Pest Management Information Service](#).

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<sup>3</sup> As per subsection 35(1) of the *Pest Control Products Act*

## List of abbreviations

AHETF	Agricultural Handlers Exposure Task Force
PPE	Personal Protective Equipment
REI	Restricted-Entry Interval
RVD	Re-evaluation Decision

## Appendix I Registered products containing isoxaflutole in Canada<sup>1</sup>

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Active ingredient (% , g/L)
26141	Technical Grade Active Ingredient	Bayer CropScience Inc.	Isoxaflutole Technical	Solid	98.0%
33596		BASF Canada Inc.	BASF Isoxaflutole Technical Herbicide		
26142	Commercial	Bayer CropScience Inc.	Converge 75 WDG Herbicide	Wettable Granules	75.0%
27446			Converge Pro	Suspension	480 g/L
29071			Converge Flexx Herbicide		240 g/L
32553		BASF Canada Inc.	Balance Bean Herbicide		480 g/L
33249			Balance Bean MTZ		Isoxaflutole: 105 g/L; Metribuzin: 420 g/L

<sup>1</sup> As of 22 October 2021, excluding discontinued products or products with a submission for discontinuation.



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**Appendix II List of commenters to PRVD2021-02**

List of commenters' affiliations for comments submitted in response to PRVD2021-02

<b>Category</b>	<b>Commenter</b>
Registrant	Bayer CropScience Inc.
Registrant	BASF

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## Appendix III Comment(s) and response(s)

Health Canada received five written comments during the public consultation for the isoxaflutole proposed re-evaluation decision. Commenters' affiliations are listed in Appendix II. These comments were considered during the final decision phase of this re-evaluation. Summarized comments and Health Canada's responses to them are provided below.

### 1.0 Comment(s) related to the health risk assessment

#### 1.1 Comments related to occupational exposure

##### 1.1.1 Comment concerning the personal protective equipment stated on labels

A comment was received from a registrant, Bayer CropScience Inc., related to the proposed personal protective equipment (PPE) requirements specified in PRVD2021-02 for occupational workers. The comment stated that new Agricultural Handlers Exposure Task Force (AHETF) data were used in the re-evaluation of isoxaflutole, and thus inquired whether single layer (long pants, long-sleeved shirt, chemical resistant gloves) PPE could replace the mid-level (coveralls over long pants, long-sleeved shirt, chemical-resistant gloves) PPE currently on labels.

#### Health Canada response:

Currently registered isoxaflutole labels indicate that workers are to wear mid-level PPE (coveralls over long-sleeved shirt, long pants, and chemical-resistant gloves). PPE requirements for individual products are established in consideration of both the human health risk assessment as well as the end-use product-specific hazard assessment. In order to determine whether a specific product label could be revised from mid-level PPE to single layer PPE, a product-specific submission would be required.

### 2.0 Comment(s) related to the value assessment

#### 2.1 Comments related to value-related label improvements

**Comment:** Can Health Canada provide further clarification regarding the proposed label amendment: Products must add "suppression" also where "control" is mentioned in the label. The requirement to add "suppression" along with "control" throughout the entire label may result in a cluttering of redundant text and may actually cause confusion as to whether the weed is labelled for control or suppression.

**Health Canada response:** Upon further examination of the labels, Health Canada has concluded that this amendment will not be required. The labelled weed that is suppressed rather than controlled is already identified with a footnote indicating "Early season suppression only".

**Comment:** How did Health Canada arrive at the proposed risk mitigation statement relative to sugar beet as a rotational crop?

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**Health Canada response:** Upon further review, Health Canada has determined that the risk mitigation statement relative to sugar beet will not be required. Sugar beet is not listed in the Rotational Crop table as a crop that can be grown in a field treated with isoxaflutole in the year following application. As indicated on the label, the earliest that a crop not listed in this table could be grown is in the second year following application, provided that a bioassay (crop injury) conducted the year prior to growing the crop demonstrates that it can be safely grown. Therefore, the proposed statement included in PRVD2021-02 relative to sugar beet is not required.

## 2.2 Comments related to application rates included in the risk assessment

**Comment:** For isoxaflutole tolerant soybean, there is also a registered use rate of 78 g a.i./ha for season long control of labelled weeds.

**Health Canada response:** Health Canada acknowledges that there is also a registered application rate calculated as 79 g a.i./ha for season long control of labelled weeds, rather than 78 g a.i./ha as indicated in the comment. This rate, along with the rate of 105 g a.i./ha, were both included in the risk assessment of isoxaflutole. Appendix II in PRVD2021-02 solely captures the maximum application rate for each use scenario, which in this case is 105 g a.i./ha.

**Comment:** For isoxaflutole tolerant soybean, can Health Canada clarify how the maximum cumulative application rate per year of 105 g a.i./ha was calculated for the early season control use pattern.

**Health Canada response:** The maximum cumulative application rate per year refers to the maximum active ingredient applied per year for that crop, regardless if used for early season control or season long control of listed weeds, which is 105 g a.i./ha.

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## Appendix IV Label amendments for products containing isoxaflutole

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the label statements given below.

### I. For isoxaflutole technical products:

The following must appear under a section titled “ENVIRONMENTAL PRECAUTIONS”:

“TOXIC to aquatic organisms and terrestrial plants.”

“DO NOT discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters.”

### II. For commercial end-use products:

#### Label amendments relating to the health risk assessment

##### General label improvements

In order to promote best practices, and to minimize human exposure from spray drift or from spray residues resulting from drift due to the use of isoxaflutole, the following label statement is required:

“Apply only to agricultural crops when the potential for drift to areas of human habitation and human activity such as houses, cottages, schools and recreational areas is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment, and sprayer settings.”

##### Restricted-entry interval

The following statement is required for all commercial-class product labels:

“DO NOT enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours.”

#### Label amendments relating to the environmental risk assessment

a) The following statements are to be added to the “Environmental Precautions” section:

“TOXIC to aquatic organisms and terrestrial plants. Observe buffer zones specified under DIRECTIONS FOR USE.”

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**b)** The following statements are required under the “Directions for Use” Section on all product labels:

“To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay.”

“Avoid application of this product when heavy rain is forecast.”

“Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative filter strip between the treated area and the edge of the water body.”

“DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.”

“As this product is not registered for the control of pests in aquatic systems, DO NOT use to control aquatic pests.”

“Field sprayer application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. DO NOT apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) medium classification. Boom height must be 60 cm or less above the crop or ground.”

“DO NOT apply by aerial application equipment.”

**“Spray Buffer Zones:**

A spray buffer zone is not required for:

- uses with hand-held application equipment permitted on this label,
- low-clearance hooded or shielded sprayers that prevent spray contact with crop, fruit or foliage

The spray buffer zones specified in the table below are for isoxaflutole. These spray buffer zones are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands), freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of application	Crop	Spray Buffer Zones (metres) Required for the Protection of:				
		Freshwater Habitat of Depths:		Estuarine/Marine Habitat of Depths:		Terrestrial Habitat:
		Less than 1 m	Greater than 1 m	Less than 1m	Greater than 1 m	
Field sprayer	Field corn, seed corn, Isoxaflutole tolerant soybeans	1	1	1	1	15

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.

The buffer zones for this product can be modified based on weather conditions and spray equipment configuration by accessing the Buffer Zone Calculator on the Pest Management Regulatory Agency web site.”

c) The following statement is required under the STORAGE heading:

“To prevent contamination, store this product away from food and feed”

d) The following statements are required under the DISPOSAL heading; inclusion of these statements is dependant on the end-use product.

For recyclable containers

The following statement would apply to plastic or metal containers that contain agricultural and non-crop land uses (for example, forestry) pesticide products, and that are designed to contain 23 L or less of product.

Disposal of Container:

“DO NOT reuse this container for any purpose. This is a recyclable container, and is to be disposed of at a container collection site. Contact your local distributor/dealer or municipality for the location of the nearest collection site. Before taking the container to the collection site:

1. Triple- or pressure-rinse the empty container. Add the rinsings to the spray mixture in the tank.
2. Make the empty, rinsed container unsuitable for further use.

If there is no container collection site in your area, dispose of the container in accordance with provincial requirements.”

For returnable containers

Disposal of Container:

“DO NOT reuse this container for any purpose. For disposal, this empty container may be returned to the point of purchase (distributor/dealer).”

For containers that can be refilled for the user by the distributor/dealer

Disposal of Container:

“For disposal, this container may be returned to the point of purchase (distributor/dealer). It must be refilled by the distributor/dealer with the same product. DO NOT reuse this container for any other purpose.”

Disposal of unused, unwanted product

A revised standard label statement providing directions for the disposal of unused, unwanted product will be added to labels of agricultural and non-crop land control products:

“For information on disposal of unused, unwanted product, contact the manufacturer or the provincial regulatory agency. Contact the manufacturer and the provincial regulatory agency in case of a spill, and for clean-up of spills.”