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Re-evaluation Decision

RVD2026-03

Iodosulfuron-methyl- sodium and Its Associated End-use Product

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Re-evaluation decision for Iodosulfuron-methyl-sodium and associated end-use product

Under the authority of the *Pest Control Products Act*, all registered pesticides must be re-evaluated by Health Canada to ensure that they meet current health and environmental standards and have value. The re-evaluation considers data and information from pesticide manufacturers, incident reports and other regulatory agencies, as well as comments directly related to the proposed re-evaluation decision, such as comments directed to the Science evaluation, received during public consultations. Health Canada applies internationally accepted risk assessment methods as well as current risk management approaches and policies. More details, on the legislative framework, risk assessment and risk management approach, are provided under the Evaluation approach Section of this document.

Iodosulfuron-methyl-sodium is a selective sulfonylurea herbicide. It inhibits the activity of acetolactate synthase (ALS), which is the key enzyme in the biosynthesis of the branch-chain amino acids, isoleucine, leucine and valine. Although the actual sequence of phytotoxic processes is unclear, plant death results from events occurring in response to inhibition of the ALS enzyme. Iodosulfuron-methyl-sodium is used to control a range of post-emergence grassy and broadleaf weeds in field corn. It is applied once a year by field sprayer. Currently registered products containing iodosulfuron-methyl-sodium can be found in the Pesticide Product Information Database and in Appendix I.

The Proposed Re-evaluation Decision PRVD2025-10, *Iodosulfuron-methyl-sodium and Its Associated End-Use Product*¹ containing the evaluation of iodosulfuron-methyl-sodium and proposed decision, underwent a 90 day consultation period ending on 28 January 2026. PRVD2025-10 proposed continued registration of iodosulfuron-methyl-sodium and the associated end-use product in Canada, with updates to label directions and precautions to reflect the current labelling standards and improve clarity (Appendix II). Risk mitigation includes updating runoff statements to reflect current standards, adding a leaching statement and storage directions.

Written comments were received during the public consultation period conducted in accordance with section 28 of the *Pest Control Products Act*. However, they did not relate to the health, environmental or value assessments in PRVD2025-10. Therefore, this decision is consistent with the proposed re-evaluation decision as described in PRVD2025-10.

A reference list of information used as the basis for the proposed re-evaluation decision is included in PRVD2025-10; no further information was used in the final re-evaluation decision. Therefore, the complete reference list of all information used in this final re-evaluation decision is set out in PRVD2025-10.

¹ “Consultation statement” as required by subsection 28(2) of the *Pest Control Products Act*.

This document presents the final re-evaluation decision² for the re-evaluation of iodosulfuron-methyl-sodium, including the required amendments (risk mitigation measures) to protect human health and the environment, as well as label amendments required to bring labels to current standards. All products containing iodosulfuron-methyl-sodium that are registered in Canada are subject to this re-evaluation decision.

Re-evaluation Decision for iodosulfuron-methyl-sodium

Health Canada has completed the re-evaluation of iodosulfuron-methyl-sodium. Under the authority of the *Pest Control Products Act*, Health Canada has completed all required evaluations and consultations and has determined that the registration of products containing iodosulfuron-methyl-sodium is required to be amended, in accordance with paragraph 21(2)(a) of the *Pest Control Products Act*. An evaluation of available scientific information respecting the health and environmental risks and value of iodosulfuron-methyl-sodium found that all uses of iodosulfuron-methyl-sodium products meets current standards for protection of human health and the environment and have acceptable value when used according to the amended conditions of registration which includes new mitigation measures. Label amendments, as summarized below and listed in Appendix II, are required.

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 iodosulfuron-methyl-sodium, are summarized below. Refer to Appendix II for details.

Human health

- No label amendments are required.

Environment

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

- Update runoff statement and add leaching and storage statements.

Implementation of the re-evaluation decision

Regulatory Directive DIR2018-01, *Policy on Cancellations and Amendments Following Re-evaluation and Special Review* provides information and general timelines regarding the implementation of post-market decisions, (for example, up to 24-month timeline for label amendments and up to 36-month phase-out timeline for cancelled registrations), and Information Note: *Update on implementation of post-market decisions* provides additional information on phase-out measures for post-market decisions that include cancellations. The post-market

² “Decision statement” as required by subsection 28(5) of the *Pest Control Products Act*.

decision considers potential health and environmental risks regarding the use of the pest control product, and its value, when establishing the implementation timelines.

Amendment timeframe

The implementation timeline of 24 months for the required amendments (mitigation measures and label updates) for pest control products containing iodosulfuron-methyl-sodium is considered acceptable. These required amendments must be implemented within 24 months after the publication date of this decision document.

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

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

The relevant confidential test data on which the decision is based (as referenced in PRVD2025-10) are available for public inspection, upon application, in the Pesticides Regulatory Directorate's Reading Room. For more information, please contact the Pesticides Information Service.

Any person may file a notice of objection,³ which must be based on scientific grounds, regarding this decision on iodosulfuron-methyl-sodium and its associated end-use product within 60 days from the date of publication of this Re-evaluation Decision through the Public Engagement Portal (Public Engagement Forms - Notice of Objection). The request for reconsideration must include the Notice of Objection form, the scientific explanation of the objection and the supporting scientific evidence in possession of the requestor that would not already be in Health Canada's possession or cite specific Health Canada documentation they wish to rely on as supporting evidence (for example, scientific reports) in the form of electronic copies of cited references. Each of the references provided or cited must be clearly associated with the objection it supports.

³ As per subsection 35(1) of the *Pest Control Products Act*.

Failure to provide a complete package may result in the Notice of Objection being considered ineligible for further consideration by Health Canada. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and pest management portion of the Canada.ca website or contact the Pesticides Information Service.

Evaluation approach

Legislative framework

The Minister of Health's primary objective under the *Pest Control Products Act* (or the Act) subsection 4(1) is to prevent unacceptable risks to individuals and the environment from the use of pest control products.

As noted in the preamble of the Act, it is in the national interest that the attainment of the objectives of the federal regulatory system continue to be pursued through a scientifically-based national registration system that addresses risks to human health, the environment and value both before and after registration and applies to the regulation of pest control products throughout Canada; and that pest control products with acceptable risk and value be registered for use only if it is shown that their use would be efficacious and if there is acceptable risk to human health and the environment, taking into account the conditions of registration.

For the purposes of the Act, the health or environmental risks of a pest control product are acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from exposure to or use of the product, taking into account its conditions of registration, as per subsection 2(2) of the *Pest Control Products Act*.

Risk for the human health and environment, and value are defined under the Act subsection 2(1) as follows:

Health risk, in respect of a pest control product, means the possibility of harm to human health resulting from exposure to or use of the product, taking into account its conditions or proposed conditions of registration.

Environmental risk, in respect of a pest control product, means the possibility of harm to the environment, including its biological diversity, resulting from exposure to or use of the product, taking into account its conditions or proposed conditions of registration

Value, in respect of a pest control product, means the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact.

When evaluating the health and environmental risks of a pesticide and determining whether those risks are acceptable, subsection 19(2) of the *Pest Control Products Act* requires Health Canada to apply a scientifically-based approach. The science-based approach to assessing pesticides considers both the toxicity and the level of exposure of a pesticide in order to fully characterize risk.

Risk and value assessment framework

Health Canada uses a comprehensive body of modern scientific methods and evidence to determine the nature as well as the magnitude of potential risks posed by pesticides. This approach allows for the protection of human health and the environment through the application of appropriate and effective risk management strategies, consistent with the purpose described in the preambular text set out above.

Health Canada's approach to risk and value assessment is outlined in *A Framework for Risk Assessment and Risk Management of Pest Control Products*.⁴ A high-level overview is provided below.

i) Assessing potential health risks

With respect to the evaluation and management of potential health risks, Health Canada's risk assessments follow a structured, predictable process that is consistent with international approaches and the Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks.⁵

The evaluation of potential health risks begins with a consideration of the toxicological profile of a pesticide to establish reference doses at which no adverse effect is expected and against which the expected exposure is assessed. This includes, where appropriate, the use of uncertainty (protection) factors to provide additional protection that accounts for the variation in sensitivity among members of human population and the uncertainty in extrapolating animal test data to humans. Under certain conditions, the *Pest Control Products Act* requires the use of another factor to provide additional protection to pregnant women, infants, and children. Other uncertainty factors, such as a database deficiency factor, are considered in specific cases. More details related to the application of the uncertainty factors are provided in SPN2008-01.⁶

Assessments estimate potential health risks to defined populations⁷ under specific exposure conditions. They are conducted in the context of the registered conditions of use, such as the use of a pesticide on a particular field crop using specified application rates, methods and equipment.

⁴ PMRA Guidance Document, *A Framework for Risk Assessment and Risk Management of Pest Control Products* (<https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/risk-management-pest-control-products.html>)

⁵ *Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks* - August 1, 2000 (<https://www.canada.ca/en/health-canada/corporate/about-health-canada/reports-publications/health-products-food-branch/health-canada-decision-making-framework-identifying-assessing-managing-health-risks.html>)

⁶ Science Policy Note: *The Application of Uncertainty Factors and the Pest Control Products Act Factor in the Human Health Risk Assessment of Pesticides* (<https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/science-policy-notes/2008/application-uncertainty-factors-pest-control-products-act-factor-human-health-risk-assessment-pesticides-spn2008-01.html>)

⁷ Consideration of Sex and Gender in Pesticide Risk Assessment (<https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/fact-sheets-other-resources/consideration-sex-gender-pesticide-risk-assessment-infographic.html>)

Potential exposure scenarios consider exposures during and after application of the pesticide in occupational or residential settings, food and drinking water exposure, or exposure when interacting with treated pets. Also considered are the anticipated durations (short-, intermediate- or long-term) and routes of exposure (oral, inhalation, or skin contact). In addition, an assessment of health risks must consider available information on aggregate exposure and cumulative effects.

ii) Assessing risks to the environment

With respect to the evaluation of environmental risks, Health Canada's environmental risk assessments follow a structured, tiered approach to determine the likelihood that exposure to a pesticide can cause adverse effects on individual organisms, populations, or ecological systems. This involves screening assessments starting with simple methods, conservative exposure scenarios and sensitive toxicity effects metrics, then moving on, where required, to more refined assessments that can include exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods.

The environmental assessment considers both the exposure (environmental fate, chemistry, and behaviour, along with the application rates and methods) and hazard (toxic effects on organisms) of a pesticide. The exposure assessment examines the movement of the pesticide in soil, water, sediments and air, as well as the potential for uptake by plants or animals and transfer through the food web. The possibility for the pesticide to move into sensitive environmental compartments such as groundwater or lakes and rivers, as well as the potential for atmospheric transport, is also examined. The hazard assessment examines effects on a large number of internationally recognized indicator species of plants and animals (terrestrial organisms include invertebrates such as bees, beneficial arthropods, and earthworms, birds, mammals, plants; aquatic organisms include invertebrates, amphibians, fish, plants and algae), and includes considering effects on biodiversity and the food chain. Acute and chronic effects endpoints are derived from laboratory and field studies that characterize the toxic response and the dose–effect relationship of the pesticide.

The characterization of environmental risk requires the integration of information on environmental exposure and effects to identify which, if any, organisms or environmental compartments may be at risk, as well as any uncertainties in characterizing the risk.

iii) Value assessment

Value assessments consist of two components: an assessment of the performance of a pest control product and its benefits.

During re-evaluation, value is examined under current conditions and in light of alternative pest control methods (both chemical and nonchemical) that may have been developed since the pesticide was first registered. An assessment of the benefits associated with the pesticide may also be conducted to demonstrate its value in the current context, and to identify potential alternatives.

Risk management

The outcomes of the assessments of risks to human health and the environment, and the assessment of value, form the basis for identifying risk management strategies. These include appropriate risk mitigation measures and are a key part of decision-making on whether health and environmental risks are acceptable. The development of risk management strategies take place within the context of the pesticide's conditions of registration. Conditions can relate to, among other things, the specific use (for example, application rates, timing, frequency and method of application), personal protective equipment, pre-harvest intervals, restricted-entry intervals, buffer zones, spray drift and runoff mitigation measures, handling, manufacture, storage or distribution of a pesticide. If feasible conditions of use that have acceptable risk and value cannot be identified, the pesticide use will not be eligible for registration.

The selected risk management strategy is then implemented as part of the re-evaluation decision. The pesticide registration conditions include legally-binding use directions on the label. Any use in contravention of the label or other specified conditions is illegal under the *Pest Control Products Act*. Implementation of post-market decisions follow the framework articulated in the *Policy on Cancellations and Amendments Following Re-evaluation and Special Review*.⁸

Following a decision, continuous oversight activities such as post-market review, monitoring and surveillance, including incident reporting, all play an essential role to help ensure the continued acceptability of risks and value of registered pesticides.

⁸ PMRA Regulatory Directive DIR2018-01, *Policy on Cancellations and Amendments Following Re-evaluation and Special Review* (<https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/regulatory-directive/2018/dir2018-01-policy-cancellations-amendments.html>).

Appendix I Registered products containing iodosulfuron-methyl-sodium in Canada

Table 1 Products containing iodosulfuron-methyl-sodium requiring (label) amendments¹

Registration number	Marketing class	Registrant	Product name	Formulation type	Active ingredient (% , g/L)
27421	Technical	Bayer CropScience Inc.	Iodosulfuron-Methyl-Sodium Technical Herbicide	Dust or Powder	IDO-92%
27422	Commercial	Bayer CropScience Inc.	Tribute Solo 32 DF Herbicide	Wettable Granules	IDO-2.0%; FMS*-30.0%

¹as of 3 February 2026, excluding discontinued products or products with a submission for discontinuation

*FMS = Foramsulfuron; IDO = Iodosulfuron-methyl-sodium

Appendix II Label amendments for products containing iodosulfuron-methyl-sodium

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. Information on labels of currently registered products should not be removed unless it contradicts the following label statements.

For technical active ingredient:

1. Replace the term “guarantee” with “active ingredient”
2. Replace “Precautions” with “Environmental Precautions”
3. Add “Toxic to aquatic organisms.” under Environmental Precautions
4. Under Directions of Use add:

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

For commercial end-use product:

Directions for Use:

1. Add:
“DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.”
2. Update the Field sprayer application statement with:
“Field sprayer application: DO NOT apply when wind speed is less than 1 km/h. Avoid application of this product when winds are gusty. DO NOT apply with sprays finer than the American Society of Agricultural and Biological Engineers (ASABE) S572 (572.1 to 572.3) Medium classification. Boom height must be 60 cm or less above the crop or ground.”

Environmental Precautions and Information:

1. Update the environmental runoff statement with:
“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 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. Additional guidance can be found on the Runoff Mitigation portion of the Canada.ca website.”

2. Add:

“This product demonstrates the properties and characteristics associated with chemicals detected in groundwater. The use of this product in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.”

Storage:

1. Add:

“Store this product away from food or feed.”