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Registration Decision

RD2026-13

Isocycloseram, A21377 CP, A21708 CP, A22466 CP, EQUENTO RFC and A23294 TO

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Under the authority of the *Pest Control Products Act*, pesticides must be assessed before they are sold or used in Canada in order to determine that they do not pose unacceptable risks to humans or the environment and have value when used according to the label instructions. The pre-market assessment considers available data and information¹ from pesticide registrants, published scientific reports, other governments, and international regulatory agencies, as well as written comments directly related to the proposed decision, such as comments directed to the Science evaluation, if received during public consultations. Health Canada applies internationally accepted current risk assessment methods as well as risk management approaches and policies. More details, on the legislative requirements, risk assessment and risk management approach, are provided in the Evaluation approach of this document.

Registration Decision Statement² for Isocycloseram

Health Canada, pursuant to subsection 8(1) of the *Pest Control Products Act*, is granting registration for the sale and use of Isocycloseram Technical, A21377 CP, A21708 CP, A22466 CP, EQUENTO RFC and A23294 TO, containing the active ingredient isocycloseram. A21377 CP and A21708 CP are for the control of various insect and mite pests by foliar application on a broad range of field vegetables, fruit and nut trees, soybean, and peanut (and corn for A21708 CP). A22466 CP is for in-furrow application to control corn rootworms and wireworms in corn (field, seed and pop). EQUENTO RFC is a seed treatment product for the control of wireworms in dry lentils. A23294 TO, also containing the active ingredient chlorantraniliprole, is for the control or suppression of various pests in greenhouse ornamentals and turf.

The Proposed Registration Decision PRD2026-02, *Isocycloseram, A21377 CP, A21708 CP, A22466 CP, EQUENTO RFC and A23294 TO*, containing the detailed evaluation of the information submitted in support of this registration, underwent a 30-day consultation period ending on 28 February 2026. The evaluation found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable. Health Canada received written comments relating to the health and environmental assessments during the public consultation period conducted in accordance with section 28 of the *Pest Control Products Act*. Health Canada also received comments that were not directly related to the proposed decision in PRD2026-02, *Isocycloseram, A21377 CP, A21708 CP, A22466 CP, EQUENTO RFC and A23294 TO*.

Comments and responses

Health Canada received a comment from the applicant regarding maximum residue limits, and comments from an individual associated with the pesticide industry and a member of the public on the health and environmental assessments of isocycloseram and its associated end-use products. The responses are provided below.

1. Comment related to maximum residue limits (MRLs)

The applicant commented that, while the proposed MRL of 0.01 ppm for each field corn and popcorn grain are included in the proposed registration decision document, PRD2026-02, in

¹ Information Note – *Determining Study Acceptability for use in Pesticide Risk Assessments*.

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

Table 3.8.1 and discussed in the text in the last paragraph of the section titled *Residue in food and drinking water*, these MRLs are missing from Appendix II, Table 1. These MRLs are also missing from PMRL2026-03.

Health Canada response:

PRD2026-02, published on 29 January 2026, proposed several MRLs on the following commodities: 10 ppm for leafy vegetables (crop group 4-13), except head lettuce; 4.0 ppm for *Brassica* head and stem vegetable group (crop group 5-13); 2.0 ppm for dried tomatoes; 1.5 ppm for dried prune plums; 1.0 ppm for stone fruits (crop group 12-09); 0.6 ppm for fruiting vegetables (crop group 8-09); 0.5 ppm for almond oil; 0.4 ppm for pome fruits (crop group 11-09), 0.2 ppm for tree nuts (crop group 14-11); 0.15 ppm for cucurbit vegetables (crop group 9) and dry soybeans; and 0.01 ppm for tuberous and corm vegetables (crop subgroup 1C); dry lentils, head lettuce and peanuts.

However, Health Canada inadvertently omitted the proposed MRLs for field corn and popcorn grain at 0.01 ppm from Appendix II, Table 1, of PRD2026-02. These same MRLs were also inadvertently omitted from PMRL2026-03. These MRLs are to support the registration of A22466 CP for in-furrow application to corn (field and pop) and the registration of A21708 CP for foliar application on corn.

Below is the revised Appendix II Table 1:

Table 1 Comparison of Proposed Canadian MRLs, U.S. Tolerances and Codex MRLs

Commodity	Proposed Canadian MRLs (ppm)	Established U.S. Tolerances (ppm)	Established Codex MRLs (ppm)
Leafy vegetables (crop group 4-13), except head lettuce	10	10	Not established
<i>Brassica</i> Head and Stem vegetable (crop group 5-13)	4.0	4	0.7 (Broccoli) 2 (Brussels sprouts) 4 (Cabbages, head) 0.5 (Cauliflower)
Dried tomatoes	2.0	2	2
Dried prune plums	1.5	1.5	1.5
Stone fruits (crop group 12-09)	1.0	1	1 (Cherries subgroup) 0.3 (Peaches (including apricots and nectarines) subgroup) 0.4 (Plums (including fresh prunes) subgroup)
Fruiting vegetables (crop group 8-09)	0.6	0.6	0.3 (Eggplant) 0.6 (Peppers chili) 4.2 (Peppers chili, dried)

Commodity	Proposed Canadian MRLs (ppm)	Established U.S. Tolerances (ppm)	Established Codex MRLs (ppm)
			0.3 (Peppers, sweet (including pimento or pimiento)) 0.5 (Tomato)
Almond oil	0.5	Not established	Not established
Pome fruits (crop group 11-09)	0.4	0.4	0.4
Tree nuts (crop group 14-11)	0.2	0.2 (almond; almond, tropical; beechnut; bunya; candlenut; chestnut; chinquapin; gingko; nut, monkey puzzle; nut, okari; nut, peach palm; nut, pili; nut, pine; pequi; pine, Brazilian; pistachio; yellowhorn) 0.01 (African nut-tree; bur oak; butternut; cashew; chestnut, Guiana; coconut; hazelnut; heartnut; horse-chestnut, Japanese; monkey-pot; nut, Brazil; nut, cajou; nut, coquito; nut, dika; nut, hickory; nut, macadamia; nut, mongongo; nut, pachira; nut, sapucaia; pecan; walnut, black; walnut, English)	Not established
Cucurbit vegetables (crop group 9)	0.15	0.15	0.1 (Cucumber) 0.15 (Melons except watermelon) 0.09 (Summer squash)
Dry soybeans	0.15	0.15	0.15
Tuberous and corm vegetables (crop subgroup 1C)	0.01	0.01	0.01 (potato)
Lentils, dry	0.01	0.01 (Vegetable, legume, pulse, bean, dried shelled, except soybean (crop	Not established

Commodity	Proposed Canadian MRLs (ppm)	Established U.S. Tolerances (ppm)	Established Codex MRLs (ppm)
		subgroup 6-22E); Vegetable, legume, pulse, pea, dried shelled (crop subgroup 6-22F))	
Peanuts	0.01	0.01	Not established
Head lettuce	0.01	10 (Vegetable, leafy; crop group 4-16)	Not established
Field corn, popcorn grain	0.01	0.01	0.01 (maize)

2. Comment related to isocycloseram being a neurotoxin

A commenter stated that the product is a neurotoxin.

Health Canada response:

As stated in PRD2026-02, the detailed analysis of the toxicology database was previously summarized in PRD2025-11, *Isocycloseram, VANECTO Cockroach Gel Bait, EQUENTO and A23128 ST*, in which it was reported that there was no evidence of selective neurotoxicity in mammals and no neurohistopathological findings observed in the acute oral neurotoxicity study or the subchronic oral neurotoxicity study with isocycloseram. The effects noted in the acute and 90-day neurotoxicity studies were found to be either within the pre-test range results, not statistically significant, showed no dose-response or were at one time point only and were considered incidental in nature. The decreased motor activity that was noted at the high dose in the acute neurotoxicity study was present at a dose level where body weight loss was evident. Therefore, the decreased motor activity was considered to be secondary to the systemic effect of body weight loss and not indicative of selective neurotoxicity. There were no signs of neurotoxicity noted in either sex at any dose level in the 90-day neurotoxicity study. Overall, it was concluded that there was no concern for neurotoxic effects in the database.

3. Comment related to isocycloseram being carcinogenic in male rats

A commenter stated that the product was carcinogenic in male rats.

Health Canada response:

In the detailed analysis of the toxicology database that was previously summarized in PRD2025-11, it was noted that there was equivocal evidence of tumourigenicity in male rats based on Leydig cell (LC) adenomas and that this tumour type was of low concern to humans. It is commonly recognized that human LCs are quantitatively less sensitive than those in rats in their proliferative response to luteinizing hormone (LH), mostly due to physiological and endocrine differences between rats and humans, including the presence of an increased number of LH receptors in rat LCs versus the number in human LCs, and the absence or low expression of

certain receptors on rat LCs versus those in humans.³ The incidences of LC adenomas at the low- and mid-doses were the same as the concurrent control incidence. The incidence was above concurrent controls at the high dose, but this slightly elevated incidence was not statistically significantly different from the control incidence by pair-wise or trend test analysis. Overall, the weight of evidence suggested that the tumours were equivocally related to treatment and that the toxicology reference values selected for the non-cancer risk assessment are protective of any residual concerns regarding the carcinogenic potential of isocycloseram.

4. Comment related to the risk to birds

The commenter stated that the product is designed to kill caterpillars, and therefore will also kill birds that feed on caterpillars containing residues of isocycloseram.

Health Canada response:

Health Canada's science based risk assessment framework for birds is internationally recognized and takes into consideration the consumption of contaminated food sources, including caterpillars. As presented in PRD2026-02, risks to insectivorous and herbivorous birds do not exceed the level of concern. As such, Health Canada determined that the risks to birds from the use of isocycloseram are acceptable when used according to label directions.

5. Comment related to the risk to butterflies and potential impacts on pollinator populations

The commenter stated that the product would kill butterflies and that this would impact pollinator populations.

Health Canada response:

As presented in PRD2026-02, a risk to bees and beneficial arthropods from the use of isocycloseram as an outdoor foliar spray was identified. In order to mitigate the identified risk, mitigation measures are included on the label. Environmental precautionary information indicating the toxicity to bees and beneficial arthropods are required on product labels. In addition, applications to bee-attractive crops must be done at night (when bees are not actively foraging). Spray buffer zones are required for labels of products used outdoors as foliar sprays to reduce impacts downwind from the target area. Health Canada determined that the risks to bees and beneficial arthropods (such as butterflies) from the use of isocycloseram are acceptable when used according to label directions.

³ Cook, J. C., Klinefelter, G. R., Hardisty, J. F., Sharpe, R. M., & Foster, P. M. D. (1999). Rodent Leydig Cell Tumorigenesis: A Review of the Physiology, Pathology, Mechanisms, and Relevance to Humans. *Critical Reviews in Toxicology*, 29(2), 169–261. <https://doi.org/10.1080/10408449991349203>

6. Comment that isocycloseram belongs to the PFAS (per- and polyfluoroalkyl substance) class of chemicals

A commenter stated that isocycloseram is classified as a PFAS chemical and this fact was not included as a consideration in the consultation documents.

Health Canada response:

It is noted that isocycloseram is an active ingredient that falls under the Organisation for Economic Co-operation and Development (OECD) definition of a PFAS,⁴ in that it is a fluorinated substance that contains at least one fully fluorinated methyl or methylene carbon atom (without any hydrogen, chlorine, bromine, or iodine atom attached to it). However, Health Canada has undertaken a thorough and complex scientific risk assessment of this new active ingredient in order to determine whether the risk to human health and the environment is acceptable. The health and environmental effects of an active ingredient in a pest control product are well characterized and form part of the risk assessment. A pest control product would not be registered for use in Canada unless it was determined that there is no unacceptable risk to human health or the environment when the product is used according to label directions.

Comments in support of this registration

The Ontario Fruit & Vegetable Growers' Association expressed support for the registration of isocycloseram, stating that the registration of isocycloseram and associated end-use products provides access to a new mode-of-action foliar insecticide across a range of crops, including tree fruits and cucurbits, which will assist growers with both effective pest control and resistance management. They commented that isocycloseram also expands the range of pests controlled by a foliar application of Insecticide Resistance Action Committee (IRAC) Group 30 products to include mites and stink bugs on some crops, and that stink bugs have been particularly difficult pests to find effective solutions for in recent years.

Other information

The relevant confidential test data on which the decision is based (as referenced in PRD2026-02, *Isocycloseram, A21377 CP, A21708 CP, A22466 CP, EQUENTO RFC and A23294 TO*) 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,⁵ which must be based on scientific grounds, regarding this registration decision on isocycloseram, A21377 CP, A21708 CP, A22466 CP, EQUENTO RFC and A23294 TO within 60 days from the date of publication of this Registration Decision through the Public Engagement Portal (Public Engagement Portal 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

⁴ Organisation for Economic Co-operation and Development (2021), *Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance*, OECD Series on Risk Management of Chemicals, OECD Publishing, Paris, <https://doi.org/10.1787/e458e796-en>.

⁵ As per subsection 35(1) of the *Pest Control Products Act*.

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. 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* 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.

Pre-market assessments are based on a required set of scientific data that must be provided by the applicants for pesticide registrations. Additional information from published scientific reports, other government departments and international regulatory agencies are also considered.⁶

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*.⁷ 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.⁸

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 SPN2008-01.⁹

Assessments estimate potential health risks to defined populations¹⁰ under specific exposure conditions. They are conducted in the context of the proposed or registered conditions of use, such as the use of a pesticide on a particular field crop using specified application rates, methods and equipment. 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.

⁶ Information Note – *Determining Study Acceptability for use in Pesticide Risk Assessments*.

⁷ Guidance Document, *A Framework for Risk Assessment and Risk Management of Pest Control Products*.

⁸ Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks - August 1, 2000.

⁹ Science Policy Note: *The Application of Uncertainty Factors and the Pest Control Products Act Factor in the Human Health Risk Assessment of Pesticides*.

¹⁰ Consideration of Sex and Gender in Pesticide Risk Assessment.

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.

Assessing pesticide performance involves an evaluation of the pesticide's efficacy in controlling the target pest and the potential for the pesticide to damage host crops or use sites. Where the efficacy of a pesticide is acceptable, the assessment serves to establish appropriate label claims and directions and an application rate (or rate range) that is effective without being excessive, and with no unacceptable damage to the use site or host organism/crop (and subsequent hosts or crops) under normal use conditions.

In many cases, proof of performance alone is sufficient to establish the value of the pesticide, so that an in-depth or extensive evaluation of benefits may not be required. However, a more thorough assessment of benefits may be undertaken in particular cases where performance alone does not sufficiently demonstrate value, or while developing risk management options.

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 and frequency of application, 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 registration 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*.

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

List of abbreviations

LC	Leydig cell
LH	Luteinizing hormone
MRL	Maximum residue limit
OECD	Organisation for Economic Co-operation and Development
PFAS	Per- and polyfluoroalkyl substances
PRD	Proposed registration decision