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Special Review Decision

SRD2023-01

Special Review Decision: Picoxystrobin and Its Associated End-use Products

Final Decision Document

(publié aussi en français)

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Special review decision for picoxystrobin and associated end-use products

Under the authority of the *Pest Control Products Act*, pesticides are regulated by Health Canada's Pest Management Regulatory Agency (PMRA) on behalf of the Minister of Health. The *Pest Control Products Act* prescribes both the pre-market and post-market assessment (re-evaluations and special reviews) of pesticides to determine the acceptability or continued acceptability of human health and environmental risks, and, acceptable value of a pesticide in Canada. Unlike a re-evaluation, a special review is triggered only under certain circumstances, as described in section 17 of the *Pest Control Products Act*, and the intent of a special review is to specifically address the identified aspect(s) of concern. The special review approach is described in the [PMRA Guidance Document: Approach to Special Reviews of Pesticides](#). More details on the legislative framework are provided under the section Legislative Framework of this document.

Health Canada evaluates the aspects of concern that prompted the special review in accordance with subsection 18(4) of the *Pest Control Products Act*. The internationally accepted science-based approach is used for the assessment of the aspect(s) of concern, similar to all other scientific assessments (for example, new product registrations, re-evaluations). This step includes both risk (or value, if applicable) assessments and risk management to address the concerns identified. Health Canada's approach to risk and value assessments as well as risk management is outlined in the Framework for Risk Assessment and Risk Management of Pest Control Products.¹

Pursuant to subsection 17(2) of the *Pest Control Products Act*, Health Canada conducted a special review of all registered pest control products containing picoxystrobin, based on the decision made by the European Union in 2017 (Official Journal of the European Union, 2017). The aspects of concern for this special review are relevant to human health and the environment. The identified aspects of concern are:

Human health

- Potential genotoxicity of the metabolite IN-H8612.

Environment

- Potential for risk to aquatic invertebrates exposed to picoxystrobin.
- Potential for risk to earthworms exposed to picoxystrobin.
- Potential for risk to earthworm-eating mammals exposed to the metabolite IN-QDY63.

¹ Canada. Health Canada. PMRA Guidance Document, A Framework for Risk Assessment and Risk Management of Pest Control Products. Ottawa, 2021. (Internet: <https://www.canada.ca/en/healthcanada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policiesguidelines/risk-management-pest-control-products.html>; cited October 2022.)

Picoxystrobin is a fungicide registered for foliar ground or aerial use on canola, dry legumes, cereals, corn, soybeans, potatoes, sunflowers, onions, sugar beets, almonds, alfalfa, grass grown for seed, and peanuts. Picoxystrobin is also registered for seed treatment use on canola, rapeseed, and mustard. All registered pest control products containing picoxystrobin (Appendix I) are considered in the special review.

This document presents the final regulatory decision² for the special review of picoxystrobin. All pest control products containing picoxystrobin that are registered in Canada are subject to this special review decision. Prior to finalizing this decision, Health Canada published the Proposed Special Review Decision PSRD2022-03, *Special Review of Picoxystrobin and Its Associated End-use Products*,³ which underwent a 45-day public consultation period ending on 17 December 2022.

No comments were received during the public consultation period conducted in accordance with section 28 of the *Pest Control Products Act*. Therefore, this decision is consistent with the proposed regulatory decision as described in PSRD2022-03.

Special review decision for picoxystrobin

Health Canada has completed the special review for picoxystrobin. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of products containing picoxystrobin is acceptable. Following an evaluation of the aspects of concern, Health Canada has determined that the use of picoxystrobin continues to be acceptable when used according to label directions.

Next steps

No additional data or mitigation measures are required at this time.

Other information

Any person may file a notice of objection⁴ regarding this decision on picoxystrobin within 60 days from the date of publication of this Special Review 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 PMRA's [Pest Management Information Service](#).

The relevant confidential test data on which the decision is based (as referenced in PSRD2022-03) are available for public inspection, upon application, in PMRA's Reading Room. For more information, please contact the [Pest Management Information Service](#).

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

³ "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*

⁴ "As per subsection 35(1) of the *Pest Control Products Act*

Legislative framework

The Minister of Health's primary objective under the *Pest Control Products Act* (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 conditions of registration can be established to prevent unacceptable risks to human health and the environment.

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. Health Canada's approach to risk and value assessment is outlined in A Framework for Risk Assessment and Risk Management of Pest Control Products.⁵

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

Appendix I Registered products containing picoxystrobin as of 1 March 2023

Registration number	Marketing class	Registrant	Product name	Formulation type	Guarantee %, g/L
30469	Technical Grade Active Ingredient	Corteva Agriscience Canada Company	Onmira Active Fungicide	Solid	98%
31569	Manufacturing Concentrate		Acapela MUP	Suspension	250 g/L
30470	Commercial		Acapela Fungicide	Suspension	250 g/L
31805	Commercial		DPX-YT669 250FS Fungicide Seed Treatment	Suspension	250 g/L
33522	Commercial		Cerefit A Fungicide	Suspension	250 g/L
34528	Commercial		Lumitreo	Suspension	Picoxystrobin 76 g/L; Oxathiapiprolin 230 g/L; Ipconazole 76 g/L
34672	Commercial		Viatude Fungicide	Suspension	Picoxystrobin 187.5 g/L; Prothioconazole 62.5 g/L