



Health
Canada Santé
Canada

Your health and
safety... our priority.

Votre santé et votre
sécurité... notre priorité.

Special Review Decision

SRD2024-02

Fosetyl-aluminum and Its Associated End-use Products

Final Decision Document

(publié aussi en français)

29 August 2024

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2 Constellation Drive
8th floor, A.L. 2608 A
Ottawa, Ontario K1A 0K9

Internet: canada.ca/pesticides
pmra.publications-arla@hc-sc.gc.ca

Information Service:
1-800-267-6315
pmra.info-arla@hc-sc.gc.ca

Canada 

ISSN: 2561-6269 (online)

Catalogue number: H113-17/2024-2E (print version)
H113-17/2024-2E-PDF (PDF version)

© His Majesty the King in Right of Canada, as represented by the Minister of Health Canada, 2024

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of Health Canada, Ottawa, Ontario K1A 0K9.

Table of Contents

Special Review Decision for Fosetyl-Aluminum and Associated End-use Products	1
Special review decision for fosetyl-aluminum	2
Risk mitigation measures.....	2
Implementation of the special review decision	2
Next steps	3
Other information	3
Evaluation approach.....	4
Legislative framework.....	4
List of abbreviations	6
Appendix I Registered products containing fosetyl-aluminum in Canada	7
Table 1 Registered products containing fosetyl-aluminum in Canada requiring label amendments ¹	7
Table 2 Products Containing fosetyl-aluminum that do not require label amendments ¹	7
Appendix II List of commenters to PSRD2023-02.....	8
Appendix III Comments and responses.....	9
Appendix IV Label amendments for products containing fosetyl-aluminum	11
Table 1 Buffer zones.....	11

Special Review Decision for Fosetyl-Aluminum 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 address specifically 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 Legislative Framework Section of this document.

Health Canada evaluates the aspect(s) 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) assessment and risk management to address the concerns identified. Health Canada's approach to risk and value assessment as well as risk management is outlined in the Framework for Risk Assessment and Risk Management of *Pest Control Products*.¹

Fosetyl-aluminum is a systemic fungicide used for the control of various diseases on a wide range of agricultural crops, ornamentals and turf. Fosetyl-aluminum end-use products are formulated as water dispersible or wettable granules, or wettable powder. Products are applied by groundboom field sprayer, airblast sprayer, or as a drench application. All currently registered products containing fosetyl-aluminum have been considered in this special review. Currently registered pest control products containing fosetyl-aluminum are listed in Appendix I.

Pursuant to subsection 17(1) of the *Pest Control Products Act*, Health Canada initiated a special review of all registered pest control products containing fosetyl-aluminum, based on an amphibian metamorphosis assay study submitted through the PMRA's Incident Reporting Program (IRP). The identified aspect of concern is:

- Potential environmental risk to amphibians from exposure to fosetyl-aluminum

This document presents the final regulatory decision² for the special review of fosetyl-aluminum. All pest control products containing fosetyl-aluminum 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 PSRD2023-02, *Proposed Special Review Decision of Fosetyl-*

¹ PMRA Guidance Document, A Framework for Risk Assessment and Risk Management of Pest Control Products

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

aluminum and Its Associated End-use Products,³ which underwent a 45-day public consultation period ending on 29 December 2023. Comments were received from a member of the public however, these comments did not change the outcome of the proposed special review decision presented in PSRD2023-02 (Appendix II and III). Therefore, this decision is consistent with the proposed regulatory decision as described in PSRD2023-02.

A reference list of information used as the basis for the proposed special review decision is included in PSRD2023-02. No further information was provided since the publication PSRD2023-02. Therefore, the complete reference list of all information used in this final special review decision is included in PSRD2023-02.

Special review decision for fosetyl-aluminum

Health Canada has completed the special review for fosetyl-aluminum. Under the authority of the *Pest Control Products Act*, Health Canada has determined that continued registration of fosetyl-aluminum is acceptable with additional risk mitigation measures.

The assessment of the aspect of concern from this special review indicates that potential risks to amphibians (related to the environment) from the use of fosetyl-aluminum are considered to be acceptable provided that risk mitigation measures are implemented, which includes additional label directions and updated spray buffer zones for the protection of freshwater habitats less than one metre deep.

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, as a result of the special review of fosetyl-aluminum, are summarized below. Refer to Appendix IV for details.

Environment

- Updated buffer zones of 1 to 25 m to protect sensitive freshwater habitats less than one metre deep (for the protection of amphibians).
- Updated label directions to prohibit releases, effluent or runoff from greenhouses containing this product to enter lakes, streams, ponds or other waters.

Implementation of the special review decision

Regulatory Directive DIR2018-01, *Policy on Cancellations and Amendments Following Re-evaluation and Special Review* provides general timelines for implementation of post-market decisions (in other words, up to 24-month timeline for label amendments and up to 36-month timeline for cancellation), 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 decision considers potential health and environmental

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

risks regarding the use of the pest control product, and its value, when establishing the implementation timelines.

With respect to fosetyl-aluminum, it is noted that the ecotoxicological effect parameter used in the risk assessment is a concentration at which no adverse effects to amphibians were observed. As such, the likelihood of the effect having an impact at the population level during a 2-year implementation period is considered to be sufficiently low and the risk is considered to be acceptable during the implementation period, when current label mitigations are followed. In addition, evidence from incident reports related to the aspect of concern was considered. There were no incidents related to the aspects of concern in the Canadian incident report database. Taking into consideration these factors, the general 2-year implementation timeline for label amendments for fosetyl-aluminum is considered appropriate.

Amendment timeframe

Based on the above consideration, the required amendments (mitigation measures and label updates) for pest control products containing fosetyl-aluminum must be implemented within 24 months from the 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 label amendments (Appendix IV) must be implemented 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.

Other information

Any person may file a notice of objection⁴ regarding this decision on fosetyl-aluminum 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 Canada.ca (Request a Reconsideration of Decision) or the PMRA's Pest Management Information Service.

The relevant confidential test data on which the decision is based (as referenced in PSRD2023-02) 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.

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

Evaluation approach

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

List of abbreviations

EEC	Estimated Environmental Concentrations
IRP	Incident Reporting Program
PCP#	Pest Control Product Registration Number
PMRA	Pest Management Regulatory Agency
PSRD	Proposed Special Review Decision
SRD	Special Review Decision

Appendix I Registered products containing fosetyl-aluminum in Canada

Table 1 Registered products containing fosetyl-aluminum in Canada requiring label amendments¹

Registration number	Marketing class	Registrant	Product name	Formulation type	Guarantee
24458	Agricultural	Bayer CropScience Inc.	Aliette WDG Systemic Fungicide	Wettable granules	80%
24564	Agricultural	Bayer CropScience Inc.	Aliette Wettable Powder Systemic Fungicide	Wettable powder	80%
27557	Commercial	2022 Environmental Science CA Inc.	Chipco Aliette Ornamental Fungicide	Wettable granules	80%
27688	Agricultural	Bayer CropScience Inc.	Aliette Systemic Fungicide Water Dispersible Granule	Wettable granules	80%
28299	Commercial	2022 Environmental Science CA Inc.	Chipco Aliette Signature Fungicide	Wettable granules	80%
32800	Commercial	2022 Environmental Science CA Inc.	Signature Xtra Stressgard	Wettable granules	60%

¹As of 4 July 2024, excluding discontinued products or products with a submission for discontinuation.

Table 2 Products Containing fosetyl-aluminum that do not require label amendments¹

Registration number	Marketing class	Registrant	Product name	Formulation type	Guarantee
24563	Technical	Bayer CropScience Inc.	Fosetyl-Al Technical	Technical	97%

¹As of 4 July 2024, excluding discontinued products or products with a submission for discontinuation.

Appendix II List of commenters to PSRD2023-02

List of commenters' affiliations for comments submitted in response to PSRD2023-02.

Category	Commenter
General Public	Member of the Public

Appendix III Comments and responses

Health Canada received comments from a member of the public during the public consultation for fosetyl-aluminium proposed special review decision. Comments relating to the special review of fosetyl-aluminum are summarised below along with Health Canada's responses.

1.1 Comment on the practice of testing pesticides on animals

A general comment was received expressing concern with potential animal cruelty involved in the testing of pest control products.

Health Canada response

With respect to animal testing, Health Canada requires information on the potential toxic effects of pesticides to protect human health and the environment from potential risks. Toxicity information typically includes, in part, animal testing data generated by pesticide manufacturers. These studies are conducted according to international testing protocols, which includes requirements to ensure protection of the welfare of laboratory animals.

While animal toxicity testing currently plays a critical role in assessing human health and environmental risks from exposure to pesticides, Health Canada supports the reduction of unnecessary animal testing where scientifically justified. To this end, Health Canada does consider requests from pesticide manufacturers to waive requirements for animal studies or to consider validated non-animal alternatives in hazard assessment whenever possible, provided that the same level of protection of human health or the environment is maintained. For example, Health Canada issued guidance for industry on the waiving of mammalian acute toxicity studies in 2013.

Health Canada is also an active participant in various international activities aimed at reducing animal testing while ensuring the protection of human health and the environment. Continued participation in these activities is important to encourage adoption of alternative approaches to animal testing.

1.2 General comments

General comments were received indicating concerns for frogs, the need to ban this pesticide, any chemical that harms animals, bioaccumulates, and that there is no safe use of pesticides.

Health Canada response

As outlined in the PSRD2023-02, Health Canada assessed the potential environmental risk of fosetyl-aluminum to amphibians, as part of the special review. To assess the effect of fosetyl-aluminum on frogs, Health Canada reviewed the latest information provided to the Pesticide Incident Reporting Program to update the amphibian risk assessment, along with information considered for the previous re-evaluation. Results from the special review show that with the implementation of updated risk mitigation measures which includes specific mitigation in order to protect amphibians, fosetyl-aluminum continues to meet Health Canada's requirements for the protection of the environment. As a result, continued registration of fosetyl-aluminum is granted with additional risk mitigation.

Other general comments are not related to the aspect of concern identified for this special review. However, note that before registering a pest control product, Health Canada thoroughly assesses the risks to human health and the environment, as well as the value of the product. Only products with acceptable health and environmental risks as well as demonstrated value are registered. In addition, Health Canada re-evaluates registered pesticides on a regular basis, to determine whether the use of these registered products continues to be acceptable according to current scientific standards. Furthermore, under certain conditions, Health Canada conducts special reviews to address a specific aspect(s) of concern of a registered pesticide if there are reasonable grounds to believe that the health, environment or value requirements of a pesticide are no longer met. Health Canada's rigorous pre-market assessments, post-market reviews, monitoring and surveillance, including incident reporting, all play an essential role to help ensure the continued acceptability of registered pesticides. The bioaccumulation of fosetyl-aluminum was previously considered as part of the re-evaluation (Proposed Re-evaluation Decision PRVD2017-19, *Fosetyl-aluminum and Its Associated End-use Products*).

Appendix IV **Label amendments for products containing fosetyl-aluminum**

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. They are limited to the additional mitigation measures related to the revised amphibian risk assessment conducted within the special review. Information on labels of currently registered products should not be removed unless it contradicts the label statements below. Furthermore, if the current labelled spray buffer zones for depths < 1 m exceed those calculated here, they should remain on the label.

Under DIRECTIONS FOR USE:

Greenhouse Uses (PCP# 24458, PCP# 24564, PCP# 27557, PCP# 27688):

DO NOT allow releases, effluent or runoff from greenhouses containing this product to enter lakes, streams, ponds or other waters

Spray buffer zones

A spray buffer zone is NOT required for:

- uses with handheld application equipment permitted on this label,
- low-clearance hooded or shielded sprayers that prevent spray contact with crop, fruit or foliage,
- soil drench or soil incorporation.

Table 1 Buffer zones

Method of application	Crop	Spray buffer zones (metres) required for the protection of:
		Freshwater habitat of depths:
		Less than 1 m
Field sprayer	Lettuce, onions, brassica and kohlrabi, rutabaga, broccoli, bok choy, tobacco, outdoor ornamentals (PCP# 24458 – normal use for ornamentals, PCP# 24564)	1
	Spinach, blackberries, raspberries, cranberries, strawberries, ginseng, outdoor ornamentals (PCP# 24458 – special use for ornamentals, PCP# 27557)	2
	Turf (PCP# 27557)	3
	Turf (PCP# 24564, PCP# 28299, PCP# 32800)	4

Method of application	Crop		Spray buffer zones (metres) required for the protection of:
			Freshwater habitat of depths:
			Less than 1 m
Airblast (PCP# 24564, PCP# 27688)	Apples	Early growth stage	20
		Late growth stage	10
	Grapes	Early growth stage	20
		Late growth stage	15
	Highbush blueberries	Early growth stage	25
		Late growth stage	15