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Proposed Special Review Decision

PSRD2023-02

Proposed Special Review Decision of Fosetyl- aluminum and Its Associated End-use Products

Consultation Document

(publié aussi en français)

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Table of Contents

Proposed special review decision for fosetyl-aluminum and associated end-use products	1
Proposed special review decision for fosetyl-aluminum	2
Proposed risk mitigation measures	2
Next steps	2
Other information	2
Evaluation of the aspect of concern that prompted the special review	3
1.0 Assessment of the aspect of concern related to amphibians	3
1.1 Risk assessment for amphibians	3
1.2 Environmental risk assessment conclusions	5
List of abbreviations	6
Appendix I Registered products containing fosetyl-aluminum in Canada	7
Table 1 Registered products containing fosetyl-aluminum in Canada ¹	7
Appendix II Proposed label amendments for products containing Fosetyl-aluminum	8
Table 1 Buffer zones	8
Appendix III Environmental risk assessment of products containing fosetyl-aluminum	10
Table 1 Amphibian risk assessment from spray drift	10
Table 2 Required spray buffer zones for the protection of amphibians	11
Table 3 Amphibian risk assessment from runoff	12
References	13

Proposed 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*.

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

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 a new amphibian metamorphosis assay 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

Pursuant to subsection 18(4) of the *Pest Control Products Act*, Health Canada has evaluated the aspects of concern that prompted the special review of pest control products containing fosetyl-aluminum, which are relevant to the environment.

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.

This proposed special review decision is a consultation document.²

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

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

Health Canada will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information on the cover page of this document).

Proposed special review decision for fosetyl-aluminum

Under the authority of the *Pest Control Products Act* and based on an evaluation of available relevant scientific information related to the aspect of concern, Health Canada is proposing 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 proposed 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.

The proposed additional mitigation measures are summarized below, and details are outlined in Appendix II.

Proposed risk mitigation measures

Environment

Evaluation of available relevant scientific information related to the aspect of concern indicated that the registered uses of fosetyl-aluminum showed acceptable potential risk to amphibians (related to the environment) with implementation of the proposed mitigation measures outlined below and in Appendix II:

- 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.

Next steps

Before making a special review decision on fosetyl-aluminum, Health Canada will consider all comments received from the public in response to this consultation document. A science-based approach will be applied in making a final decision on fosetyl-aluminum. Health Canada will then publish a special review decision document, which will include the decision, the reasons for it, a summary of the comments received on the proposed decision, and Health Canada's response to these comments.

Other information

The relevant confidential test data on which the proposed decision is based (see References section of this document) 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.

Evaluation of the aspect of concern that prompted the special review

Following the initiation of the special review, Health Canada requested information related to the aspect of concern from provinces, territories and other relevant federal government departments and agencies in accordance with subsection 18(2) of the *Pest Control Products Act*. No information was received as part of the above request.

To assess the aspect of concern, Health Canada considered the information that prompted the special review and other information currently available relevant to the aspect of concern, including information considered for the previous re-evaluation of fosetyl-aluminum. There were no incidents related to the aspects of concern in the Canadian incident report database. No additional information was identified from the public literature or from other jurisdictions (for example, European Food Safety Authority, United States Environmental Protection Agency).

1.0 Assessment of the aspect of concern related to amphibians

The aspect of concern for this special review is related to a potential environmental risk to amphibians from exposure to fosetyl-aluminum. The review of an amphibian metamorphosis assay submitted through the IRP resulted in a more sensitive ecotoxicology endpoint (21 day NOEC of 0.097 mg a.i./L) than what was considered in the re-evaluation of fosetyl-aluminum (32 day NOEC of 0.213 mg a.i./L for fish used as surrogate). Therefore, the aquatic amphibian risk assessment was updated based on this new endpoint.

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing estimated environmental concentrations (EECs) with concentrations at which adverse effects occur. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications.

Initially, a screening level risk assessment is performed to identify specific uses that do not pose a risk to non-target organisms. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct overspray application) and the relevant effects metric. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate effects metric, and the risk quotient is then compared to the level of concern (LOC). If the screening level RQ is below the LOC, the risk is considered negligible, and no further risk characterization is necessary. If the screening level RQ is equal to or greater than the LOC, further characterization of the risk is conducted by taking into consideration more realistic exposure scenarios and effects metrics. These considerations may include additional exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods.

1.1 Risk assessment for amphibians

Environmental risks were characterised following exposure from spray drift, overland runoff into a water body, flood water from use on cranberries and risks from greenhouse use.

Spray Drift

The risk to amphibians from spray drift was assessed for all outdoor uses at 1 m downwind from the treated site, taking into consideration the spray drift deposition for an ASAE medium spray quality for groundboom (6%) and for airblast-early season (74%) and airblast-late season (59%) applications. RQs exceeded the LOC for all methods of application and all rates (Appendix III, Table 1):

- For ground boom applied to turf, RQs ranged from 1 to 7.
- For other ground boom applications, RQs ranged from 1.5 to 3.
- For airblast application to apples, grapes and berries, application scenarios are separated into early and late season applications. For early season airblast, the RQs ranged from 20 to 26. For late season application, they ranged from 16 to 20.

For all scenarios which exceeded the LOC, spray buffer zones for the protection of amphibians were calculated.

Based on the new toxicity endpoint for amphibians, spray buffer zones are proposed for all crops:

- 1 to 4 metres for field sprayer
- 20 to 25 meters for airblast sprayer- early season and 10 to 15 meters for airblast sprayer-late season.

See Appendix III, Table 2 for additional details. Potential risks to amphibians from spray drift are considered to be acceptable with the implementation of the proposed spray buffer zones for all uses.

Runoff

Fosetyl-aluminum may be transported in runoff, both as a solute and as bound residues on eroded soil, into adjacent water bodies following a rainfall event. Potential exposure of fosetyl-aluminum to amphibians through runoff was assessed using the EECs from water modelling, as reported in PRVD2017-19.

Amphibian RQs ranged across crops from 0.002 to 0.005, which are all below the LOC (Appendix III, Table 3). Therefore, potential risks to amphibians due to exposure from runoff are acceptable, and no further mitigation is required.

Flood water from cranberry use

Flood water used to harvest cranberries may be assumed to become a habitat for amphibians. As a conservative preliminary assessment, it was assumed that 50% of the applied pesticide was transferred to the flood water from soil, that the flood water was successively used on 10 fields and that it was transferred to a retaining pond, undiluted. It was estimated that approximately five days are required for the flooding and harvesting operations for each field. Four applications with 30-day intervals were considered, at the maximum application rate of 4.4 kg a.i./ha. When estimating expected environmental concentrations, a conservative half-life of one day in soil was considered (in PRVD2017-19, the soil DT₅₀ is indicated as < 1 d). A flood water depth of 60 cm

was used for calculation of the expected water concentration. Based on label instructions, the product cannot be applied within three days of harvest, so the concentration in water was estimated three days after the last application. Based on these conservative parameters, the expected environmental concentration of fosetyl-aluminum in flood water may reach a maximum of 0.08 mg_{a.i.}/L, with a resulting RQ of 0.9, which is below the LOC of 1 for amphibians. It can be concluded that the risk to amphibians from exposure to flood water from cranberry harvest is acceptable.

Greenhouse uses

The aquatic risk assessment for greenhouses is qualitative. Fosetyl-aluminum was shown to cause effects to amphibians at low concentrations. Potential exposure of aquatic habitats through the release of effluent or runoff containing fosetyl-aluminum from greenhouses must be avoided. A label statement prohibiting the release of effluent from greenhouses is required to prevent entry into aquatic waterbodies. With this additional proposed mitigation measure, risk to amphibians from greenhouse uses is considered to be acceptable.

1.2 Environmental risk assessment conclusions

Health Canada has concluded that the environmental risks to amphibians from the use of fosetyl-aluminum are acceptable when the proposed updated buffer zones and label directions are followed.

List of abbreviations

a.i.	Active ingredient
ASAE	American Society of Agricultural Engineers
Cm	Centimetre
D	Day
DT ₅₀	Dissipation time 50, the time required for the concentration to decline to half of the initial value
EEC	Estimated Environmental Concentrations
Ha	Hectare
IRP	Incident Reporting Program
Kg	Kilograms
L	Liters
LOC	Level of Concern
M	Metre
mg	Milligrams
NOEC	No-Observed Effects Concentration
PCP#	Pest Control Product Registration Number
PMRA	Pest Management Regulatory Agency
PRVD	Proposed Re-evaluation Decision
PSRD	Proposed Special Review Decision
RQ	Risk Quotient
RVD	Re-evaluation Decision
SRD	Special Review Decision
WDG	Water Dispersible Granules
WG	Wettable Granules
WP	Wettable Powder

Appendix I Registered products containing fosetyl- aluminum in Canada

Table 1 Registered products containing fosetyl-aluminum in Canada¹

Registration number	Marketing class	Registrant	Product name	Formulation type	Guarantee
24458	Agricultural	Bayer CropScience Inc.	Aliette WDG Systemic Fungicide	WDG	80%
24563	Technical	Bayer CropScience Inc.	Fosetyl-Al Technical	Technical	97%
24564	Agricultural	Bayer CropScience Inc.	Aliette Wettable Powder Systemic Fungicide	WP	80%
27557	Commercial	2022 Environmental Science CA Inc.	Chipco Aliette Ornamental Fungicide	WDG	80%
27688	Agricultural	Bayer CropScience Inc.	Aliette Systemic Fungicide Water Dispersible Granule	WDG	80%
28299	Commercial	2022 Environmental Science CA Inc.	Chipco Aliette Signature Fungicide	WG	80%
32800	Commercial	2022 Environmental Science CA Inc.	Signature Xtra Stressgard	WG	60%

¹ As of 25 August 2023, excluding discontinued products or products with a submission for discontinuation.

Appendix II Proposed label amendments for products containing Fosetyl-aluminum

The proposed 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. 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

Method of application	Crop		Spray Buffer Zones (metres) Required for the Protection of:
			Freshwater Habitat of Depths:
			Less than 1 m
	Turf (PCP# 24564, PCP# 28299, PCP# 32800)		4
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

Appendix III Environmental risk assessment of products containing fosetyl-aluminum

Table 1 Amphibian risk assessment from spray drift

Use pattern	Endpoint (mg a.i./L)	EEC (mg a.i./L)	RQ	LOC exceeded
Apples- early season (3 × 4 kg a.i./ha at 6 weeks interval)	NOEC = 0.097	2.0	20	Yes
Apples- Late season (3 × 4 kg a.i./ha at 6 weeks interval)		1.6	16	Yes
Blackberries, raspberries (4 × 4.4 kg a.i./ha at 21 d interval)		0.2	2	Yes
Cranberries (4 × 4.4 kg a.i./ha at 30 d interval)		0.2	2	Yes
Grapes (7 × 3 kg a.i./ha at 7 d interval)-early season		2.2	23	Yes
Grapes (7 × 3 kg a.i./ha at 7 d interval)-late season		1.8	18	Yes
Lettuce, onions (5 × 2.24 kg a.i./ha at 7 d interval)		0.1	1.4	Yes
Ornamentals (3 × 2.24 kg a.i./ha at 14 d interval)		0.1	1.0	Yes
Ornamentals (4 × 4 kg a.i./ha at 14 d interval)		0.2	2	Yes
Spinach (7 × 3.6 kg a.i./ha at 7 d interval)		0.2	2	Yes
Strawberries (4 × 4.48 kg a.i./ha at 30 d interval)		0.2	2	Yes
Brassica and kohlrabi (including broccoli and bok choy), rutabaga (5 × 2.5 kg a.i./ha at 7 d interval)		0.2	2	Yes
Ginseng (5 × 4.4 kg a.i./ha at 7 d interval)		0.3	3	Yes
Tobacco (4 × 2.6 kg a.i./ha at 7 d interval, 8 kg _{a.i.} /ha total)		0.2	1.5	Yes
Highbush blueberries- early season (4 × 4.48 kg a.i./ha at 14 d interval)		2.5	26	Yes
Highbush blueberries- late season (4 × 4.48 kg a.i./ha at 14 d interval)		2.0	20	Yes
Turf (1 × 16 kg a.i./ha)	0.6	7	Yes	
Turf (4 × 9.6 kg a.i./ha at 14 d interval)	0.4	4.4	Yes	

Use pattern	Endpoint (mg a.i./L)	EEC (mg a.i./L)	RQ	LOC exceeded
Turf (4 × 10.8 kg a.i./ha at 7 d interval, 38.4 kg _{a.i.} /ha total)		0.6	6.6	Yes

Table 2 Required spray buffer zones for the protection of amphibians

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, PCP# 24564)		1
	Spinach, blackberries, raspberries, cranberries, strawberries, ginseng, outdoor ornamentals (PCP# 24458 – special use, PCP# 27557)		2
	Turf (PCP# 27557)		3
	Turf (PCP# 24564, PCP# 28299, PCP# 32800)		4
Airblast	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

Table 3 Amphibian risk assessment from runoff

Use pattern	Endpoint (mg a.i./L)	EEC (mg a.i./L)	RQ	LOC exceeded
Spinach (7 × 3.6 kg a.i./ha at 7 d interval)	NOEC = 0.097	0.00049	0.005	No
Turf (4 × 9.6 kg a.i./ha at 14 d interval)		0.00024	0.002	No

References

List of Studies/Information Submitted by Registrant

PMRA Document Number	Reference
3273719	2021, Fosetyl-Aluminium Technical - Modified Amphibian Metamorphosis Assay with African Clawed Frog (<i>Xenopus laevis</i>), DACO: 9.5.3

Additional Information Considered

Published Information

PMRA Document Number	Reference
2818275	Health Canada Pest Management Regulatory Agency (2017). Proposed Re-evaluation Decision: Fosetyl-Aluminum and Its Associated End-use Products- Consultation Document. H113-27/2017-19E, 110pp.
3005007	Health Canada Pest Management Regulatory Agency (2019). Re-evaluation Decision: Fosetyl-Aluminum and Its Associated End-use Products. H113-28/2019-8E, 49 pp.