Australian Government

Australian Pesticides and Veterinary Medicines Authority

TRADE ADVICE NOTICE

on fluopyram in the product ILeVO Seed Treatment Fungicide for use on canola

APVMA product number 85677

JANUARY 2019

ISBN 978-1-925767-19-3 (electronic)

ISSN 2200-3894 (electronic)

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Director Parliamentary and Communications
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604 Australia

Telephone: +61 2 6210 4701

Email: communications@apvma.gov.au

This publication is available from the APVMA website: www.apvma.gov.au.

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PREFACE

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an independent statutory authority with responsibility for assessing and approving agricultural and veterinary chemical products prior to their sale and use in Australia.

The APVMA has a policy of encouraging openness and transparency in its activities and of seeking stakeholder involvement in decision making. Part of that process is the publication of Trade Advice Notices for all proposed extensions of use for existing products where there may be trade implications.

The information and technical data required by the APVMA to assess the safety of new chemical products and the methods of assessment must be undertaken according to accepted scientific principles. Details are outlined in regulatory guidance published on the APVMA website.

About this document

This is a Trade Advice Notice.

It indicates that the APVMA is considering an application to vary the use of an existing registered agricultural or veterinary chemical. It provides a summary of the APVMA's residue and trade assessment.

Comment is sought from industry groups and stakeholders on the information contained within this document.

Making a submission

The APVMA invites any person to submit a relevant written submission as to whether the application to vary the registration of ILeVO Seed Treatment Fungicide should be granted. Submissions should relate only to matters that the APVMA is required by legislation to take into account in deciding whether to grant the application. These grounds relate to the trade implications of the extended use of the product. Submissions should state the grounds on which they are based. Comments received outside these grounds cannot be considered by the APVMA.

Submissions must be received by the APVMA by close of business on 6 February 2019 and be directed to the contact listed below. All submissions to the APVMA will be acknowledged in writing via email or by post.

Relevant comments will be taken into account by the APVMA in deciding whether to grant the application and in determining appropriate conditions of registration and product labelling.

When making a submission please include:

- contact name
- company or group name (if relevant)
- postal address
- email address (if available)
- the date you made the submission.

All personal and confidential commercial information (CCI)[1] material contained in submissions will be treated confidentially.

Written submissions on the APVMA's proposal to grant the application for registration that relate to the grounds for registration should be addressed in writing to:

Residues and Trade
Scientific Assessment and Chemical Review
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Kingston ACT 2604

Phone: +61 2 6210 4701
Email: enquiries@apvma.gov.au

Further information

Further information can be obtained via the contact details provided above.

Further information on public release summaries can be found on the APVMA website: www.apvma.gov.au

[1] A full definition of 'confidential commercial information' is contained in the Agvet Code.

1 INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Bayer CropScience Pty Ltd, to register ILeVO Seed Treatment Fungicide containing fluopyram for use on canola. The proposed use will be the first use of fluopyram in a broadacre crop in Australia, with current uses being for tree crops only.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Canola seed, oil and meal are considered to be major export commodities[1], as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feeds produced from treated canola. Residues in these commodities resulting from the use of *ILeVO Seed Treatment Fungicide* may have the potential to unduly prejudice trade. However as quantifiable residues of fluopyram are not expected to occur in canola seed, oil or meal or in grain of rotational crops as a result of the proposed use, only animal commodities require further consideration with respect to trade.

2.2 Destination of exports

The significant export markets for Australian beef, sheep, pig meat and offals are listed in the APVMA Regulatory Guidelines—Data Guidelines: Agricultural—overseas trade (Part 5B).

2.3 Proposed Australian use-pattern

ILeVO Seed Treatment Fungicide (380 g/L Fluopyram)

CROP	DISEASE	RATE	CRITICAL COMMENTS
Canola	Blackleg (*Leptosphaeria maculans*) (Suppression)	800 mL/100 kg of seed (304 g ai/100 kg of seed)	Apply with a seed treatment applicator designed for liquid seed treatments. Apply ILeVO undiluted or mixed with sufficient water to give even coverage of seed. ILeVO will reduce blackleg infection on the cotyledons and early leaves and will reduce lodging and stem infection later in the season. DO NOT use on dual purpose canola that may be grazed by livestock producing milk for human consumption.

Withholding periods:
Harvest: Not required when used as directed.
Grazing: Livestock not producing milk for human consumption:
DO NOT graze crops grown from treated seed, or cut for stock food within 6 weeks of sowing.
Livestock producing milk for human consumption:

[1] APVMA Regulatory Guidelines–Data Guidelines: Agricultural–overseas trade (Part 5B)

DO NOT graze crops grown from treated seed before harvest, or feed forage or hay grown from treated seed.

Export Slaughter Interval (ESI) – 5 weeks

Livestock that have been grazing on crops grown from treated seed prior to crop harvest, or have been fed hay, haylage or silage from crops grown with treated seed, should be placed on clean feed for 5 weeks prior to export slaughter.

Protection of Livestock

Seed treated with this product must not be used for animal consumption or poultry feed or mixed with animal feed. DO NOT allow seed treated with this product to contaminate seed intended for animal consumption.

2.4 Results from residues trials presented to the APVMA

Canola grain

Seven GLP trials conducted in Australia were considered. Residues of fluopyram in canola grain at harvest after a seed treatment at 336 g ai/100 kg seed (1.1× proposed) were <0.01 mg/kg (n = 7). Residues in grain were also <0.01 mg/kg (n = 7) after seed treatment at 504 g ai/100 kg seed (1.7× proposed). An MRL of *0.01 mg/kg for fluopyram on SO 0495 Rape seed [canola seed] is considered appropriate.

Canola forage and fodder

Residues of fluopyram in canola forage approximately 6 weeks or more after a seed treatment at 336 g ai/100 kg seed (1.1× proposed) were 0.35, 0.41, 0.66, 0.81, 0.82, 0.89, 1.1 and 1.7 mg/kg on a dry weight basis. The OECD MRL calculator recommends an MRL of 3 mg/kg. The HR is 1.7 mg/kg, the STMR is 0.82 mg/kg. An MRL of 3 mg/kg for fluopyram on Canola forage (green) is considered appropriate.

Residues of fluopyram in canola fodder at harvest after a seed treatment at 336 g ai/100 kg seed (1.1× proposed) were <0.01 (n = 6) and 0.02 mg/kg (dry weight). The OECD MRL calculator recommends an MRL of 0.03 mg/kg. An MRL of 0.03 mg/kg for fluopyram on Canola fodder (dry) is considered appropriate.

Canola oil and meal

Quantifiable residues of fluopyram are not expected to occur in canola seed. A canola processing study also showed fluopyram residues do not concentrate on processing to oil or meal. It is not necessary to establish a separate MRL for fluopyram on canola oil or meal.

Rotational crops

Data was provided from 46 sites in overseas studies where residues in the plant material of various rotational crops were determined; the highest residue was 1.2 mg/kg dry weight in wheat forage grown after a soybean crop which had been undergone seed treatment at 82.4 g ai/ha. Scaled for the maximum proposed application rate for seed treatment to canola of 15.2 g ai/ha (assuming a seeding rate of 5 kg/ha), highest residues of fluopyram in plant material from the 46 sites were ≤0.03 mg/kg (n=35), 0.04, 0.06 (n=2), 0.07, 0.08, 0.10 (n=2), 0.12 (n=2), 0.14 and 0.22 mg/kg on a dry weight basis. The estimated HR in forage from the following crop is 0.22 mg/kg dry weight.

An MRL of 0.3 mg/kg is appropriate for fluopyram on Primary feed commodities [except Canola fodder (dry) and Canola forage (green)] to cover residues in the forage/fodder of following crops.

Residues were not observed in the grain of the following crops after seed treatment of a primary soybean crop.

Animal commodities

Canola forage and canola meal are feeds for cattle in Australia. Almond hulls and apple pomace may also contain fluopyram from registered uses. The estimated livestock dietary burden was calculated to be 2 ppm for beef cattle and 0.58 ppm for dairy cattle using the OECD Feed Calculator. The calculations assume that dairy cattle will not graze treated canola plant material until after harvest.

Predicted residues in tissues and milk (enforcement definition) and required MRL changes are summarised below:

Cattle

FEEDING LEVEL (PPM)	MILK	MUSCLE	FAT	LIVER	KIDNEY
	FLUOPYRAM + BENZAMIDE RESIDUE (mg/kg)				
14.4 (1.5 milk)	0.03	0.45	0.37	2.25	0.39
2.0 – beef, estimated burden	-	0.063	0.051	0.31	0.054
0.58 – dairy, estimated burden	0.012	-	-	-	-
Established MRLs	*0.02 (milks)	*0.02 (meat)	-	0.2 (offal)	
Recommended MRLs	No change	0.1	-	0.5	

Poultry

Although residues are not expected to occur in seed/meal from the proposed use it is proposed to establish poultry commodity MRLs at the LOQ for the method to recognise that canola meal may be fed to poultry.

2.5 Overseas registration and approved label instructions

The applicant indicated that fluopyram products are registered for use on canola in several countries as a foliar spray, but not as a seed treatment.

2.6 Codex alimentarius commission and overseas MRLs

The Codex Alimentarius Commission (Codex) is responsible for establishing Codex Maximum Residue Limits (CXLs) for pesticides. Codex CXLs are primarily intended to facilitate international trade, and accommodate differences in Good Agricultural Practice (GAP) employed by various countries. Some countries may accept Codex CXLs when importing foods. Fluopyram has been considered by Codex. The following relevant Codex CXLs and overseas MRLs have been established for fluopyram:

Current and proposed Australian and overseas MRLs/tolerances for fluopyram in animal commodities

COMMODITY	TOLERANCE FOR RESIDUES ARISING FROM THE USE OF FLUOPYRAM (mg/kg)					
	AUSTRALIA	CANADA	EU	JAPAN	CODEX	USA
Animal Commodities Compliance Residue Definition - Sum of fluopyram and 2-(trifluoromethyl) benzamide, expressed as fluopyram						
Bovine kidney			0.8	0.8	0.8	
Edible offal (Mammalian)	0.2 (current) 0.5 (proposed)	10 (meat by products of cattle)				7.5 (cattle meat byproducts)
Bovine liver			5	5	5	
Meat (mammalian)	*0.02 (current) 0.1 (proposed)	1.5 (meat of cattle)	0.8 (bovine muscle)	0.8 (cattle muscle)	0.8	0.80 (cattle meat)
Milks	*0.02	2	0.6	0.6	0.6	0.40

Animal commodity MRLs for fluopyram have not been established by China, Taiwan or Korea (although Korea appears to have a milk MRL established at 0.3 mg/kg; Taiwan has notified the WTO that they will establish MRLs at 0.1 mg/kg for livestock muscle, 0.7 mg/kg for livestock edible offal, 0.1 mg/kg for fat (cattle, goat, sheep) and 0.1 mg/kg for milk). Bayer have also indicated that China has published draft MRLs for fluopyram in animal matrices which were open for comment until 30 November 2018. They are due to be included in the new Chinese MRL regulation GB 2763/2018 which is overdue. Bayer indicated that the proposal includes temporary limits for Mammal meat (except marine mammals) and Mammal fat (except milk fat) both at 1.5 mg/kg.

2.7 Current and proposed Australian MRLs for fluopyram

Current MRL Standard – Table 1

COMPOUND		FOOD	MRL (mg/kg)
Fluopyram			
MO	0105	Edible offal (Mammalian)	0.2
MM	0095	Meat (mammalian)	*0.02
ML	0106	Milks	*0.02
SO	0495	Rape seed [canola seed]	T*0.01

Proposed MRL Standard – Table 1

COMPOUND		FOOD	MRL (mg/kg)
Fluopyram			
DELETE:			
MO	0105	Edible offal (Mammalian)	0.2
MM	0095	Meat (mammalian)	*0.02
SO	0495	Rape seed [canola seed]	T*0.01
ADD:			
MO	0105	Edible offal (Mammalian)	0.5
PE	0112	Eggs	*0.02
MM	0095	Meat (mammalian)	0.1
PO	0111	Poultry, Edible offal of	*0.02
PM	0110	Poultry meat	*0.02
SO	0495	Rape seed [canola seed]	*0.01

Proposed MRL Standard – Table 4

COMPOUND	ANIMAL FEED COMMODITY	MRL (mg/kg)
Fluopyram		
DELETE:		
	Canola forage (green)	T2
	Canola fodder (dry)	T0.05
ADD:		
	Canola fodder (dry)	0.03
	Canola forage (green)	3
	Primary feed commodities [except Canola fodder (dry) and Canola forage (green)]	0.3

2.8 Potential risk to trade

Export of treated produce containing finite (measurable) residues of fluopyram may pose a risk to Australian trade in situations where (i) no residue tolerance (import tolerance) is established in the importing country or (ii) where residues in Australian produce are likely to exceed a residue tolerance (import tolerance) established in the importing country.

While an increase has been proposed to the fluopyram offal and meat MRLs, appropriate MRLs are established in most markets, including Codex MRLs. However, as MRLs are in the process of being established in China and Taiwan and are not established in Korea, an Export Slaughter Interval (ESI) is considered below.

Livestock feeding on primary crops

A 5 week ESI is proposed to manage the risk to trade in animal commodities from livestock that have been fed on the primary crop.

In the depuration phase of the dairy cattle transfer study residues of parent were below the LOQ (0.01 mg/kg) in all tissues after 14 days on clean feed when the animals had been dosed initially at 145.9 ppm. A 5 week ESI should therefore ensure residues of parent are below detectable limits.

The average half-life of the benzamide metabolite in liver (the tissue with the highest residue) was 7.6 days. The highest benzamide residue observed in liver in the transfer study from dosing at 14.4 ppm was 1.9 mg/kg. Scaled for a burden of 2 ppm, the estimated benzamide residue in liver is 0.26 mg/kg. It would take 35.7 days for a residue of 0.26 mg/kg in liver to decline to 0.01 mg/kg based on a half-life of 7.6 days. A 5 week ESI will ensure benzamide residues in liver of livestock consuming treated crops will decline below the method LOQ.

Livestock feeding on rotational crops

An ESI cannot be readily applied to following crops which have not been directly treated. The highest estimated residue in the forage of a following crop in overseas trials involving seed treatment of a primary crop was 0.22 mg/kg dry weight. In a fluopyram dairy cattle transfer study dosing at 1.5 ppm gave a maximum residue in liver of 0.26 mg/kg parent and 0.10 mg/kg benzamide metabolite (in parent equivalents). The estimated residues in liver from dosing at 0.22 ppm would be 0.038 mg/kg parent and 0.0147 mg/kg benzamide metabolite. Estimated residues in other tissues would be <0.01 mg/kg, with the HR for benzamide in milk 0.013 mg/kg (based on one outlier result of 0.09 mg/kg benzamide in milk after dosing at 1.5 ppm, all other results were ≤0.03 mg/kg for a 1.5 ppm feeding level).

The approximate half-life for parent in liver is 1.2 days, while the average half-life for benzamide in liver is estimated at 7.6 days. It would take approximately 2 days for parent and 4 days for benzamide residues in liver to decline to 0.01 mg/kg. It is considered that the risk to trade in animal commodities from feeding on rotational crops is low, noting also that appropriate offal MRLs are established in most markets, including by Codex.

3 CONCLUSIONS

Bayer CropScience Pty Ltd have applied to register ILeVO Seed Treatment Fungicide containing fluopyram for use on canola. This would require an increase to the current animal commodity MRLs for fluopyram.

Comment is sought on the potential for ILeVO Seed Treatment Fungicide to prejudice Australian trade when used on canola as a seed treatment according to the proposed label directions.