Australian Government

Australian Pesticides and Veterinary Medicines Authority

Trade Advice Notice

on cyantraniliprole in the product Exirel Insecticide for use on forage brassicas

APVMA product number 64103

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This publication is available from the APVMA website.

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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 Trade Advice Notice indicates that the Australian Pesticides and Veterinary Medicines Authority (APVMA) is considering an application to vary the use of an existing registered agricultural 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 Exirel Insecticide 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 31 August 2021 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 organisation name (if relevant)
- email or postal address (if available)

- the date you made the submission.

Please note: submissions will be published on the APVMA's website, unless you have asked for the submission to remain confidential, or if the APVMA chooses at its discretion not to publish any submissions received (refer to the public consultation coversheet).

Please lodge your submission using the public consultation coversheet, which provides options for how your submission will be published.

Note that all APVMA documents are subject to the access provisions of the *Freedom of Information Act 1982* and may be required to be released under that Act should a request for access be made.

Unless you request for your submission to remain confidential, the APVMA may release your submission to the applicant for comment.

Written submissions should be addressed to:

Executive Director, Risk Assessment Capability
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Phone: +61 2 6770 2300
Email: enquiries@apvma.gov.au

Further information

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

Further information on Trade Advice Notices can be found on the APVMA website: apvma.gov.au.

Introduction

The APVMA has before it an application from FMC Australasia Pty Ltd to vary the registration of Exirel Insecticide containing cyantraniliprole to include a new use pattern for the control of sucking and chewing insects in forage brassicas (including kale, forage rape, swede and turnips). The proposed primary crops are not significant export commodities according to the APVMA Regulatory Guidelines – Data Guidelines: Agricultural - Overseas trade (Part 5B).

Livestock commodities are major export commodities. As the use is proposed on forage crops, which may be consumed by livestock, the potential for the proposed use to result in residues in animal commodities will be discussed in this Trade Advice Notice.

Trade considerations

Commodities exported

Forage brassicas are not considered major export commodities; however, commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feeds produced from treated forage brassicas, should be taken into consideration. Residues in these commodities resulting from the use of cyantraniliprole may have the potential to unduly prejudice trade.

Destination and value of exports

The significant export markets for Australian beef, sheep, pig meats and offal are listed in the APVMA Regulatory Guidelines – Data Guidelines: Agricultural - Overseas trade (Part 5B). It is noted that while Russia is currently listed in APVMA guidance as a major export destination for cattle and sheep meat, contemporary export figures reveal that Russia has not been a significant export market in recent years. The contemporary export statistics for cattle and sheep meat and offal, and dairy, are summarised below.

Cattle, sheep meat and offal

In 2019–20, Australia exported 1,290 kt of beef and veal (worth $11.26 billion)[1]. Significant export markets for Australian beef and veal include China, Japan, the United States, the Republic of Korea and Indonesia.

In 2019–20, Australia exported 620 kt of lamb (worth $6b), 391 kt of mutton (worth $2.9 billion) and 3,157 kt of live sheep (worth $449 million)[2]. The significant export markets for sheep commodities include China, the Middle East and the United States.

Dairy

The total value of Australian dairy exports in 2019–20 was $3.39 billion[3]. The major export markets for Australian dairy products, including butter and butterfat, cheese, milk, milk powder and other dairy products in 2019–20 are presented in Table 1.

[1] ABARES (2020), Rural commodities – meat – beef and veal, accessed 27 July 2021

[2] ABARES (2020), Rural commodities – meat - sheep, accessed 27 July 2021

[3] ABARES (2020),Rural commodities – dairy products, accessed 27 July 2021

Table 1: Major export markets for Australian dairy products

Country	Greater China*	Japan	Singapore	Indonesia	Malaysia	Philippines	Thailand	New Zealand
Volume (tonnes)	75,990	76,626	15,352	24,698	11,890	14,464	11,241	3,749
	25%	25%	5%	8%	4%	5%	4%	1%
Value (A$ million)	471	458	91	106	83	70	50	26
	26%	26%	5%	6%	5%	4%	3%	1%

* Includes China and Hong Kong

Proposed Australian use pattern

The following use pattern in Table 2 is being considered by the APVMA.

Table 2: Proposed use pattern – Exirel Insecticide (100 g a.i./L cyantraniliprole)

Crop	Pest	Rate/concentration	Critical comments
Forage brassicas	Cabbage white butterfly *(Pieris rapae)*Centre grub *(Hellula hydralis)* Diamondback moth *(Plutella xylostella)*Native budworm *(Helicoverpa punctigera)* Soybean looper *(Thysanoplusia orichalcea)*	150 mL (15 g a.i/ha) + ethylated seed oil or non-ionic surfactant (refer Surfactant/Wetting agent section)	Regularly scout crops to monitor for eggs and larvae. Apply when insects or damage first appear and before a build-up of pest numbers. Entrenched larvae may not be controlled.
	Grey cabbage aphid *(Brevicoryne brassicae)* – suppression only		Apply when aphids first appear before a build-up of pest numbers – not a salvage option. A maximum of 2 applications are to be applied to any one crop per season. Further treatments should be made with alternative mode of action insecticides.

Withholding periods:

Grazing: DO NOT graze or cut for stock food for 14 days after application.

Trade advice information:

LIVESTOCK DESTINED FOR EXPORT MARKETS

The grazing withholding period only applies to stock slaughtered for the domestic market. Some export markets apply different standards. To meet these standards, ensure that in addition to complying with the grazing withholding period, the export slaughter interval is observed before stock are sold or slaughtered.

EXPORT SLAUGHTER INTERVAL (ESI) 2 DAYS

Livestock that has grazed on or been fed treated crops should be placed on clean feed for 2 days prior to slaughter.

Results from residues trials presented to the APVMA

The applicant provided full details of 3 Australian and 7 New Zealand trials pertaining to forage brassicas [rape (5), turnip (3) and kale (2)] with the current application. For all studies cyantraniliprole was applied at the nominal rates of 150 mL/ha (15 g ai/ha, 1× proposed rate) or 300 mL/ha (30 g ai/ha, 2× proposed rate). The product was applied one to 4 times with 12 to 26 days between treatment intervals. Samples were taken at 0, 14 ± 1, 28, and either 49 or 56 days after the last application, depending on the trial. Residues of the metabolite IN-J9Z38-002 were below LOQ (<0.01 mg/kg) in all samples.

Based on the available data for forage brassicas, the combined dataset for cyantraniliprole residues in forage brassicas (dry weight basis) at the proposed 14 day grazing WHP for MRL estimation is, in rank order; 0.207, 0.29, 0.31, 0.372, 0.38, 0.404, 0.58, 1.12, 1.23, 1.64 mg/kg (STMR = 0.392 mg/kg, n = 10). The OECD MRL calculator estimates an MRL of 3 mg/kg. A cyantraniliprole MRL of 3 mg/kg for brassica forage crops is recommend.

Animal commodities

The expected maximum livestock dietary burden for cattle will be as a result of the consumption of forage brassicas at 100% of the diet for beef cattle and 40% for dairy (OECD feed calculator) with a parent HR of 1.6 ppm. The maximum livestock dietary exposure to parent for compliance with MRLs is therefore 1.6 ppm for beef cattle and 0.7 ppm for dairy cattle from feeding on brassica forage. Estimated residues of parent in tissues and milk based on extrapolation from residues observed in the transfer study after dosing at 3 ppm are calculated below in Table 3.

Table 3: Cattle MRL estimation

Feeding level (ppm)	Milk	Milk fats	Muscle	Liver	Kidney	Fat
	Cyantraniliprole residue (mg/kg)					
3†	0.030	0.072	0.011	0.066	0.031	0.015
1.6 – estimated burden (beef)	--	--	0.006	0.035	0.017	0.008
0.7 – estimated burden (dairy)	0.007	0.042	0.003	0.015	0.007	0.004
Established MRLs	*0.01	*0.01	--	*0.01 (offal)		*0.01 (meat in the fat)
Recommended MRLs	No change	**0.07**	No change		**0.05**	No change

† For tissues, highest residues from lactating cows dosed with cyantraniliprole at 3 ppm for 28 days. For milk, average residues from lactating cows dosed with cyantraniliprole at 3 ppm for 28 days.

Codex Alimentarius Commission and overseas MRLs

The Codex Alimentarius Commission (Codex) is responsible for establishing Codex Maximum Residue Limits (CXLs) for pesticides and veterinary medicines. 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. Cyantraniliprole has been considered by Codex. The following relevant Codex CXLs and overseas MRLs in Table 4 have been established for cyantraniliprole.

Table 4: International MRLs for cyantraniliprole

Commodity	Tolerance for residues arising from the use of Cyantraniliprole (mg/kg)						
	Australia	EU	Japan	Codex	Korea	Taiwan	USA
Residue definition	Cyantraniliprole (for enforcement)	Cyantraniliprole	Cyantraniliprole	Cyantraniliprole	--	--	Cyantraniliprole
Edible offal (mammalian)	0.05 (proposed)	1.5	2	1.5	--	--	0.4
Mammalian fats (except milk fats)	*0.01(meat (mammalian) [in the fat]	0.5	0.5	0.5 (mammalian fats except milk fats)	--	--	0.1
Meat (from mammals other than marine mammals)	*0.01	0.2	0.2	0.2	--	--	0.1
Milks	*0.01	0.02	0.6	0.6	--	--	0.2
Milk fats	0.07 (proposed)	--	--	--	--	--	--

Current and proposed Australian MRLs for cyantraniliprole

Table 5: Current MRL Standard – Table 1

Compound		Food	MRL (mg/kg)
Cyantraniliprole			
		All other foods	0.05
SO	0691	Cotton seed	*0.01
MO	0105	Edible offal (mammalian)	*0.01
PE	0112	Eggs	*0.01
MM	0095	Meat (mammalian) [in the fat]	*0.01
FM	0183	Milk fats	*0.01
ML	0106	Milks	*0.01
PM	0110	Poultry meat [in the fat]	*0.01
PO	0111	Poultry, edible offal of	*0.01

Table 6: Proposed MRL Standard – Table 1

Compound		Food	MRL (mg/kg)
Cyantraniliprole			
Delete:			
MO	0105	Edible offal (mammalian)	*0.01
FM	0183	Milk fats	*0.01
Add:			
MO	0105	Edible offal (mammalian)	0.05
FM	0183	Milk fats	0.07

Table 7: Current MRL Standard – Table 4

Compound		Food	MRL (mg/kg)
Cyantraniliprole			
		All other foods	0.05
SO	0691	Cotton seed	*0.01
MO	0105	Edible offal (mammalian)	*0.01
PE	0112	Eggs	*0.01
MM	0095	Meat (mammalian) [in the fat]	*0.01
FM	0183	Milk fats	*0.01
ML	0106	Milks	*0.01
PM	0110	Poultry meat [in the fat]	*0.01
PO	0111	Poultry, edible offal of	*0.01

Table 8: Proposed MRL Standard – Table 4

Compound	Food	MRL (mg/kg)
Cyantraniliprole		
Delete:		
	Primary feed commodities {except Legume animal feeds}	1
Add:		
	Brassica forage crops (kale; rape; swede; turnips)	3
	Primary feed commodities {except Brassica forage crops (kale; rape; swede; turnips); Legume animal feeds}	1

Potential risk to trade

Export of treated animal commodities containing finite (measurable) residues of cyantraniliprole 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.

Finite residues of cyantraniliprole are expected in offal (liver and kidney) and milk fats following livestock consumption of forage brassicas treated with the proposed use. While overseas tolerances for cyantraniliprole have been established in many major markets, they have not yet been established in Taiwan. A potential risk to trade in animal commodities derived from livestock fed treated crops could occur. In addition, animal commodity MRLs for cyantraniliprole have not been established by the Republic of Korea, however the Republic of Korea currently may accept Codex MRLs but this may change in the future as they implement their Positive List System.

For tissues, liver tissue showed the greatest residue potential. Residue depletion data from the cattle feeding study was used to calculate a cyantraniliprole half-life. Using a liver concentration of 1.7 mg/kg on day 29 and 0.063 mg/kg on day 32, a half-life of 0.63 days for cyantraniliprole in liver tissue was derived. An export slaughter interval (ESI) can manage this potential risk to trade and the LOQ (0.01 mg/kg) is considered to be a suitable ESI endpoint and it is estimated that residues will decline from 0.035 mg/kg to 0.01 mg/kg in 2 days. A 2 day ESI is recommended to ensure that there are no quantifiable residues in animal commodities for export.

For milk fats, the proposed MRL is 0.07 mg/kg; however, a potential risk to trade may be present for markets without established cyantraniliprole MRLs.

Conclusion

FMC Australasia Pty Ltd has applied to vary the registration of Exirel Insecticide (containing cyantraniliprole) to include a new use pattern for the control of sucking and chewing insects in forage brassicas. Finite residues of cyantraniliprole are expected in offal (liver and kidney) and milk fats following livestock consumption of forage brassicas treated with the proposed use.

Comment is sought on the potential risk to Australian trade if Exirel Insecticide is used on selected forage brassicas as proposed.