



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**



Trade Advice Notice

on cyantraniliprole in the product Exirel Insecticide for use on canola

APVMA product number 64103

February 2023

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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 APVMA is considering an application to vary the use of an existing registered agricultural chemical.

It provides a summary of the APVMA's Residues 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 Wednesday 22 March 2023 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](#).

Introduction

The APVMA has before it an application from FMC Australasia Pty Ltd to vary the registration of Exirel Insecticide to add uses on canola. Exirel Insecticide contains cyantraniliprole as its only active constituent. Although there is currently a temporary Maximum Residue Limit (MRL) of 0.03 mg/kg for cyantraniliprole on SO 0495 Rape seed [canola] in Table 1 of the APVMA MRL Standard associated with a research permit, this will be the first registration of uses of cyantraniliprole on canola in Australia.

Exirel Insecticide is currently registered for use on forage brassicas, including rape forage crops, at the same rate and grazing withholding period as proposed for canola but with 2 applications allowed per season compared to one application per season proposed for canola.

Trade considerations

Commodities exported

Oilseeds, including canola seed, derived oils and meals are considered major export commodities¹, 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 Exirel Insecticide on canola may have the potential to unduly prejudice trade.

The maximum livestock dietary burden is unchanged and the proposed Export Slaughter Interval ESI is consistent with that for the current label use on forage brassicas and will ensure there will be no quantifiable residues in animal tissues for export. The risk to trade in animal commodities for export is unchanged and does not require further consideration at this time.

Destination and value of exports

Australia exported 5,172 kt tonnes of canola, 187 kt canola oil and 7.0 kt oilseed meal in the fiscal year 2021 (Australian Bureau of Agricultural and Resource Economics and Sciences ABARES, Agricultural Commodity Statistics).² Major export destinations were China, Germany, France, The Netherlands, Belgium, Japan, Bangladesh and Pakistan.

Proposed Australian use pattern

Exirel Insecticide (100 g/L cyantraniliprole)

Table 1: Proposed use pattern

Crop	Pest	Rate/concentration	Critical comments
Canola	Diamondback moth (<i>Plutella xylostella</i>)	150 mL plus ethylated seed oil (refer to surfactant/wetting agent section) (15 g ai/ha)	Target 1st – 3rd instar larvae when they reach the economic spray threshold and before they become entrenched in pods.
	Native budworm (<i>Helicoverpa punctigera</i>)		
	Grey cabbage aphid (<i>Brevicoryne brassicae</i>) – suppression only		
	Turnip aphid (<i>Lipaphis erysimi</i>) – suppression only		A maximum of one application is to be applied to any one crop per season. Further treatments should be made with alternative mode of action insecticides.

¹ Australian Pesticides and Veterinary Medicines Authority, [APVMA Regulatory Guidelines – Data Guidelines: Agricultural – Overseas trade \(Part 5B\)](#), APVMA website, 20 July 2020, accessed January 2023.

² Australian Bureau of Agricultural and Resource Economics and Sciences, [Agricultural commodities and trade data](#), accessed January 2023

Withholding periods

Harvest

Do not harvest for 21 days after application.

Grazing

Do not graze or cut for stock food for 14 days after application.

Trade advice

Export of treated produce

Suitable MRLs or import tolerances for produce treated with Exirel insecticide may not be established in some countries. Consult with your exporter or FMC before applying Exirel insecticide to crops from which produce is to be exported.

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 proposed use of cyantraniliprole on canola is for a single foliar application at 15 g ai/ha in conjunction with a harvest withholding period of 21 days and grazing withholding period of 14 days. Seven relevant Australian residue trials conducted under Good Laboratory Practice (GLP) on canola (for seed, oil, and stubble) have been provided along with 3 relevant Australian GLP residue trials for canola forage and 2 non-GLP New Zealand residue trials on forage rape.

Canola forage

Residues of cyantraniliprole in canola forage at 14 days after a single application at approximately 15 g ai/ha (1x proposed) were 0.21, 0.37 and 0.40 mg/kg on a dry weight basis. Residues in forage rape from New Zealand trials at 14 days after the last of 3 applications at 15 g ai/ha (1x proposed per application) were 0.29 and 1.2 mg/kg. Based on the Australian dataset the Organisation for Economic Cooperation and Development (OECD) MRL Calculator recommends an MRL of 1 mg/kg (STMR= 0.37 mg/kg, n= 3), noting a high uncertainty due to the small dataset. Based on the full dataset, including the New Zealand forage rape trials involving multiple applications the OECD MRL calculator recommends an MRL of 3 mg/kg (Supervised Trial Median Residue (STMR) 0.37 mg/kg, n= 5), noting a high uncertainty due to the small dataset. The cyantraniliprole Primary feed commodities {except Brassica forage crops (kale, rape, swede, turnips); Legume animal feeds} at 1 mg/kg should cover residues from the proposed use noting also that an MRL of 3 mg/kg is established for cyantraniliprole on Brassica forage crops (kale, rape, swede, turnips) which includes rape grown specifically as a forage crop (as currently registered for Exirel).

Canola seed

Residues of cyantraniliprole in canola seed at 14 to 15 days (or later if residues increased) after application at approximately 15 g ai/ha (1x proposed) from trials conducted in 2021 and 2009 were <0.003, <0.003 and 0.01 mg/kg. Two of these 3 trials involved application of a desiccant at 6 days prior to harvest. In further trials (from 2021, 2017 and 2009) sampling at 19 to 23 days after application (or 5 to 9 days after desiccation) at approximately 15 g ai/ha (1x proposed) residues were <0.003, <0.003, <0.01 and 0.01 mg/kg. All of these trials involved application of a desiccant prior to harvest.

Chemical desiccation is an alternative to windrowing and very effective where crops have lodged or where weeds have emerged in maturing crops. The most commonly used desiccant is diquat (Reglone®), which is registered for aerial application to canola crops.³

Application of a desiccant would be expected to kill the plant and stop metabolism of the active ingredient. The trials involving application of a desiccant should therefore be expected to be the worst case for residues. This may also reflect normal agricultural practices where canola is typically desiccated prior to harvest. It is noted that a withholding period is defined as the minimum period between the last use of the product and the harvesting or cutting of the crop.⁴ The use of an additional chemical to desiccate the crop is not clearly

³Grains Research & Development Corporation, [GRDC Grownotes: Canola – Section 11, Crop Desiccation/Spray out](#), GRDC website, accessed January 2023

⁴Australian Pesticides and Veterinary Medicines Authority, [Agricultural data guidelines – Withholding periods \(residues\)](#), APVMA website, 13 January 2013, accessed January 2023

defined in relation to the withholding period required for the initial pesticide product but it would be considered prudent to consider the withholding period as the interval between the last treatment of the pesticide and desiccation as a worst case given that the desiccant is expected kill the plant and stop metabolism of the active ingredient.

Based on all the data points for canola seed (<0.01 (5), 0.01 and 0.01 mg/kg) the OECD MRL calculator recommends an MRL of 0.02 mg/kg (STMR= 0.01 mg/kg, n= 7) noting a high uncertainty due to the small dataset and high level of censoring (i.e. results <LOQ, Limit of Quantitation). An MRL of 0.03 mg/kg will be recommended for cyantraniliprole on SO 0495 Rape seed [canola] to cover the proposed use, replacing the current temporary MRL at the same level. As there were only 3 data points around 14 days after application, the supported harvest withholding period is 21 days.

Canola oil

Residues of cyantraniliprole in canola oil at 14 to 15 days (or later if residues increased) after application at approximately 15 g ai/ha (1x proposed) were <0.003, <0.003 and 0.01 mg/kg. Two of these 3 trials involved application of a desiccant prior to harvest. In further trials sampling at 19 to 23 days after application at approximately 15 g ai/ha (1x proposed) residues were <0.003, <0.01, 0.02 and 0.02 mg/kg. All of these trials involved application of a desiccant prior to harvest. Based on all the data points (<0.01 (4), 0.01, 0.02 and 0.02 mg/kg) the OECD MRL calculator recommends an MRL of 0.04 mg/kg (unrounded 0.032 mg/kg, STMR= 0.01 mg/kg, n= 7), noting a high uncertainty due to the small dataset and high level of censoring (i.e. results <LOQ). Residues in canola oil will be covered by the MRL of 0.03 mg/kg recommended above for SO 0495 Rape seed [canola], noting also that oil will be bulked and blended.

Canola stubble

Residues of cyantraniliprole in canola stubble at 14 to 15 days after application at approximately 15 g ai/ha (1x proposed) were <0.003, <0.01 and 0.15 mg/kg on a dry weight basis. Two of these 3 trials involved application of a desiccant prior to harvest. In further trials sampling at 19 to 23 days after application at approximately 15 g ai/ha (1x proposed) residues were 0.06, 0.08, 0.08 and 0.44 mg/kg on a dry weight basis. All of these trials involved application of a desiccant prior to harvest. Based on all the data points (<0.01 (2), 0.06, 0.08, 0.08, 0.15 and 0.44 mg/kg) the OECD MRL calculator recommends an MRL of 0.8 mg/kg (STMR= 0.08 mg/kg, n= 7) noting a high uncertainty due to the small dataset. Residues of cyantraniliprole in canola stubble after a 21-day harvest withholding period will be covered by the current MRL of 1 mg/kg for Primary feed commodities {except Brassica forage crops (kale, rape, swede, turnips); Legume animal feeds}.

Canola meal

A processing study for canola meal is not available. However, processing factors for cyantraniliprole were <1 for cottonseed meal in cotton processing studies provided by the applicant and reported by the 2013 and 2015 United Nations Food and Agriculture Organization (FAO) and the World Health Organization (WHO) Joint Meeting on Pesticide Residues (JMPR). Residues in canola meal should be covered by the MRL of 0.03 mg/kg recommended above for SO 0495 Rape seed [canola].

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 international MRLs have been established for cyantraniliprole.

Table 2: Codex and International MRLs for cyantraniliprole

Commodity	Tolerance for residues arising from the use of cyantraniliprole (mg/kg)						
	Australia	China ⁵	Codex ⁶	EU ⁷	Japan ⁸	Korea ⁹	USA ¹⁰
Residue definition	Cyantraniliprole	Cyantraniliprole	Cyantraniliprole	Cyantraniliprole	Cyantraniliprole	–	Cyantraniliprole

⁵ United States Department of Agriculture, Foreign Agricultural Service, [Translation of Maximum Residue Limits for Pesticides in Foods. Beijing, China – People's Republic of](#), USDA website 24 August 2021, accessed January 2023.

⁶ Food and Agriculture Organisation of the United Nations, [Codex Alimentarius, International Food Standards](#), FAO website, accessed January 2023.

⁷ European Commission, [EU Pesticides Database](#), European Commission website, 2016, accessed January 2023.

⁸ Japanese Food Chemistry Research Foundation, [Table of MRLs for Agricultural Chemicals](#), JFCRPF website, accessed January 2023

⁹ Ministry of Food and Drug Safety Korea, [MRLs in Pesticides](#), 2015, accessed January 2023

¹⁰ Electronic Code of Federal Regulations, [USA Electronic Code of Federal Regulations](#), eCFR website, accessed January 2023.

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Commodity	Tolerance for residues arising from the use of cyantraniliprole (mg/kg)						
	Australia	China ⁵	Codex ⁶	EU ⁷	Japan ⁸	Korea ⁹	USA ¹⁰
Rape seed [canola]	0.03 (proposed) T0.03 (current) [1.5 for oilseed in schedule 20]	0.8 ¹¹¹²	0.8	0.8	2	0.8	1.5 (Oilseed group 20)

¹¹ The MRL is the temporary limit. An MRL for cyantraniliprole in Rape seed is not established in Taiwan (see 12 below)

¹² Taiwan Food and Drug Administration, [Standards for Pesticide Residue Limits in Foods](#), accessed January 2023

Current and proposed Australian MRLs for cyantraniliprole

Table 3: Current MRL Standard – Table 1

Compound	Food	MRL (mg/kg)
Cyantraniliprole		
	All other foods	0.05
MO 0105	Edible offal (mammalian)	0.05
PE 0112	Eggs	*0.01
MM 0095	Meat (mammalian) [in the fat]	*0.01
FM 0183	Milk fats	0.07
ML 0106	Milks	*0.01
PM 0110	Poultry meat [in the fat]	*0.01
PO 0111	Poultry, edible offal of	*0.01
SO 0495	Rape seed [canola]	T0.03

Table 4: Current MRL Standard – Table 4

Compound	Animal Feed Commodity	MRL (mg/kg)
Cyantraniliprole		
	Brassica forage crops (kale, rape, swede, turnips)	3
AL 0157	Legume animal feeds	T30
	Primary feed commodities (except Brassica forage crops (kale, rape, swede, turnips); Legume animal feeds)	1

Table 5: Proposed MRL Standard – Table 1

Compound	Food	MRL (mg/kg)
Cyantraniliprole		
Delete:		
SO 0495	Rape seed [canola]	T0.03
Add:		
SO 0495	Rape seed [canola]	0.03

Potential risk to trade

Export of treated produce 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.

The STMR for treated canola seed was <0.01 mg/kg. In addition, the recommended Australian rape seed MRL is lower than that established by Codex and other major export destinations including China and the EU. The risk to trade is expected to be low.

Conclusion

FMC Australasia Pty Ltd has applied for approval of new uses of Exirel Insecticide containing cyantraniliprole on canola. Comment is sought on the potential for the proposed new uses of cyantraniliprole on canola to prejudice Australian trade.