Australian Government

Australian Pesticides and Veterinary Medicines Authority

TRADE ADVICE NOTICE

on Flutriafol in the Product Intake Combi Sapphire In-Furrow and Foliar Fungicide for use on Canola

APVMA Product Number 66358

OCTOBER 2017

ISBN 978-1-925390-89-6 (electronic)

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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.

In undertaking this task, the APVMA works in close cooperation with advisory agencies, including the Department of Health and Aging, Department of the Environment and Energy, and State Departments of Primary Industry.

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 Australian Pesticides and Veterinary Medicines Authority (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 Intake Combi In-Furrow and Foliar 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 8 November 2017 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
Symonston ACT 2609
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 Crop Care Australasia Pty Ltd, to vary the registration of Intake Combi Sapphire In-Furrow and Foliar Fungicide containing 500 g/L flutriafol as its active constituent. Crop Care are proposing to increase the in-furrow application rate to canola from 200 mL/ha (100 g ai/ha) to 400 mL/ha (200 g ai/ha) when mixed with granulated fertilizer or injected into the soil at the time of planting.

A Trade Advice Notice was previously published for this use pattern in April 2015. The use was not supported at that time as relevant MRLs for flutriafol in canola were not established in all markets. An MRL for flutriafol on canola has since been established by Codex.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Canola grain, oil and meal are considered to be major export commodities[2], 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 *Intake Combi Sapphire In-furrow and Foliar Fungicide* may have the potential to unduly prejudice trade.

2.2 Destination and value of exports

Australian exports of canola grain, oil and meal totalled 1945.6 kt ($1097 million), 154.1 kt and 22.86 kt respectively in 2015–16[3].

The major export markets for canola grain in 2015–16 included Belgium, France, Germany, Japan, and The Netherlands. Destinations for canola oil included China, Japan, the Republic of Korea, Malaysia and New Zealand in 2014–15 (2015–16 figures not available). The major market for Canola meal in 2015–16 was New Zealand.

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] APVMA Regulatory Guidelines—Data Guidelines: Agricultural—Overseas trade (Part 5B)

[3] Australian Commodity Statistics 2016

2.3 Proposed Australian use-pattern

INTAKE COMBI SAPPHIRE IN-FURROW AND FOLIAR FUNGICIDE (500 G/L FLUTRIAFOL)

<table>
<tr><th>CROP</th><th>PEST</th><th>RATE PER HECTARE</th><th>CRITICAL COMMENTS</th></tr>
<tr><td>Canola</td><td>Blackleg
(Leptosphaeria maculans)</td><td>200 mL to 400 mL
(100 to 200 g ai/ha)</td><td>
Treatment will reduce blackleg infection in both susceptible and tolerant canola varieties. Use the higher rate of application (400 mL/ha) when heavy blackleg infection pressure is expected and to reduce stem and crown infection later in the season, particularly on more susceptible varieties.

Application: Granulated Fertiliser

Spray product evenly onto granulated fertiliser and immediately mix thoroughly in a mechanical mixer or auger. Apply at a rate which will deposit the specific rate of the product on the quantity of fertiliser required to be sown in furrow per hectare, using the table below as a guide.
<table>
<tr><td rowspan="2">Granular Fertiliser Rate (kg/ha)</td><td colspan="2">Volume of Product per 100 kg of Granular Fertiliser (mL/100kg)</td></tr>
<tr><td>200 mL rate</td><td>400 mL rate</td></tr>
<tr><td>60</td><td>333</td><td>667*</td></tr>
<tr><td>70</td><td>286</td><td>571</td></tr>
<tr><td>80</td><td>250</td><td>500</td></tr>
<tr><td>100</td><td>200†</td><td>400</td></tr>
<tr><td>120</td><td>167†</td><td>333</td></tr>
</table>
†Where application volume is low, product may be diluted with water to improve coverage.

*Application volumes over 600 mL per 100 kg of fertiliser may adversely affect the flow rate and handling characteristics of dusty/poorly granulated fertilisers and some high nitrate fertilisers.

Application: In-furrow Injection in Water

Mix the product thoroughly with water in a suitable mixing tank. Apply as soon as possible after mixing by injecting the mixture 3–4 cm below or to the side of the seed. Mix at a rate which will result in the specific rate of the product in the volume of water required to be injected in-furrow per hectare, using the table below as a guide.
<table>
<tr><td rowspan="2">Water Rate
(L/ha)</td><td colspan="2">Volume of Product per 100 L of Water (mL/100 L)</td></tr>
<tr><td>200 mL rate</td><td>400 mL rate</td></tr>
<tr><td>75</td><td>267</td><td>533</td></tr>
<tr><td>100</td><td>200</td><td>400</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><th>CROP</th><th>PEST</th><th>RATE PER HECTARE</th><th>CRITICAL COMMENTS</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>125</td><td>160</td><td>320</td></tr>
<tr><td>150</td><td>133</td><td>267</td></tr>
<tr><td>175</td><td>114</td><td>229</td></tr>
<tr><td>200</td><td>100</td><td>200</td></tr>
</table>
</td></tr>
</table>

Restraints: DO NOT use open loading and mixing for aerial application

Withholding periods:

Grazing: Do not graze or cut for stock food for 4 weeks after sowing.

General Instructions:

Fertiliser Application: Granulated Fertiliser

To determine the correct volume of Intake Combi Sapphire required to be applied to the fertiliser, refer to the Critical Comments in the Directions for Use table which provides a guide based on a range of common fertiliser application rates. Ensure that treated fertiliser is dry before sowing with the crop. Treated fertiliser should be applied in a band 3–4 cm below or to the side of seed in the planting furrow. It should not be broadcast. Note that the flow rate of fertiliser may be changed after treatment, and the seeder should be calibrated with the treated material to ensure that the correct rates of fertiliser and fungicide are delivered.

Do not mix seed with treated fertiliser.

In-Furrow Injection in Water

Mix the product thoroughly with water in a suitable mixing tank. Apply as soon as possible after mixing by injecting the mixture 3–4cm below or to the side of the seed.

2.4 Results from residues trials presented to the APVMA

Canola seed

Four Australian GLP residue trials conducted on canola in 2013 have been provided. At all 4 sites in-furrow granule treatments were applied on MAP fertiliser placed in the plant furrow below the seed. At 2 of the sites in-furrow liquid treatments were also applied in separate plots at planting in a solid stream in the open plant furrow, below the seed. Residues in canola seed at harvest after application to the planting furrow by either granulated fertiliser coating or liquid soil injection at 200 g ai/ha (1× proposed) were <0.005, 0.005, *0.006*, *0.008*, 0.008 and 0.036 mg/kg (liquid soil injection results shown in italics).

It is proposed that a flutriafol MRL of 0.07 mg/kg be established for SO 0495 Rape seed [canola].

Canola forage and straw

Residues in canola forage at 4 weeks (or longer if higher residues were observed) after application to the planting furrow by either granulated fertiliser coating or liquid soil injection at 200 g ai/ha (1× proposed) were 3.24, 6.73, *6.86*, 8.90, *10.9* and 11.4 mg/kg on a dry weight basis. An MRL of 20 mg/kg is proposed for flutriafol on Canola forage (green) in conjunction with a 4 week grazing WHP.

Residues in canola straw at harvest after application to the planting furrow by either granulated fertiliser coating or liquid soil injection at 200 g ai/ha (1× proposed) were 0.091, 0.15, *0.19*, 0.20, *0.24* and 0.26 mg/kg. Residues in canola straw will be covered by the current MRL of 5 mg/kg for flutriafol on Primary feed commodities.

Canola meal and oil

In the residue trials provided by the applicant, residues in the seed were generally below the LOQ. Noting the K_{ow} log P for flutriafol is 2.3, significant concentration of residues in oil is not expected. A soya bean processing study is available from the 2011 JMPR. Calculated processing factors for meal and refined oil were both 1.3×. Based on a median residue in canola seed of 0.007 mg/kg and a processing factor of 1.3×, estimated residues in canola meal and oil are both 0.009 mg/kg, which will be covered by the recommended MRL of 0.07 mg/kg for flutriafol on Rape seed.

Animal commodities

For cattle the estimated maximum livestock burden for flutriafol is 11.4 ppm, based on a diet of 100% canola forage. The expected residues and established MRLs for ruminants are summarised below:

FEEDING LEVEL (ppm)	MILK	MUSCLE	LIVER	KIDNEY	FAT
	FLUTRIAFOL RESIDUE (mg/kg)				
55	<0.02	<0.02	0.72	0.03	<0.02
11.4, estimated burden	<0.02	<0.02	0.15	0.006	<0.02
Established MRLs	*0.05 (milks)	*0.05 (meat)	0.5 (offal)		-
Recommended MRLs	No change	No change	No change		No change

The maximum livestock dietary burden for poultry is unchanged by this proposal.

No changes are required to established flutriafol animal commodity MRLs and there is no significant change to the risk to trade in animal commodities associated with the proposed use. Residues in animal commodities will not be discussed further.

2.5 Overseas registration and approved label instructions

The applicant indicated that flutriafol products are registered for use on cereals as both foliar and seed treatments in many overseas countries including the USA, Europe and Brazil. Other overseas registered uses include uses on peanuts, soya bean, coffee and some horticultural crops.

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. Flutriafol has been considered by Codex. The following relevant Codex and overseas MRLs have been established for flutriafol.

Table 1: Overseas MRLs for flutriafol

COMMODITY	TOLERANCE FOR RESIDUES ARISING FROM THE USE OF FLUTRIAFOL (mg/kg)				
	AUSTRALIA	CODEX	EU	JAPAN	USA
Residue Definition	Flutriafol	Flutriafol	Flutriafol	Flutriafol	Flutriafol
Rape seed (canola)	0.07 (proposed)	0.5	0.5	0.2	-
Edible offal (Mammalian)	0.5	-	0.3 (bovine liver) *0.01 (bovine kidney)	0.5 (Cattle, edible offal)	1.0 (Cattle liver)
Meat [mammalian]	*0.05	0.02	*0.01 (bovine muscle)	0.05 (Cattle, muscle)	0.05 (Cattle muscle)
Milks	*0.05	0.01	*0.01	0.05	0.02

*MRLs for flutriafol in canola or animal commodities are not known to be established in China, Korea or Taiwan.

2.7 Current and proposed Australian MRLs for flutriafol

Table 2: Current MRL Standard—Table1

COMPOUND		FOOD	MRL (mg/kg)
Flutriafol			
MO	0105	Edible offal (Mammalian)	0.5
PE	0112	Eggs	*0.05
MM	0095	Meat [mammalian]	*0.05
ML	0106	Milks	*0.05
SO	0088	Oilseed	0.05
PO	0111	Poultry, Edible offal	*0.05
PM	0110	Poultry meat	*0.05

Table 3: Proposed changes to MRL Standard—Table1

COMPOUND		FOOD	MRL (mg/kg)
Flutriafol			
DELETE:			
SO	0088	Oilseed	0.05
ADD:			
SO	0088	Oilseed [except Rape seed [canola]]	0.05
SO	0495	Rape seed [canola]	0.07

2.8 Potential risk to trade

Export of treated produce containing finite (measurable) residues of flutriafol 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 proposed use requires establishment of a rape seed MRL for flutriafol of 0.07 mg/kg, which is higher than the established MRL for oilseeds of 0.05 mg/kg. In residue trials reflecting the proposed use pattern, 5 of the 6 results for canola grain were between the LOD (0.005 mg/kg) and the LOQ (0.02 mg/kg) of the analytical method. The highest residue was 0.04 mg/kg.

Of the main export markets for canola seed and oil, the EU and Japan have established relevant MRLs for canola/rapeseed which are higher than that proposed for Australia. The risk to trade to Japan and the EU is low. A Codex MRL for rape seed is now established at a higher level than the proposed Australian MRL. The export of canola oil and meal to New Zealand does not present a risk to trade as New Zealand will accept Australian MRLs under the Trans-Tasman Mutual Recognition Agreement.

3 CONCLUSIONS

Crop Care Australasia Pty Ltd has made an application to vary the registration of Intake Combi Sapphire In-Furrow and Foliar Fungicide containing 500 g/L flutriafol as its active constituent. Crop Care are proposing to increase the in-furrow application rate to canola from 200 mL/ha (100 g ai/ha) to 400 mL/ha (200 g ai/ha) when mixed with granulated fertilizer or injected into the soil at the time of planting. The proposed use will require establishment of a flutriafol Rape seed MRL at 0.07 mg/kg, which is higher than the established oilseed MRL of 0.05 mg/kg.

Comment is sought on the potential for Intake Combi Sapphire In-Furrow and Foliar Fungicide to prejudice Australian trade when used on canola according to the proposed label directions.