



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



TRADE ADVICE NOTICE

on Azoxystrobin and Tebuconazole in the Product Veritas Fungicide for use on
Canola and Pulses

APVMA Product Number 82348

SEPTEMBER 2018

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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 **Veritas 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 **1st October 2018** 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: (02) 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:
<http://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 Adama Australia Pty Limited, to vary the registration of Veritas Fungicide to add uses on canola and various pulses. Veritas contains azoxystrobin and tebuconazole as its only active ingredients.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Canola seed (including derived oils and meals) and pulses (lupins, field peas, chickpeas, faba beans, navy beans, mung beans) are considered to be major export commodities², 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 and pulses. Residues in these commodities resulting from the use of Veritas Fungicide may have the potential to unduly prejudice trade.

No changes are required to the current animal commodity MRLs as the maximum dietary burden is unchanged from registered uses. The risk to trade in animal commodities is low and will not be considered further.

2.2 Destination and value of exports

Australian exports of canola grain, oil and meal totalled 3,598 kt (\$2,128 million), 148 kt and 6.1 kt respectively in 2016/17.³

The major export markets for canola grain in 2016/17 included Belgium, China, France, Germany, Japan and The Netherlands. Destinations for canola oil included China, Japan, the Republic of Korea, Malaysia and New Zealand in 2014/15 (2015/2016/2017 figures not available). The major market for Canola meal in 2016/17 was Vietnam with lesser amounts going to New Zealand and Taiwan.

Total pulse exports were 3,698 kilotonnes, valued at \$3.086 billion, in 2016/17, with the most significant export commodities being chickpeas (1,970 kt, \$1,920 m), lupins (414 kt, \$147 m) and field peas (225 kt, \$109 m). Major export markets for Australian pulse crops are presented below.

CROP	MAJOR DESTINATIONS
Beans, dry	Saudi Arabia, Sri Lanka, Egypt, Philippines
Chickpeas	Bangladesh, India, Pakistan, United Arab Emirates, United Kingdom
Faba beans	Middle East, Southern Europe, Southeast Asia
Lentils	Pakistan, Sri Lanka, Bangladesh, Egypt

² APVMA Regulatory Guidelines – Data Guidelines: Agricultural - Overseas trade (Part 5B)

³ Australian Commodity Statistics 2017

CROP	MAJOR DESTINATIONS
Peas, dry	India, Malaysia, Sri Lanka, Bangladesh

2.3 Proposed Australian use-pattern

Veritas Fungicide (120 g/L azoxystrobin, 200 g/L tebuconazole)

Crop	Disease	Application	Rate/ha	WHP	Critical Comments
Canola	Sclerotinia Rot (<i>Sclerotinia sclerotiorum</i>)	Ground Application: Apply in at least 60 – 100 L of water/ha Aerial Application: Apply in at least 20 L of water/ha	1 L (120 + 200 g ai/ha)	Not required when used as directed (H) 14 days (G)	Apply a single application of VERITAS® between 20% and 50% (full bloom) flowering. Under high disease pressure, apply as part of a multiple spray program for sclerotinia in rotation with fungicides from alternative modes of action i.e. Chief® 250, Sporex® or Spiral AquaFlo®. Best results are achieved when VERITAS® is applied as a preventative application prior to significant disease expression and in rotation with a fungicide from an alternate mode of action group. DO NOT apply after 50% (full bloom) flowering growth stage. Use a spray volume to ensure good coverage i.e. minimum of 30 L/ha for aerial spraying, or 80 L/ha for ground applications. Higher volumes of 100 - 150 L/ha can improve coverage and efficacy.
Chickpeas, Faba Beans and Broad Beans, Field Peas, Lupins, Lentils, Vetch	Botrytis Grey Mould (<i>Botrytis cinerea</i>)	Ground Application: Apply in at least 60 – 100 L of water/ha Aerial Application: Apply in at least 30 L of water/ha	0.75 to 1.0 L (up to 120 + 200 g ai/ha)	28 days (H, G)	VERITAS® can be applied up to two times per season as part of a season long spray program for control of Ascochyta and Botrytis diseases. Fungicide applications should commence at the first sign of disease or if an infection period is forecast, with repeat applications if conditions favour further infection. Use a 14 day spray interval when applying consecutive applications of VERITAS®. Use the higher rate of VERITAS® if conditions favour infection, on a susceptible variety and/or if the crop canopy is dense. Application of VERITAS® in a tank mixture with an approved protectant fungicide i.e. Cavalry, Mancozeb; can improve disease control, particularly when applying the lower rate of VERITAS®. Resistance Management The use of VERITAS® on Botrytis Grey Mould is subject to a CropLife Australia resistance management strategy. Refer to the CropLife website for more information prior to using VERITAS®.
Chickpeas	Ascochyta (<i>Ascochyta rabiei</i>)				
Lentils	Ascochyta (<i>Ascochyta lentis</i>)				
Faba Beans and Broad Beans	Ascochyta Blight (<i>Ascochyta fabae</i>), Chocolate spot (<i>Botrytis fabae</i>)				
Lentils, Vetch	Chocolate spot (<i>Botrytis fabae</i>)				
Faba Beans	Rust				
			300 mL		Apply at the first sign of disease or when conditions favour the disease. Apply up to

and Broad Beans, Field Peas, Vetch	<i>(Uromyces viciaefabae)</i>				three applications per season on a 14 - 21 day interval. Ensure thorough coverage of all foliage to achieve good control.
Faba Beans and Broad Beans, Lentils, Vetch	Cercospora Leaf Spot (<i>Cercospora zonata</i>)				

Restraints:

DO NOT apply more than one application of Veritas per season in canola
 DO NOT apply more than 2 L/ha of Veritas per season in winter pulses

Withholding periods:

Canola:

Harvest: Not required when used as directed

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

Pulse crops:

Harvest: Do not harvest for 28 days after application.

Grazing: Do not graze or cut for stock food for 28 days after application.

2.4 Results from residues trials presented to the APVMA

Canola

Three Australian trials investigating application of azoxystrobin and tebuconazole to canola at multiple rates are supported by overseas trials for azoxystrobin (2) and tebuconazole (4).

Azoxystrobin

In the Australian trials, azoxystrobin residues in canola grain at harvest after application at 50% flowering (BBCH 65) at approximately 120 g ai/ha (1x proposed rate) were <0.002 and <0.01 (2) mg/kg. Residues of azoxystrobin in canola grain in European trials involving application at 154 – 159 g ai/ha (~1.3x) at BBCH 67 – 68 were <0.003 and <0.01 mg/kg. The combined dataset suitable for MRL recommendation is <0.002, <0.003 and <0.01 (3) mg/kg. In the Australian trials residues of azoxystrobin in canola grain in the trials involving application at approximately 360 g ai/ha (3x) were <0.01, 0.02 and 0.04 mg/kg. It is recommended that the current temporary MRL of T*0.01 mg/kg for azoxystrobin on SO 0495 Rape seed [canola] be replaced with an MRL at 0.01 mg/kg.

Tebuconazole

In the Australian trials, tebuconazole residues in canola grain at harvest after application at 50% flowering (BBCH 65) at approximately 200 g ai/ha (1x proposed rate) were <0.002 and <0.01 (2) mg/kg. In the European trials, tebuconazole residues in canola grain at harvest after application at BBCH 65 at approximately 300 g ai/ha (1.5x) were <0.01 (4) mg/kg. No changes are required to the current MRL of 0.3 mg/kg for tebuconazole on SO 0495 Rape seed [canola] to cover the proposed use pattern.

Canola processing

No canola processing studies have been provided by the applicant. However, no changes are required to the current MRL of 0.3 mg/kg for tebuconazole on SO 0495 Rape seed [canola] with the available residue trials also showing quantifiable residues of tebuconazole are unlikely to occur in canola seed from the proposed use. A canola processing study for tebuconazole is not required.

A finite MRL of 0.01 mg/kg has been proposed for azoxystrobin on canola. However, in the available residue trials quantifiable residues were not observed in seed after application at 1x the proposed rate. The HR was 0.04 mg/kg after application at 3x the proposed rate and is also below the 0.1 mg/kg threshold for the requirement of a processing study. In sunflower and peanut processing studies reported by the 2008 JMPR processing factors for refined oil were 0.15x and 3x respectively. Processing factors for sunflower meal were <0.08x. Given the low azoxystrobin residues observed in canola seed in the available trials, separate MRLs are not required for azoxystrobin on canola oil and canola meal.

Pulses

Azoxystrobin

Eight Australian trials on pulses [Chickpeas (5), faba beans (1), lentils (2)] determining azoxystrobin residues after application at multiple rates and timings are available.

The combined data set for azoxystrobin residues in pulse grain at 28 – 36 days after the last of 2 applications at approximately 120 g ai/ha is <0.01, 0.02, 0.04, 0.06, 0.09, 0.10, 0.11 and 0.12 mg/kg. The OECD MRL calculator recommends an MRL of 0.3 mg/kg, the STMR is 0.08 mg/kg. Given the range of pulses to be covered, an MRL of 0.3 mg/kg is proposed for azoxystrobin on VD 0070 Pulses replacing the temporary MRLs for adzuki bean (dry), common bean (dry) [navy bean] and mung bean (dry) at T0.7 mg/kg, broad bean (dry) [Faba bean (dry)] at T0.05 mg/kg, chick-pea (dry) at T0.5 mg/kg, field pea (dry) at T0.05 mg/kg, lentil (dry) at T0.5 mg/kg and lupin (dry) at T0.05 mg/kg.⁴

Tebuconazole

Twelve Australian trials on pulses [Chickpeas (5), faba beans (1), lentils (2), mung beans (2), soya beans (2)] determining tebuconazole residues after application at multiple rates and timings are available, supported by 5 overseas trials (on peas and beans).

The combined data set for tebuconazole residues in pulse grain at approximately 28 days after the last application at approximately 200 g ai/ha (or scaled for application rate in italics) is <0.01, 0.02, 0.02, 0.02, 0.05, 0.08, 0.08, 0.08, 0.09, 0.09, 0.10, 0.10, 0.14, 0.16, 0.25, 0.26 and 0.74 mg/kg. The OECD MRL calculator recommends an MRL of 0.9 mg/kg, the STMR is 0.09 mg/kg. It is proposed that the current temporary MRL of T1 mg/kg for tebuconazole on VD 0070 Pulses [except soya bean (dry)] be made permanent. The proposed 28 day harvest withholding period is supported.

2.5 Overseas registration and approved label instructions

The applicant has not provided details of overseas registrations of azoxystrobin/tebuconazole products, but has noted that MRLs are established in many countries.

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

⁴ The proposed azoxystrobin pulse MRL is sufficient to cover uses that remain current under permit.

countries may accept Codex CXLs when importing foods. Azoxystrobin and tebuconazole have considered by Codex. The following relevant Codex CXLs and international MRLs have been established for azoxystrobin and tebuconazole:

Table 1: Current and proposed Australian and overseas MRLs/tolerances for azoxystrobin

Commodity	Tolerance for residues arising from the use of azoxystrobin (mg/kg)					
	Australia	EU	Japan	Taiwan	Codex	USA
Residue Definition	Azoxystrobin	Azoxystrobin	Azoxystrobin	-	Azoxystrobin	Sum of azoxystrobin and the Z-isomer of azoxystrobin
Rape seed (canola)	0.01 (proposed)	0.5	1	0.05	- (2017 JMPR recommended a rape seed MRL at 0.5 mg/kg, which was recommended for adoption at step 5/8 by 2018 CCPR and adopted by the CAC 2018)	1
Pulses	0.3 (proposed)	0.15	0.5 (beans, dried; peas; broad beans; other legumes / pulses)	0.05 (adzuki bean, broad bean (dry); mung bean) 0.5 (chickpea; pea; peas and beans)	0.07	0.5 (pea and bean, dried shelled, except soybean, subgroup 6C)

Azoxystrobin MRLs for rape seed and pulses (other than soy bean) are not established in Korea.

Table 2: Current and proposed Australian and overseas MRLs/tolerances for tebuconazole

Commodity	Tolerance for residues arising from the use of tebuconazole (mg/kg)					
	Australia	EU	Japan	Taiwan	Codex	USA
Residue Definition	Tebuconazole	Tebuconazole	Tebuconazole	-	Tebuconazole	Tebuconazole
Rape seed (canola)	0.3	0.5	0.3	-	0.3	-

Commodity	Tolerance for residues arising from the use of tebuconazole (mg/kg)					
	Australia	EU	Japan	Taiwan	Codex	USA
Pulses	1 (except soya bean (dry)) (proposed)	0.3 (beans) 0.2 (lentils, peas, lupins, others)	0.5 (beans, dried; peas; broad beans; other legumes / pulses)	0.5 (dry beans)	0.3 (beans (dry))	0.1 (Bean, dry seed)

Tebuconazole MRLs for rape seed and pulses (other than soy bean) are not established in Korea, although the Korean website highlights the Codex MRL for Rape seed.

2.7 Current and proposed Australian MRLs for Azoxystrobin and Tebuconazole

Table 3: Current MRL Standard - Table1

COMPOUND	FOOD	MRL (mg/kg)
Azoxystrobin		
VD 0560	Adzuki bean (dry)	T0.7
VD 0523	Broad bean (dry) [Faba bean (dry)]	T0.05
VD 0524	Chick-pea (dry)	T0.5
VD 0526	Common bean (dry) [navy bean]	T0.7
MO 0105	Edible offal (Mammalian)	0.03
PE 0112	Eggs	*0.01
VD 0561	Field Pea (dry)	T0.05
VD 0533	Lentil (dry)	T0.5
VD 0545	Lupin (dry)	T0.05
MM 0095	Meat (mammalian) [in the fat]	0.02
ML 0106	Milks	0.005
VD 0536	Mung bean (dry)	T0.7
PO 0111	Poultry, Edible offal of	*0.01
PM 0110	Poultry meat	*0.01
SO 0495	Rape seed [canola]	T*0.01
Tebuconazole		
MO 0105	Edible offal (Mammalian)	0.5
PE 0112	Eggs	0.1

COMPOUND	FOOD	MRL (mg/kg)
MM 0095	Meat [mammalian]	0.1
ML 0106	Milks	0.05
PO 0111	Poultry, Edible offal of	0.5
PM 0110	Poultry meat	0.1
VD 0070	Pulses [except soya bean (dry)]	T1
VD 0541	Soya bean (dry)	T0.1

Table 4: Proposed MRL Standard - Table1

COMPOUND	FOOD	MRL (mg/kg)
Azoxystrobin		
DELETE:		
VD 0560	Adzuki bean (dry)	T0.7
VD 0523	Broad bean (dry) [Faba bean (dry)]	T0.05
VD 0524	Chick-pea (dry)	T0.5
VD 0526	Common bean (dry) [navy bean]	T0.7
VD 0561	Field Pea (dry)	T0.05
VD 0533	Lentil (dry)	T0.5
VD 0545	Lupin (dry)	T0.05
VD 0536	Mung bean (dry)	T0.7
SO 0495	Rape seed [canola]	T*0.01
ADD:		
VD 0070	Pulses	0.3
SO 0495	Rape seed [canola]	0.01
Tebuconazole		
DELETE:		
VD 0070	Pulses [except soya bean (dry)]	T1
ADD:		
VD 0070	Pulses [except soya bean (dry)]	1

2.8 Potential risk to trade

Export of treated produce containing finite (measurable) residues of azoxystrobin and tebuconazole 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.

Canola

The MRL proposed for azoxystrobin on rape seed is lower than those established in the EU, Japan, the USA, and Taiwan. A Codex MRL for azoxystrobin on canola has not been established but has been recommended by the 2017 JMPR at 0.5 mg/kg (recommended for adoption at step 5/8 by 2018 CCPR and adopted by the CAC 2018).

No changes have been proposed to the current MRL for tebuconazole on rape seed which is at the same level as those established by Codex and Japan and lower than that established in the EU.

Pulses

The proposed Australian MRL for azoxystrobin on pulses is higher than some tolerances established overseas. However, the STMR in the available trials was 0.08 mg/kg which is below the MRLs established in EU, Japan and the USA and only slightly above the Codex MRL.

The proposed Australian MRL for tebuconazole on pulses [except soya bean (dry)] is higher than those tolerances established overseas. However, the STMR in the available trials was 0.09 mg/kg, which is below the MRLs established for pulses by the EU, Japan and the MRLs established for dry beans by Codex, Taiwan and the USA.

The draft label includes the following export trade advice:

Seeds or grain harvested from canola and pulse crops treated with VERITAS may contain finite (measurable) residues of azoxystrobin and tebuconazole, and may pose a risk to trade in situations where no import tolerance is established in the importing country or where residues in Australian commodities are likely to exceed an import tolerance established by the importing country.

Before you use this product, you are advised to contact ADAMA and/or your industry body about potential trade issues and their management.

Additionally, given pulse and canola grain/seeds are bulked and blended prior to export, the potential risk to trade of treated commodities will be further mitigated.

3 CONCLUSIONS

Adama Australia Pty Limited have made an application to vary the registration of Veritas Fungicide containing azoxystrobin and tebuconazole. Adama propose adding uses on canola and various pulses which require the establishment of a permanent MRL for azoxystrobin on canola, and permanent MRLs for azoxystrobin and tebuconazole on pulses.

Comment is sought on the potential for Veritas Fungicide to prejudice Australian trade when used on canola and pulses according to the proposed label directions.