Australian Government

Australian Pesticides and Veterinary Medicines Authority

TRADE ADVICE NOTICE

on tebuconazole in the product Genfarm Tebuconazole 430 Fungicide for use on wheat, oats and barley, faba beans, mung beans and soya beans

APVMA Product Number 59267

MAY 2017

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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 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 genfarm tebuconazole 430 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 12 June 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 Landmark Operations Ltd, to vary the registration of the product, genfarm tebuconazole 430 fungicide containing 430 g/L tebuconazole. An increase to the number of applications allowed on wheat, barley and oats is proposed, as are new uses on faba means, mung beans and soya beans.

The potential for tebuconazole residues arising from the proposed use to unduly prejudice trade is discussed below. It is noted that no changes to established animal commodity MRLs for tebuconazole are required as a result of the proposed uses and the risk to the trade of animal commodities is considered to be unchanged.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Cereal and pulse grains are considered to be major export commodities[2].

2.2 Destination and value of exports

Australian exports of wheat totalled 24,168 kt and were valued at ~ $5,195m in 2015-16[3]. Australian exports of coarse grains totalled 6,844 kt and were valued at ~$2,313m in 2015–16**Error! Bookmark not defined.**. Barley was the most significant export (~$1790m) followed by and oats (~$104m).

The peas[4] exports for 2014–15 and 2015–16 were 179 kt (valued at $91 million) and 133 kt (valued at $74 million) respectively. Other pulses exports for 2014–15 and 2015–16 were 597 kt (valued at $541 million) and 481 kt (valued at $179 million)[5] respectively.

Major export markets for relevant cereal and pulse crops are shown below:

Table 1: Major destinations for relevant Australian cereal and pulse crops

GRAIN	MAJOR DESTINATIONS
Barley	China, Japan, Korea, Vietnam, Thailand, the Philippines, Taiwan, Middle east
Oats	Statistics not available
Wheat	Indonesia, Korea, China, Thailand, Malaysia, Egypt, Yemen, Iraq, New Zealand
Faba beans	Middle East, Southern Europe, Southeast Asia
Mung beans	India, Indonesia, Sri Lanka, Thailand, Vietnam

[2]Overseas trade (Part 5B): apvma.gov.au/node/1017#major_export_food_commodity_groups

[3]www.agriculture.gov.au/abares/publications/display?url=http://143.188.17.20/anrdl/DAFFService/display.php?fid=pb_agcomd9abcc20170307_0S6mp.xml

[4]Field pea and cow pea figures, no separate data for faba beans are outlined in ABARES, thus it will be considered under other pulses category

[5]ABARES, Agriculture commodities, June quarter 2016

GRAIN	MAJOR DESTINATIONS
Soya beans	Statistics not available

Proposed Australian use-pattern

Table 2: Proposed use pattern for cereals

CROP	DISEASE	RATE	WHP	CRITICAL COMMENTS
Wheat	Leaf rust, stripe rust, septoria, nodorum blotch, yellow leaf spot	145 or 290 ml/ha ***(62 or 125 g ai/ha)***	H: 5 weeks G: 14 days	Use higher rate when longer disease control is required. Stripe rust: See spray timings under General Instructions. Apply from full flag leaf emergence to early head emergence. The addition of mineral crop oil (eg D-C-Trate or equivalent) at 1%, may improve performance of Tebuconazole on wheat, oats and barley. Ground application: Apply in at least 50 L water/ha. Aerial application: Apply in at least 10 L water/ha.
	Septoria tritici blotch	290 ml/ha ***(125 g ai/ha)***		
Oats	Crown rust	145 or 290 ml/ha ***(62 or 125 g ai/ha)***		
Barley	Scald	145 ml/ha ***(62 ai/ha)***		Apply at late tillering to early jointing. Ground application: Apply in at least 50 L water/ha. Aerial application: Apply in at least 10 L water/ha.
	Powdery mildew	145 or 290 ml/ha ***(62 or 125 g ai/ha)***		Apply when 5% of the leaf area is infected. Use higher rate when longer disease control is required. Ground application: Apply in at least 50 L water/ha. Aerial application: Apply in at least 10 L water/ha.
Wheat, oats	Stem rust			Apply if more than 5% of stems become infected between full flag leaf emergence to late flowering. Where stem rust is the major disease, yield responses are usually optimised by delaying application until full head emergence, and using the higher rate. In severe cases, if a majority of stems are infected prior to full head emergence, apply at 145 ml/ha as soon as possible and if necessary, repeat after 3 weeks when heads are fully emerged. Ground application: Apply in at least 50 L water/ha. Aerial application: Apply in at least 10 L water/ha.

WITHHOLDING PERIODS

Harvest (H): Cereals: DO NOT harvest for 5 weeks after application.

Grazing (G): Cereals: DO NOT graze or cut for stock food for 14 days after application.

GENERAL INSTRUCTIONS

Foliar diseases on cereal crops: DO NOT apply to cereal crops more than twice per season (290 ml/ha rate) or more than four times per season (145 ml/ha rate). Treatment will give approximately three weeks disease suppression. Economic responses may not be gained by spraying crops past flowering stage. The effects of fungicide application will not be clearly seen for 7–10 days after application. Yield potential: crops with potential yield under 2 t/ha are unlikely to give economic responses to a fungicide spray except under conditions of very severe disease.

Economic responses are most likely with crops with potential yield of over 3 t/ha.

Table 3: Proposed use pattern for pulses

CROP	DISEASE	RATE	WHP	CRITICAL COMMENTS
Faba Beans	Cercospera Leaf Spot (Cercospera zonata), Faba Bean Rust (Uromyces vicia-fabae)	145 ml/ha ***(62 g ai/ha)***	H: 3 weeks G: 3 weeks	Apply at first sign of disease or when conditions favour development of disease. Apply a maximum of three (3) spray treatments per season, at an interval of 14–21 days between consecutive sprays. Complete and thorough coverage of all foliage and other parts of the crop is essential to achieve good control. DO NOT apply spray under weather conditions, or from spray equipment that may cause spray drift onto nearby susceptible plants or crops, cropping lands or pastures. Using accurately calibrated equipment, apply in a spray volume of 100 L/ha for ground application, and a minimum spray volume of 30–50 L/ha for aerial application.
Mung Beans	Powdery mildew			DO NOT apply more than three (3) applications per crop with a minimum retreatment interval of 14 days between consecutive applications. For optimal disease control apply at first sign of disease. A second spray 14 days later may be necessary under some conditions Using accurately calibrated equipment, apply in a spray volume of 100 L/ha for ground application, and a minimum spray volume of 30–50 L/ha for aerial application.
Soya Beans	Scald Soybean rust (Phakospora pachyrhizi), Powdery mildew (Erisyphe diffusa)	184–243 ml/ha ***(79–104 ai/ha)***		DO NOT apply more than two (2) applications per season. DO NOT apply more after R5 growth stage. Add non-ionic wetter/surfactant (e.g. BS1000) at 100 mL product/ 100 L spray volume. DO NOT add crop oils or any other adjuvants as phytotoxic effects can result. Using accurately calibrated equipment, apply in a spray volume of 100 L/ha for ground application, and a minimum spray volume of 30–50 L/ha for aerial application.

WITHHOLDING PERIODS

Harvest (H): Cereals: DO NOT harvest for 3 weeks after application.

Grazing (G): Cereals: DO NOT graze or cut for stock food for 3 weeks after application.

2.3 Results from residues trials presented to the APVMA

Wheat

The complete dataset for *wheat*, scaled for the proposed rate of 125 g ai/ha following two applications, made 21 days apart, is <0.01 (n=20), 0.01 (n=4), 0.02 (n=9), 0.03 (n=5), 0.04, 0.05 (n=4), 0.07, 0.08 (n=4), 0.10 and 0.14 mg/kg (STMR = 0.02 mg/kg). The available wheat data suggests that the currently established tebuconazole for cereal grains MRL at 0.2 mg/kg remains appropriate for the proposed use in wheat with a 5 week withholding period.

Barley and oats

The complete dataset for barley, scaled for the proposed rate of 125 g ai/ha following two applications, made 21 days apart, is 0.01, 0.02, 0.03, 0.04, 0.05, 0.05, 0.05, 0.05, 0.07, 0.08, 0.09, 0.10, 0.10, 0.11, 0.11, 0.11, 0.15, 0.16, 0.17, 0.20, 0.42 and 0.94 mg/kg (STMR = 0.09 mg/kg). The available barley data suggests that a tebuconazole MRL at 1 mg/kg would be required for the proposed use on barley with a 5 week withholding period.

The extrapolation of the large dataset for barley to oats is considered to be appropriate for this late season use pattern. A tebuconazole MRL at 1 mg/kg is required for the proposed use on oats with a 5 week withholding period.

Faba beans and mung beans

In the Australian trials, residues of tebuconazole observed in grain samples, following three applications at ~1X the proposed rate, made 14 days apart, with a 21 day withholding period, were 0.027 and 0.32 mg/kg in faba beans and were <0.05, 0.087, 0.13 and 0.28 mg/kg in mung beans. At ~2X the proposed rate with a 21 day withholding period, tebuconazole residues were 0.17 and 0.48 mg/kg in mung beans.

Based on the supplied residues data, an MRL of 0.7 mg/kg is recommended for tebuconazole on Broad bean (dry) [Faba bean (dry)] (VD 0523) and Mung beans (dry) (VD 0536), in conjunction with a 3 week harvest WHP.

Soya beans

In the Australian trials, residues of tebuconazole observed in treated soya bean seed/grain samples, following two applications at ~1X the proposed rate, made 14 days apart, with a 21 day withholding period, were
<0.01 (4) mg/kg. At ~2X the proposed rate with a 21 day withholding period, tebuconazole residues were <0.01 and 0.065 mg/kg. The 2011 JMPR evaluation summarised 20 US soybean trials which involved 3 applications at ~125 gi/ha and a 21 day PHI and the STMR and HR was 0.02 and 0.05 mg/kg respectively.

Based on the available residues data, a TMRL of 0.1 mg/kg will be replaced with a permanent MRL of 0.1 mg/kg for tebuconazole use on Soya beans, dry (VD 0541), in conjunction with a 3 week harvest WHP.

Animal feeds

For cereal and pulse forage and fodder, the current tebuconazole MRL for 'Primary feed commodities' at 50 mg/kg remains appropriate for the proposed uses.

2.4 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. Tebuconazole has been considered by Codex. The following relevant Codex CXLs and international MRLs have been established for tebuconazole.

Table 4: Comparison of Australian, Codex and International MRLs for tebuconazole

COMMODITY	TOLERANCE FOR RESIDUES ARISING FROM THE USE OF TEBUCONAZOLE (mg/kg)					
	AUSTRALIA	EU[6]	JAPAN[7]	CODEX[8]	KOREA[9]	USA[10]
Residue Definition	Tebuconazole	Tebuconazole	Tebuconazole	Tebuconazole	Tebuconazole	Tebuconazole
Cereal grains	0.2 (established)	-	-	-	-	-
Barley	1 (proposed)	2	3	2	-	0.3
Oats	1 (proposed)	2	2 (other cereal grains)	2	-	0.15
Wheat	0.2 (as cereal grains)	0.3	2	0.15	-	0.15
Pulses [except soya bean (dry)]	T1 (established)	-	0.5 (other legume and pulses)	-	-	-

[6] ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN

[7] www.m5.ws001.squarestart.ne.jp/foundation/search.html

[8] www.codexalimentarius.net

[9] eng.kfda.go.kr/file/PesiticideMRLs.pdf

[10] www.ecfr.gov

COMMODITY	TOLERANCE FOR RESIDUES ARISING FROM THE USE OF TEBUCONAZOLE (mg/kg)					
	AUSTRALIA	EU[6]	JAPAN[7]	CODEX[8]	KOREA[9]	USA[10]
Bean (dry)	-	0.3	0.5	0.3	-	0.1
Broad bean (dry)	0.7 (proposed)	-	0.5	-	-	-
Mung bean (dry)	0.7 (proposed)	=	-	-	-	-
Soya bean (dry)	T0.1 (established) 0.1 (proposed)	0.15	0.3	0.15	-	0.08

2.5 Current and proposed Australian MRLs for Tebuconazole

Table 5: Current MRL Standard—Table1

COMPOUND		FOOD	MRL (mg/kg)
Tebuconazole			
GC	0080	Cereal grains	0.2
MO	0105	Edible offal (Mammalian)	0.5
PE	0112	Eggs	0.1
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 6: MRLs required for the proposed use patterns—Table1

COMPOUND		FOOD	MRL (mg/kg)
Tebuconazole			
GC	0640	Barley	1
VD	0523	Broad beans (dry) [faba beans]	0.7
GC	0080	Cereal grains [except barley and oats]	0.2
VD	0536	Mung bean (dry)	0.7

COMPOUND		FOOD	MRL (mg/kg)
GC	0647	Oats	1
VD	0541	Soya bean (dry)	0.1

2.6 Potential risk to trade

It is proposed that the individual tebuconazole MRLs for barley and oats be established at 1 mg/kg while no changes are proposed to the cereals MRL at 0.2 mg/kg, which covers the proposed use of tebuconazole on wheat. Codex and EU MRLs for barley and oats have been established at 2 mg/kg and Japanese MRLs for barley and other cereal grains (including oats) have been established at 3 mg/kg and 2 mg/kg respectively. These international MRLs are higher than that proposed for barley and oats (1 mg/kg). The risk to trade following the use of tebuconazole in cereals is not considered to be undue.

For faba beans and mung beans, an MRL of 0.7 mg/kg is proposed. This MRL is slightly higher than those established in Japan for broad beans (dry), beans (dry) at 0.5 mg/kg. The highest residue observations at 1x the proposed rate in faba beans and mung beans were 0.32 mg/kg and 0.28 mg/kg respectively, lower than the Japanese MRL. The Codex MRL of 0.3 mg/kg is established for beans (dry), which is similar to the high residues observed in mung beans and faba beans. Significant export markets where relevant MRLs have not been established are likely to comply with the Codex MRL. The risk to trade following the use of tebuconazole in faba beans and mung beans is not considered to be undue.

For soya beans, the proposed MRL of 0.1 mg/kg is in line with the EU and Codex MRLs and lower than Japanese MRL of 0.3 mg/kg. Noting that finite residues of tebuconazole were not observed in soya beans at the proposed GAP, the risk to trade following the use of tebuconazole in soya beans is not considered to be undue.

3 CONCLUSIONS

Comments are sought on the potential for tebuconazole in Genfarm Tebuconazole 430 Fungicide to unduly prejudice Australian trade when it is used for the control of various fungal diseases as per the proposed label.