Australian Government

Australian Pesticides and Veterinary Medicines Authority

TRADE ADVICE NOTICE

on Prothioconazole and Tebuconazole in the Product Prosaro 420 SC Foliar Fungicide

APVMA Product Numbers 63243

SEPTEMBER 2012

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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 Ageing, Office of Chemical Safety (OCS), Department of the Environment, Water, Heritage and the Arts (DEWHA), 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 the APVMA's publication *Ag MORAG: Manual of Requirements and Guidelines*.

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 **Prosaro 420 SC Foliar Fungicide** containing the existing active constituents prothioconazole and tebuconazole 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 **26 October 2012** 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:

Contact Officer

Pesticides Program
Australian Pesticides and Veterinary Medicines Authority

PO Box 6182

Symonston ACT 2609

Phone: 02 6210 4748

Fax: 02 6210 4776

Email: pesticides@apvma.gov.au

Further information

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

[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 Bayer CropScience Pty Ltd to vary the registration of the product, *Prosaro 420 SC Foliar Fungicide*, containing 210 g/L prothioconazole and 210 g/L tebuconazole, to include the control of Sclerotinia stem rot in canola. The proposed use does not require modification of existing MRLs, however, the proposed use involves application at a later growth stage and hence the potential for higher residues in canola seed.

Meat and dairy products from animals that have been fed feeds containing residues arising from the proposed use may be exported. The potential for prothioconazole and tebuconazole residues arising from the proposed use in canola and in animal commodities to unduly prejudice trade is discussed below.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Canola is considered to be a major export commodity,[2] as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feed produced from treated canola.

2.2 Destination and value of exports

Canola is Australia's third largest broad acre crop after wheat and barley, and it is widely grown across south east Australia and Western Australia. During the 2009-10 season, Australia produced 1.92 million tonnes of canola over 1.71 million hectares. Australia exported 1,238,000 tonnes of this production as seed, small quantities of oil (87,000 tonnes) and canola meal (19,000 tonnes).

Australian exports of canola seed and oil totalled 1557 kt and were valued at ~$962m in 2010-11.[3]

Major export markets for canola seed and canola oil are presented below.[3]

Table 1: Major destinations for Australian canola exports

GRAIN	MAJOR DESTINATIONS
Canola seeds	Netherlands, Pakistan, Japan, Germany, United Arab Emirates, Bangladesh, Belgium, India, South Africa, Indonesia
Canola oil	Republic of Korea, New Zealand, China, Brazil, Singapore, Japan, Malaysia, Hong Kong, United Arab Emirates, Vietnam

The significant export markets for Australian beef, sheep and pig meat and offals are listed in Appendix 3 of Part 5B of Ag MORAG. Australia exports significant quantities of dairy products (~$2275m in 2010-11) with the main markets being Japan and other countries in Asia. Less significant are exports of poultry meat and eggs. Exports of poultry meat were valued at ~$38m in 2010-11 with the major markets being South Africa, the Philippines, Hong Kong, Singapore and the South Pacific Islands.[4] Exports of eggs were valued at ~$4m in 2005-06 with the major markets being Singapore, the USA and the Philippines.[5]

[2] www.apvma.gov.au/morag_ag/vol_3/part_05b_trade.php
[3] faostat.fao.org/site/537/default.aspx
[4] www.daff.gov.au/agriculture-food/meat-wool-dairy/ilg/industries/chicken_meat
[5] http://www.daff.gov.au/agriculture-food/meat-wool-dairy/ilg/industries/australian_egg_industry

2.3 Proposed Australian use-pattern

The proposed Australian use pattern for *Prosaro 420 SC Foliar Fungicide* (210 g/L prothioconazole, 210 g/L tebuconazole) is summarised below.

Table 2: P*rosaro 420 SC Foliar Fungicide* (210 g/L prothioconazole, 210 g/L tebuconazole)

CROP	DISEASE/USE	RATE	CRITICAL COMMENTS
Canola	Sclerotinia stem rot (*Sclerotinia sclerotiorum*)	375 to 450 mL/ha (95 g ai/ha, for each active)	Apply at 20 to 50% (full bloom) flowering. For best results apply as a preventative application at 20-30% flowering prior to significant disease expression. Good coverage throughout the entire canopy is essential. Using a water rate at the higher end of the range (ie, 100 L/ha for ground application and 30 L/ha for aerial application) will improve spray coverage. Apply the higher rate (450 mL/ha) under high disease pressure.

WITHHOLDING PERIODS

Canola: Not required when used as directed
DO NOT graze or cut for stock food for 14 DAYS after application

Export of treated produce

Growers should note that MRLs or import tolerances do not exist in all markets for produce treated with Prosaro. If you are growing produce for export, please check with Bayer CropScience for the latest information on MRLs and import tolerances before using Prosaro.

2.4 Results from residues trials presented to the APVMA

The proposed use of *Prosaro 420 SC Foliar Fungicide* on canola involves a single application of prothioconazole and tebuconazole at a maximum rate of 94.5 g ai/ha for each active. The user is directed to make the application at 20-50% flowering (BBCH GS 62-65). No change to the currently established 14 day grazing withholding period is proposed. A harvest withholding period is not required when used as directed.

Australian field trials on canola involved up to two applications of prothioconazole and tebuconazole at a rate of 79-165 g ai/ha, which is 0.84-1.7× the proposed rate. The first application was made at canola growth stage BBCH 51 (green bud) and the second at BBCH 65 (full flowering).

Prothioconazole

Detectable residues of prothioconazole were not observed in canola seed at harvest when prothioconazole was applied at rates of 79 (n=8), 95 (n=4), 110 (n=4) and 165 (n=4) g ai/ha. The currently established MRL of *0.02 mg/kg for prothioconazole in rape seed [canola] remains appropriate for the proposed use.

When a single application of prothioconazole was made at full flower at a rate of 79 g ai/ha (0.83× the proposed rate), residues of prothioconazole in canola stubble at harvest were <0.02 (×3) and 0.03 mg/kg.

Applied at a rate of 110 g ai/ha (1.16× the proposed rate), residues of prothioconazole in canola stubble at harvest were <0.02 (×2), 0.04 and 0.06 mg/kg.

When a single application of prothioconazole was made at full flower at a rate of 79 g ai/ha (0.83× the proposed rate), residues of prothioconazole in canola forage 14 days after the last treatment were 0.15 (×2), 0.23 and 0.25 mg/kg. Applied at a rate of 110 g ai/ha, (1.16× the proposed rate), residues of prothioconazole in canola forage 14 days after the last treatment were 0.22, 0.30 (×2) and 0.40 mg/kg. Forage samples were presented on a fresh weight basis. Based on an assumed DM content of 30% for rape greens, the highest residue observed at 14 DALA is calculated to be 1.33 mg/kg on a dry weight basis. The established MRL of 3 mg/kg for prothioconazole on rape seed fodder and forage remains appropriate.

Tebuconazole

When a single application of tebuconazole was made at full flower at a rate of 79 g ai/ha (0.83× the proposed rate), residues of tebuconazole in canola seed at harvest were <0.01 (n=4) mg/kg. When applied at a rate of 110 g ai/ha (1.16× the proposed rate), residues of tebuconazole in canola seed at harvest were <0.01 (×3) and 0.06 mg/kg. The currently established MRL of 0.3 mg/kg for tebuconazole in rape seed [canola] remains appropriate.

When a single application of tebuconazole was made at full flower at a rate of 79 g ai/ha (0.83× the proposed rate), residues of tebuconazole in canola stubble at harvest were 0.01, 0.03, 0.12 and 0.26 mg/kg. Applied at a rate of 110 g ai/ha (1.16× the proposed rate), residues of tebuconazole in canola stubble at harvest were <0.01, 0.04, 0.41 and 0.49 mg/kg.

When a single application of tebuconazole was made at a rate of 79 g ai/ha (0.83× the proposed rate), residues of tebuconazole in canola forage 14 days after the last treatment were 0.29, 0.67, 0.97 and 1.00 mg/kg. Applied at a rate of 110 g ai/ha (1.16× the proposed rate), residues of tebuconazole in canola forage 14 days after the last treatment were 0.38, 0.98, 1.12 and 2.08 mg/kg. Forage samples were presented on a fresh weight basis. Based on an assumed DM content of 30% for rape greens, the highest residue observed at 14 DALA is calculated to be 6.9 mg/kg on a dry weight basis. The previously established primary feed commodities MRL of 50 mg/kg remains appropriate for the proposed use.

Animal Commodities

Animal commodity MRLs were based on the maximum animal dietary burden from the consumption of cereal forage and fodder (HR of 4.67 mg/kg prothioconazole, 20.7 mg/kg tebuconazole). Canola forage, like cereal forage can contribute up to 100% of the diet in beef cattle. However the anticipated burden associated with canola feeds is much lower than cereal feeds (HR of 1.33 mg/kg prothioconazole, 6.9 mg/kg tebuconazole). There is no proposal to amend the prothioconazole and tebuconazole MRLs associated with canola and therefore the proposed use should not result in the current animal commodity MRLs being exceeded. No change to the animal commodity MRLs for prothioconazole and tebuconazole are required at this time.

2.5 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. Prothioconazole and tebuconazole have been considered by Codex. MRLs have been established in most if not all major export markets and are summarised below.

Table 3: Comparison of prothioconazole and tebuconazole MRLs (mg/kg) for rape seed.

Residue definitions for prothioconazole are the sum of prothioconazole and prothioconazole-desthio, expressed as prothioconazole. The residue definitions for tebuconazole are tebuconazole.

	PROTHIOCONAZOLE	TEBUCONAZOLE
Australia	*0.02	0.3
Codex	0.1	0.5
EU	0.1	0.5
Japan	0.15	0.05
USA	0.15	-
Russia	0.05	0.3
Taiwan	-	*0.01 (others)

Prothioconazole MRLs for canola are not known to be established in China, Taiwan or Republic of Korea.
Tebuconazole MRLs for canola are not known to be established in the USA, China or the Republic of Korea.

2.6 Current and proposed Australian MRLs for prothioconazole and tebuconazole

Current relevant MRLs and the residue definition for prothioconazole and tebuconazole are presented below. A full listing of MRLs can be found at www.apvma.gov.au/residues/standard.php. No changes to current MRLs or the residue definition have been proposed.

Table 4: Relevant current entries in Table 1 of the APVMA MRL Standard

COMPOUND	FOOD	CURRENT MRL (mg/kg)
PROTHIOCONAZOLE		
SO 0495	Rape seed [canola]	*0.02
TEBUCONAZOLE		
SO 0495	Rape seed [canola]	0.3

Table 5: Relevant current entries in Table 3 of the APVMA MRL Standard

COMPOUND	RESIDUE
PROTHIOCONAZOLE	For commodities of plant origin: sum of prothioconazole and prothioconazole desthio (2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1H-1,2,4-triazol-1-yl)-propan-2-ol), expressed as prothioconazole. For commodities of animal origin: sum of prothioconazole, prothioconazole desthio (2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1H-1,2,4-triazol-1-yl)-propan-2-ol), prothioconazole-3-hydroxy-desthio (2-(1-chlorocyclopropyl)-1-(2-chloro-3-hydroxyphenyl)-3-(1H-1,2,4-triazol-1-yl)-propan-2-ol) and prothioconazole-4-hydroxy-desthio (2-(1-chlorocyclopropyl)-1-(2-chloro-4-hydroxyphenyl)-3-(1H-1,2,4-triazol-1-yl)-propan-2-ol), expressed as prothioconazole
TEBUCONAZOLE	Tebuconazole

Table 6: Relevant current entries in Table 4 of the APVMA MRL Standard

COMPOUND	FOOD	CURRENT MRL (mg/kg)
PROTHIOCONAZOLE		
	Cereal forage and fodder	7
	Rape seed [canola] forage, fodder and straw	3
TEBUCONAZOLE		
	Primary feed commodities	50

2.7 Potential risk to trade

Export of treated produce containing finite (measurable) residues of prothioconazole 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.

While several overseas countries have established prothioconazole and tebuconazole MRLs in rape seed, some key Australian export markets for these commodities have not. As detectable residues may occur if the product is used as directed this creates a potential risk to trade.

In Japan the MRL for tebuconazole in rape seed is 0.05 mg/kg, this is below the Australian MRL of 0.3 mg/kg. However, it is noted that the residue considered as the highest residue was 0.06 mg/kg, and the supervised trial median residue was <0.01 mg/kg. Bayer CropScience have also advised that a proposal to revise the current Japanese MRL of 0.05 mg/kg to 0.5 mg/kg for tebuconazole on rape seed has recently been accepted by a subcommittee for the Japanese Ministry of Health, Labour and Welfare, with the revision expected to be accepted by other agencies and notification to be made in early 2013.

The applicant is proposing to mitigate this risk to trade through the inclusion of the following statement on the label:

Export of treated produce

Growers should note that MRLs or import tolerances do not exist in all markets for produce treated with Prosaro. If you are growing produce for export, please check with Bayer CropScience for the latest information on MRLs and import tolerance before using Prosaro.

3 CONCLUSIONS

It is not proposed to vary the MRLs for prothioconazole and tebuconazole in canola associated with the proposed later application time (50% flowering *c.f.* green bud). Comment is sought on the potential for prothioconazole and tebuconazole residues to prejudice Australian trade when *Prosaro 420 SC Foliar* Fungicide is used on canola.

A more detailed technical assessment report on the evaluation of the trade implications of this chemical can be obtained by contacting the APVMA at (02) 6210 4748. Alternatively, the reports can be viewed at the APVMA Library, which is located at:

18 Wormald Street
Symonston ACT, 2609

Office hours: 9.00am–5.00pm (EST) Monday to Friday