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 Number P63243

APRIL 2012

The Manager, Public Affairs
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PREFACE

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the Australian Government regulator 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 proposed extensions of use for existing chemicals where there may be trade implications, as defined in *Ag MORAG: Manual of Requirements and Guidelines* Part 5B.

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. In relation to this document, these grounds relate to the **trade implications** of the extended use of the product. Comments received outside these grounds cannot be considered by the APVMA.

Submissions must be received by the APVMA by close of business on 10th **May 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
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Kingston ACT 2604

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.

Further information on trade advice notices 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 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 various diseases in oats, stripe rust in triticale and blackleg in canola. The proposed extensions of use require the establishment of permanent MRLs for prothioconazole in cereal grains and rape seed as well as the establishment of permanent MRLs for tebuconazole in rape seed.

Cereal grains and canola are exported along with meat and dairy products from animals that have been fed feeds containing residues arising from the proposed use. The potential for prothioconazole and tebuconazole residues in cereal grains, canola and animal commodities to unduly prejudice trade is discussed below.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Cereal grains and canola are considered to be major export commodities, as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock feeding on treated crops. Residues in these commodities resulting from the use of *Prosaro 420 SC Foliar Fungicide* may have the potential to unduly prejudice trade.

2.2 Destination and value of exports

Cereal grains

Export volumes and values for cereals, including oats, are tabulated below.

Table 1: Value of Australian Cereal Exports 2006-07 to 2010-11

COMMODITY	EXPORT VALUE ($ MILLION)				
	2006-07	2007-08	2008-09	2009-10	2010-2011
Wheat (including flour)	2315	3354	5116	3778	5867
Barley (including malt)	833	1496	1321	1093	1295
Oats	20	37	64	53	37
Sorghum	13	76	405	116	146
Maize	9	11	30	19	15
Triticale	44	113	93	120	149

Source: Australian Bureau of Agricultural and Resource Economics (ABARE), Australian commodity statistics, 2011

Details of the export destination of Australian oats were not presented in the ABARE Australian commodity statistics (2011) due to confidentiality restrictions. However, the applicant has supplied the following key export destinations from 2008.[2]

[2] http://faostat.fao.org/site/537/default.aspx

Table 2: Major export markets for Australian oat, 2008

EXPORT COMMODITY	KEY EXPORT MARKET	EXPORTS (TONNE)	EXPORTS ($ MILLION)
Oats	Philippines	6774	2.19
	Japan	3865	2.15
	Saudi Arabia	1400	0.48
	USA	1100	0.59
	United Arab Emirates	1032	0.40
Oats, rolled	China	13751	8.42
	Malaysia	13607	8.63
	Philippines	10697	7.42
	India	8879	5.55
	New Zealand	3376	3.07

Approximately 720 kilotonne of hay is exported from Australia, to the value of ~$230-250 million, per annum.[3] Approximately 85% of exports are oaten hay, while 10% is straw and the balance is predominantly lucerne hay and chaff. Approximately 85% of Australian export hay is destined for Japan, while the volume of hay exported to China and the UAE is increasing.

[3] Personal communication, AFIA, August 2010

Canola

Export volumes and values for canola are tabulated below.

Table 3: Value of Australian Canola Exports 2006-07 to 2010-11

COMMODITY	EXPORT VALUE ($ MILLION)				
	2006-07	2007-08	2008-09	2009-10	2010-2011
EXPORT VOLUME (KILO TONNE)					
Canola seed	238	519	973	1238	1453
Canola oil	28	57	76	87	104
Canola meal	0.01	2.04	1.29	19.03	31.50
EXPORT VALUE[a] ($ MILLION)					
Canola seed	108	320	612	596	802
Canola oil	43	99	152	157	160
Canola meal	0.007	0.85	0.71	8.84	10.97

[a] Value estimated from percentage of total oilseeds exported, assuming same value for all oilseeds per tonne.

Source: Australian Bureau of Agricultural and Resource Economics (ABARE), Australian commodity statistics, 2011

The major export markets and volume of canola exported to each country from 2008 were supplied by the applicant and presented below.[4]

Table 4: Major export markets for Australian canola, 2008

EXPORT COMMODITY	KEY EXPORT MARKET	EXPORTS (TONNE)	EXPORTS ($ MILLION)
Canola seeds	Netherlands	172572	99.75
	Pakistan	138358	72.65
	Japan	103849	59.89
	Germany	58000	31.85
	United Arab Emirates	54470	28.65
	Bangladesh	1513	1.00
	Belgium	739	0.46
	India	514	0.29
	South Africa	123	0.34
	Indonesia	60	0.11
Canola oil	Republic of Korea	20901	27.80
	New Zealand	18481	26.53
	China	12441	16.45
	Brazil	6000	7.49
	Singapore	5864	8.11
	Japan	3093	4.82
	Malaysia	2332	2.82
	Hong Kong	1996	2.95
	United Arab Emirates	1582	1.47
	Vietnam	814	0.78

[4] http://faostat.fao.org/site/537/default.aspx

Animal Commodities

The significant export markets for Australian meat, kidney and liver are listed in Appendix 3 of Part 5B of Ag MORAG. The destination and value of Australian dairy exports are summarised in Table 1 below.

Table 5: Destination and value of Australian dairy exports

DESTINATION	VALUE OF AUSTRALIAN EXPORTS OF DAIRY PRODUCTS, BY DESTINATION ($ MILLION)						
	2002-03	2003-04	2004-05	2005-06	2006-07	2007-08	2008-09
CHEESE							
Japan	272.0	299.6	378.9	298.5	337.9	426.7	398.9
Saudi Arabia	98.9	69.0	81.5	103.5	86.7	89.7	30.6
United States	36.1	33.9	45.4	54.2	52.7	37.2	59.7
Other	393.3	336.7	370.9	381.0	346.9	414.8	306.9
TOTAL	800.3	739.2	876.7	837.2	824.2	968.4	796.1
BUTTER AND BUTTER FAT							
Egypt	18.9	6.4	10.5	12.5	13.9	5.0	22.0
Malaysia	12.7	13.5	11.6	15.8	11.0	17.4	14.0
Singapore	15.5	18.2	16.8	21.1	14.4	26.2	20.2
Other	176.9	144.8	149.6	175.3	139.3	146.0	175.9
TOTAL	224.0	182.9	188.5	224.7	178.6	194.6	232.1
SKIM MILK POWDER							
Malaysia	51.4	52.7	64.2	77.1	72.2	63.4	49.0
Philippines	71.8	60.1	49.4	72.0	46.1	64.1	99.7
Singapore	38.4	42.4	57.8	56.1	67.1	61.8	54.0
Other	246.9	232.3	248.7	323.7	319.6	343.9	350.2
TOTAL	408.5	387.5	420.1	528.9	505.0	533.2	552.9

CASEIN							
Japan	20.6	23.3	23.1	30.4	31.8	38.4	43.6
United States	81.4	68.8	56.6	27.3	32.4	42.2	29.5
Other	26.4	30.5	36.5	31.3	49.3	44.2	34.4
TOTAL	128.4	122.5	116.2	89.0	113.5	124.8	107.5
WHOLEMILK POWDER							
Malaysia	22.3	28.9	33.1	23.8	14.5	27.3	14.9
Singapore	25.2	21.4	30.9	44.6	41.4	88.9	77.0
Taiwan	44.9	40.0	31.5	22.8	13.5	11.8	9.3
Other	284.4	231.6	228.9	242.4	205.4	264.1	374.2
TOTAL	379.8	321.8	324.4	333.6	274.9	392.2	475.3
OTHER PRODUCTS							
Fresh milk	98.2	104.0	108.8	107.3	96.3	83.6	102.1
Other fresh products	5.6	9.6	9.1	6.3	11.8	12.0	0.4
Condensed milk	133.3	121.0	139.8	147.5	156.9	152.4	158.9
Other powders	274.4	257.3	248.3	241.5	211.0	247.4	249.7
TOTAL	511.5	492.0	506.0	502.6	476.0	495.5	511.1
TOTAL DAIRY PRODUCTS	2,453	2,246	2,432	5,516	2,372	2,709	2,675
Source: ABARE, Australian commodity statistics 2009, Canberra							

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) in oats and canola is summarised below.

Table 6: Proposed use pattern

Prosaro 420 SC Foliar Fungicide (210 g/L prothioconazole, 210g/L tebuconazole)

CROP	STATE	DISEASE	RATE	CRITICAL COMMENTS
Oats	All States	Stem rust (*Puccinia graminis* f. sp. *Avenae*)	300 mL/ha + adjuvant (refer to use of adjuvant)	Monitor crops from early stem elongation, and on susceptible varieties apply at the first sign of infection.
		Leaf rust (*Puccinia coronate* f. sp. *Avenae*)		Monitor crops from early stem elongation, and on susceptible varieties apply at the first sign of infection.
		Septoria blotch (*Phaeosphaeria avenaria*)	150 to 300 mL/ha	Monitor crops from early tillering, and on susceptible varieties apply at the first sign of infection. Use the higher rate (up to 300 mL/ha) in higher yielding crops where conditions favour disease development or susceptible varieties are grown. Continue to monitor crops after application. Re-application may be required if conditions favour disease development. Where lower rates are used, apply with a suitable adjuvant (refer to use of adjuvant)
Triticale	All States	Stripe rust (*Puccinia striformis*)	150 mL/ha to 300 mL/ha + adjuvant	Monitor crops form early stem elongation, and on susceptible varieties apply at the first sign of infection. Use the higher rate (up to 300 mL/ha) in higher yielding crops where conditions favour disease development or susceptible varieties are grown. Continue to monitor crops after application. Re-application may be required if conditions favour disease development and initial application is made before the flag leaf has emerged.
Canola	All States	Blackleg	375 to 450 mL/ha	Apply to the 4 to 6 leaf crop stage of blackleg susceptive varieties (blackleg ratings of MS) or in situations of high blackleg risk. Will reduce lodging and stem canker from blackleg. An effective seed treatment or in-furrow treatment should be used for early blackleg control as Prosaro will not protect form early loss of seedlings due to blackleg. A follow up application may be required at green bud stage in high disease risk situations.

WITHHOLDING PERIODS

Canola: Not required when used as directed
DO NOT graze or cut for stock food for 14 DAYS after application
Cereals: DO NOT harvest for 5 WEEKS after application
DO NOT graze or cut for stock food for 14 DAYS after application

2.4 Results from residues trials presented to the APVMA

Cereal grains

The proposed use pattern for prothioconazole and tebuconazole on oats and triticale is the same as that approved for wheat and barley, 63 g prothioconazole/ha, with up to two applications allowed per crop, a harvest withholding period of 5 weeks and a grazing withholding period of 14 days.

Prothioconazole

Data were submitted from sixteen residues trials during the original evaluation for *Prosaro 420SC Foliar Fungicide* in which prothioconazole was applied alone or in combination with tebuconazole twice to wheat (n=8), barley (n=4) and oats (n=4) at 63 g prothioconazole/ha. At 8 sites, residue data were also available following application at 125 g prothioconazole/ha to wheat (n=4), barley (n=2) and oats (n=2). Forage samples were taken after a single application made no later than GS39 (flag leaf fully unrolled, ligule just visible), and grain and straw samples were taken after one or two applications, with the final application made no later than 28 days (+/- 3 days) prior to commercial harvest. It is appropriate to consider the residue data for wheat, barley and oats together.

Grain: Prothioconazole residues were measured in accordance with the Australian residue definition (*prothioconazole and prothioconazole desthio expressed as prothioconazole*). Residues in wheat, barley and oat grain were <LOQ (<0.05 mg/kg; n=11), 0.07, 0.07, 0.07, 0.07, 0.12 mg/kg, following 2 applications at 63 g prothioconazole/ha at about GS37-39 and 27-40 days before commercial harvest. All observed residues were present as *prothioconazole desthio* and, based on the results of metabolism studies and observations in the residue trials; it was assumed that residues of parent prothioconazole were not present. In 2 trials where prothioconazole was applied twice at 125 g ai/ha, with the final application occurring 26-28 days before commercial harvest, residues in grain were <LOQ (<0.05 mg/kg). An MRL of 0.3 mg/kg for prothioconazole in cereal grains is recommended in conjunction with a 35 day (5 week) WHP.

Straw: Residues according to the Australian residue definition in wheat, barley and oat straw at 27-40 days after the second of two applications at 63 g prothioconazole/ha were 0.25, 0.39, 0.39, 0.45, 0.48, 0.49, 0.51, 0.63, 0.69, 0.72, 0.74, 0.81, 0.85, 1.01, 1.08, 1.35 mg/kg. An MRL of 3 mg/kg for cereal straw is recommended in conjunction with a 14 day grazing and cutting WHP.

Forage: Residue data in forage following two applications at 63 g prothioconazole/ha were not provided. Data following a single application at 125 g prothioconazole/ha were considered. Residues in forage were 0.39, 0.49, 0.81, 0.88, 1.21, 2.64, 4.47 and 4.67 mg/kg (dry weight, DW), at 13-14 days after application. An MRL of 7 mg/kg for cereal forage and fodder is recommended in conjunction with a 14 day grazing and cutting WHP.

Tebuconazole

Grain: Tebuconazole has been approved for many years for foliar application to cereals at the same rate as that proposed for *Prosaro 420SC Foliar Fungicide*. For example *Folicur 430SC Fungicide* (active ingredient 430g/L tebuconazole) is registered for the use of tebuconazole on wheat, oats and barley at a maximum rate of one application per season at 290 mL/ha (≡ 125 g ai/ha) or two applications per season at 145 mL/ha

(62.5 g ai/ha), with a 35 day harvest withholding period. The proposed rate for the application of *Prosaro 420SC Foliar Fungicide* is up to two applications per crop at a maximum rate of 63 g ai/ha. Therefore, the previously established tebuconazole MRL of 0.2 mg/kg for cereal grains remains appropriate for the proposed use.

Forage: Tebuconazole residues in wheat, barley and oat forage were determined after application of various tebuconazole-based formulations in the original application for *Prosaro 420SC Foliar Fungicide*. This data (single application at 1× or 2× the proposed rate and approximation of the residues from two applications) shows that the existing animal feed MRL (Primary Feed Commodities - 50 mg/kg) will cover any likely tebuconazole residues in forage from the proposed use of *Prosaro 420SC Foliar Fungicide* on barley, oats or wheat with a 14 day grazing WHP. Therefore, the current MRL for the use of tebuconazole in primary feed commodities of 50 mg/kg should remain unchanged.

Canola

The proposed use of prothioconazole and tebuconazole on canola involves a maximum of two applications at rates of up to 94.5 g ai/ha for each active. The applicant has proposed a 14 day grazing withholding period, and that a harvest withholding period is not required when used as directed, as the user is directed to apply at the 4-6 leaf growth stage, with reapplication at the green bud stage in high disease risk situations.

Data were submitted from Australian trials on canola involving 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). It is noted that the proposed use pattern specifies the first application to be made at the 4 to 6 leaf crop stage (BBCH 14-16), with reapplication at green bud (BBCH 51). This is earlier than in the trials submitted by the applicant.

Prothioconazole

When prothioconazole was applied at a rate of 79, 95, 110 and 165 g ai/ha detectable residues of prothioconazole in canola seed at harvest were not observed in any sample. It is recommended that an MRL for prothioconazole be established at *0.02 mg/kg for rape seed.

The processing factors of prothioconazole residues were determined to be less than 1× for the processed canola products of meal and refined oil. The results of this study indicate that prothioconazole residues are not likely to accumulate in processed canola commodities.

When prothioconazole was applied at a rate of 79 g ai/ha (0.83× the proposed rate), residues of prothioconazole in canola stubble at harvest were <0.02 (×2), 0.04 and 0.06 mg/kg. When applied at a rate of 95 g ai/ha (1× the proposed rate), residues of prothioconazole in canola stubble at harvest were 0.05, 0.06 and 0.12 (×2) mg/kg.

When prothioconazole was applied 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, 0.23, 0.27 and 0.37 mg/kg. When applied at a rate of 95 g ai/ha, (1× the proposed rate), residues of prothioconazole in canola forage 14 days after the last treatment were 0.16, 0.22, 0.28 and 0.30 mg/kg.

It is noted that the available 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 days after the last application is calculated to be 1.23 mg/kg on a dry weight basis. It is recommended that MRLs for prothioconazole be established at 3 mg/kg for rape seed fodder and forage.

Tebuconazole

When tebuconazole was applied at a rate of 79 g ai/ha (0.83× the proposed rate), residues of tebuconazole in canola seed at harvest were <0.01 (×3) and 0.04 mg/kg. When applied at a rate of 95 g ai/ha (1× the proposed rate), residues of tebuconazole in canola seed at harvest were <0.01, 0.04, 0.09 and 0.13 mg/kg. It is recommended that an MRL of 0.3 mg/kg be established for rape seed.

The processing factors of tebuconazole residues were determined to be less than 1× for the processed canola products of press cake, extracted press cake meal and refined oil. The results of this study indicate that tebuconazole residues are not likely to accumulate in these processed canola commodities, including refined oil. For screw-pressed oil, solvent extracted oil and crude oil, residues of tebuconazole were 1.1×, 1.25× and 1.2× greater than that in the RAC (canola seed), respectively. On the basis of these studies it is considered that the establishment of processed commodity MRLs are unnecessary for tebuconazole in canola.

When tebuconazole was applied at a rate of 79 g ai/ha (0.83× the proposed rate), residues of tebuconazole in canola stubble at harvest were 0.01, 0.05, 0.35 and 0.63 mg/kg. When applied at a rate of 95 g ai/ha, residues of tebuconazole in canola stubble at harvest were 0.25, 0.42, 0.44 and 0.52 mg/kg.

When tebuconazole was applied 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 2.85 mg/kg. When applied at a rate of 95 g ai/ha, residues of tebuconazole in canola forage 14 days after the last treatment were 0.87, 2.13, 2.40 and 2.95 mg/kg.

It is noted that the available 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 9.8 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

Based on the proposed uses of *Prosaro 420 SC Foliar Fungicide*, the maximum animal dietary burden is from the consumption of cereal forage and fodder. The predicted residues in animal commodities derived from livestock fed on treated forage and fodder (HR of 4.67 mg/kg prothioconazole, 20.7 mg/kg tebuconazole) are summarised below. The proposed uses do not result in an increase in potential animal dietary burden and so no change is proposed to existing animal commodity MRLs. For a full discussion of

the potential risk to trade in animal commodities when animals consume treated feeds, please refer to the previous Trade Advice Notice for *Prosaro 420 SC Foliar Fungicide*.[5]

SAMPLE	ESTIMATED RESIDUE PROTHIOCONAZOLE (BASED ON HR; mg/kg)	ESTIMATED RESIDUE TEBUCONAZOLE (BASED ON HR; mg/kg)
Liver	0.06	0.06
Kidney	0.04	<0.05
Muscle	<0.01	<0.05
Fat	<0.05	<0.05
Milk	<0.005	<0.01

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.

[5] http://www.apvma.gov.au/registration/assessment/docs/tan_tebuconazole_prothioconazole.pdf

Table 7: Codex CXLs and overseas residue MRLs/tolerances for prothioconazole in plant commodities

Commodity	Tolerance for residues arising from the use of prothioconazole (mg/kg)				
	Australia	**Codex**	**EU**	**Japan**	**US**
Plant Commodities					
Residue Definition	Prothioconazole sum of prothioconazole and prothioconazole desthio, expressed as prothioconazole.	Prothioconazole prothioconazole-desthio	Prothioconazole prothioconazole-desthio	Prothioconazole the sum of residues of prothioconazole and its metabolites M17 (prothioconazole-desthio)	Prothioconazole prothioconazole and its metabolite prothioconazole-desthio, calculated as parent.
Cereal grains	0.3[a]				
Barley		0.2	0.3	0.35	
Oats		0.05	0.05		
Triticale		0.05			
Wheat		0.1	0.1	0.07	
Rye			0.1	0.05	
Buckwheat			*0.02	1.0	
Maize			*0.02		
Millet			*0.02		
Rice			*0.02	0.1	
Sorghum			*0.02		
Other cereal grains (All cereal grains, except rice (brown rice), wheat, barley, rye, corn (maize) and buckwheat.)				0.05	
Grain, cereal, group 15, except sweet corn and sorghum					0.35
Rape seed	*0.02[a]	0.1	0.1	0.15	0.15
Cereal forage and fodder	7			Not established[b]	
Cereal straw	0.3			Not established[b]	
Fodder (dry) of cereal grains		5		Not established[b]	
Straw and fodder (dry) of cereal grains		4		Not established[b]	
Grain, aspirated grain fractions					11
Grain, cereal, forage, fodder and straw, group 16, except sorghum, and rice; forage					8.0
Grain, cereal, forage, fodder and straw, group 16, except sorghum, and rice; hay					7.0
Grain, cereal, forage, fodder and straw, group 16, except sorghum, and rice; stover					10
Grain, cereal, forage, fodder and straw, group 16, except sorghum, and rice; straw					5.0

[a] proposed MRL, [b] The Ordinance of the Standards of Feed and Feed Additives - http://www.famic.go.jp/ffis/feed/obj/shore_eng.pdf

Table 8: Codex CXLs and overseas residue MRLs/tolerances for tebuconazole in plant commodities

Commodity	Tolerance for residues arising from the use of tebuconazole (mg/kg)				
	Australia	**CODEX**	**EU**	**Japan**	**USA**
Plant Commodities					
Residue Definition	Tebuconazole Tebuconazole	Tebuconazole Tebuconazole	Tebuconazole Tebuconazole	Tebuconazole Tebuconazole	Tebuconazole Tebuconazole
Cereal grains	0.2				
Barley		0.2	2	3	0.15
Oats		*0.05	2		0.15
Triticale					
Wheat		0.05	0.2	2	0.15
Rye		*0.05	0.2	0.2	
Buckwheat			0.2	0.05	
Maize			0.2		
Millet			0.2		
Rice			2	0.05	
Sorghum			0.2		
Other cereal grains (All cereal grains, except rice (brown rice), wheat, barley, rye, corn (maize) and buckwheat.)				0.2	
Rape seed	0.3[a]	0.5	0.5	0.05	
Primary feed commodities	50				
Barley straw and fodder, dry		10			
Rye straw and fodder, dry		5			
Wheat straw and fodder, dry		10			
Grain, aspirated grain fractions					16.0
Barley, hay					7.0
Barley, straw					3.5
Oat, forage				Not established[b]	0.10
Oat, hay				Not established[b]	0.10
Oat, straw				Not established[b]	0.10
Wheat, forage					3.0
Wheat, germ					0.20
Wheat, hay					7.0
Wheat, shorts					0.20
Wheat, straw					1.5

[a] proposed MRL, [b] The Ordinance of the Standards of Feed and Feed Additives - http://www.famic.go.jp/ffis/feed/obj/shore_eng.pdf

Table 9: Codex CXLs and overseas residue MRLs/tolerances for prothioconazole in animal commodities

Commodity[α]	Tolerance for residues arising from the use of prothioconazole (mg/kg)				
	Australia	Codex	EU	Japan	US
Animal Commodities					
Residue Definition	Prothioconazole sum of prothioconazole, prothioconazole desthio, prothioconazole-3-hydroxy-desthio and prothioconazole-4-hydroxy-desthio, expressed as prothioconazole.	Prothioconazole Prothioconazole-desthio	Prothioconazole prothioconazole-desthio	Prothioconazole sum of prothioconazole and its metabolites M17 [2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1*H*-1,2,4-triazole-1-il)-2 propanol] calculated as prothioconazole and glucronic acid conjugates of prothioconazole and metabolate M17, calculated as prothioconazole	Prothioconazole prothioconazole, 2-[2-(1-chlorocylcopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thion, including its metabolites and degradates.
Edible offal (mammalian)	0.1	0.5			
Cattle kidney			0.2	0.2	
Sheep kidney			0.2		
Cattle liver			0.2	0.2	
Sheep liver			0.2		
Cattle meat by-products					0.2
Sheep meat by-products					0.2
Edible offal, sheep			0.2		
Cattle, edible offal			0.2		
Poultry liver			0.05	0.02	0.02
Poultry kidney			0.05		
Poultry edible offal	*0.05				
Meat (mammalian) [in the fat]	*0.01				
Meat (from mammals other than marine mammals)		0.01			
Cattle fat			0.05	0.1	0.1
Sheep fat			0.05		0.1
Poultry fat			0.05		
Cattle, meat			0.05	0.02	0.02
Sheep meat			0.05		0.02
Poultry meat	*0.05 (in the fat)		0.05		
Milks	*0.004	0.004	*0.01	0.02	0.02
Eggs	*0.01		0.05		

Note: Standards are not known to be established in Russia or China.

Table 10: Codex CXLs and overseas residue MRLs/tolerances for tebuconazole in animal commodities

Commodity	Tolerance for residues arising from the use of tebuconazole (mg/kg)				
	Australia	**CODEX**	**EU**	**Japan**	**USA**
Animal Commodities					
Residue Definition	Tebuconazole Tebuconazole	Tebuconazole Tebuconazole	Tebuconazole Tebuconazole	Tebuconazole Tebuconazole	Tebuconazole sum of tebuconazole (alpha-[2-(4-chlorophenyl)ethyl]-alpha-(1,1-dimethylethyl)-1 *H* -1,2,4-triazole-1-ethanol) and its diol metabolite (1-(4-chlorophenyl)-4,4-dimethyl-3-(1 *H* -1,2,4-triazole-1-yl-methyl)-pentane-3,5-diol), calculated as the stoichiometric equivalent of tebuconzole
Edible offal (mammalian)	0.5				
Cattle kidney			0.1		
Sheep kidney			0.1		
Cattle liver			0.1	0.05	
Sheep liver			0.1	0.05	
Cattle meat by-products					0.2
Sheep meat by-products					0.2
Cattle, edible offal					
Poultry liver			0.1	0.05	
Poultry kidney			0.1	0.05	
Poultry edible offal	0.5	*0.05			
Meat (mammalian)	0.1	*0.05			
Cattle fat			0.1	0.05	
Sheep fat			0.1		
Poultry fat			0.1	0.05	
Cattle, meat			0.1	0.05	
Sheep meat			0.1		
Poultry meat	0.1	*0.05	0.1	0.05	
Milks	0.05	*0.01	*0.05	0.01	0.1
Eggs	0.1	*0.05	0.1	0.05	

Note: Standards are not known to be established in Russia or China.

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 http://www.apvma.gov.au/residues/standard.php.

Table 11: Current relevant entries in the MRL Standard – Table 1, Table 3 and Table 4

MRL STANDARD: TABLE 1

COMPOUND	FOOD	MRL (mg/kg)
PROTHIOCONAZOLE		
CM 0081	Bran, unprocessed of cereal grain	0.5
GC 0080	Cereal grains	T0.3
MO 0105	Edible offal (Mammalian)	0.1
PE 0112	Eggs	*0.01
MM 0095	Meat (Mammalian)[in the fat]	*0.01
ML 0106	Milks	*0.004
GC 0647	Oats	*0.05
PO 0111	Poultry, Edible offal of	*0.05
PM 0110	Poultry meat [in the fat]	*0.05
SO 0495	Rape seed [canola]	T*0.02
CF 1210	Wheat germ	0.5
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
SO 0495	Rape seed [canola]	T0.3

MRL STANDARD: TABLE 3

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

MRL STANDARD: TABLE 4

COMPOUND	ANIMAL FEED COMMODITY	MRL (mg/kg)
PROTHIOCONAZOLE		
	Cereal forage and fodder	7
	Cereal straw	0.3
AL 0157	Legume animal feeds	T3
	Rape seed [canola] forage, fodder and straw	T2
TEBUCONAZOLE		
	Primary feed commodities	50

The following changes are proposed to Australian prothioconazole and tebuconazole MRLs:

Table 12: Proposed changes to the MRL Standard – Table1, Table 4

MRL STANDARD: TABLE 1

COMPOUND	FOOD	MRL (mg/kg)
PROTHIOCONAZOLE		
DELETE:		
GC 0080	Cereal grains	T0.3
GC 0647	Oats	*0.05
SO 0495	Rape seed	T*0.02
ADD:		
GC 0080	Cereal grains	0.3
SO 0495	Rape seed	*0.02
TEBUCONAZOLE		
DELETE:		
SO 0495	Rape seed	T0.3
ADD:		
SO 0495	Rape seed	0.3

MRL STANDARD: TABLE 4

COMPOUND	FOOD	MRL (mg/kg)
PROTHIOCONAZOLE		
DELETE:		
	Rape seed [canola] forage, fodder and straw	T2
ADD:		
	Rape seed [canola] forage, fodder and straw	3

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 MRL/residue tolerance (import tolerance) is established in the importing country or (ii) where residues in Australian produce are likely to exceed an MRL/residue tolerance (import tolerance) established in the importing country.

While several overseas countries have established prothioconazole and tebuconazole MRLs in oats, triticale and 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 0.13 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 MRL established by Codex and the EU for prothioconazole in oats is 0.05 mg/kg. The MRL established by Codex for prothioconazole in triticale is also 0.05 mg/kg, below the Australian cereal grain MRL of 0.3 mg/kg. However, it is noted that the residue considered as the highest residue in cereal grains was 0.16 mg/kg, and the supervised trial median residue was 0.01 mg/kg.

Codex and the USA have also established MRLs of 0.05 and 0.15 mg/kg for tebuconazole in oats below the Australian MRL of 0.2 mg/kg.

The risk to export trade in grains is low for grains moving through major bulk handling systems. However, for grains exported by smaller marketers the risk may be higher than the major bulk handlers.

Approximately 85% of Australian hay exports are oaten hay, with the majority of this going to Japan. The Japanese Ordinance of the Standards of Feed and Feed Additives has not set import tolerances for oaten hay and therefore the risk to Australian exports is low.

Detectable residues of prothioconazole in animal commodities derived from animals that have consumed treated cereal and canola forage are not expected in milk, muscle and fat. Detectable residues may occur in liver and kidney, however, these are expected to be less than MRLs/import tolerances established in most major export markets. The anticipated residues of tebuconazole in milk, muscle, fat and kidney are expected to be below the limits of detection. However, residues in the liver may occur at up to 0.06 mg/kg based on the supplied animal feeding studies. This is slightly above the Japanese MRL of 0.05 mg/kg established for tebuconazole in the liver of cattle. The risk is no different to that of already approved uses and the conservative estimate to exposure and resulting residues is based on residues at the HR.

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.

The relevant industry groups should be given the opportunity to comment on the perceived level of risk and whether any industry-initiated strategies are required to manage the risk.

3 CONCLUSIONS

It is proposed to vary the MRLs for prothioconazole and tebuconazole in cereal grains and rape seed. Comment is sought on the potential for prothioconazole and tebuconazole in Prosaro 420 SC Foliar Fungicide to prejudice Australian trade when it is used to control various diseases in oats, stripe rust in triticale and blackleg in canola and when treated feeds are fed to animals

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: 9.00 - 5.00 (EST) Monday to Friday