

**Trade Advice Notice**

on

Tebuconazole and Prothioconazole

in the product

**Prosaro 420SC Foliar Fungicide**

[APVMA Product Number 63423]

June 2009

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# 1. PREFACE

## 1.1 About this Document

This is a Trade Advice Notice.

It indicates that the Australian Pesticides and Veterinary Medicines Authority (APVMA) is considering an application for registration of an 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 notice.

The APVMA will only consider comment on submissions that relate to the **trade implications** of the proposed use of the product. Comments received on matters other than trade implications will not be considered by the APVMA. Comments received on appropriate grounds will be considered with details posted on the APVMA website noting what action has/will be taken in regard to concerns.

Any advice the APVMA receives through this consultation which it relies on to grant this application will be noted in a subsequent Advice Summary.

Advice Summaries can be found at: [http://www.apvma.gov.au/registration/data\\_requirements\\_subpage.shtml](http://www.apvma.gov.au/registration/data_requirements_subpage.shtml)

## 1.2 Prior to Submission

Please note that subject to the *Freedom of Information Act 1982*, the *Privacy Act 1988* and the Agvet Codes all submissions received may be made publicly available. They may be listed or referred to in any papers or reports prepared on this subject matter.

The APVMA reserves the right to reveal the identity of a respondent (you) unless a request for anonymity accompanies your submission. If no request for anonymity is made, you will be taken to have consented to the disclosure of your identity for the purposes of Information Privacy Principle 11 of the *Privacy Act 1988*.

The contents of any submission will not be treated as confidential or confidential commercial information unless they are marked as such and you have provided justification such that the material is capable of being classified as confidential or confidential commercial information in accordance with the *Freedom of Information Act 1982* or the Agvet Codes as the case may be.

## 1.3 About this consultation

The APVMA invites comment on this Trade Advice Notice until the 8 July 2009.  
Submissions should be addressed to:

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## 2. INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Bayer CropScience Pty Ltd to register the new foliar fungicide Prosaro 420SC Foliar Fungicide (210 g/L tebuconazole and 210 g/L prothioconazole) for the control of various foliar diseases in wheat and barley.

Tebuconazole has previously been registered for foliar application to cereals at a maximum single application rate of 125g a.i./ha (e.g. Folicur 430 SC Fungicide APVMA Approval No. 46794). The proposal under consideration is for up to two applications at 63g a.i./ha. The proposed use of Prosaro 420SC Foliar Fungicide on wheat and barley will not require the establishment of new tebuconazole MRLs and no further consideration of trade risk associated with the use of tebuconazole is required here.

The potential for prothioconazole residues resulting from the proposed use of Prosaro 420SC Foliar Fungicide to unduly prejudice Australian trade is discussed below.

### 2.1 Proposed Use

The proposed use pattern for Prosaro 420 SC Foliar Fungicide is presented below:

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

CROP	PEST	RATE	CRITICAL COMMENTS
Barley	Net Form Net Blotch ( <i>Pyrenophora teres</i> f. <i>teres</i> )	150 to 300 mL/ha  (≡ 31.5 to 63 g tebuconazole /ha and 31.5 to 63 g prothioconazole /ha)	Monitor crops from mid-tillering.
	Spot Form Net Blotch ( <i>Pyrenophora teres</i> f. <i>maculata</i> )		On susceptible varieties apply at the first sign of disease development. Monitor and reapply within 14 to 21 days if conditions favour disease development.  Use the higher rates (up to 300 mL/ha) where conditions favour severe disease.  Where lower rates are used apply with Hasten at 1% v/v.  A maximum of two applications may be made per crop.
	Powdery Mildew ( <i>Blumeria graminis</i> f.sp. <i>hordei</i> )	150 to 300 mL/ha  (≡ 31.5 to 63 g tebuconazole /ha and 31.5 to 63 g prothioconazole /ha)	Monitor crops from mid-tillering.  Use the higher rate in higher yielding crops where conditions favour disease development or susceptible varieties are grown.  Up to two applications may be made per crop.

	Leaf scald ( <i>Rhynchosporium secalis</i> )	150 to 300 mL/ha  (≡ 31.5 to 63 g tebuconazole /ha and 31.5 to 63 g prothioconazole /ha)	Monitor crops from mid-tillering (earlier if no effective seed treatment has been applied).  On susceptible varieties apply at the first sign of disease development. Monitor and reapply within 14 to 21 days if conditions favour disease development.  Use the higher rates (up to 300 mL/ha) where conditions favour severe disease.  Where lower rates are used apply with Hasten at 1% v/v.  Up to two applications may be made per crop.
	Leaf rust ( <i>Puccinia hordei</i> )	150 to 300 mL/ha  (≡ 31.5 to 63 g tebuconazole /ha and 31.5 to 63 g prothioconazole /ha)	Monitor crops from late tillering.  Apply at the first sign of disease development. Monitor and reapply within 14 to 21 days if conditions favour disease development.  Use the higher rates (up to 300 mL/ha) where conditions favour severe disease, or disease is established in the lower canopy.  Where lower rates are used apply with Hasten at 1% v/v.  Up to two applications may be made per crop.

Crop	Pest	Rate	Critical Comments
Wheat	Stripe rust ( <i>Puccinia striiformis</i> )	150 to 300 mL/ha + Hasten at 1% v/v  (≡ 31.5 to 63 g tebuconazole /ha and 31.5 to 63 g prothioconazole /ha)	Monitor crops from 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.
	Stem rust ( <i>Puccinia graminis tritici</i> )		
	Leaf rust ( <i>Puccinia recondita</i> f.sp. <i>tritici</i> , <i>Puccinia triticina</i> )		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.  Up to two applications may be made per crop.

	Yellow leaf spot ( <i>Pyrenophora tritici-repentis</i> )	150 to 300 mL/ha  (≡ 31.5 to 63 g tebuconazole /ha and 31.5 to 63 g prothioconazole /ha)	Monitor crops from late tillering and spray before disease has infected any of the top three leaves of the crop. Aim to protect the three top leaves of the plant from disease.  Up to two applications may be made per crop.
	Septoria nodorum-glume blotch ( <i>Phaeosphaeria nodorum</i> )	150 to 300 mL/ha  (≡ 31.5 to 63 g tebuconazole /ha and 31.5 to 63 g prothioconazole /ha)	Monitor crops from late tillering.  Aim to protect the three top leaves of the plant from disease.  Where lower rates are used apply with Hasten at 1% v/v.  Up to two applications may be made per crop.

### Withholding periods:

#### Wheat and barley:

DO NOT harvest for 5 weeks after application.

DO NOT graze or cut for stock food for 14 days after application.

Proposed trade advice information:

### 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 Pty Ltd for the latest information on MRLs and import tolerances before using Prosaro.

## 2.2 Current and Proposed Australian MRLs for Prothioconazole

Current MRLs and residue definition for prothioconazole are presented below.

Table 1

Compound	Food	Current MRLs mg/kg
Prothioconazole	GC 0640 Barley	T*0.05
	MO 0105 Edible offal (mammalian)	*0.05
	PE 0112 Eggs	*0.01
	MM 0095 Meat (mammalian) [in the fat]	*0.01
	ML 0106 Milks	*0.004
	PO 0111 Poultry, edible offal of	*0.05
	PM 0110 Poultry meat [in the fat]	*0.05
	GC 0654 Wheat	*0.05

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

Table 4

Compound	Food	Current MRLs mg/kg	
Prothioconazole	AS 0640	Barley forage (fresh weight)	T*0.05
		Barley straw and fodder, dry	T*0.05
	AS 0654	Wheat forage (fresh weight)	*0.05
		Wheat straw and fodder	*0.05

The following amendments to the MRL Standard are proposed. MRLs in Tables 1 will be recommended for inclusion in the Australia New Zealand Food Standards Code:

Table 1

Compound	Food	MRL (mg/kg)	
DELETE			
Prothioconazole	GC 0640	Barley	T*0.05
	GC 0654	Wheat	*0.05
	MO 0105	Edible offal (mammalian)	*0.05
ADD:			
Prothioconazole	GC 0640	Barley	0.3
	GC 0654	Wheat	0.3
	CM 0081	Bran, unprocessed of cereal grain	0.5
	CF 1210	Wheat germ	0.5
	MO 0105	Edible offal (mammalian)	0.1

Table 4

Compound	Food	MRL (mg/kg)	
DELETE			
Prothioconazole	AS 0640	Barley forage (fresh weight)	T*0.05
		Barley straw and fodder, dry	T*0.05
		Wheat forage (fresh weight)	*0.05
	AS 0640	Wheat straw and fodder, dry	*0.05
ADD:			
Prothioconazole		Barley forage and fodder	7
		Barley straw	3
		Wheat forage and fodder	7
		Wheat straw	3

### 3. TRADE CONSIDERATIONS

#### 3.1 Commodities Exported

Major export commodities relevant to the consideration are wheat and barley grain and livestock commodities derived from animals fed on wheat and barley grain, forage, fodder

and straw. Residues in these commodities resulting from the use of ProSaro have the potential to unduly prejudice trade.

### 3.2 Destination and Value of Exports

In 2007/2008 Australia exported 7,421 kt of wheat and flour valued at \$2,997 million.<sup>1</sup> The major export markets are summarised below.

Table 1: Export Markets for Australian Wheat and Flour in 2007/2008

Export Market	Quantity (kt)
Indonesia	1621
Japan	878
Korea, Rep. of	694
Malaysia	623
Yemen	408
Egypt	284
New Zealand	275
Thailand	255
Kuwait	233
Iraq	198
Papua New Guinea	153

In 2007/2008 Australia exported 4,050 kt of barley (including grains and the grain equivalent of malt exported), valued at \$1,496 million.<sup>1</sup>

#### *Animal Commodities*

Animal commodities derived from livestock fed on wheat and barley grain, forage and straw are considered to be major export commodities. Based on available grain, forage and straw residue data for prothioconazole, residues may be found in animal commodities. No animal commodity MRLs/tolerances have been established for prothioconazole by some major trading partners for these commodities.

The value and destinations of Australian exports of beef, mutton, lamb and dairy products are summarised in the following tables.<sup>1</sup>

Table 2: Value of Australian beef exports from 2000 – 2007.

	2000 \$m	2001 \$m	2002 \$m	2003 \$m	2004 \$m	2005 \$m	2006 \$m	2007 \$m
<b>Beef and veal</b>								
Americas								
Canada	148.1	204.4	320.2	110.9	38.1	32.6	43.8	51.2
United States	1 172.8	1 699.7	1 593.6	1 332.3	1 374.4	1 186.4	1 180.7	1 136.3
Asia								
Chinese Taipei	116.7	132.6	152.3	126.7	124.2	148.3	134.6	117.4
Hong Kong, China	18.2	17.8	17.1	15.0	27.3	18.7	13.5	21.5
Indonesia	40.8	37.2	46.1	38.4	26.7	33.5	39.0	83.3
Japan	1 537.3	1 728.2	1 237.7	1 384.4	2 189.9	2 244.7	2 172.1	1 844.0
Korea, Rep. of	221.8	228.9	320.4	250.7	434.4	494.8	734.7	725.6
Malaysia	15.0	16.0	20.2	15.9	12.1	7.8	10.0	17.1
Philippines	34.3	55.8	36.1	23.0	4.3	5.9	3.7	7.2
Singapore	18.5	20.4	20.8	22.5	17.3	15.5	19.2	29.7
Europe								
European Union a	37.3	48.4	53.5	49.2	62.8	56.8	77.2	61.6
CIS	3.8	14.4	2.9	0.7	2.0	4.6	61.0	32.2
Eastern Europe	6.3	1.2	9.1	4.5	1.3	0.4	0.4	0.1
Middle East								
Kuwait	0.3	4.6	1.8	9.8	3.4	1.0	0.9	2.3
Saudi Arabia	2.1	23.0	11.6	7.8	3.1	1.7	4.5	3.0
United Arab Emirates	4.4	11.6	10.9	7.8	12.0	13.7	15.6	20.4

<sup>1</sup> Australian Commodity Statistics 2008, ABARE

Oceania								
New Zealand	11.1	6.3	25.6	15.9	9.8	8.8	8.0	7.8
Pacific Isles	5.2	7.2	7.4	5.4	4.5	4.0	6.3	10.0
Papua New Guinea	14.1	11.5	9.8	4.9	5.2	4.3	5.8	7.6
Total beef and veal	3 464.0	4 357.3	4 002.6	3 475.4	4 390.3	4 346.6	4 604.0	4 258.1

a Regarded as fifteen countries to May 2004, twenty five countries from June 2004, then twenty seven countries from January 2007.  
Source: Department of Agriculture, Fisheries and Forestry, *Export Statistics, Livestock Exports*, Canberra; ABS, *International Trade*, Australia, cat. no. 5465.0, Canberra

Table 3: Value of Australian sheep exports from 2000 – 2007.

	2000	2001	2002	2003	2004	2005	2006	2007
	\$m	\$m	\$m	\$m	\$m	\$m	\$m	\$m
<b>Mutton a</b>								
Canada	4.6	6.8	5.2	3.6	5.8	5.4	7.1	2.9
Chinese Taipei	26.3	36.9	48.9	32.2	41.9	34.8	29.8	23.2
CIS	3.1	3.7	5.4	1.3	5.8	13.5	33.1	23.5
European Union b	34.1	42.0	41.4	28.1	43.2	48.3	46.7	40.3
Japan	34.0	42.7	51.1	29.9	47.1	38.1	31.5	29.9
Korea, Rep. of	1.7	2.3	3.3	2.2	3.1	3.1	2.9	2.6
Malaysia	16.5	21.7	22.9	15.9	22.6	18.5	25.1	21.8
Papua New Guinea	6.2	7.4	6.6	6.1	5.1	5.2	4.2	6.5
Saudi Arabia	43.9	90.1	77.5	65.0	53.0	63.9	67.3	58.9
Singapore	18.4	23.4	23.2	20.4	22.0	18.6	19.5	19.3
South Africa	46.3	30.9	17.6	11.1	14.1	18.7	29.2	21.8
United States	43.9	56.4	64.7	67.9	48.6	44.4	50.2	43.2
Other	97.1	146.3	152.0	91.7	113.6	119.7	141.3	135.2
Total	376.4	510.6	519.7	375.3	426.0	432.0	487.9	429.2
<b>Lamb</b>								
European Union b	74.3	105.7	89.3	96.9	93.4	83.9	85.6	82.2
Japan	30.7	37.0	40.8	42.3	53.5	79.1	83.0	56.0
Papua New Guinea	16.0	18.0	15.7	14.4	17.3	19.4	20.0	23.8
South Africa	15.3	5.5	1.2	2.1	3.5	5.3	9.0	7.5
United Arab Emirates	24.2	27.4	31.6	29.9	27.0	32.8	47.1	56.4
United States	150.2	219.9	218.2	257.5	259.9	324.2	319.0	328.4
Other	137.0	165.7	169.5	159.8	184.7	233.1	229.4	268.0
Total	447.7	579.1	566.2	602.9	639.3	777.8	793.2	822.3

a Includes young sheep and hoggets. b Regarded as twenty five countries  
Sources: ABS, *International Trade*, Australia, cat. no. 5465.0, Canberra.

Table 4: Value of Australian dairy exports from 2001 – 2008.

	Unit	2001-02	2002-03	2003-04	2004-05	2005-06	2006-07	2007-08
<b>Cheese</b>								
Japan	\$m	429.5	272.0	299.6	378.9	298.5	337.9	426.7
Philippines	\$m	20.0	15.7	11.1	18.4	13.7	13.1	23.4
Saudi Arabia	\$m	148.2	98.9	69.0	81.5	103.5	86.7	89.7
United Kingdom	\$m	21.5	15.2	18.3	20.5	20.1	14.8	21.2
United States	\$m	48.3	36.1	33.9	45.4	54.2	52.7	37.2
Other	\$m	367.3	362.4	307.4	332.0	347.2	319.0	370.1
Total	\$m	1 034.8	800.3	739.2	876.7	837.2	824.2	968.3
<b>Butter and butterfat a</b>								
Egypt	\$m	23.5	18.9	6.4	10.5	12.5	13.9	5.0
Malaysia	\$m	14.4	12.7	13.5	11.6	15.8	11.0	17.4
Philippines	\$m	5.1	3.7	1.9	2.8	5.4	3.2	2.4
Singapore	\$m	20.4	15.5	18.2	16.8	21.1	14.4	26.2
Thailand	\$m	23.0	13.2	12.7	13.5	12.0	9.8	13.9
Other	\$m	211.1	160.0	130.1	133.2	157.9	126.2	129.6
Total	\$m	297.5	224.0	182.9	188.5	224.7	178.6	194.6
<b>Skim milk powder</b>								
Japan	\$m	53.7	29.6	13.3	10.6	12.5	11.1	9.8
Malaysia	\$m	88.4	51.4	52.7	64.2	77.1	72.2	63.4
Philippines	\$m	143.5	71.8	60.1	49.4	72.0	46.1	64.1

Singapore	\$m	52.8	38.4	42.4	57.8	56.1	67.1	61.8
Thailand	\$m	69.1	33.2	20.0	21.7	76.8	51.1	48.6
Other	\$m	290.5	184.1	199.0	216.4	234.3	257.3	285.6
Total	\$m	698.0	408.5	387.5	420.1	528.9	505.0	533.2
<b>Casein</b>								
Japan	\$m	26.7	20.6	23.3	23.1	30.4	31.8	38.4
United States	\$m	80.5	81.4	68.8	56.6	27.3	32.4	42.2
Other	\$m	15.5	26.4	30.5	36.5	31.3	49.3	44.2
Total	\$m	122.6	128.4	122.5	116.2	89.0	113.5	124.8
<b>Wholemilk powder</b>								
Malaysia	\$m	39.2	22.3	28.9	33.1	23.8	14.5	27.3
Singapore	\$m	29.7	25.2	21.4	30.9	44.6	41.4	88.9
Taiwan	\$m	54.1	44.9	40.0	31.5	22.8	13.5	11.8
Thailand	\$m	22.6	14.0	12.0	8.6	10.5	12.3	14.7
Other	\$m	425.5	273.4	219.6	220.3	231.9	193.1	249.4
Total	\$m	571.1	379.8	321.8	324.4	333.6	274.9	392.2
<b>Other products</b>								
Fresh milk	\$m	98.2	98.2	104.0	108.8	107.3	96.3	83.6
Other fresh products	\$m	7.9	5.6	9.6	9.1	6.3	11.8	12.0
Condensed milk	\$m	123.7	133.3	121.0	139.8	147.5	156.9	152.4
Other powders	\$m	277.3	274.4	257.3	248.3	241.5	211.0	247.4
Total	\$m	507.0	511.5	492.0	506.0	502.6	476.0	495.4
a Includes ghee, dry butterfat, butter concentrate and butter oil, all expressed as butter.								
Source: ABS, <i>International Trade</i> , Australia, cat. no. 5465.0, Canberra.								

### 3.3 Results from Residues Trials Presented to the APVMA

Data were submitted from sixteen residues trials 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 (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. MRLs of 0.3 mg/kg for prothioconazole in wheat and barley grain are 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. MRLs of 3 mg/kg for wheat and barley straw are 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 (DW), at 13 - 14 days after application. MRLs of 7 mg/kg for wheat and barley forage and fodder are recommended in conjunction with a 14 day grazing and cutting WHP.

**Processed fractions:** In a wheat processing study, calculated processing factors were 2.4x for bran and 2.0x for germ. MRLs of 0.5 mg/kg are recommended for prothioconazole in unprocessed bran of cereal grain and wheat germ, based on a highest residue of 0.12 mg/kg in whole grain.

**Animal commodity MRLs:** An animal feeding study was submitted to the APVMA where residues of prothioconazole and its metabolites JAU6476 -desthio and JAU6476 -4-hydroxy were determined in lactating dairy cows following administration of prothioconazole at levels equivalent to 10 ppm, 30 ppm and 100 ppm in the feed. Based on metabolism studies, the residues may be slightly underestimated relative to the Australian residue definition however this is not considered to be significant in the context of the anticipated livestock burden. The results of this study are consistent with those of another lactating cow study where dosing was conducted with JAU6476-desthio and residues of JAU6476-3-hydroxy-desthio, JAU6476-4-hydroxy-desthio and JAU6476-desthio residues determined.

Residues in tissues and milk at a feeding level of 10 ppm, estimated residues at a maximum dietary burden of 5 ppm, and proposed prothioconazole MRLs are summarised below.

Sample	Prothioconazole residues after dosing at 10 ppm (mg/kg)	Estimated Residue (based on HR; mg/kg)	Proposed MRL (mg/kg)
Liver	0.07, 0.10, 0.12	0.06	0.1
Kidney	0.06, 0.07, 0.08	0.04	
Muscle	<0.01, <0.01, <0.01	<0.01	No change
Fat	<0.05, <0.05, <0.05	<0.05	No change
Milk (30 ppm)	<0.005	<0.005	No change

The estimated livestock burden of 5ppm is based on the highest residue observed in forage following treatment at twice the proposed rate. An increase in the edible offal MRL for prothioconazole to 0.1 mg/kg is recommended.

No changes are required to the current MRLs for poultry tissues and eggs.

### 3.4 Overseas registration and approved label instructions

Use-patterns for prothioconazole/ tebuconazole co-formulations registered overseas, as supplied by the Applicant, is tabulated below.

Country	Product (active in g/L)	Crop	Use-pattern
Austria	Prosaro (125g prothioconazole/L + 125g tebuconazole/L, EC)	Barley, Rye, Triticale, Wheat	Apply 1 L/ha at infection, up to 2 applications at 14-21 day intervals.
Belgium	Prosaro (125g prothioconazole/L + 125g tebuconazole/L, EC)	Oat, Rye, Spelt, Triticale, Wheat	Apply 1 L/ha as a single application, from BBCH 32 – 65.
Germany	Prosaro (125g prothioconazole/L + 125g tebuconazole/L, EC)	Barley, Rye, Triticale, Wheat	Apply 1 L/ha at infection, up to 2 applications at 14 - 21 day intervals.
Hungary	Prosaro (125g prothioconazole/L + 125g tebuconazole/L, EC)	Wheat	Apply 0.75 – 1 L/ha at BBCH 32 – 69, up to 2 applications, 35 day PHI.
Ireland	Prosaro (125g prothioconazole/L	Barley, Oats, Rye,	Apply 1 - 1.2 L/ha at infection, 2-3

	+ 125g tebuconazole/L, EC)	Triticale, Wheat	applications, 61 day PHI (barley, oats, triticale), 71 day PHI (rye, wheat).
Luxembourg	Prosaro (125g prothioconazole/L + 125g tebuconazole/L, EC)	Oat, Rye, Spelt, Triticale, Wheat	Apply 1 L/ha between BBCH 32 and 65.
New Zealand	Prosaro (125g prothioconazole/L + 125g tebuconazole/L, EC)	Barley, Wheat	Apply 1 L/ha at infection, up to 2 applications at 21 - 28 day intervals, 42 day PHI (forage), 56 day PHI (grain).
Switzerland	Prosaro (125g prothioconazole/L + 125g tebuconazole/L, EC)	Barley, Rye, Triticale, Wheat	Apply 1 L/ha either at BBCH 13 or BBCH 31 – 61 (rye, wheat) or at infection, 1 application only , 51 day PHI (barley), 61 day PHI (rye, triticale, wheat).
United Kingdom	Prosaro (125g prothioconazole/L + 125g tebuconazole/L, EC)	Barley, Oats, Rye, Wheat	Apply 1 L/ha (oats) or 1.2 L/ha (rye, oats, barley, wheat) at infection, up to 2 applications (oats, barley) or 3 applications (rye, wheat), 61 day PHI (barley) or 71 day PHI (rye, wheat).

### 3.5 Codex Alimentarius Commission and overseas MRLs

Relevant residue tolerances for prothioconazole in plant and animal commodities are tabulated below. Codex CXLs, Japanese, Taiwanese and Korean MRLs have not yet been established for prothioconazole.

Commodity <sup>a</sup>	Tolerance for residues arising from the use of prothioconazole (mg/kg)			
	Australia	Codex	EU	USA
<b>Plant Commodities</b>				
Residue Definition	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 <sup>7</sup> .	Prothioconazole-desthio (JMPR)	Prothioconazole (Prothioconazole-desthio)	Prothioconazole, 2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione, and prothioconazole-desthio, $\alpha$ -(1-chlorocyclopropyl)- $\alpha$ -[(2-chlorophenyl)methyl]-1H-1,2,4-triazole-1-ethanol, calculated as parent
Oats		0.05 <sup>^</sup>	0.05	
Oat straw		2 <sup>^</sup>		
Wheat	*0.05 (current) <b>0.3 (proposed)</b>	0.05 <sup>^</sup>	*0.02 (Buckwheat) 0.1 (Spelt triticale)	0.07 (grain)
Wheat forage	*0.05 (Wheat forage (fresh weight)) <b>7 (Wheat forage, dry)</b>			8
Wheat straw and fodder, dry	*0.05 (Wheat straw and fodder) <b>3 (proposed straw)</b> <b>7 (proposed fodder)</b>	2 <sup>^</sup> (Wheat straw)		4.5 (hay) 5.0 (straw)
Barley	T*0.05 <b>0.3 (proposed)</b>	0.05 <sup>^</sup>	0.3	0.35 (grain)
Barley forage (fresh weight)	*0.05 Barley forage (fresh weight) <b>7 (proposed)</b>			
Barley straw and fodder, dry	T*0.05 <b>3 (proposed straw)</b> <b>7 (proposed fodder)</b>	2 <sup>^</sup> (Barley straw)		7.0 (hay) 4.0 (straw)

Grain, aspirated fractions				11
<b>Animal Commodities</b>				
Residue Definition	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 <sup>7</sup> .	Prothioconazole-desthio, prothioconazole-desthio-3-hydroxy (M14) and prothioconazole-desthio-4-hydroxy (M15) and their conjugates expressed as prothioconazole-desthio (JMPR)	Prothioconazole (Prothioconazole-desthio)	Prothioconazole, 2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione, and prothioconazole-desthio, $\alpha$ -(1-chlorocyclopropyl)- $\alpha$ -[(2-chlorophenyl)methyl]-1H-1,2,4-triazole-1-ethanol, and conjugates that can be converted to these two compounds by acid hydrolysis, calculated as parent
Edible offal (mammalian)	*0.05 <b>0.1</b>	0.2 <sup>^</sup>		
Cattle kidney			0.05	
Sheep kidney			0.05	
Cattle liver			0.2	
Sheep liver			0.05	
Cattle meat by-products				0.2
Sheep meat by-products				0.2
Edible offal, sheep			0.05	
Cattle, edible offal			0.05	
Other poultry liver			0.05 (Poultry liver)	0.02 (Poultry liver)
Chicken kidney				
Other poultry kidney			0.05 (Poultry kidney)	
Other poultry edible offal	*0.05 (Poultry edible offal)		*0.01 (Poultry edible offal)	
Meat (mammalian) [in the fat]	*0.01	0.01 <sup>^</sup> Mammalian fats (except milk fats)		
Cattle fat			0.05	0.1
Sheep fat			0.05	0.1
Other poultry fat			0.05 (Poultry fat)	
Cattle, meat		0.01 <sup>^</sup>	0.05	0.02

		Meat (from mammals other than marine mammals)		
Sheep meat			0.05	0.02
Chicken muscle				
Other poultry muscle	*0.05 (Poultry meat [in the fat])		0.05 (Poultry meat)	
Milks	*0.004	*0.004 <sup>^</sup>	*0.01 (Cattle milk and cream) *0.01 (Sheep milk and cream)	0.02
Eggs	*0.01		0.05 (Chicken eggs)	

<sup>a</sup> Commodity covered by tolerance. For instance, tolerance may be for bovine liver which covers cattle liver.

<sup>^</sup> Proposed draft MRLs. Recommended for adoption at Step 5/8 with omission at steps 6 and 7. To be considered at the Thirty-second session of Codex Alimentarius Commission in Rome, Italy 29/6/09 – 4/7/09.

Note: Australian MRLs which are bold and italicised are those which are proposed as a result of this evaluation.

### 3.6 Potential Risk to Trade

Export of treated produce containing finite (measurable) residues of prothioconazole may pose a risk to Australian trade in situations where (i) no residue tolerance (import tolerance) is established in the importing country or (ii) where residues in Australian produce are likely to exceed a residue tolerance (import tolerance) established in the importing country.

The applicant has proposed the following label statement:

#### **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 Pty Ltd for the latest information on MRLs and import tolerances before using Prosaro.

#### Wheat and barley grain:

The highest observed residue in grain following application of prothioconazole according to the proposed GAP which includes 2 applications, was 0.12 mg/kg. Noting that:

- The method LOQ, based on the residue definition rather than individual analytes, is 0.11 mg/kg.
- The expectation of the applicant is that 2 applications to wheat will seldom be needed, and if so the retreatment interval is likely to be greater than the 14 days addressed in the residue trials.
- The Codex Alimentarius Commission is considering the establishment of relevant Codex MRLs of 0.05 mg/kg in 2009.

The risk to export trade in wheat and barley grain is low for grains moving through major bulk handling systems. For grains exported by smaller marketers the risk may be higher but is still considered acceptable.

#### Animal Commodities:

Prothioconazole animal commodity MRLs have not been established in some overseas markets. Finite residues in the order of 0.06 mg/kg may occur in offals of animals fed treated forages and fodders. Noting that:

- The likely residue in offal is based on a high residue of 4.7 mg/kg (DW) in forage following a single treatment at twice the label rate. Residues as a result of exposure to forage and fodder treated with 2 applications at the label rate are expected to be lower. The highest residue observed at the proposed grazing withholding period in forage following a single treatment at the label rate was 2.4 ppm.
- The expectation of the applicant is that 2 applications to wheat will seldom be needed, and if so the retreatment interval is likely to be greater than the 14 days addressed in the residue trials.
- The Codex Alimentarius Commission is considering the establishment of mammalian offal MRLs of 0.2 mg/kg in 2009.

#### 4. CONCLUSION

Comment is sought on the potential for the proposed uses of Prosaro 420SC Foliar Fungicide to prejudice Australian trade in wheat, barley and animal commodities.

A more detailed technical assessment report on the evaluation of the trade implications of this chemical can be obtained by contacting the APVMA at [to be arranged] 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