

Trade Advice Notice

on

Fenbuconazole

in the product

Indar Fungicide
[APVMA product number 54526]

Date June 2009

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 extended use of the product. Comments received outside these grounds will not be considered by the APVMA. Comments made 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

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.

About this consultation

The APVMA invites comment on this Trade Advice Notice until the 1 July 2009

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1. INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Dow AgroSciences Australia Ltd to extend the current use pattern of Indar Fungicide containing fenbuconazole, to include the control of stripe rust on wheat.

The proposed Australian use pattern for Indar Fungicide to control stripe rust on wheat is given below:

Indar Fungicide (240 g/L fenbuconazole)

Crop	Pest	Rate	Critical Comments
Wheat	Stripe rust (<i>Puccinia striiformis</i>)	150-300 mL/ha (36-72 g ai/ha) plus Uptake™ Spraying Oil at 500 mL/100 L	<p>Apply before 1% of the leaf area is infected. Best results will be achieved when applied before disease is detected in the crop. Use the higher rate when disease is present at application; or when conditions favour disease development; or where longer residual protection is required.</p> <p>If a spray is applied prior to flag leaf emergence and conditions are favourable for disease development, then a second spray may be required. In this situation, spray at full flag leaf emergence and before 1% of the leaf area is infected.</p> <p>Crop growth stages: -Do not apply later than head emergence (Z GS 59). -Do not apply more than 2 applications of 300 mL/ha.</p> <p>Adjuvants: Always apply with Uptake Spraying Oil at 500 mL/100L</p>

Withholding periods:

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

Harvest (Wheat): Not required when used as directed.

Livestock destined for export markets

The grazing withholding period only applies to stock slaughtered for the domestic market. Some export markets apply different standards. To meet these standards, ensure that in addition to complying with the grazing withholding period, the Export Slaughter Interval is observed before stock are sold or slaughtered.

Export slaughter interval (ESI)

After observing the withholding period for grazing or cutting for stock food, livestock that have been grazed on or fed treated crops should be placed on clean feed for 3 days prior to slaughter.

2. TRADE CONSIDERATIONS

2.1 Commodities Exported

Wheat is considered a major export commodity.

2.2 Destination and Value of Exports

In 2006/07 Australia exported 11,196 kt of wheat and flour valued at \$2,765 million.¹ Major export markets are summarised in Table 1.

Table 1: Export markets for Australian wheat and flour in 2006/07

Export market	Quantity (kt)
Indonesia	2 574
India	1 593
Japan	1 114
Korea, Rep. of	989
Malaysia	629
Yemen	385
Iraq	362
New Zealand	350
Egypt	251
Kuwait	250

The value and destinations of Australian exports of beef, mutton, lamb, and dairy products are summarised in the tables 2 to 4.

¹ Australian Commodity Statistics 2007, ABARE

Table 2: Export markets for Australian beef.

	2000	2001	2002	2003	2004	2005	2006	2007
	\$m	\$m	\$m	\$m	\$m	\$m	\$m	\$m
Beef and veal								
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
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, <i>Export Statistics, Livestock Exports</i> , Canberra; ABS, <i>International Trade</i> , Australia, cat. no. 5465.0, Canberra								

Table 3: Export markets for Australian sheep meat.

	2000	2001	2002	2003	2004	2005	2006	2007
	\$m	\$m	\$m	\$m	\$m	\$m	\$m	\$m
Mutton a								
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
Lamb								
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, <i>International Trade</i> , Australia, cat. no. 5465.0, Canberra.								

Table 4: Export markets for Australian dairy products.

	Unit	2001-02	2002-03	2003-04	2004-05	2005-06	2006-07	2007-08
Cheese								
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
Butter and butterfat ^a								
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
Skim milk powder								
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
Casein								
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
Wholemilk powder								
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
Other products								
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.								

2.3 Results from residues trials presented to the APVMA

Dow AgroSciences Australia Ltd provided details of nine trials conducted in Australia. Wheat was treated with two applications of fenbuconazole at 72g/ha or 144 g/ha at 2nd node (GS32) and full head emergence (GS59). Wheat forage was collected at 7, 14, 28 and 42 days after application. Grain and straw were collected at commercial harvest.

Fourteen days after two applications at the proposed rate of 72 g ai/ha, fenbuconazole residue levels (DW) in forage were 0.41, 0.51, 0.54 and 1.04 mg/kg. The data shows a continual gradual decrease in the amount of residue detected from 0 days after application till 42 days after application. Trial data shows that two applications at twice the application rate (144 g ai/ha) lead to residue levels of 0.72, 0.85, 0.95 and 1.6 mg/kg on forage. A wheat forage MRL of 2 mg/kg of fenbuconazole is recommended with a 14 day withholding period for grazing and cutting for stockfood.

After two applications at the proposed rate of 72 g ai/ha fenbuconazole residues in straw were <0.003, 0.06 (2), 0.07, 0.08, 0.09, 0.1, 0.11 (2) mg/kg. Two applications at twice the application rate (144 g ai/ha) gave residue levels of 0.15, 0.17 (3), 0.18, 0.2, 0.22, 0.25, 0.34 mg/kg in straw. A wheat straw MRL of 1 mg/kg of fenbuconazole is recommended.

No fenbuconazole residues were detected above the LOD (0.003 mg/kg) on wheat grain at harvest on crops treated with 72 or 144 mg/kg in any of the nine trials. The residue trials support a wheat grain MRL of *0.01 mg/kg with a WHP of 'Not Required When Used As Directed'.

An animal transfer study where lactating cows were administered fenbuconazole at 6.5, 19.5 and 65 ppm in the feed was used to determine animal commodity MRLs. Maximum fenbuconazole residues at the administered dose equivalent to 6.5 ppm were 0.01 mg/kg in muscle, 0.093 mg/kg in liver and <0.01 mg/kg in fat, kidney and milk. These values, when corrected for an exposure of 2 ppm fenbuconazole in feed (proposed wheat forage MRL) result in residues of 0.029 mg/kg in liver, 0.0031 mg/kg in muscle and <0.01 mg/kg in fat and kidney. At the highest residue level in wheat forage of 1.04 ppm, the predicted residue level in the liver is 0.015 mg/kg. The current animal MRLs of 0.01 mg/kg for meat (mammalian) and milk remain appropriate and accommodate livestock exposure from forage treated with fenbuconazole as proposed in the use pattern. However it is recommended that the edible offal (mammalian) MRL be increased from *0.01 to 0.05 mg/kg.

The animal transfer study showed that residues in the liver decreased from a mean of 0.0775 mg/kg to 0.037 mg/kg, 0.175 mg/kg to 0.096 mg/kg and 0.615 mg/kg to 0.14 mg/kg after a depuration period of 3 days at feeding levels of 6.5 ppm, 19.5 ppm and 65 ppm respectively. Based on the slowest observed depuration rate at the highest observed residue level of 1.04 ppm in the feed, it is estimated that residues of 0.0068 mg/kg will result in the liver after 3 days on clean feed. This is below the limit of quantification (0.01 mg/kg), the target level for an export slaughter interval. An export slaughter interval of 3 days is appropriate to mitigate any risk to trade animal commodities from the proposed use.

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) approved by various countries. Some countries may accept Codex CXLs when importing foods. Fenbuconazole has been considered by Codex. A Codex CXL of 0.1 mg/kg for wheat has been established in addition to CXLs of 0.05 mg/kg in mammalian meat, mammalian meat, in fat, milk, kidney and liver.

Table 5. The following overseas residue MRLs/tolerances have been established for fenbuconazole.

	Australia	Codex	US	EU	Japan	Korea
Wheat, grain	*0.01 (proposed)	0.1	0.1	0.1	0.1	None est.

Table 6. Comparison of Australian MRLs with overseas MRLs for fenbuconazole.

Commodity	Australia	Codex	Japan	USA	Korea	Taiwan	EU
Mammalian meat	0.01*	0.05*	0.05	0.01	0.05	-	0.05*
Mammalian meat, in the fat	-	0.05*	0.05	0.01	0.05	-	0.05*
Milk	0.01*	0.05*	0.05	-	0.05	-	0.05*
Milk, fat	-	-	-	-	-	-	0.05*
Edible offal	#0.05	-	0.05	0.05	-	-	0.05*
Kidney	-	0.05*	0.05	-	0.05	-	0.05*
Liver	-	0.05	0.05	-	0.05	-	0.05*

#proposed MRL

It is noted that the Codex residue definition for fenbuconazole is the parent compound (FAO and WHO, 1998²). However the US has established a more complex residue definition which includes the metabolites *cis*-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl)-2-3*H*furanone and *trans*-5-(4-chlorophenyl)dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl)-2-3*H*-furanone.

² Pesticide residues in food- 1997 Evaluations Part 1- Residues, FAO and WHO 1998 page 453.

2.5 Current and proposed Australian MRLs for fenbuconazole.

The current MRLs for fenbuconazole are listed below:

Table 1

Compound	Food	MRL (mg/kg)	
Fenbuconazole	MO 0105	Edible offal (mammalian)	*0.01
	MM 0095	Meat (mammalian)	*0.01
	ML 0106	Milks	*0.01
	PE 0112	Eggs	*0.01
	PO 0111	Poultry, Edible offal	*0.01
	PM 0110	Poultry meat	*0.01
	FS 0012	Stone fruit (except nectarine)	T1

Table 3

Compound	Residue
Fenbuconazole	Fenbuconazole

The following amendments to the MRL Standard are proposed as a result of evaluation of data for Indar Fungicide:

Table 1

Compound	Food	MRL (mg/kg)	
Fenbuconazole			
DELETE:	MO0105	Edible offal (mammalian)	*0.01
ADD:	GC0654	Wheat	*0.01
	MO0105	Edible offal (mammalian)	0.05

Table 4

Compound	Animal feed commodity	MRL (mg/kg)	
ADD:			
Fenbuconazole	AS0654	Wheat fodder	1
		Wheat forage (green)	2

2.6 Required WHPs for above MRLs

Withholding periods:

Wheat:

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

Harvest: Not required when used as directed.

2.7 Potential Risk to Trade

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

Wheat is considered in a major export commodity³. The trials provided by the applicant showed that all grain samples had residues that were below the limit of detection (0.003 mg/kg) for fenbuconazole. Of the countries that have established fenbuconazole MRLs for wheat, all are 0.1 mg/kg which is higher than the proposed Australian MRL for wheat of 0.01 mg/kg. Therefore the overall risk to export trade of wheat is considered to be negligible.

Residues may be present in the liver of animals that have consumed fodder containing fenbuconazole residues at levels above the limit of quantification. Taiwan does not have a suitable MRL established to cover these residues in liver.

The animal transfer study showed that following a depuration period of 3 days, residues in the liver decreased by 52%, 45% and 77% at feeding levels of 6.5 ppm, 19.5 ppm, and 65 ppm respectively. Based on the slowest observed depuration rate at the highest observed residue level of 1.04 ppm, it is estimated that residues of 0.0068 mg/kg will result in the liver after 3 days on clean feed. This is below the limit of quantification (0.01 mg/kg), the target level for an export slaughter interval. An export slaughter interval of 3 days is appropriate to mitigate any risk to trade animal commodities from the proposed use.

3 CONCLUSION

Residues of fenbuconazole in wheat as a result of the proposed use of Indar Fungicide are expected to be below detectable levels. It is proposed that an MRL for wheat be set at the limit of quantification (*0.01 mg/kg). The risk to trade in wheat grain is considered to be low.

Detectable residues may be present in the forage and fodder of wheat which may result in detectable residues in liver following grazing of treated forage. A 3 day Export Slaughter Interval is recommended for livestock that have been grazed on or fed treated forage or fodder to mitigate the risk to trade in offal associated with the proposed use.

Comment is sought on the potential for Indar Fungicide to prejudice Australian trade when it is used to treat stripe rust on wheat.

³ <http://www.apvma.gov.au/archive/0203downloads/gazette0203p39.pdf>

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