Australian Government

Australian Pesticides and Veterinary Medicines Authority

TRADE ADVICE NOTICE

on quinoxyfen in the product Legend Fungicide

APVMA Product Number 53607

[MARCH 2016]

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PREFACE

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an independent statutory authority with responsibility for assessing and approving agricultural and veterinary chemical products prior to their sale and use in Australia.

In undertaking this task, the APVMA works in close cooperation with advisory agencies, including the Department of Health and Aging, Office of Chemical Safety and Environmental Health (OCSEH), 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 regulatory guidance published on the APVMA website.

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 Legend Fungicide should be granted. Submissions should relate only to matters that the APVMA is required by legislation to take into account in deciding whether to grant the application. These grounds relate to the trade implications of the extended use of the product. Submissions should state the grounds on which they are based. Comments received outside these grounds cannot be considered by the APVMA.

Submissions must be received by the APVMA by close of business on Thursday 7 April 2016 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:

Scientific Assessment and Chemical Review
Residues and Trade
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Symonston ACT 2609

Phone: +61 2 6210 4701
Email: enquiries@apvma.gov.au.

Further information

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

Further information on public release summaries can be found on the APVMA website: www.apvma.gov.au.

[1] A full definition of 'confidential commercial information' is contained in the Agvet Code.

1 INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Dow AgroSciences Australia Limited, to vary the registration of Legend Fungicide to include application to barley for the control of powdery mildew.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Barley 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 feeds produced from treated barley. Residues in these commodities resulting from the use of Legend Fungicide may have the potential to unduly prejudice trade.

2.2 Destination and value of exports

In 2014–15 Australia exported 6208 kt of barley, valued at $2137 million (source ABARES 2015).

The largest export markets for Australian barley are shown below.

Table 1: Major destinations for Australian barley

GRAIN	MAJOR DESTINATIONS
Barley	Asia including China, Japan, Rep. of Korea, Thailand and Vietnam; Middle East including the United Arab Emirates and Kuwait

The significant export markets for animal commodities are defined in Part 5B of the Data Guidelines.

[2] APVMA Regulatory Guidelines—Data Guidelines: Agricultural—Overseas trade (Part 5B)

2.3 Proposed Australian use-pattern

Table 2: Proposed use pattern

CROP	PEST	RATE/HA	CRITICAL COMMENTS
Barley	Powdery mildew	50–75 g a.i./ha	DO NOT apply after barley growth stage Z39 DO NOT apply more than 2 applications to any barley crop in one season. Legend Fungicide should be applied at the first sign of infection as a protectant treatment only. Monitor barley crops regularly from early tillering and apply at or before Z31. Monitor if conditions favour disease development and reapply from 21 to 28 days after the first application (Z39). Use the higher rates where conditions favour severe disease development. Legend Fungicide will only be effective on powdery mildew in barley. If other diseases are suspected or detected then apply with the label rate of PropiMax Fungcide.

Withholding periods

Harvest: Not required when used as directed.

Grazing: Do not graze or cut for stock food for 28 days after application.

Trade advice:

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)—14 days

After observing the withholding period for grazing and cutting for stock food, livestock that have been grazed on or fed treated crops should be placed on clean feed for 14 days prior to slaughter.

2.4 Results from residues trials presented to the APVMA

The Applicant submitted details of five Australian trials conducted on barley in 2013 approximating the proposed Australian GAP. Supporting information from seventeen European trials was available however these did not approximate the proposed Australian use pattern and were not considered for the purpose of MRL setting.

No detectable residues were observed in grain (LOD = 0.003 mg/kg), after two applications at target rates of 50 g a.i./ha (0.67× the maximum proposed application rate) and 100 g a.i./ha (1.33×), with the final application occurring at or before growth stage BBCH 39, analogous to Z39.

As the Australian trials were carried out at the proposed GAP timing, at application rates up to 1.33× the proposed application rate and no detectable residues were observed, it is appropriate to establish an MRL at *0.01 mg/kg for the use of quinoxyfen on barley.

A harvest WHP of 'Not required when used as directed' in conjunction with the restraint 'DO NOT apply after barley growth stage Z39' is supported.

In the Australian trials dry weight residues in forage at a 28–29 day WHP, after two applications at a target rate of 100 g a.i./ha (1.33×) scaled to expected residues at 1× the proposed application rate (75 g a.i./ha) then residues in rank order are:

0.38, 0.65, 1.7, 1.7 and 1.8 mg/kg.

A quinoxyfen MRL of 5 mg/kg for Barley forage (green), is considered appropriate for the use of quinoxyfen on barley in conjunction with a 28–day grazing WHP.

In the Australian trials conducted on barley in 2013, observed dry weight residues in straw at a 70–102 day WHP, after two applications at a target rate of 100 g a.i./ha (1.33×) scaled to expected residues at 1× the proposed application rate (75 g a.i./ha) then residues in rank order are:

0.075, 0.14, 0.28, 0.36 and 0.53 mg/kg.

A quinoxyfen MRL of 2 mg/kg for AS 0640 Barley straw and fodder, dry, is considered appropriate.

Based on the highest barley forage and barley straw residue observations in the Australian trials of 1.8 mg/kg and 0.53 mg/kg respectively, (after scaling to 1×), and <0.01 mg/kg for barley grain, the anticipated dietary burden of quinoxyfen to livestock (beef and dairy cattle) is calculated below, with contributions from grape pomace (approved use):

Beef Cattle 500 kg bw, 20 kg dm/day

COMMODITY	RESIDUE (mg/kg)	BASIS	DM (%)	RESIDUE DW (mg/kg)	MAXIMUM DIET CONTENT (%)	CALCULATED DIET CONTENT (%)	MG/ANIMAL	RESIDUE CONTRIBUTION (ppm)
Barley forage	1.8	HR	100	1.8	50	50	18	0.9
Barley straw	0.53	HR	100	0.53	100	30	3.18	0.16
Barley grain	<0.01	STMR	88	0.01	80	–	–	–
Grape pomace	4.32*	STMR	100	4.32	20	20	17.28	0.86
Total						100		1.92

*Concentration factor of 9.6 and the STMR from Australian grape trials of 0.45 mg/kg (Dow Legend Fungicide 53607)

Dairy Cattle 500 kg bw, 20 kg dm/day

COMMODITY	RESIDUE (mg/kg)	BASIS	DM (%)	RESIDUE DW (mg/kg)	MAXIMUM DIET CONTENT (%)	CALCULATED DIET CONTENT (%)	MG/ANIMAL	RESIDUE CONTRIBUTION (ppm)
Barley forage	1.8	HR	100	1.8	50	50	18	0.9
Barley straw	0.53	HR	100	0.53	50	30	3.18	0.16
Barley grain	<0.01	STMR	88	0.01	40	–	–	–
Grape pomace	4.32*	STMR	100	4.32	20	20	17.28	0.86
Total						100		1.92

*Concentration factor of 9.6 and the STMR from Australian grape trials of 0.45 mg/kg (Dow Legend Fungicide 53607)

The estimated maximum residues in milk and tissues after feeding at the calculated maximum dietary burdens of 1.92 ppm (beef and dairy cattle), after interpolation from the observed maximum mean residues for milk, or the highest residues in tissues, after feeding dairy cattle for 28 days at 2.5 and 0.75 ppm (previously submitted feeding study) are as follows:

Table 3: Predicted quinoxyfen residues in animal commodities after feeding at calculated maximum dietary burdens for beef and dairy cattle.

FEEDING LEVEL (ppm)	MILK	CREAM	MUSCLE	LIVER	KIDNEY	SUBCUTANEOUS FAT	PERITONEAL FAT
	QUINOXYFEN RESIDUE (mg/kg)						
2.5–feeding study	0.009 (max. mean at 10, 14 and 18 days)	0.068 (max. mean)	<0.01	<0.01	<0.01	<0.01	0.10
0.75–feeding study	0.002 (max. mean)	0.018 (max. mean)	<0.002	<0.01	<0.01	<0.01	0.02
1.92–beef, estimated burden	–	–	–	<0.01	<0.01	<0.01	0.07
1.92–dairy, estimated burden	0.007	0.051	–	–	–	–	–
Established MRLs	0.01 (milks)	–	–	*0.01(offal)		0.1 [meat (mammalian) in the fat]	
Recommended MRLs	No change	0.2 milk fats (based on 40% fat content of cream)	–	No change		No change	

The animal transfer study showed that after feeding at 1.92 ppm (estimated maximum dietary burden for beef and dairy cattle), the resulting maximum residues in animal commodities are predicted to be 0.007 mg/kg in milk, 0.07 mg/kg for peritoneal fat and <0.01 mg/kg for subcutaneous fat, liver, kidney and muscle.

Therefore there is no necessity to increase the following established MRLs [edible offal (mammalian) *0.01 mg/kg, meat (mammalian) in the fat 0.1 mg/kg and milks 0.01 mg/kg].

In the previously submitted feeding study, residues were observed to concentrate into cream. The predicted residues in cream based on observed residues in the feeding study at 2.5 and 0.75 ppm feeding levels and a maximum calculated dietary burden of 1.92 ppm are 0.051 mg/kg. The fat content of cream is approximately 40% therefore in milk fats the predicted highest residues would be 0.128 mg/kg. An MRL of 0.2 mg/kg for quinoxyfen in milk fats (FM 0183) is recommended.

2.5 Overseas registration and approved label instructions

The applicant indicated that quinoxyfen products with a similar barley GAP to that proposed, are registered for use in other countries including the United Kingdom, Germany, France, Austria and Ireland.

2.6 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. Quinoxyfen has been considered by Codex. The following relevant Codex CXLs have been established for quinoxyfen.

Table 4: Relevant Codex MRLs and overseas MRLs for quinoxyfen

COMMODITY	TOLERANCE FOR RESIDUES ARISING FROM THE USE OF QUINOXYFEN (mg/kg)				
	AUSTRALIA	EU	JAPAN	CODEX	TAIWAN
Residue Definition	Quinoxyfen	Quinoxyfen	Quinoxyfen	Quinoxyfen	Quinoxyfen
Barley	*0.01 (proposed)	0.2	0.01	*0.01	0.01
Cattle muscle		0.2	0.01		
Cattle fat		0.2	0.1		
Cattle liver		0.2	0.01		
Cattle kidney		0.2	0.01		
Cattle, edible offal		0.2 (other than liver and kidney)	0.01		
Edible offal (mammalian)				*0.01	
Meat (from mammals other than marine mammals)		0.2		0.2	
Milk fats	0.2 (proposed)			0.2	
Milks	0.01	0.05	0.01	0.01	

2.7 Current and proposed Australian MRLs for quinoxyfen

Table 5: Current MRL Standard—Table 1

COMPOUND		FOOD	MRL (mg/kg)
QUINOXYFEN			
VL	0464	Chard [silver beet]	T3
VL	0465	Chervil	T5
		Coriander (leaves, stems, roots)	T5
DF	0269	Dried grapes	2
MO	0105	Edible offal (Mammalian)	*0.01
FB	0269	Grapes	0.5
HH	0092	Herbs	T5
MM	0095	Meat (mammalian)[in the fat]	0.1
ML	0106	Milks	0.01
		Mizuna	T5
VL	0496	Rucola [Rocket]	T5
FB	0275	Strawberry	T*0.01

Table 6: Proposed amendments to MRL Standard—Table 1

COMPOUND		FOOD	MRL (mg/kg)
QUINOXYFEN			
ADD:			
GC	0640	Barley	*0.01
FM	0183	Milk fats	0.2

Table 7: Current MRL Standard—Table 4

COMPOUND		FOOD	MRL (mg/kg)
QUINOXYFEN			
AB	0269	Grape pomace, dry	5

Table 8: Proposed amendments to MRL Standard—Table 4

COMPOUND		FOOD	MRL (mg/kg)
QUINOXYFEN			
ADD:			
		Barley forage (green)	5
AS	0640	Barley straw and fodder, dry	2

2.8 Potential risk to trade

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

Quantifiable residues are not expected to occur in barley grain from the proposed use pattern. Thus the risk to trade in barley is considered to be low.

No changes have been recommended to existing quinoxyfen MRLs for mammalian commodities (mammalian edible offal, mammalian meat in the fat and eggs).

Therefore the risk to Australian trade associated with quinoxyfen residues in these animal commodities arising from the proposed use has not changed significantly. There is the potential for quantifiable residues to occur in fat when feeding at 1.92 ppm (at the proposed 28 day WHP). The Applicant has proposed an Export Slaughter Interval of 14 days.

Based on the supplied depuration data, an Export Slaughter Interval of 14 days is sufficient to bring quinoxyfen residues down below detectable levels for liver and muscle and <0.01 mg/kg in kidney, subcutaneous fat and peritoneal fat.

A new MRL is established for milk fats at 0.2 mg/kg based on the worst case Australian exposure, with estimated residues of 0.128 mg/kg. Estimated residues in milk fat resulting from feeding livestock treated barley forage and straw only, are 0.075 mg/kg. It is noted that only one relevant MRL is established overseas (Codex 0.2 mg/kg).

3 CONCLUSIONS

Dow AgroSciences Australia Limited, has made an application to vary the registration of Legend Fungicide to include application to barley for the control of powdery mildew.

Quantifiable residues are not expected to occur in barley grain from the proposed use pattern.

The proposed use will require the establishment of an MRL of *0.01 mg/kg for quinoxyfen in barley. A milk fats MRL will be established at 0.2 mg/kg.

The applicant has proposed including the following statement on the label:

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)—14 days
After observing the withholding period for grazing and cutting for stock food, livestock that have been grazed on or fed treated crops should be placed on clean feed for 14 days prior to slaughter.

The APVMA is proposing to consider that the risk to trade associated with the proposed new use of quinoxyfen on barley is manageable under established industry systems. Comment is sought on this proposed decision.