



**Australian Government**

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**Australian Pesticides and  
Veterinary Medicines Authority**



**Trade advice notice**

on bixafen and prothioconazole for use on cotton

Minor use permit PER87169

JULY 2019

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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.

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 trade advice notice indicates that the Australian Pesticides and Veterinary Medicines Authority (APVMA) is considering an application for a minor use permit to allow a new use of an existing registered agricultural 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 minor use permit for the use of bixafen and prothioconazole on cotton 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 **Friday, 9 August 2019** 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)
- submission date.

All personal and *confidential commercial information (CCI)*<sup>1</sup> 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:

Residues and Trade  
Risk Assessment Capability  
Australian Pesticides and Veterinary Medicines Authority  
PO Box 6182  
Kingston ACT 2604

**Phone:** +61 2 6770 2300

**Email:** [enquiries@apvma.gov.au](mailto: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](#).

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<sup>1</sup> 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 Cotton Australia Ltd for a minor use permit for the use of bixafen and prothioconazole on cotton. The permit is proposed for use in NSW, Qld, Vic and WA for a period of three years. The proposed scale of use is not anticipated to exceed 10,000 ha.

The use of bixafen and prothioconazole on cotton has not previously been assessed in Australia.

The livestock dietary burden of bixafen and prothioconazole are not expected to increase as a result of the proposed use. No further consideration to the trade risk for animal commodities is required.

## 2 TRADE CONSIDERATIONS

### 2.1 Destination and quantity of exports

The cottonseed exports for 2015–16, 2016–17 and 2017–18 were, 147 kt, 316 kt<sup>2</sup> and 234 kt respectively. The main markets for cottonseed being Japan, Korea, Saudi Arabia, Taiwan and the USA.

The cottonseed oil exports for 2015–16, 2016–17 and 2017–18 were 5.2 kt, 12.5 kt and 21.9 kt respectively.

The cottonseed meal exports for 2015–16, 2016–17 and 2017–18 were 0.2 kt, 11.8 kt and 5.3 kt respectively. The main markets for cottonseed meal being Korea and New Zealand.

### 2.2 Proposed Australian use-pattern

**Table 1: Proposed use pattern: Aviator Xpro Foliar Fungicide (75 g/L Bixafen and 150 g/L Prothioconazole)**

Crop	Pest	Rate/CONCENTRATION	Critical comments
Cotton	Sclerotinia Stem Rot	550–800ml	Spray volume 70–150L/ha. Boomspray application only
	( <i>Sclerotinia sclerotiorum</i> )	(41.25–60 g bixafen / ha and 82.5–120 g prothioconazole/ha)	Maximum 2 applications per season. 10 day minimum re-treatment interval.

Withholding periods:

Harvest: Do not harvest for five weeks after application.

Grazing: Do not allow livestock to graze treated cotton crop, stubble or gin trash.

### 2.3 Results from residues trials presented to the APVMA

Details of eight relevant Brazilian trials involving the application of bixafen to cotton have been provided in support of this minor use permit. Six trials summarised by the 2017 JMPR<sup>3</sup> involving the application of prothioconazole on cotton were also evaluated.

<sup>2</sup> ABARES, Agriculture commodity statistics, 2018

<sup>3</sup> 2017 JMPR evaluation for prothioconazole:  
fao.org/fileadmin/templates/agphome/documents/Pests\_Pesticides/JMPR/Evaluation2017/PROTHIOCONAZOLE\_\_232\_.pdf

## Bixafen

Bixafen (parent) residues in cotton seed after four applications made 13–14 days apart at approximately 60 g ai/ha (1x the proposed rate) sampled 35 days after the last application were <0.01 (4), 0.01, 0.03, 0.06 and 0.16 mg/kg (n=8). The STMR was 0.01 mg/kg. The OECD MRL calculator estimates an MRL of 0.3 mg/kg. A bixafen MRL of T0.3 mg/kg for cottonseed is recommended in-conjunction with a five week harvest WHP.

The Public Release Summary for bixafen<sup>4</sup> determined the highest processing factors for parent bixafen to be 2X for canola meal, 2.5X for crude canola oil and 2.1X for refined canola oil.

Applying the highest canola processing factor for seed to crude oil (2.5x) to the cotton seed HR gives a HR-P of 0.4 mg/kg. It is recommended an MRL for Cotton seed oil, crude at T0.5 mg/kg be established.

Applying the highest canola processing factor for seed to meal (2x) to the cotton seed HR gives a HR-P of 0.32 mg/kg. It is recommended a Table 4 MRL for Cotton seed meal and hulls at T0.5 mg/kg be established.

## Prothioconazole

Total prothioconazole residues in cotton seed after three applications (RTI 12–15 days) at 149–253 g ai/ha (approximately 1.2–2.1x proposed rate) sampled 34–40 days after the last application were <0.040, <0.040, 0.042, 0.051, 0.054, 0.056 mg/kg (n=6). The STMR was 0.047 mg/kg. The 2017 JMPR noted that in all trials matching the US GAP (3x 0.20–0.21 kg ai/ha, 30 day PHI) the prothioconazole-desthio residues (the main component) were <0.018 (3), 0.028, 0.031, 0.033, 0.070, 0.075, 0.079, 0.081, 0.083 and 0.18 mg/kg. Scaled for the proposed application rate the HR in these trials is 0.11 mg/kg. A prothioconazole MRL of T0.2 mg/kg for cottonseed is recommended in-conjunction with a five week harvest WHP.

The available prothioconazole processing data indicates that residues did not concentrate on processing to meal, hulls, crude oil or refined oil. Prothioconazole residues arising in cotton oil and meal following the proposed use will be covered by the cotton seed MRL.

## 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) employed by various countries. Some countries may accept Codex CXLs when importing foods. bixafen and prothioconazole has been considered by Codex. The following relevant Codex CXLs and overseas MRLs/tolerances have been established for bixafen and prothioconazole.

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<sup>4</sup> APVMA PRS for Aviator Xpro foliar fungicide: [apvma.gov.au/node/19926](http://apvma.gov.au/node/19926)

Table 2: Current and proposed Australian and overseas MRLs/tolerances for bixafen

Commodity	Tolerance for residues arising from the use of bixafen (mg/kg)				
	Australia	EU	Japan	Codex	NZ
Cottonseed	T0.3 (proposed)	*0.01	-	-	-
Cotton seed oil, crude	T0.5 (proposed)	-	-	-	-
Cotton seed meal and hulls	T0.5 (proposed)	-	-	-	-

No bixafen MRLs for cottonseed have been established by the USA, Korea, Japan and Taiwan.

Table 3: Current and proposed Australian and overseas MRLs/tolerances for prothioconazole

Commodity	Tolerance for residues arising from the use of prothioconazole (mg/kg)				
	Australia	EU	Japan	Codex	USA
Residue Definition	Plants: Prothioconazole and the desthio metabolite	Prothioconazole-desthio (sum of isomers)	Plants: Prothioconazole and the desthio metabolite (M17)	Prothioconazole-desthio	Plants: Prothioconazole and the desthio metabolite
Cottonseed	T0.2 (proposed)	0.3	-	0.3	0.4
Cotton seed oil, crude	-	-	-	-	-
Cotton seed meal and hulls	-	-	-	-	-

No prothioconazole MRLs for cottonseed have been established by Korea, Japan and Taiwan.

## 2.5 Current and proposed Australian MRLs for bixafen and prothioconazole

Table 4: Proposed MRL Standard—Table1

COMPOUND	FOOD	MRL (mg/kg)
BIXAFEN		
DELETE:		
SO 0088	Oilseed	*0.01
ADD:		
SO 0691	Cotton seed	T0.3
OC 0691	Cotton seed oil, crude	T0.5
SO 0088	Oilseed [except cotton seed]	*0.01

COMPOUND	FOOD	MRL (mg/kg)
PROTHIOCONAZOLE		
SO 0691	Cotton seed	T0.2

Table 5: Proposed MRL Standard—Table4

COMPOUND	FOOD	MRL (mg/kg)
BIXAFEN		
ADD:		
	Cotton seed meal and hulls	T0.5

## 2.6 Potential risk to trade

Export of treated produce containing finite (measurable) residues of bixafen and 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.

**Bixafen:** Appropriate standards for bixafen residues in cotton seed that may result from the proposed use are not established in major markets, including by Codex. A finite MRL of T0.3 mg/kg for cotton seed and T0.5 mg/kg for Cotton seed oil, crude is proposed noting the high residue in cotton seed in 8 trials of 0.16 mg/kg and the median residue of 0.01 mg/kg.

**Prothioconazole:** Appropriate standards for residues that may result from the proposed uses are not established in all major markets. A Codex and EU MRL for cotton seed is established at 0.3 mg/kg, while the US MRL is 0.4 mg/kg. A finite MRL of T0.2 mg/kg is proposed noting the high residue in 6 trials of 0.06 mg/kg and the median residue of 0.05 mg/kg.

It is noted that the applicant has indicated the scale of use is not anticipated to exceed 10,000 ha and that the permit will be issued for three years.

### 3 CONCLUSION

Prior to making a determination on issue of the permit discussed here the APVMA must be satisfied that the proposed use does not constitute an undue prejudice to trade.

Based on the low median residues for bixafen and prothioconazole observed in cotton seed in the available trials and the small scale of use under the proposed permit, we propose to determine that the risk to trade for the proposed use on cotton is not undue. Stakeholders are requested to provide comment on industry systems that can manage any potential risks to international trade associated with the proposed use.