



**Australian Government**  
**Australian Pesticides and  
Veterinary Medicines Authority**



**Trade Advice Notice**

For use of Merivon Fungicide containing pyraclostrobin and fluxapyroxad on  
cotton

APVMA PER144790

November 2024

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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 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 for use of Merivon Fungicide 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 26 November 2024 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 organisation name (if relevant)
- email or postal address (if available)
- the date you made the submission.

Please note: submissions will be published on the APVMA's website, unless you have asked for the submission to remain confidential, or if the APVMA chooses at its discretion not to publish any submissions received (refer to the [public consultation coversheet](#)).

Please lodge your submission using the [public consultation coversheet](#), which provides options for how your submission will be published.

Note that all APVMA documents are subject to the access provisions of the *Freedom of Information Act 1982* and may be required to be released under that Act should a request for access be made.

Unless you request for your submission to remain confidential, the APVMA may release your submission to the applicant for comment.

Written submissions should be addressed to:

Executive Director, Risk Assessment and Capability  
Australian Pesticides and Veterinary Medicines Authority  
GPO Box 574  
Canberra ACT 2601

**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 Trade Advice Notices can be found on the APVMA website: [apvma.gov.au](http://apvma.gov.au).

## **Introduction**

The APVMA has before it an application from Cotton Australia Limited for a minor use permit for the use of Merivon Fungicide containing 250 g/L of pyraclostrobin and fluxapyroxad on cotton.

## Trade considerations

### Commodities exported

Cotton seed and its derived oils and meals are considered to be major export commodities<sup>1</sup>, as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock or poultry fed feeds produced from treated cotton seeds. Residues in these commodities resulting from the use of Merivon Fungicide may have the potential to unduly prejudice trade.

### Destination and value of exports

Australia exported an estimated ~680 kt of cottonseed worth ~AUD\$417 million in 2023–24<sup>2</sup> as reported by the Australian Bureau of Agricultural and Resource Economics (ABARES) in September quarter Agricultural commodities statistics.

The major export markets for cottonseed in 2023–24 were China, USA, Korea and Japan<sup>3</sup>.

The significant export markets for Australian beef, sheep, pig meat and offal are listed in the APVMA Regulatory Guidelines – Data Guidelines: Agricultural – Overseas trade (Part 5B). However, no changes are required to the current animal commodity MRLs, and an ESI is not required for the use considered here.

### Proposed Australian use pattern

Table 1: Proposed use pattern

Crop	Pest	Rate/concentration	Critical comments
Cotton	Target Spot ( <i>Corynespora cassiicola</i> )	390 mL/ha (97.5 g ai/ha for each of pyraclostrobin and fluxapyroxad)	Apply up to 3 foliar applications per crop up to crop maturity with a minimum re-treatment interval of 7 days. Apply using a boom spray or aircraft in a spray volume of 30-100L/ha.

### Restrictions

Do not graze or cut treated cotton crops, stubble or gin trash.

<sup>1</sup> APVMA Regulatory Guidelines – Data Guidelines: Agricultural - Overseas trade (Part 5B)

<sup>2</sup> Australian Bureau of Agricultural and Resource Economics – [Agricultural Commodity Statistics](#), website accessed November 2024.

<sup>3</sup> World bank Trade Figures- [Cotton seed export markets](#), date accessed November 2024

## Withholding periods

### Harvest

Do not harvest for 30 days after the last application.

### Grazing

Do not graze or cut treated cotton crops, stubble or gin trash.

## Results from residues trials considered by the APVMA

### Fluxapyroxad

The residues of fluxapyroxad (parent) in cotton seed following 3 foliar applications made at a rate of ~1× the proposed rate with a re-treatment interval of 7 days at PHIs ranging from 28-32 days including at the proposed WHP of 30 days are in rank order: <0.01, 0.01, 0.01, 0.02, 0.02, 0.07, 0.09, 0.11, 0.11 and 0.13 mg/kg. The OECD calculator estimates an MRL of 0.3 mg/kg (STMR= 0.045 mg/kg, n=10).

Based on the available information, a temporary MRL of 0.3 mg/kg for fluxapyroxad is considered appropriate for cotton seed (SO 0691) in conjunction with a harvest WHP of 30 days.

Processing: The available fluxapyroxad processing data on cotton seed indicates that residues did not concentrate in cotton seed by-products - meal, hulls and refined oil therefore no separate MRLs are required for these commodities.

### Pyraclostrobin

The residues of pyraclostrobin in cotton seed followed by a single at-planting in-furrow application and three broadcast foliar applications at 1× the proposed rate were <0.02 (6), 0.02, 0.03 (2), 0.04, 0.05 and 0.07 mg/kg.

The OECD MRL Calculator recommends an MRL of 0.1 mg/kg (n = 12, STMR = 0.02 mg/kg).

Based on the available information, a temporary MRL of 0.1 mg/kg for pyraclostrobin is considered appropriate for cotton seed (SO 0691) in conjunction with a harvest WHP of 30 days.

Processing study showed that residues of pyraclostrobin and its metabolite (BF500-3) were below their quantifiable levels in cotton seed by-products meal, hull, crude oil and refined oil. Therefore, no separate MRLs are required for cotton seed by-products.

Due to the proposed grazing restraint of "Do not graze or cut treated cotton crops, stubble or gin-trash" residues aspects relating to animal feeds or gin trash are not discussed here for the proposed use.



## 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. The following MRLs for fluxapyroxad and pyraclostrobin on cotton seed have been established in the key international markets.

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Table 2: Current and proposed Australian and overseas MRLs/tolerances for fluxapyroxad and pyraclostrobin.

Commodity	Tolerance for residues arising from the use of fluxapyroxad (mg/kg)						
	Australia	Codex <sup>4</sup>	EU <sup>5</sup>	Japan <sup>6</sup>	Korea <sup>7</sup>	Taiwan <sup>8</sup>	USA <sup>9</sup>
Residue Definition (Enforcement)	Parent	Parent	Parent	Parent	-	-	Parent
Cotton seed	T0.3 (Proposed)	0.5	0.5	0.5	0.5	0.3	0.5

Commodity	Tolerance for residues arising from the use of pyraclostrobin (mg/kg)						
	Australia	Codex	EU	Japan	Korea	Taiwan	USA
Residue Definition (Enforcement)		Parent	Parent	Parent	-	-	Pyraclostrobin+ its desmethoxy metabolite (methyl-N-[[[1-(4-chlorophenyl)-1H-pyrazol3-

<sup>4</sup> Food and Agriculture Organisation of the United Nations, [Codex Alimentarius. International Food Standards](#), FAO website, accessed November 2024.

<sup>5</sup> European Commission, [EU Pesticide residue\(s\) and maximum residue levels \(mg/kg\)](#), European Commission website, accessed November 2024.

<sup>6</sup> Japanese Food Chemistry Research Foundation, [Table of MRLs for Agricultural Chemicals](#), JFCRPF website, accessed November 2024

<sup>7</sup> Ministry of Food and Drug Safety, Korea, [MRLs in Pesticides](#), accessed November 2024

<sup>8</sup> Taiwan Food and Drug Administration, [Standards for Pesticide Residue Limits in Foods](#), accessed November 2024

<sup>9</sup> Electronic Code of Federal Regulations, [USA Electronic Code of Federal Regulations](#), eCFR website, accessed November 2024.

Commodity	Tolerance for residues arising from the use of pyraclostrobin (mg/kg)						
	Australia	Codex	EU	Japan	Korea	Taiwan	USA
							yl[oxy]methyl] phenylcarbamate)
Cotton seed	T0.1 (Proposed)	0.4 (oilseed except peanut)	0.3	0.4	0.3	-	0.45 (oilseed group 20)

## Proposed Australian MRLs for fluxapyroxad and pyraclostrobin

Table 3: proposed MRL – Table1

Compound	Food	MRL (mg/kg)
Fluxapyroxad		
SO 0691	Cotton seed	T0.3

Table 4: Proposed MRL – Table1

Compound	Food	MRL (mg/kg)
Pyraclostrobin		
SO 0691	Cotton seed	T0.1

### Potential risk to trade

Export of treated produce containing finite (measurable) residues of fluxapyroxad and pyraclostrobin 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 overall risk to export trade in animal commodities is considered to be unaffected by the proposed use in cotton seed. Therefore, no changes are required to the current animal commodity MRLs, and an ESI is not required.

All major markets including Codex have MRLs for fluxapyroxad for cotton seed at higher or at the same levels as the proposed Australian MRL. The risk to trade from the proposed use of fluxapyroxad on cotton is considered to be low.

The proposed Australian MRL of T0.1 mg/kg for pyraclostrobin in cotton seed is lower than MRLs established by Codex (0.4 mg/kg), EU (0.3 mg/kg), Japan (0.4 mg/kg), Korea (0.3 mg/kg) and USA (0.45 mg/kg). Taiwanese MRLs for pyraclostrobin on cotton have not been established.

### Spray Drift

The proposed use involves aerial and ground application. The no spray buffer zones are estimated for both actives and will be driven by pyraclostrobin. The no spray buffer zones for ground boom and aerial applications for the protection of international trade are presented below.

## Regulatory Acceptable Limit (RAL)

In a lactating cow feeding study evaluated by the 2004 JMPR, feeding at 7 ppm gave highest residues of 0.20 mg/kg in liver tissue. For residues in liver to be at the LOQ (0.05 mg/kg), the maximum feeding level is 1.75 ppm (RAL).

The following label statements were generated using the APVMA spray drift risk assessment tool and an RAL of 1.75 ppm for protection of international trade:

The buffer zones for boom (medium droplet) and aerial application (coarse) droplet size are determined by the APVMA spray drift risk assessment tool should be added to the permit based.

## Pyraclostrobin

DO NOT apply by a boom sprayer unless the following requirements are met:

- spray droplets not smaller than a MEDIUM spray droplet size category
- minimum distances between the application site and downwind sensitive areas (see 'Mandatory buffer zones' section of the following table titled 'Buffer zones for boom sprayers') are observed.

Buffer zones for boom sprayers						
Application rate	Boom height above the target canopy	Bystander areas	Natural aquatic areas	Pollinator areas	Vegetation areas	Livestock areas
Up to maximum label rate	0.5 m or lower	Not yet assessed	Not yet assessed	Not yet assessed	Not yet assessed	Not required
	1.0 m or lower	Not yet assessed	Not yet assessed	Not yet assessed	Not yet assessed	Not required

- spray droplets not smaller than a COARSE spray droplet size category
- for maximum release heights above the target canopy of 3m or 25% of wingspan or 25% of rotor diameter whichever is the greatest, minimum distances between the application site and downwind sensitive areas (see 'Mandatory buffer zones' section of the following table titled 'Buffer zones for aircraft') are observed.

Buffer zones for aircraft					
Type of aircraft	Bystander areas	Natural aquatic areas	Pollinator areas	Vegetation areas	Livestock areas
Fixed-wing	Not yet assessed	Not yet assessed	Not yet assessed	Not yet assessed	20 metres
Helicopter	Not yet assessed	Not yet assessed	Not yet assessed	Not yet assessed	20 metres

## Conclusion

Cotton Australian Limited has applied for the use of Merivon Fungicide containing 250 g/L of pyraclostrobin and fluxapyroxad on cotton. Comment is sought on the potential for the proposed use to pose a risk to Australian trade.