Australian Government

Australian Pesticides and Veterinary Medicines Authority

Trade Advice Notice

on fludioxonil and pydiflumetofen in the product Miravis Star Adepidyn Technology Fungicide for use on cotton under permit

APVMA permit number 96484

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This publication is available from the APVMA website.

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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 chemical under permit.

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 a permit for use of Miravis Star Adepidyn Technology 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 2 February 2026 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 permit conditions and 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, Agricultural Chemicals Branch
Australian Pesticides and Veterinary Medicines Authority
GPO Box 574
Canberra ACT 2601

Phone: +61 2 6770 2300
Email: 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.

Introduction

The APVMA has before it an application from Cotton Australia Limited for a minor use permit to use Miravis Star Adepidyn Technology Fungicide (APVMA Product number 89771) on cotton to control *Alternaria* sp. The product is a suspension concentrate (SC) product containing 150 g/L fludioxonil and 100 g/L pydiflumetofen. An estimated 25,000 ha of cotton will be treated.

The use of fludioxonil has previously been assessed for use on cotton as a seed treatment. The registered use pattern for Vibrance CST Fungicide Seed Treatment (APVMA Product number 85035) involves seed treatment at rates of 2.5 g fludioxonil/100 kg seed with a harvest withholding period of 'Not required when used as directed' and a grazing restraint prohibiting the feeding of treated cotton crop, stubble or gin trash to livestock. A fludioxonil Maximum Residue Limit (MRL) is established at *0.05 mg/kg for SO 0691 Cotton seed.

The use of pydiflumetofen on cotton has not previously been assessed in Australia.

Trade considerations

Commodities exported

Cotton seed and its derived oils and meals are major export commodities[1], as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feeds produced from treated cotton. Residues in these commodities resulting from the use of Miravis Star may have the potential to unduly prejudice trade.

The risk to trade in animal commodities does not require further consideration here, as the maximum livestock dietary burden for fludioxonil and pydiflumetofen is unchanged, noting the proposed grazing restraint of 'DO NOT feed cotton fodder or cotton trash to livestock', and the supervised trial median residues (STMRs) of <0.01 and 0.02 mg/kg for fludioxonil and pydiflumetofen respectively in cotton seed. No changes are required to the animal commodity MRLs for fludioxonil or pydiflumetofen.

Destination and value of exports

Australia exported an estimated ~680 kt of cottonseed worth ~AUD$416 million in 2023–24 as reported by the Australian Bureau of Agricultural and Resource Economics (ABARES)[2]

The major export markets for cottonseed in 2023–24 were China, USA, Japan and Korea.[3]

Proposed Australian use pattern

Miravis Star Adepidyn Technology Fungicide (APVMA Product number 89771, 150 g/L fludioxonil and 100 g/L pydiflumetofen).

Table 1: Proposed use pattern

Crop	Pest	Rate/concentration	Critical comments
Cotton	Alternaria	500 mL/ha	Apply at seedling to 80% boll size
		(75 g fludioxonil/ha and 50 g pydiflumetofen/ha)	A maximum of 2 applications per crop, with a minimum re-treatment interval of 21 days
			Application method is foliar spray by Ground boom spray or Aerial. Spray volume is 100 L/ha (ground), 30 L/ha (air).

[1] APVMA Regulatory Guidelines – Data Guidelines: Agricultural - Overseas Trade (Part 5B), APVMA Website, accessed November 2025

[2] Australian Bureau of Agricultural and Resource Economics – Agricultural Commodity Statistics, website accessed November 2025.

[3] World Bank Trade Figures- Cotton seed export markets, date accessed November 2025

Withholding periods:

Harvest: Do not harvest for 30 days after application.
Grazing: Do not feed treated cotton fodder or cotton trash to livestock.

Results from residues trials presented to the APVMA

The proposed use on cotton involves 2 applications at 500 mL product/ha (75 g fludioxonil/ha and 50 g pydiflumetofen/ha) applied by ground boom spray or aerially at seedling to 80% boll size with a retreatment interval 21 days and a harvest withholding period of 30 days. The proposed grazing restraint is 'DO NOT feed treated cotton fodder or cotton trash to livestock'.

Cotton seed - fludioxonil

Studies involving 8 Brazilian fludioxonil cotton trials involving 4 foliar applications have been provided. Residues of fludioxonil in cotton seed at 30 Days After the Last Application (DALA) were <0.01, 0.01, 0.03 (3), 0.06, 0.07, 0.08 mg/kg (n=8). Scaled to the proposed rate of 75 g ai/ha residues would be expected to be <0.01, 0.002, 0.006 (2), 0.012, 0.014 and 0.016 mg/kg. The STMR was 0.006 mg/kg. The Organisation for Economic Cooperation and Development (OECD) MRL calculator estimates an MRL of 0.03 mg/kg. A fludioxonil MRL of T0.05 mg/kg for SO 0691 Cotton seed is recommended in conjunction with the proposed 30 day harvest withholding period, replacing the current MRL at *0.05 mg/kg.

Cotton seed – pydiflumetofen

Studies involving 12 North American pydiflumetofen cotton trials and 4 Brazilian pydiflumetofen cotton trials involving 2-3 foliar applications have been provided.

Residues of pydiflumetofen in cotton seed at approximately 30 DALA in the North American trials were <0.01 (2), 0.02, 0.04 (2), 0.06, 0.09 (2), 0.10 (2), 0.14 and 0.32 mg/kg (n=12). Scaled to the proposed rate of 50 g ai/ha residues would be expected to be <0.01 (2), 0.01, 0.02 (3), 0.04 (4), 0.06 and 0.13 mg/kg.

Residues of pydiflumetofen in cotton seed at 28 DALA in the Brazilian trials were <0.01, 0.02 (2) and 0.08 mg/kg (n=4). Scaled to the proposed rate of 50 g ai/ha residues would be expected to be <0.01, 0.01 (2) and 0.04 mg/kg.

The combined dataset suitable for MRL estimation is, in rank order, <0.01 (3), 0.01 (3), 0.02 (3), 0.04 (5), 0.06, 0.13 mg/kg (n=16). The STMR was 0.02 mg/kg. The OECD MRL calculator estimates an MRL of 0.15 mg/kg. A pydiflumetofen MRL of T0.2 mg/kg for SO 0691 Cotton seed is recommended in conjunction with the proposed 30 day harvest withholding period.

Processing

Cotton processing studies have not been provided for fludioxonil. However, the estimated High Residue (HR) is 0.016 mg/kg for cotton seed. This is below the 0.1 mg/kg threshold for the requirement for a processing study. It is noted that there are the fludioxonil cotton processing studies from the 2004 Joint Meeting on Pesticide Residues (JMPR) related to the seed treatment use where residues were not detected in seed, oil or meal. Further information on the effect of processing on fludioxonil residues in cotton seed is not required at this time.

A processing study has been provided for pydiflumetofen on cotton. As all processing factors for pydiflumetofen in cotton processed commodities (oil, hulls and meal) were <1, it is not necessary to set separate MRLs for these commodities.

Overseas registration and approved label instructions

Details of relevant overseas registrations have not been provided by the applicant. However, several overseas MRLs are established for fludioxonil and pydiflumetofen on cotton (see below).

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. Fludioxonil and pydiflumetofen have been considered by Codex. The following relevant Codex CXLs and international MRLs have been established for fludioxonil and pydiflumetofen:

Table 2: International MRLs for fludioxonil

Commodity	Tolerance for residues arising from the use of fludioxonil (mg/kg)							
	Australia[4]	Codex[5]	China[6]	EU[7]	Japan[8]	Korea[9]	Taiwan[10]	USA[11]
Residue Definition	Fludioxonil	Fludioxonil	Fludioxonil	Fludioxonil	Fludioxonil	-	-	Fludioxonil
Cotton seed	*0.05 (current) T0.05 (proposed)	*0.05	0.05	0.01*	0.05	-	0.05	0.05

[4] Agricultural and Veterinary Chemicals (MRL Standard for Residues of Chemical Products) Instrument 2023, Federal Register of Legislation, accessed November 2025

[5] Food and Agriculture Organisation of the United Nations, *Codex Alimentarius, International Food Standards*, FAO website, accessed November 2025.

[6] United States Department of Agriculture, Translation of Maximum Residue Limits for Pesticides in Foods, China – People's Republic of, accessed November 2025.

[7] European Commission, *EU Pesticide residue(s) and maximum residue levels (mg/kg)*, European Commission website, accessed November 2025.

[8] Japanese Food Chemistry Research Foundation, *Table of MRLs for Agricultural Chemicals*, JFCRPF website, accessed November 2025.

[9] Ministry of Food and Drug Safety, Korea, MRLs in Pesticides, accessed November 2025.

[10] Laws & Regulations Database of the Republic of China (Taiwan), Standards for Pesticide Residue Limits in Foods, accessed November 2025.

[11] Electronic Code of Federal Regulations, *USA Electronic Code of Federal Regulations*, eCFR website, accessed November 2025.

Table 3: International MRLs for pydiflumetofen

Commodity	Tolerance for residues arising from the use of pydiflumetofen (mg/kg)							
	Australia	Codex[12]	China[13]	EU[14]	Japan[15]	Korea[16]	Taiwan[17]	USA[18]
Residue Definition	Parent	Parent	Parent	Parent	Parent	-	-	Parent
Cotton seed	T0.2 (proposed)	0.02	-	-	0.4	0.4	0.4	0.4

Parent = Pydiflumetofen

Current and proposed Australian MRLs for fludioxonil and pydiflumetofen

Table 4: Current MRL Standard – Table1

Compound	Food	MRL (mg/kg)
Fludioxonil		
SO 0691	Cotton seed	*0.05
MO 0105	Edible offal (mammalian)	0.1
PE 0112	Eggs	*0.01
MM 0095	Meat (mammalian)	0.05
ML 0106	Milks	0.05
PM 0110	Poultry meat	*0.01
Pydiflumetofen		
	All other foods	0.05

[12] Food and Agriculture Organisation of the United Nations, *Codex Alimentarius, International Food Standards*, FAO website, accessed November 2025.

[13] United States Department of Agriculture, National Food Safety Standard for Maximum Residue Limits of 112 Pesticides in Foods Released, China – People's Republic of, accessed November 2025.

[14] European Commission, *EU Pesticide residue(s) and maximum residue levels (mg/kg)*, European Commission website, accessed November 2025.

[15] Japanese Food Chemistry Research Foundation, *Table of MRLs for Agricultural Chemicals*, JFCRPF website, accessed November 2025.

[16] Ministry of Food and Drug Safety, Korea, MRLs in Pesticides, accessed November 2025.

[17] Laws & Regulations Database of the Republic of China (Taiwan), Standards for Pesticide Residue Limits in Foods, accessed November 2025.

[18] Electronic Code of Federal Regulations, *USA Electronic Code of Federal Regulations*, eCFR website, accessed November 2025.

Compound	Food	MRL (mg/kg)
MO 0105	Edible offal (mammalian)	0.02
PE 0112	Eggs	*0.01
MM 0095	Meat (mammalian) [in the fat]	0.02
ML 0106	Milks	*0.01
PM 0110	Poultry meat	*0.01
PO 0111	Poultry, edible offal of	*0.01

Table 5: Proposed MRL Standard – Table1

Compound	Food	MRL (mg/kg)
Fludioxonil		
Delete:		
SO 0691	Cotton seed	*0.05
Add:		
SO 0691	Cotton seed	T0.05
Pydiflumetofen		
Add:		
SO 0691	Cotton seed	T0.2

Potential risk to trade

Export of treated produce containing finite (measurable) residues of fludioxonil and pydiflumetofen 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 proposed Australian MRL of T0.05 mg/kg for fludioxonil on cotton seed is at the same level as those established by Codex, China, Japan, Taiwan and the USA but higher than that established by EU (0.01 mg/kg). However, the STMR for cotton seed is 0.006 mg/kg, which is lower than the EU MRL. An MRL for fludioxonil in cotton seed is not established in Korea.

The proposed Australian MRL of T0.2 mg/kg for pydiflumetofen on cotton seed is lower than that established by Japan, Korea, Taiwan and the USA but is higher than that established by Codex. However, the STMR for cotton seed (0.02 mg/kg) is at the same level as the Codex MRL. MRLs for pydiflumetofen in cotton seed are not established in China or the EU.

Conclusion

Comment is sought from relevant industry groups and stakeholders on the potential risk to trade from the proposed use of Miravis Star Adepidyn Technology Fungicide on cotton under a minor use permit.