Australian Government

Australian Pesticides and Veterinary Medicines Authority

# Trade Advice Notice

on azoxystrobin, difenoconazole, fluopyram, isopyrazam and tebuconazole for use on plums

Permit: PER92785

June 2023

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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 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 a permit for use of azoxystrobin, difenoconazole, fluopyram, isopyrazam and tebuconazole on plums 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 21 July 2023 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 Capability

Australian Pesticides and Veterinary Medicines Authority

GPO Box 3262

Sydney NSW 2001

**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.

## Introduction

The APVMA has before it a minor use permit application from Yenda Producers Co-Operative Society Ltd for the use of azoxystrobin, difenoconazole, fluopyram, isopyrazam and tebuconazole on plums for control of prune rust.

The foliar use of azoxystrobin, difenoconazole, isopyrazam and tebuconazole on plums has not been previously assessed by the APVMA.

The foliar use of fluopyram is registered for use on stone fruits. No change to the existing fluopyram Stone fruit MRL at 2 mg/kg is required for the proposed use considered under this permit therefore no further consideration of fluopyram is required from a trade perspective.

# Trade considerations

## Commodities exported

Plums, including prunes, are considered to be major export commodities[1]. Residues in plums and prunes resulting from the proposed uses of azoxystrobin, difenoconazole, isopyrazam and tebuconazole may have the potential to unduly prejudice trade.

As finite (measurable) residues may be expected from the proposed uses on plums, the following trade risk mitigation statement has been recommended for inclusion on the permit.

> *Treated crop commodities destined for export may require extra time being allowed between application and harvest, to be accepted in some export markets. Before you use this product, you are advised to contact Yenda Producers Co-Operative Society Ltd and/or your industry body about any potential trade issues and their management.*

Plums are not considered a significant animal feed and a grazing withholding period of 'DO NOT graze treated areas or cut for stock food' has been recommended for each use. The existing livestock dietary burdens for each active are not expected to increase as a result of the proposed uses. The risk to trade with respect to animal commodities is considered to be low and does not require further consideration.

## Destination and value of exports

In 2021–22 Australia exported 6,105 tonnes of fresh plums valued at $25.9 million and 807 tonnes of prunes valued at $2.9 million[2] Major export markets for fresh plums were China, Singapore, Hong Kong, Indonesia and Malaysia representing 72, 12, 7, 3 and 2% of fresh exported plums.

1 Australian Pesticides and Veterinary Medicines Authority (APVMA), 2020. *Agricultural data guidelines – Pesticides: Overseas trade (Part 5B) – Major export food commodity groups*, APVMA website.

2 Hort Innovation, *Australian Horticulture Statistics Handbook 2021–22 – Fruit*, Hort Innovation website, accessed April 2023.

## Proposed Australian use patterns

The proposed use of Amistar Top Fungicide (200 g/L azoxystrobin and 125 g/L difenoconazole) and other similar registered products involves up to 4 foliar applications per season, applied by airblast sprayer from flowering through to harvest, at up to 234 g azoxystrobin/ha plus 146 g difenoconazole/ha with the addition of a non-ionic surfactant (see Table 1). The proposed harvest withholding period is 'Nil' and the recommended grazing withholding period is 'DO NOT graze treated areas or cut for stock food'.

**Table 1: Proposed use pattern for azoxystrobin and difenoconazole on plums**

| Amistar Top Fungicide (63898), containing 200 g/L azoxystrobin and 125 g/L difenoconazole as the only active constituents and all other similar registered products | | | |
|---|---|---|---|
| **Crop** | **Pest** | **Rate** | **Critical comments** |
| Plums (for fresh market and dried production) | Prune rust (*Tranzschelia discolor*) | 1025 to 1170 mL product/ha (205 to 234 g azoxystrobin/ha plus 128 to 146 g difenoconazole/ha) | Apply foliar applications via airblast sprayer between flowering through until harvest in a sufficient volume of water to achieve thorough coverage of all foliage.<br>DO NOT apply more than 4 applications per season at a minimum spray volume of 1500 L/ha with a minimum retreatment interval of 7 days.<br>Resistance management: This use is subject to a CropLife Australia fungicide resistance management strategy. As per Amistar Top label.<br>Use with a non-ionic based surfactant. |

### Restraints

DO NOT apply more than 4 applications per season.

### Withholding period

#### *Harvest*

Nil.

#### *Grazing*

DO NOT graze treated areas or cut for stock food.

**Table 2: Proposed use pattern for isopyrazam on plums**

The proposed use of Seguris Flexi Fungicide (125 g/L isopyrazam) involves a maximum of 2 foliar applications per season, applied by airblast sprayer from flowering through to harvest, at up to 12.5 g ai/100L with a minimum spray volume of 1,500 L/ha (see Table 2). The proposed harvest withholding period is 14 days and the recommended grazing withholding period is 'DO NOT graze treated areas or cut for stock food'.

| Seguris Flexi Fungicide (80618), containing 125 g/L isopyrazam as the only active constituent | | | |
|---|---|---|---|
| **Crop** | **Pest** | **Rate** | **Critical comments** |
| Plums (for fresh market and dried production) | Prune rust (*Tranzschelia discolor*) | 75 to 100 mL product per 100 L of water (9.4 to 12.5 g isopyrazam/100 L) | Apply foliar applications via airblast sprayer between flowering through until harvest in a sufficient volume of water to achieve thorough coverage of all foliage.<br>DO NOT apply more than 2 applications per season at a minimum spray volume of 1,500 L/ha with a retreatment interval of 10 to 21 days.<br>Resistance management: This use is subject to a CropLife Australia fungicide resistance management strategy. As per Seguris Flexi label. |

## Restraints

DO NOT apply more than 2 applications per season.

DO NOT apply more than 2.5 L product/ha (312.5 g ai/ha) per application.

## Withholding periods

### *Harvest*

DO NOT harvest for 14 days after application.

### *Grazing*

DO NOT graze treated areas or cut for stock food.

**Table 3: Proposed use pattern for isopyrazam being considered by the APVMA**

The proposed use of Luna Experience Fungicide (200 g/L fluopyram and 200 g/L tebuconazole) involves 2 foliar applications per season, applied by airblast sprayer from flowering through to harvest, at up to 148 g fluopyram/ha plus 148 g tebuconazole/ha (see Table 3). The proposed harvest withholding period is 'Nil' and the recommended grazing withholding period is 'DO NOT graze treated areas or cut for stock food'.

| Luna Experience Fungicide (87841), containing 200 g/L fluopyram and 200 g/L tebuconazole as the only active constituents | | | |
|---|---|---|---|
| **Crop** | **Pest** | **Rate** | **Critical Comments** |
| Plums (for fresh market and dried production) | Prune rust (*Tranzschelia discolor*) | 593 to 740 mL product/ha (119 to 148 g fluopyram/ha plus 119 to 148 g tebuconazole/ha) | Apply foliar applications via airblast sprayer between flowering through until harvest in a sufficient volume of water to achieve thorough coverage of all foliage.<br>DO NOT apply more than 2 applications per season at a minimum spray volume of 1500 L/ha with a retreatment interval of 7 to 14 days.<br>Resistance management: This use is subject to a CropLife Australia fungicide resistance management strategy. As per Luna Experience label. |

## Restraints

DO NOT apply more than 2 applications per season.

## Withholding periods

### *Harvest*

Nil.

### *Grazing*

DO NOT graze treated areas or cut for stock food.

## Results from residues trials presented to the APVMA

### Plums

The azoxystrobin dataset suitable for MRL estimation of the proposed GAP on plums is, in rank order, 0.02, 0.09, 0.24 (2), 0.25, 0.30, 0.37 and 0.42 mg/kg (n=8). The supervised trial median residue (STMR) was 0.25 mg/kg. An azoxystrobin MRL of T0.8 mg/kg for FS 0014 Plums is considered appropriate in conjunction with the proposed harvest withholding period of 'Nil'.

The difenoconazole dataset suitable for MRL estimation in plums is, in rank order, 0.07, 0.09, 0.13, 0.15, 0.16, 0.18 and 0.20 mg/kg (n=7). The STMR was 0.15 mg/kg. A difenoconazole MRL of T0.5 mg/kg for FS 0014 Plums is considered appropriate in conjunction with the proposed harvest withholding period of 'Nil'.

For isopyrazam, the combined apricot and peach dataset considered suitable for extrapolation and MRL estimation in plums is, in rank order, 0.08, 0.11, 0.12, 0.17, 0.18, 0.25, 0.33 and 0.39 mg/kg (n=8). The STMR was 0.17 mg/kg. An isopyrazam MRL of T0.7 mg/kg for FS 0014 Plums is recommended in conjunction with the proposed harvest withholding period of 14 days.

The tebuconazole dataset suitable for MRL estimation in plums is, in rank order, <0.05 (4), 0.05 (2), 0.06 (2), 0.07 (2), 0.08 (2), 0.10, 0.11 (2) and 0.21 mg/kg (n=16). The STMR was 0.07 mg/kg. A tebuconazole MRL of T0.3 mg/kg for FS 0014 Plums is recommended in conjunction with the proposed harvest withholding period of 'Nil'. Consequently, the established tebuconazole MRL of *0.01 mg/kg for FS 0012 Stone fruits should be deleted and replace with an MRL at *0.01 mg/kg for FS 0012 Stone fruits {except plums}.

### Processing to prunes

From the 2008 JMPR, residues of azoxystrobin were not observed to concentrate in prunes with a processing factor of 0.19 reported. Based on the HR of 0.42 mg/kg in plums and the PF of 0.19 the HR-P is estimated to be 0.08 mg/kg in prunes. It is concluded that residues of azoxystrobin in prunes will be covered by the MRL at T0.8 mg/kg recommended for the raw agricultural commodity (RAC).

From the 2007 JMPR, no processing data was reported for difenoconazole in prunes, however a processing factor of 1.2 was reported for raisins. Based on the HR of 0.20 mg/kg in plums and the PF of 1.2 the HR-P is estimated to be 0.24 mg/kg in prunes. It is concluded that residues of difenoconazole in prunes will be covered by the MRL at T0.5 mg/kg recommended for the RAC.

No relevant processing factor for isopyrazam residues in prunes is available, therefore using a moisture content on 90% for fresh plums and 20% for prunes, a default processing factor of 4.5 will be used for MRL estimation in prunes. Based on the HR of 0.39 mg/kg in peaches and the PF of 4.5 the HR-P is estimated to be 1.76 mg/kg in prunes. It is recommended that an isopyrazam MRL for DF 0014 Prunes at T3 mg/kg should be established to cover residues in prunes from the proposed use.

From the 2008 JMPR, residues of tebuconazole were observed to concentrate in prunes with a processing factor of 4.7 reported for prunes. Based on the HR of 0.21 mg/kg in plums and the PF of 4.7 the HR-P is estimated to be 0.99 mg/kg in prunes. It is recommended that a tebuconazole MRL for DF 0014 Prunes at T2 mg/kg should be established to cover residues in prunes from the proposed use.

## Overseas registration and approved label instructions

The applicant indicated that products containing azoxystrobin, difenoconazole, fluopyram and tebuconazole products are registered for use on stone fruits in the United States of America.

## 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. Azoxystrobin, difenoconazole, isopyrazam and tebuconazole have been considered by Codex. The following relevant Codex CXLs and/or international MRLs have been established for azoxystrobin, difenoconazole, isopyrazam and tebuconazole (see Tables 4, 5, 6 and 7):

**Table 4: Current and proposed Australian and overseas MRLs/tolerances for azoxystrobin**

| Commodity | Tolerance for residues arising from the use of azoxystrobin (mg/kg) | | | | | | |
|---|---|---|---|---|---|---|---|
| | Australia[3] | Codex[4] | China[5] | Hong Kong[6] | Singapore[7] | EU[8] | USA[9] |
| Residue definition | Azoxystrobin | Azoxystrobin | Azoxystrobin | Azoxystrobin | – | Azoxystrobin | Azoxystrobin |
| Plums | T0.8 (proposed) | – | 2 | – | – | 2 | – |
| Stone fruits (group) | – | 2 | – | 2 | – | – | 2 |

[3] Federal Register of Legislation, 2019. *Agricultural and Veterinary Chemicals Code (MRL Standard) Instrument 2019*, Federal Register of Legislation website, accessed 2 May 2023

[4] Food and Agriculture Organisation of the United Nations (FAO), 2023. *Codex Alimentarius International Food Standards Pesticide Index*, FAO website, accessed 2 May 2023.

[5] United States Department of Agriculture (USDA) Foreign Agricultural Service, *Translation of Maximum Residue limits – People's Republic of China – 24 August 2021*, accessed 2 May 2023.

[6] The Government of the Hong Kong Special Administration Region Centre for Food Safety (2017). *Hong Kong Pesticide MRL Database*, accessed 2 May 2023.

[7] Singapore Food Agency (SFA), n.d. *Ninth Schedule – Regulation 30(2) and (5) – Food with Maximum Amounts of Pesticides*, SFA website, accessed 2 May 2023.

[8] European Commission, 2023. *EU Pesticides Database: Pesticide residue(s) and maximum residues levels (mg/kg), European Commission website*, accessed 2 May 2023.

[9] Electronic Code of Federal Regulations (eCFR), 2023. *Part 180 – Tolerances and exemptions for pesticide chemical residues in food*, eCFR website, accessed 2 May 2023.

**Table 5: Current and proposed Australian and overseas MRLs/tolerances for difenoconazole**

| Commodity | Tolerance for residues arising from the use of difenoconazole (mg/kg) | | | | | | |
|---|---|---|---|---|---|---|---|
| | Australia[10] | Codex[11] | China[12] | Hong Kong[13] | Singapore[14] | EU[15] | USA[16] |
| Residue definition | Difenoconazole | Difenoconazole | Difenoconazole | Difenoconazole | – | Difenoconazole | Difenoconazole |
| Plums | T0.5 (proposed) | 0.2 (subgroup) | 0.2 (including prunes) | 2.5 (including prunes) | – | 0.5 | – |
| Stone fruits (group) | – | – | – | – | – | – | 2.5 |

[10] Federal Register of Legislation, 2019. *Agricultural and Veterinary Chemicals Code (MRL Standard) Instrument 2019*, Federal Register of Legislation website, accessed 2 May 2023

[11] Food and Agriculture Organisation of the United Nations (FAO), 2023. *Codex Alimentarius International Food Standards Pesticide Index*, FAO website, accessed 2 May 2023.

[12] United States Department of Agriculture (USDA) Foreign Agricultural Service, *Translation of Maximum Residue limits – People's Republic of China – 24 August 2021*, accessed 2 May 2023.

[13] The Government of the Hong Kong Special Administration Region Centre for Food Safety (2017). *Hong Kong Pesticide MRL Database*, accessed 2 May 2023.

[14] Singapore Food Agency (SFA), n.d. *Ninth Schedule – Regulation 30(2) and (5) – Food with Maximum Amounts of Pesticides*, SFA website, accessed 2 May 2023.

[15] European Commission, 2023. *EU Pesticides Database: Pesticide residue(s) and maximum residues levels (mg/kg), European Commission website*, accessed 2 May 2023.

[16] Electronic Code of Federal Regulations (eCFR), 2023. *Part 180 – Tolerances and exemptions for pesticide chemical residues in food*, eCFR website, accessed 2 May 2023.

Table 6: Current and proposed Australian and overseas MRLs/tolerances for isopyrazam

| Commodity | Tolerance for residues arising from the use of isopyrazam (mg/kg) | | | | | | |
|---|---|---|---|---|---|---|---|
| | Australia[10] | Codex[11] | China[12] | Hong Kong[13] | Singapore[14] | EU[15] | USA[16] |
| Residue definition | Isopyrazam | Isopyrazam | Isopyrazam | – | – | Isopyrazam | Isopyrazam |
| Plums | T0.7 (proposed) | – | – | – | – | *0.01 | – |
| Prunes | T3 | – | – | – | – | – | – |
| Stone fruits (group) | – | – | 0.4[17] | – | – | – | – |

[17] Temporary MRL

**Table 7: Current and proposed Australian and overseas MRLs/tolerances for tebuconazole**

| Commodity | Tolerance for residues arising from the use of tebuconazole (mg/kg) | | | | | | |
|---|---|---|---|---|---|---|---|
| | Australia[18] | Codex[19] | China[20] | Hong Kong[21] | Singapore22 | EU[23] | USA[24] |
| Residue definition | Tebuconazole | Tebuconazole | Tebuconazole | Tebuconazole | – | Tebuconazole | Tebuconazole |
| Plums | T0.3 (proposed) | 1 (subgroup) | 1 | – | – | 1 | 1 (subgroup) |
| Prunes | T2 | 3 | 3 | – | – | – | – |
| Stone fruits (group) | *0.01 (established) *0.01 Stone fruits {except Plums} (proposed) | – | – | 1(except cherries) | – | – | – |

[18] Federal Register of Legislation, 2019. *Agricultural and Veterinary Chemicals Code (MRL Standard) Instrument 2019*, Federal Register of Legislation website, accessed 2 May 2023

[19] Food and Agriculture Organisation of the United Nations (FAO), 2023. *Codex Alimentarius International Food Standards Pesticide Index*, FAO website, accessed 2 May 2023.

[20] United States Department of Agriculture (USDA) Foreign Agricultural Service, *Translation of Maximum Residue limits – People's Republic of China – 24 August 2021*, accessed 2 May 2023.

[21] The Government of the Hong Kong Special Administration Region Centre for Food Safety (2017). *Hong Kong Pesticide MRL Database*, accessed 2 May 2023.

[22] Singapore Food Agency (SFA), n.d. *Ninth Schedule – Regulation 30(2) and (5) – Food with Maximum Amounts of Pesticides*, SFA website, accessed 2 May 2023.

[23] European Commission, 2023. *EU Pesticides Database: Pesticide residue(s) and maximum residues levels (mg/kg), European Commission website*, accessed 2 May 2023.

[24] Electronic Code of Federal Regulations (eCFR), 2023. *Part 180 – Tolerances and exemptions for pesticide chemical residues in food*, eCFR website, accessed 2 May 2023.

## Current and proposed Australian MRLs

### Table 8: Current MRL Standard – Table 1 of the MRL standard

| Compound | | Food | MRL (mg/kg) |
|---|---|---|---|
| Fluopyram | | | |
| FS | 0013 | Cherries | 3 |
| FS | 0012 | Stone fruits {except Cherries} | 2 |
| Tebuconazole | | | |
| FS | 0012 | Stone fruits | *0.01 |

### Table 9: Proposed MRL Standard – Table 1 of the MRL standard

| Compound | | Food | MRL (mg/kg) |
|---|---|---|---|
| Azoxystrobin | | | |
| Add: | | | |
| FS | 0014 | Plums (including prunes) | T0.8 |
| Difenoconazole | | | |
| Add: | | | |
| FS | 0014 | Plums (including prunes) | T0.5 |
| Isopyrazam | | | |
| Add: | | | |
| FS | 0014 | Plums | T0.7 |
| DF | 0014 | Prunes | T3 |
| Tebuconazole | | | |
| Delete: | | | |
| FS | 0012 | Stone fruits | *0.01 |
| Add: | | | |
| FS | 0014 | Plums | T0.3 |
| DF | 0014 | Prunes | T2 |
| FS | 0012 | Stone fruits {except Plums} | *0.01 |

## Potential risk to trade

Export of treated produce containing finite (measurable) residues of azoxystrobin, difenoconazole, isopyrazam and tebuconazole 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.

For azoxystrobin, the proposed MRL for Plums (including prunes) at T0.8 mg/kg is lower than the MRL coverage for Stone fruits that is established at 2 mg/kg in most significant markets except Singapore where no MRL is established. It is however noted that Singapore recognises Codex MRLs for pesticides which do not have MRLs specifically stipulated under their Food Regulations[25].

For difenoconazole, the proposed MRL for Plums (including prunes) at T0.5 mg/kg is lower than the MRL for Plums established in Hong Kong (2.5 mg/kg), the EU (0.5 mg/kg) and the USA (2.5 mg/kg) but is higher than the MRL for Plums established in China and by Codex (and by reference, Singapore) at 0.2 mg/kg.

For isopyrazam, the proposed MRLs are for Plums at T0.7 mg/kg and Prunes at T3 mg/kg. MRLs for Plums or Stone fruits are not established in most significant markets except for the EU where an MRL for Plums is established at the limit of quantification (*0.01 mg/kg).

For tebuconazole, the proposed MRLs are for Plums at T0.3 mg/kg and Prunes at T2 mg/kg. Higher MRLs for Plums are established by Codex (and by reference, Singapore), China, the EU and the USA at 1 mg/kg, however MRLs are not established in Hong Kong. For prunes, MRLs are established by Codex and China at 3 mg/kg but are not established separately in other markets. It is noted that high residues from the proposed Australian use are expected in the processed commodity at <1 mg/kg and should be covered by the RAC MRL in most markets except Hong Kong and Singapore.

[25] Singapore Food Agency (SFA), 2020. *Singapore Food Agency Circular 20 April 2020*, SFA website, accessed 13 June 2023

## Conclusion

Comment is sought on the ability of industry to manage the potential trade risks associated with the proposed uses.