



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



Trade Advice Notice

on fluxapyroxad and mefentrifluconazole in the product
Revystar Fungicide for use on wheat, barley, oats and canola

APVMA product number 89744

March 2021

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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 active constituents 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 to register Revystar 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 Tuesday 27 April 2021 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: apvma.gov.au.

Introduction

The APVMA has before it an application from BASF Australia Ltd to register Revystar Fungicide, containing fluxapyroxad and mefentrifluconazole, for use on wheat, barley, oats and canola.

Fluxapyroxad is currently registered for the foliar treatment of barley (Imbrex Fungicide, 64104, allows 2 applications each at 62.5 g ai/ha up to Z59) and as a seed treatment for barley and wheat. Fluxapyroxad is also registered in combination with epoxiconazole and pyraclostrobin as a foliar treatment for wheat and barley (Ceriax Fungicide, 83267, allows 2 applications each at 31.5 g ai/ha up to Z59). Fluxapyroxad is not currently approved for use in oats or canola in Australia.

In Australia, mefentrifluconazole is currently registered for use on apples and grapes only. The current proposal is for first use of mefentrifluconazole in wheat, barley, oats and canola in Australia and also represents an increase in the maximum dietary burden for livestock and poultry.

Trade considerations

Commodities exported

Wheat, barley, oats (including hay) and canola (including derived oils and meals) are considered to be major export commodities, as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feeds produced from treated forages and fodders. Residues in these commodities resulting from the use of Revystar Fungicide may have the potential to unduly prejudice trade.

Destination and value of exports

Total exports of barley were estimated at 4,684 kilotonnes in 2018 to 2019, valued at \$1.8 billion. Major export destinations for Australian barley are China, Japan, Korea, Vietnam, Thailand, the Philippines, Taiwan, Saudi Arabia, Kuwait and United Arab Emirates (ABARES).

Total exports of wheat (including flour) were 9,805 kilotonnes in 2018 to 2019, valued at \$3.7 billion. Major export destinations for Australian wheat are Indonesia, India, Korea, China, Japan, Thailand, Malaysia, the Philippines, Vietnam, Egypt, Yemen, Iraq and New Zealand (ABARES).

Total exports of oat grain were 124 kt in 2018 to 2019, valued at \$106 million. Major export destinations in 2017 were Japan, India, Philippines, China and Singapore (ABARES).

Major export markets for Australian oaten hay are Japan, China, Taiwan and South Korea.

Australian exports of canola grain, oil and meal totalled 1569 kt, 157 kt and 0 kt respectively in 2018 to 2019. The value of Australian oilseeds, oils and meals totalled \$1 billion, \$358 million and \$12.4 million respectively in 2018 to 2019. The major export markets for canola grain in 2018 to 2019 included Belgium, Germany, France, Japan and China. Destinations for canola oil included Malaysia, the Republic of Korea, China and New Zealand. The major markets for Canola meal included New Zealand and the Republic of Korea (ABARES).

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)*.

Proposed Australian use pattern

Revystar Fungicide (50 g/L fluxapyroxad, 100 g/L mefentrifluconazole).

Table 1: Proposed use pattern for Revystar Fungicide

| Crop | Disease | Rate | Critical comments |
|--------|--|--------------------------------------|---|
| Wheat | Leaf rust (<i>Puccinia persistens</i> f. sp. <i>triticultura</i>) | 750 ml/Ha (37.5 + 75 g ai/ha) | Monitor crops from early stem elongation (Z32), and on susceptible varieties apply at the first sign of infection. |
| | Stripe rust (<i>Puccinia striiformis</i>) | | Continue to monitor crops after application, a second application may be required if conditions favour disease development and initial application is made before the flag leaf has emerged. |
| | Septoria nodorum blotch (<i>Phaeosphaeria nodorum</i>) | | A maximum of 2 applications may be made per crop. DO NOT apply after Z59 (ear emergence). |
| | Powdery mildew (<i>Blumeria graminis</i> f.sp. <i>tritici</i>) | | When targeting septoria, yellow leaf spot or powdery mildew, if an SDHI (Group 7) seed treatment has been used with foliar activity (as determined by label claims), the first foliar applied fungicide should not contain an SDHI (Group 7) fungicide. |
| | Septoria tritici (<i>Mycosphaerella garminicola</i>) | | |
| | Suppression of Yellow leaf spot (<i>Pyrenophora tritici-repentis</i>) | | |
| Barley | <i>Ramularia</i> (<i>Ramularia collo-cygni</i>) | 750 ml/ha | Apply as a preventative spray on susceptible cultivars and when conditions favour disease. Otherwise, apply at the first appearance of disease. Continued disease pressure or reinfection may requires further treatment 3 to 5 weeks later. |
| Barley | Leaf rust (<i>Puccinia hordei</i>) | 750 ml/Ha | Monitor crops from mid-tillering. |
| | Spot form of net blotch (<i>Pyrenophora teres</i> f. sp. <i>maculata</i>) | | On susceptible varieties apply at the first sign of disease development. Monitor and reapply within 14 to 21 days if conditions favour disease development. |
| | Net form of net blotch (<i>Pyrenophora teres</i> f. sp. <i>teres</i>) | | A maximum of 2 applications may be made per crop. DO NOT apply after Z59 (ear emergence). |
| | Leaf scald (<i>Rynchosporium secalis</i>) | | When targeting powdery mildew, scald or net blotch if an SDHI (Group 7) seed treatment has been used with foliar activity (as determined by label claims), the first foliar applied fungicide should not contain an SDHI (Group 7) fungicide. |
| | Powdery mildew (<i>Blumeria graminis</i> f. sp. <i>hordei</i>) | | |
| | | | |

| Crop | Disease | Rate | Critical comments |
|------------------|--|--|---|
| Oats & Oaten Hay | Septoria leaf blotch (<i>Phaeosphaeria avenaria</i>) Red leather leaf (<i>Spermospora avenae</i>) | 750 ml/ha | Aim to apply between stem elongation and completion of flag leaf emergence (Z32-41) if disease is present or conditions favour disease development. Repeat spraying may be required, particularly if infection occurs early. Regularly monitor the crop from 2 weeks after the first application for signs of re-infection. DO NOT apply later than Z59. |
| Canola | Black leg (<i>Leptosphaeria maculans</i>) | 750 ml/ha | Apply at the 4 to 6 leaf crop stage. When planting canola varieties of blackleg rating MS or lower combine with an effective seed treatment of in-furrow fungicide. Application of Revystar at this crop growth stage will reduce lodging and stem canker from blackleg. Where an effective seed treatment or in-furrow fungicide has not been used in high disease risk situations a follow up application at green bud may be required. If an SDHI (Group 7) seed treatment has been used with foliar activity on black leg (as deemed by the label claims), DO NOT apply Revystar or any other SDHI (Group 7) containing foliar fungicide if targeting black leg at the 4 to 6 leaf growth stage. |
| | Sclerotinia (<i>Sclerotinia sclerotiorum</i>) | 750 ml - 1L/ha (up to 50 + 100 g ai/ha) | Apply between 20% and 50% (full bloom) flowering. For best results apply as a preventative application at 20% to 30% flowering prior to significant disease expression. Use the higher rate (up to 1 L/ha) in higher yielding crops where conditions favour disease development. Good coverage throughout the entire canopy is essential, particularly ensuring spray coverage reaches down to the base of the canopy. Using a water rate at the higher end of the range (see application instructions) will improve spray coverage. A second application may be required if seasonal conditions are conducive for continued disease development or when the risk of disease is high. DO NOT apply after 50% (full bloom) flowering growth stage. DO NOT apply more than 2 applications of Revystar or any SDHI (Group 7) containing fungicide during the flowering period for the control of sclerotinia in canola. |

Withholding periods:

Harvest: Not required when used as directed.

Grazing: DO NOT graze or cut for stock food for 4 weeks after application.

Restrains:

DO NOT apply more than 2 applications to any one crop.

Canola: Do not apply after 50% flowering growth stage.

Wheat, Barley and Oats: DO NOT apply after Z59 (ear emergence).

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) 10 DAYS: Livestock that has grazed on or been fed treated crops should be placed on clean feed for 10 days prior to slaughter.

Results from residues trials presented to the APVMA

Cereal grains

The critical use pattern for wheat, barley and oats is for up to 2 applications each at 37.5 g fluxapyroxad/ha + 75 g mefentrifluconazole/ha with a latest growth stage for application of Z59/BBCH59.

Australian trials for fluxapyroxad and mefentrifluconazole on wheat (4 trials), barley (2 trials) and oats (2 trials) addressed the proposed application timing and involved 1× and 2× rate treatments. The Australian trials are supported by European trials for wheat and barley which addressed a later application timing of BBCH 69 and an application rate 2× higher than is proposed for fluxapyroxad and mefentrifluconazole. Additional Australian and European trials for fluxapyroxad on wheat and barley at 2× rate treatments were considered previously for Imbrex Fungicide.¹

Fluxapyroxad

In Australian trials, residues of fluxapyroxad in wheat grain at 49 to 85 days after the last of 2 applications at the nominal rate of 37.5 g ai/ha (1× proposed) with the second application at BBCH 59-61 were <0.01 (3) and 0.01 mg/kg. Further Australian data for fluxapyroxad on wheat showed residues in wheat grain at harvest after 2 applications at 62.5 g ai/ha (1.7× proposed) with the last application at Z59-61 were <0.01 (2) and 0.01 (2) mg/kg. Scaled for application rate residues were <0.01 (4) mg/kg. From EU wheat trials involving a last application at BBCH 69 at 75 g ai/ha (2× proposed) residues of fluxapyroxad in grain (42–49 DALA) were <0.01 (3), 0.02, 0.02, 0.03, 0.03 and 0.06 mg/kg. Scaled for application rate residues were <0.01 (3), 0.01, 0.01, 0.02, 0.02 and 0.03 mg/kg. The combined dataset for fluxapyroxad on wheat from Australian and EU trials is <0.01 (10), 0.01, 0.01, 0.01, 0.02, 0.02 and 0.03 mg/kg. The OECD maximum residue limit (MRL) calculator recommends an MRL of 0.04 mg/kg (STMR 0.010 mg/kg, n = 16). No changes are required to the current MRL of 0.1 mg/kg for fluxapyroxad on GC 0654 wheat in conjunction with a withholding period of 'Not required when used as directed' and a restraint of 'DO NOT apply after Z59 (ear emergence)'.¹

¹ Australian Pesticides and Veterinary Medicines Authority, [Public Release Summary on the Evaluation of the New Active Fluxapyroxad in the Product Imbrex Fungicide](#), APVMA website, August 2012, accessed 19 February 2021.

Data for barley and oats will be considered together as they are in the same crop subgroup, with barley being the representative crop. In Australian trials, residues of fluxapyroxad in barley and oat grain at 49 to 59 days after the last of 2 applications at the nominal rate of 37.5 g ai/ha (1× proposed) with the second application at BBCH 59–61 were <0.01, 0.02, 0.02 and 0.03 mg/kg. Further Australian data for fluxapyroxad on barley showed residues in barley grain at harvest after 2 applications at 62.5 g ai/ha (1.7× proposed) with the last application at Z59–61 were 0.03 and 0.05 mg/kg. Scaled for application rate residues were 0.02 and 0.03 mg/kg. From EU barley trials involving a last application at BBCH 69 at 75 g ai/ha (2× proposed) residues of fluxapyroxad in grain (34–51 DALA) were 0.03, 0.05, 0.08, 0.08, 0.11, 0.16, 0.25 and 0.31 mg/kg. Scaled for application rate residues were 0.02, 0.02, 0.04, 0.04, 0.06, 0.08, 0.13 and 0.16 mg/kg. In additional EU barley trials involving 2 applications at 83 g ai/ha (2.2× proposed) with the last application at BBCH 69, residues in grain were 0.02, 0.03, 0.05 (2), 0.06, 0.07 (3), 0.09, 0.10, 0.11, 0.13, 0.14, 0.14, 0.15 and 0.18 mg/kg. Scaled for application rate residues were <0.01, 0.01, 0.02 (3), 0.03 (3), 0.04, 0.04, 0.05, 0.06, 0.06, 0.06, 0.07 and 0.08 mg/kg.

The combined dataset for fluxapyroxad on barley and oats from Australian and EU trials is <0.01 (2), 0.01, 0.02, 0.02, 0.02, 0.02 (2), 0.02, 0.02, 0.02, 0.03, 0.03 (3), 0.03, 0.04, 0.04, 0.04, 0.04, 0.05, 0.06, 0.06, 0.06, 0.06, 0.07, 0.08 (2), 0.13 and 0.16 mg/kg. The OECD MRL calculator recommends an MRL of 0.2 mg/kg (STMR 0.033 mg/kg, n = 30). Given the highest residues were in EU trials involving a later application timing than proposed and that all results were still within the current MRL of 0.2 mg/kg for fluxapyroxad on GC 0640 Barley it is recommended that this established MRL will remain appropriate. An MRL of 0.2 mg/kg is also recommended for fluxapyroxad on GC 0647 oats in conjunction with a withholding period of 'Not required when used as directed' and a restraint of 'DO NOT apply after Z59 (ear emergence)'.

Mefentrifluconazole

In Australian trials, residues of mefentrifluconazole in wheat grain at 49 to 85 days after the last of 2 applications at the nominal rate of 75 g ai/ha (1× proposed) with the second application at BBCH 59–61 were <0.01 (3) and 0.02 mg/kg. From EU wheat trials involving a last application at BBCH 69 at 150 g ai/ha (2× proposed) residues of mefentrifluconazole in grain (42–49 DALA) were <0.01 (7) and 0.04 mg/kg. Scaled for application rate residues were <0.01 (7) and 0.02 mg/kg. The combined dataset for mefentrifluconazole on wheat from Australian and EU trials is <0.01 (10), 0.02 and 0.02 mg/kg. The OECD MRL calculator recommends an MRL of 0.03 mg/kg (STMR = 0.01 mg/kg, n = 12). An MRL of 0.03 mg/kg is recommended for mefentrifluconazole on GC 0654 wheat in conjunction with a withholding period of 'Not required when used as directed' and a restraint of 'DO NOT apply after Z59 (ear emergence)'.

In Australian trials, residues of mefentrifluconazole in barley and oat grain at 49 to 59 days after the last of 2 applications at the nominal rate of 75 g ai/ha (1× proposed) with the second application at BBCH 59–61 were <0.01, 0.02, 0.03 and 0.06 mg/kg. From EU barley trials involving a last application at BBCH 69 at 150 g ai/ha (2× proposed) residues of mefentrifluconazole in grain (34–51 DALA) were 0.02, 0.03, 0.07, 0.10, 0.11, 0.14, 0.15 and 0.30 mg/kg. Scaled for application rate residues were 0.01, 0.01, 0.04, 0.05, 0.06, 0.07, 0.08 and 0.15 mg/kg. The combined dataset for mefentrifluconazole on barley and oats from Australian and EU trials is <0.01, 0.01, 0.01, 0.02, 0.03, 0.04, 0.05, 0.06, 0.06, 0.07, 0.08 and 0.15 mg/kg. The OECD MRL calculator recommends an MRL of 0.2 mg/kg (STMR = 0.044 mg/kg, n = 12). MRLs of 0.2 mg/kg are recommended for mefentrifluconazole on GC 0640 barley and GC 0647 oats in conjunction with a withholding period of 'Not required when used as directed and a restraint of 'DO NOT apply after Z59 (ear emergence)'.

Cereal straw

Fluxapyroxad

In Australian trials, residues of fluxapyroxad in cereal straw (wheat, barley, oats) at 49 to 85 days after the last of 2 applications at the nominal rate of 37.5 g ai/ha (1x proposed) with the second application at BBCH 59–61 were <0.01, 0.92, 1.0, 1.8, 3.4, 3.8, 4.7 and 6.0 mg/kg (dry weight). After application at 2x proposed, residues were <0.01, 1.7, 2.9, 3.6, 5.3, 9.3, 10.5 and 12.2 mg/kg (dry weight). Based on the 1x dataset the OECD MRL calculator recommends an MRL of 15 mg/kg (STMR = 2.59 mg/kg, n = 8). No changes are required to the current MRL of 20 mg/kg for fluxapyroxad on the forage and fodder of cereal grains.

Mefentrifluconazole

In Australian trials, residues of mefentrifluconazole in cereal straw (wheat, barley, oats) at 49 to 85 days after the last of 2 applications at the nominal rate of 75 g ai/ha (1x proposed) with the second application at BBCH 59–61 were <0.01, 2.0, 2.1, 4.0, 4.9, 7.8, 8.3 and 9.0 mg/kg (dry weight). After application at 2x proposed, residues were <0.01, 3.8, 5.1, 7.6, 10.1, 17.5, 18.9 and 20.2 mg/kg (dry weight). Based on the 1x dataset the OECD MRL calculator recommends an MRL of 20 mg/kg (STMR = 4.415 mg/kg, n = 8). Given the similar residues observed in cereal forage below, it is recommended that a mefentrifluconazole MRL of 20 mg/kg be established for forage and fodder of cereal grains.

Cereal forage

Fluxapyroxad

In Australian trials, residues of fluxapyroxad in wheat, barley and oat forage at 28 days after the last of 2 applications at the nominal rate of 37.5 g ai/ha (1x proposed) were 0.71, 0.81, 1.4, 1.5, 1.6, 2.0, 2.5 and 2.77 mg/kg (dry weight). After application at 2x proposed, residues were 1.5, 2.0, 3.0, 3.0, 4.0, 4.5, 6.3 and 7.0 mg/kg (dry weight). Based on the 1x dataset the OECD MRL calculator recommends an MRL of 5 mg/kg (STMR = 1.57 mg/kg, n = 8). No changes are required to the current MRL of 20 mg/kg for fluxapyroxad on the forage and fodder of cereal grains in conjunction with a 4 week grazing withholding period.

Mefentrifluconazole

In Australian trials, residues of mefentrifluconazole in wheat, barley and oat forage at 28 days after the last of 2 applications at the nominal rate of 75 g ai/ha (1x proposed) were 2.0, 2.4, 2.5, 3.7, 4.1, 4.3, 5.0 and 8.4 mg/kg (dry weight). After application at 2x proposed, residues were 4.9, 6.9, 7.0, 7.2, 8.5, 9.1, 18.0 and 19.1 mg/kg (dry weight). Based on the 1x dataset the OECD MRL calculator recommends an MRL of 15 mg/kg (STMR = 3.91 mg/kg, n = 8). The MRL of 20 mg/kg recommended above for mefentrifluconazole on the forage and fodder of cereal grains will cover residues in forage from the proposed use in conjunction with a 4 week grazing withholding period.

Canola seed

The critical use pattern for canola is for up to 2 applications each at 50 g fluxapyroxad/ha + 100 g mefentrifluconazole/ha with a latest growth stage for application of 50% (full bloom) flowering growth stage (= BBCH 65).

Nine Australian trials for fluxapyroxad and mefentrifluconazole on canola addressed the proposed application timing and involved 1× and 2× rate treatments. It is noted that one trial failed to produce grain and straw samples.

Fluxapyroxad

Residues of fluxapyroxad in canola seed at harvest 36 to 60 days after an application at BBCH 65 at a nominal rate of 50 g ai/ha (1× proposed) were 0.02 and 0.10 mg/kg. Residues at 64 to 74 days after an application at BBCH 65 at a nominal rate of 75 g ai/ha (1.5× proposed) were <0.01 (4), 0.01 and 0.02 mg/kg. Scaled for the proposed application rate residues were <0.01 (5) and 0.01 mg/kg. The combined dataset suitable for MRL recommendation is <0.01 (5), 0.01, 0.02 and 0.10 mg/kg. The OECD MRL calculator recommends an MRL of 0.15 mg/kg (STMR = 0.01 mg/kg, n = 8). An MRL of 0.2 mg/kg is recommended for fluxapyroxad on SO 0495 rape seed (canola). As there is a restraint on the label preventing application after 50% flowering, the supported harvest withholding period is 'Not required when used as directed'.

Mefentrifluconazole

Residues of mefentrifluconazole in canola seed at harvest 36 to 60 days after an application at BBCH 65 at a nominal rate of 100 g ai/ha (1× proposed) were <0.01 and 0.03 mg/kg. Residues at 64 to 74 days after an application at BBCH 65 at a nominal rate of 150 g ai/ha (1.5× proposed) were <0.01 (4), 0.01 and 0.02 mg/kg. Scaled for the proposed application rate residues were <0.01 (5) and 0.01 mg/kg.

The combined data set suitable for MRL recommendation is <0.01 (6), 0.01 and 0.03 mg/kg. The OECD MRL calculator recommends an MRL of 0.04 mg/kg (STMR = 0.01 mg/kg, n = 8). An MRL of 0.05 mg/kg is recommended for mefentrifluconazole on SO 0495 rape seed (canola) noting the high residue of 0.03 mg/kg. The supported harvest withholding period is 'Not required when used as directed'.

Canola straw

Fluxapyroxad

Residues of fluxapyroxad in canola straw at harvest 36 to 60 days after an application at BBCH 65 at a nominal rate of 50 g ai/ha (1× proposed) were 0.04 and 0.07 mg/kg (dry weight). Residues at 64 to 74 days after an application at BBCH 65 at a nominal rate of 75 g ai/ha (1.5× proposed) were <0.01, 0.02, 0.02, 0.04, 0.05 and 0.06 mg/kg (dry weight). Scaled for the proposed application rate residues were <0.01, 0.01, 0.01, 0.03, 0.03 and 0.04 mg/kg. The combined dataset suitable for MRL recommendation is <0.01, 0.01, 0.01, 0.03, 0.03, 0.04, 0.04 and 0.07 mg/kg. The OECD MRL calculator recommends an MRL of 0.15 mg/kg (STMR = 0.03 mg/kg, n = 8). No changes are required to the current MRL of 1 mg/kg for fluxapyroxad on primary feed commodities (except chickpea forage and fodder; forage and fodder of cereal grains; lentil forage and fodder).

Mefentrifluconazole

Residues of mefentrifluconazole in canola straw at harvest 36 to 60 days after an application at BBCH 65 at a nominal rate of 100 g ai/ha (1× proposed) were 0.77 and 0.80 mg/kg (dry weight). Residues at 64 to 74 days after an application at BBCH 65 at a nominal rate of 150 g ai/ha (1.5× proposed) were 0.24, 0.33, 0.41, 0.57, 0.70 and 1.0 mg/kg (dry weight). Scaled for application rate residues were 0.16, 0.22, 0.27, 0.38, 0.47 and 0.67 mg/kg. The combined dataset suitable for MRL recommendation is 0.16, 0.22, 0.27, 0.38, 0.47, 0.67, 0.77 and 0.80 mg/kg (dry weight). The OECD MRL calculator recommends an MRL of 1.5 mg/kg (STMR 0.43 mg/kg, n = 8). Given similar residues observed if forage below, an MRL of 2 mg/kg is recommended for mefentrifluconazole on rape seed (canola) forage and fodder.

Canola forage

Fluxapyroxad

Residues of fluxapyroxad in canola forage at 28 days after application at the nominal rate of 50 g ai/ha (1× proposed) were <LOD (4) mg/kg. In separate trials at 21 days after application at 50 g ai/ha (1× proposed) residues were 0.24, 0.54 and 1.0 mg/kg (dry weight). No changes are required to the current MRL of 1 mg/kg for fluxapyroxad on primary feed commodities (except chickpea forage and fodder; forage and fodder of cereal grains; lentil forage and fodder). The supported grazing withholding period is 4 weeks.

Mefentrifluconazole

Residues of mefentrifluconazole in canola forage at 28 days after application at the nominal rate of 100 g ai/ha (1× proposed) were 0.55, 0.58, 0.77 and 0.86 mg/kg (dry weight). The OECD MRL calculator recommends an MRL of 2 mg/kg (STMR = 0.68 mg/kg, n = 4). The MRL of 2 mg/kg recommended above for mefentrifluconazole on rape seed (canola) forage and fodder will also cover residues in forage in conjunction with a 4 week grazing withholding period.

Animal commodities

No changes are required to the current fluxapyroxad forage and fodder of cereal grains MRL at 20 mg/kg. As cereal forage and fodder can form 100% of the diet, the maximum dietary burden for fluxapyroxad for mammalian livestock is unchanged and the current mammalian animal commodity MRLs for fluxapyroxad should remain acceptable. It is noted that the fluxapyroxad product registered for use on barley (Imbrex Fungicide, 64104) has a 2 day Export Slaughter Interval (ESI).

Currently there are apple pomace and grape pomace MRLs for mefentrifluconazole each at 5 mg/kg. The livestock dietary burden for mefentrifluconazole will therefore be driven by the new use on cereals with a forage and fodder of cereal grains MRL proposed at 20 mg/kg. Given a mefentrifluconazole HR of 9.0 mg/kg (dry weight) in cereal forage and fodder which can form 100% of the diet, the maximum mammalian livestock dietary burden for mefentrifluconazole is 9.0 ppm.

A dairy cattle transfer study for mefentrifluconazole has been previously considered.² Estimated residues in tissues and milk from a dietary burden of 9.0 ppm are summarised below:

Cattle

Table 2: Feeding level in cattle

| Feeding level (ppm) | Milk | Muscle | Liver | Kidney | Fat |
|------------------------|-------------------------------------|------------------------|--------------|--------|-------|
| | Mefentrifluconazole residue (mg/kg) | | | | |
| 7.49 (observed) | 0.014 | <0.01 | 0.182 | 0.074 | 0.077 |
| 49.0 (observed) | | 0.105 | | | |
| 9.0 (estimated burden) | 0.017 | 0.019 | 0.219 | 0.089 | 0.093 |
| Established MRLs | *0.01 (milks) | 0.02 (meat in the fat) | 0.02 (offal) | | - |
| Recommended MRLs | 0.03 | 0.2 (meat in the fat) | 0.3 (offal) | | |

To account for the potential transfer of mefentrifluconazole residues to livestock commodities which may occur as a result of the proposed use on cereals, it is recommended that the MRLs for edible offal (mammalian), meat (mammalian) (in the fat) and milks increase to 0.3, 0.2 and 0.03 mg/kg respectively. As finite residues are now expected in milk and residues were up to 6.6× higher in cream it is appropriate to consider establishment of a milk fats MRL for mefentrifluconazole. Applying the 6.6× processing factor to the milk HR of 0.017 mg/kg and assuming cream has a fat content of 40%, the HR in fat is 0.28 mg/kg. An appropriate MRL for mefentrifluconazole on FM 0183 milk fats is 0.4 mg/kg.

Consideration of an Export Slaughter Interval

No Codex MRLs are established for mefentrifluconazole. In addition no animal commodity MRLs are established in Korea or Taiwan, so the endpoint for an Export Slaughter Interval (ESI) will be taken as the LOQ (0.01 mg/kg). Subcutaneous fat was the tissue with the longest half-life for mefentrifluconazole residue decline and is the driver for consideration of an ESI. Based on an estimated residue in fat of 0.093 mg/kg and a half-life of 3 days, it would take approximately 10 days on clean feed for residues to decline to below the LOQ (0.01 mg/kg). A 10 day ESI would therefore be required to ensure residues of mefentrifluconazole in animal tissues for export were below the LOQ, noting this is longer than the 2 day ESI required for fluxapyroxad on a product currently registered for use on barley (Imbrex Fungicide, 64104).

² Australian Pesticides and Veterinary Medicines Authority, [Public Release Summary on the Evaluation of the New Active Mefentrifluconazole in the Product Belanty Fungicide](#), APVMA website, April 2019, accessed 19 February 2021.

Poultry

No changes are required to the current fluxapyroxad barley MRL at 0.2 mg/kg. As cereal grains can form 100% of the diet for poultry, the maximum livestock dietary burden for fluxapyroxad for poultry is unchanged and the current fluxapyroxad poultry commodity MRLs should remain appropriate.

For the registered uses of mefentrifluconazole it was previously considered that grape pomace may be fed to turkeys at 20% of the diet. Current uses would add cereal grains as the remaining 80% of the diet with an STMR of 0.044 mg/kg (for barley and oats). The new dietary burden for mefentrifluconazole is calculated below:

Table 3: Turkeys 10 kg bw, 0.4 kg DM/day

| Crop | Commodity | % in diet | Feed intake (kg) | Residue, mg/kg | % DM | Livestock dietary exposure | | |
|-------|---------------|-----------|------------------|----------------|------|----------------------------|----------|---------|
| | | | | | | mg/animal ppm | mg/kg bw | |
| Grape | Pomace, dry | 20 | 0.08 | 1.58 (STMR-P) | 100 | 0.126 | 0.32 | 0.0126 |
| | Cereal grains | 80 | 0.32 | 0.044 (STMR) | 88 | 0.0128 | 0.04 | 0.00128 |
| Total | | | | | | | 0.36 | |

STMR-P grape pomace (0.25 x 6.3 = 1.58)

Estimated mefentrifluconazole residues in tissues and eggs from a maximum dietary burden of 0.36 ppm are calculated below. For liver, residues are calculated after interpolation from the observed maximum residues after feeding laying hens for 33 days at 0.18 and 1.74 ppm, which are the closest feeding levels in the mefentrifluconazole laying hen feeding study to the calculated maximum dietary burden.

Table 4: Poultry feeding level

| Feeding level (ppm) | Eggs | Muscle | Liver | Fat | Skin with fat |
|------------------------|-------------------------------------|-------------------------|--------------|-------|---------------|
| | Mefentrifluconazole residue (mg/kg) | | | | |
| 1.74 | <0.01 | <0.01 | 0.017 | <0.01 | <0.01 |
| 0.18 | - | <0.01 | <0.01 | <0.01 | <0.01 |
| 0.36, estimated burden | <0.01 | <0.01 | 0.011 | <0.01 | <0.01 |
| Established MRLs | *0.01 (eggs) | *0.01 (meat in the fat) | 0.02 (offal) | - | - |
| Recommended MRLs | No change | No change | No change | | |

The current mefentrifluconazole MRLs for poultry commodities remain appropriate for the proposed uses.

Codex Alimentarius Commission and overseas MRLs

The Codex Alimentarius Commission (Codex) is responsible for establishing Codex Maximum Residue Limits (CXLs) for pesticides and veterinary medicines. 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. Fluxapyroxad has been considered by Codex. Mefentrifluconazole has not been considered by Codex at this time but the applicant indicated that Codex MRLs are expected for cereals and canola in Q3 2021. The following relevant Codex CXLs and/or international MRLs have been established for fluxapyroxad and mefentrifluconazole.

Table 5: Overseas MRLs/tolerances for fluxapyroxad

| Commodity | Tolerance for residues arising from the use of fluxapyroxad (mg/kg) | | | | | | |
|--------------------|---|--------------------------|-------------------------|---------------|--------|---|--|
| | Australia | EU | Japan | Korea | Taiwan | Codex | USA |
| Residue definition | Fluxapyroxad (plant commodities) | Fluxapyroxad | Fluxapyroxad | - | - | Fluxapyroxad (for compliance with MRLs) | Fluxapyroxad |
| Oats | 0.2 (proposed) | 2 (3 not yet applicable) | 3 (other cereal grains) | - | 2 | 2 | 3 (Grain, cereal, group 15, (except corn, field, grain; except corn, pop, grain; except corn, kernels plus cobs with husks removed; except rice; except wheat) |
| Rape seed (canola) | 0.2 (proposed) | 0.9 | 0.9 | 0.8 (oilseed) | 0.8 | 0.8 (oilseed) | 0.9 (Oilseeds, group 20 (except cottonseed)) |
| Oaten hay | 20 (forage and fodder of cereal grains – current) | | - | | | 30 (oat straw and fodder, dry) | 20 (Grain, cereal, forage, fodder and straw, group 16) |

Table 6: Overseas MRLs/tolerances for mefentrifluconazole

| Commodity | Tolerance for residues arising from the use of mefentrifluconazole (mg/kg) | | | | |
|--------------------|--|---------------------|---------------------|-------|---------------------|
| | Australia | EU | Japan | Codex | USA |
| Residue definition | Mefentrifluconazole | Mefentrifluconazole | Mefentrifluconazole | - | Mefentrifluconazole |

| Commodity | Tolerance for residues arising from the use of mefentrifluconazole (mg/kg) | | | | |
|------------------------------|--|---|-------------------------|-------|--|
| | Australia | EU | Japan | Codex | USA |
| Edible offal (mammalian) | 0.02 (current) | 0.4 (bovine liver) | | - | 1.5 (cattle meat byproducts) |
| | 0.3 (proposed) | 0.1 (bovine kidney - 0.15 not yet applicable) | 0.3 (cattle liver) | | |
| Meat (mammalian)(in the fat) | 0.02 (current) | 0.04 (bovine muscle) | 0.03 (cattle muscle) | - | 0.15 (cattle meat) |
| | 0.2 (proposed) | 0.2 (bovine fat) | 0.2 (cattle fat) | | 1 (cattle fat) |
| Milks | *0.01 (current) | 0.02 (cattle milk) | 0.03 | - | 0.15 (milk) |
| | 0.03 (proposed) 0.4 (milk fats, proposed) | 0.03 (cattle milk - not yet applicable) | | | 4 (milk fat) |
| Barley | 0.2 (proposed) | 0.6 | 4 | - | 4 (grain, cereal, group 15, except wheat and corn) |
| Oats | 0.2 (proposed) | 0.6 | 4 (other cereal grains) | - | 4 (grain, cereal, group 15, except wheat and corn) |
| Wheat | 0.03 (proposed) | 0.05 | 0.3 | - | 0.3 |
| Rape seed (canola) | 0.05 (proposed) | *0.01 (0.06 not yet applicable) | 1 | - | 1 |
| Oaten hay | 20 (forage and fodder of cereal grains – proposed) | | - | | 15 (grain, cereal, forage, fodder, and straw, group 16, hay) |

MRLs for mefentrifluconazole have not been established for animal commodities, cereals or canola in Korea and no MRLs for mefentrifluconazole are established in Taiwan. The applicant indicated that import tolerances in line with the US MRLs will be applied for in Korea. The applicant also indicated that Codex MRLs were expected for cereals and canola in Q3 2021 (Mefentrifluconazole had been scheduled for JMPR evaluation in September 2020, but the meeting has been delayed due to COVID-19) and that an MRL for wheat in China could potentially be set in 2022. An import tolerance application for Taiwan has yet to be finalised.

Current and proposed Australian MRLs for fluxapyroxad and mefentrifluconazole

Table 7: Current MRL Standard – Table1

| Compound | Food | MRL (mg/kg) |
|---------------------|-------------------------------|-------------|
| Fluxapyroxad | | |
| | All other foods | 0.1 |
| GC 0640 | Barley | 0.2 |
| CM 0640 | Barley bran, unprocessed | 0.5 |
| MO 0105 | Edible offal (mammalian) | 0.03 |
| PE 0112 | Eggs | 0.005 |
| MM 0095 | Meat (mammalian) [in the fat] | 0.05 |
| FM 0183 | Milk fats | 0.1 |
| ML 0106 | Milks | 0.005 |
| PM 0110 | Poultry meat [in the fat] | *0.01 |
| PO 0111 | Poultry, edible offal of | *0.01 |
| GC 0654 | Wheat | 0.1 |
| Mefentrifluconazole | | |
| 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 [in the fat] | *0.01 |
| PO 0111 | Poultry, edible offal of | 0.02 |

Table 8: Current MRL Standard – Table4

| Compound | Animal Feed Commodity | MRL (mg/kg) |
|--------------|------------------------------------|-------------|
| Fluxapyroxad | | |
| | Forage and fodder of cereal grains | 20 |

| Compound | Animal Feed Commodity | MRL (mg/kg) |
|----------------------------|--|-------------|
| | Primary feed commodities {except chickpea forage and fodder; forage and fodder of cereal grains; lentil forage and fodder} | 1 |
| Mefentrifluconazole | | |
| AB 0226 | Apple pomace, dry | 5 |
| AB 0269 | Grape pomace, dry | 5 |

Table 9: Proposed MRL Standard – Table1

| Compound | Food | MRL (mg/kg) |
|----------------------------|-------------------------------|-------------|
| Fluxapyroxad | | |
| Add: | | |
| GC 0647 | Oats | 0.2 |
| SO 0495 | Rape seed (canola) | 0.2 |
| Mefentrifluconazole | | |
| Delete: | | |
| MO 0105 | Edible offal (mammalian) | 0.02 |
| MM 0095 | Meat (mammalian) [in the fat] | 0.02 |
| ML 0106 | Milks | *0.01 |
| Add: | | |
| GC 0640 | Barley | 0.2 |
| MO 0105 | Edible offal (mammalian) | 0.3 |
| MM 0095 | Meat (mammalian) [in the fat] | 0.2 |
| FM 0183 | Milk fats | 0.4 |
| ML 0106 | Milks | 0.03 |
| GC 0647 | Oats | 0.2 |
| SO 0495 | Rape seed (canola) | 0.05 |
| GC 0654 | Wheat | 0.03 |

Table 10: Proposed MRL Standard – Table4

| Compound | Animal Feed Commodity | MRL (mg/kg) |
|---------------------|--------------------------------------|-------------|
| Mefentrifluconazole | | |
| Add: | | |
| | Forage and fodder of cereal grains | 20 |
| | Rape seed (canola) forage and fodder | 2 |

Potential risk to trade

Export of treated produce containing finite (measurable) residues of fluxapyroxad and mefentrifluconazole 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 recommended 10 day ESI should ensure there are no quantifiable residues of fluxapyroxad or mefentrifluconazole in mammalian animal tissues for export. The risk to trade in these commodities is considered to be low. An increase has been proposed to the mefentrifluconazole milk MRL to 0.03 mg/kg, which is similar or lower than those MRLs established or to be established in the EU, Japan, and the USA, however no mefentrifluconazole milk MRL is established by Codex, China, Korea or Taiwan. A milk fats MRL is also proposed for mefentrifluconazole at 0.4 mg/kg, lower than the level established in the USA, which is the only overseas market that currently lists a milk fats MRL for mefentrifluconazole.

The proposed new fluxapyroxad oat and rape seed MRLs are lower than those currently established overseas, including by Codex.

The proposed new mefentrifluconazole wheat, barley, oats and rape seed MRLs are lower than those established in Japan and the USA and lower than those established or to be established in the EU (expected in the second quarter of this year). However, no mefentrifluconazole MRLs have been established by Codex at this time.

With respect to oaten hay, MRLs at 20 mg/kg for cereal forage and fodder are considered appropriate for both actives and it is noted that Japan has not established tolerances for fluxapyroxad or mefentrifluconazole in animal feeds.

Conclusion

BASF Australia Ltd have made an application to register Revystar Fungicide, containing fluxapyroxad and mefentrifluconazole, for use on wheat, barley, oats and canola. Comment is sought on the potential for Revystar Fungicide to prejudice Australian trade when used as proposed and the ability of industry to manage potential trade risk.