



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



Trade Advice Notice

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

APVMA product number 93947

December 2023

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ISSN 2200-3894 (electronic)

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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 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 18th January 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 submission coversheet](#)).

Please lodge your submission using the [public submission 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
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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 the new product Revystar Fungicide, containing fluxapyroxad and mefentrifluconazole, for use on barley, oats, wheat 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 Zadok's growth stage 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 registered for use in oats or canola in Australia.

In Australia, mefentrifluconazole is currently registered for use on apples, grapes almonds, macadamias, cucurbits and fruiting vegetables (Belanty Fungicide, 84344). The current proposal is for the first registration of mefentrifluconazole in wheat, barley, oats and canola in Australia and also represents an increase in the maximum dietary burden for livestock and poultry.

The proposed uses on barley, oats, wheat and canola were consulted on previously in a Trade Advice Notice published in March 2021¹. The uses were not supported at that time as, based on comments received on the Trade Advice Notice, the APVMA could not be satisfied that the risk to trade in barley, oats, wheat and canola could be adequately managed by industry practices until appropriate Codex/international Maximum Residue Limits (MRLs) for mefentrifluconazole had been progressed. Mefentrifluconazole has since been evaluated by the 2022 Joint Meeting on Pesticide Residues (JMPR) with relevant MRLs proposed for barley, oats, wheat, small seed oilseeds and animal commodities². These MRLs have been proposed for adoption by Codex³. The applicant also indicated that relevant import tolerances for mefentrifluconazole were established in Korea for barley and wheat as of April 2023 and are expected to be established in Taiwan for barley, oats, wheat, canola and cereal forage/fodder by Quarter 4 2024.

¹ Australian Pesticides and Veterinary Medicines Authority (APVMA), 2021. [Trade Advice Notice on fluxapyroxad and mefentrifluconazole in the product Revystar Fungicide](#), APVMA website, accessed December 2023.

² Food and Agricultural Organization of the United Nations (FAO) and the World Health Organisation (WHO), 2022. [Joint Meeting on Pesticide Residues – Pesticide Residues in Food 2022 – Mefentrifluconazole](#), WHO website, accessed December 2023.

³ Food and Agricultural Organization of the United Nations (FAO), 2023. [The Report of the 54th Session of the Codex Committee on Pesticide Residues \(26 June to 1 July 2023\) agreed to advance all the relevant proposed mefentrifluconazole MRLs for adoption at Step 5/8, as recommended by the 2022 JMPR](#), FAO website, accessed December 2023.

Trade considerations

Commodities exported

Barley, oats (including hay), wheat and canola (including derived oils and meals) are considered to be major export commodities⁴, 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 8105 kt in the 2021 fiscal year, valued at \$2.98 billion. Major export destinations for Australian barley were Saudi Arabia, Japan, Vietnam, Kuwait, the Philippines, United Arab Emirates, Korea, Thailand and Taiwan (Australian Bureau of Agricultural and Resource Economics and Sciences, ABARES)⁵.

Total exports of oat grain were 613 kt in the 2021 fiscal year, valued at \$179 million. Export destinations for that year were not recorded. Major export destinations in 2017 were Japan, India, Philippines, China and Singapore (ABARES).

Key export markets for Australian fodder crops (including oaten hay) include Japan, Korea, China and Taiwan⁶.

Total exports of wheat were 25890 kt in the 2021 fiscal year, valued at \$11.3 billion. Major export destinations for Australian wheat were China, Indonesia, Vietnam, the Philippines, Korea, Japan, Malaysia, Yemen, Thailand, New Zealand, Sudan, Bangladesh, Kuwait, Taiwan, South Africa, Myanmar, Mozambique, Papua New Guinea, Fiji, Iraq and Egypt (ABARES).

Australian exports of canola grain, canola oil and oilseed meal totalled 5172 kt, 187 kt and 7 kt respectively in the 2021 fiscal year (ABARES).

The value of Australian oilseeds and meals exports totalled \$5.97 billion and \$8.3 million respectively in the 2021 fiscal year (ABARES).

The major export markets for canola grain in 2021 included Germany, Belgium, Japan, France, the Netherlands, Bangladesh and Pakistan. Destinations for canola oil included New Zealand, the Republic of Korea, China and Japan. The major markets for Canola meal previously included New Zealand and the Republic of Korea (ABARES).

⁴ Australian Pesticides and Veterinary Medicines Authority (APVMA), 2020. [Regulatory Guidelines – Data Guidelines: Agricultural – Overseas trade \(Part 5B\)](#), APVMA website, accessed December 2023

⁵ Australian Bureau of Agricultural and Resource Economics and Sciences (ABARES), 2022. [Agricultural commodities and trade data – Agricultural commodity statistics – 2022](#), ABARES website, accessed December 2023

⁶ AgriFutures Australia, 2023. [Export Fodder](#), AgriFutures website, accessed December 2023

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 below shows the proposed Australian use pattern for Revystar Fungicide (50 g/L fluxapyroxad, 100 g/L mefentrifluconazole).

Table 1: Proposed use pattern

Crop	Disease	Rate	Critical comments
Wheat	Leaf rust (<i>Puccinia persistens</i> f. sp. <i>tritricina</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.	
	<i>Septoria tritici</i> (<i>Mycosphaerella garminicola</i>)		
	Suppression of Yellow leaf spot (<i>Pyrenophora tritici-repentis</i>)		
Barley	Ramularia (<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 require 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 and Oaten Hay	Septoria leaf blotch (<i>Phaeosphaeria avenaria</i>) Red leather leaf (<i>Spermospora avenae</i>)	750 ml/ha	<p>Aim to apply between stem elongation and completion of flag leaf emergence (Z32-41) if disease is present or conditions favour disease development.</p> <p>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.</p> <p>DO NOT apply later than Z59.</p>
Canola	Black leg (<i>Leptosphaeria maculans</i>)	750 ml/ha	<p>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.</p> <p>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.</p>
	Sclerotinia (<i>Sclerotinia sclerotiorum</i>)	750 ml – 1 L/ha (up to 50+ 100 g ai/ha)	<p>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.</p> <p>Use the higher rate (up to 1 L/ha) in higher yielding crops where conditions favour disease development.</p> <p>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.</p> <p>A second application may be required if seasonal conditions are conducive for continued disease development or when the risk of disease is high.</p> <p>DO NOT apply after 50% (full bloom) flowering growth stage.</p> <p>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.</p>

Withholding periods

Harvest

Not required when used as directed.

Grazing

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

Restraints

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 (ear emergence complete) which is equivalent to BBCH59 (End of heading: inflorescence fully emerged)⁷.

Australian trials for fluxapyroxad and mefentrifluconazole on wheat (4 trials), barley (2 trials) and oats (2 trials) addressed the proposed application timing and involved 1x and 2x 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 2x higher than is proposed for fluxapyroxad and mefentrifluconazole. Additional Australian and European trials for fluxapyroxad on wheat and barley at 2x rate treatments were considered previously for Imbrex Fungicide⁸.

Fluxapyroxad

In Australian trials, residues of fluxapyroxad in wheat grain at 49 – 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 (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 (1.7x proposed) with the last application at Z59-61 were <0.01 (2)

⁷ BBCH is a growth stage scale based on standardised definitions of plant development stages.

⁸ Australian Pesticides and Veterinary Medicines Authority (APVMA), 2012. [Public Release Summary on the evaluation of the new active fluxapyroxad in the product MBREX Fungicide](#), APVMA website, accessed December 2023

and 0.01 (2) mg/kg. Scaled for application rate residues were <0.01 (4) mg/kg. From European 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 European trials is <0.01 (10), 0.01, 0.01, 0.01, 0.02, 0.02 and 0.03 mg/kg. The Organisation for Economic Cooperation and Development (OECD) MRL calculator recommends an MRL of 0.04 mg/kg (Supervised Trial Median Residue (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)'.

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 – 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 European 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 European 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 European 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 European 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. A permanent MRL of 0.2 mg/kg is also recommended for fluxapyroxad on GC 0647 Oats, replacing the current temporary MRL at the same level, 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 – 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 European 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 European 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). A permanent MRL of 0.03 mg/kg is recommended for mefentrifluconazole on GC 0654 Wheat, replacing the current temporary MRL at the same level, 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 – 59 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, 0.02, 0.03 and 0.06 mg/kg. From European barley trials involving a last application at BBCH 69 at 150 g ai/ha (2x 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 European 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). Permanent MRLs of 0.2 mg/kg are recommended for mefentrifluconazole on GC 0640 Barley and GC 0647 Oats, replacing the current temporary MRLs at the same level, 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 – 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 – 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 permanent mefentrifluconazole MRL of 20 mg/kg be established for Forage and fodder of cereal grains, replacing the current temporary MRL at the same level.

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 (1× 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 2× 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 1× 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 (equivalent to 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 of these trials failed to produce grain and straw samples.

Fluxapyroxad

Residues of fluxapyroxad in canola seed at harvest 36 – 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 – 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). A permanent MRL of 0.2 mg/kg is recommended for fluxapyroxad on SO 0495 Rape seed [canola], replacing the current temporary MRL at the same level. 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 – 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). A permanent MRL of 0.05 mg/kg is recommended for mefentrifluconazole on SO 0495 Rape seed [canola], replacing the current temporary MRL at the same level, 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 – 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 – 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 Forage and fodder of cereal grains}.

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 – 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, a permanent MRL of 2 mg/kg is recommended for mefentrifluconazole on Rape seed [canola] forage and fodder, replacing the current temporary MRL at the same level.

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 Forage and fodder of cereal grains}. 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.

Currently there are apple pomace and grape pomace MRLs for mefentrifluconazole each at 5 mg/kg. Almond hulls and tomato pomace MRLs have also recently been established at 7 and 15 mg/kg respectively, STMRs are 2.0 and 1.6 mg/kg (dry weight) respectively. 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 High Residue (HR) of 9.00 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 9.00 ppm.

A dairy cattle transfer study for mefentrifluconazole has been previously considered⁹. Estimated residues in tissues and milk from a dietary burden of 9.0 ppm are summarised in table 2 below:

Table 2: Estimated residues in mammalian tissues and milk and required MRLs

Feeding level (ppm)	Mefentrifluconazole residue (mg/kg)				
	Milk	Muscle	Liver	Kidney	Fat
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)	T0.2 (meat in the fat)		T0.3 (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 temporary MRLs for Edible offal (mammalian), Meat (mammalian) [in the fat] at T0.3 and T0.2 mg/kg be made permanent, and the Milks MRL be increased to 0.03 mg/kg. 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 ESI

The 2022 JMPR has proposed animal commodity MRLs for mefentrifluconazole, which were expected to be adopted by Codex in November 2023. However, no animal commodity MRLs are established in Korea or Taiwan, so the endpoint for an 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 Export Slaughter Interval. 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 Export Slaughter Interval 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).

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.

⁹ Australian Pesticides and Veterinary Medicines Authority (APVMA), 2019. [Public Release Summary on the evaluation of the new active mefentrifluconazole in the product Belanty Fungicide](#), APVMA website, accessed December 2023

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: Estimated maximum livestock dietary burden for poultry

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
Cereals	Cereal grains	80	0.32	0.044 (STMR)	88	0.0128	0.04	0.00128
Total							0.36	

STMR-P grape pomace ($0.25 \times 6.3 = 1.58$)

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: Estimated residues in poultry tissues and eggs and required MRLs

Feeding level (ppm)	Eggs	Muscle	Liver	Fat	Skin with fat
1.74 (observed)	<0.01	<0.01	0.017	<0.01	<0.01
0.18 (observed)	–	<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. 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 is being considered by Codex as relevant MRLs have been proposed by the 2022 JMPR. The following relevant Codex CXLs and/or international MRLs have been established for fluxapyroxad and mefentrifluconazole, as shown in table 5 below.

Table 5: Overseas MRLs/tolerances for fluxapyroxad

Commodity	Tolerance for residues arising from the use of fluxapyroxad (mg/kg)						
	Australia	EU ¹⁰	Codex ¹¹	Japan ¹²	Korea ¹³	Taiwan ¹⁴	USA ¹⁵
Residue definition	Fluxapyroxad (plant commodities)	Fluxapyroxad	Fluxapyroxad (for compliance with MRLs)	Fluxapyroxad	–	–	Fluxapyroxad
Oats	T0.2 (current)0.2 (proposed)	3	2	3 (other cereal grains)	–	2	3 [Grain, cereal, group 15, (except corn, field, grain;

¹⁰ European Commission (EC), 2016. [EU Pesticide residue\(s\) and maximum residue levels \(mg/kg\)](#). EC website, accessed December 2023.

¹¹ Food and Agriculture Organisation of the United Nations (FAO), 2023. [Codex Alimentarius, International Food Standards](#). FAO website, accessed December 2023.

¹² Japanese Food Chemistry Research Foundation (JFCRPF), 2023. [Table of MRLs for Agricultural Chemicals](#). JFCRPF website, accessed December 2023.

¹³ Ministry of Food and Drug Safety Korea, 2023. [MRLs in Pesticides](#), accessed December 2023.

¹⁴ Laws & Regulations Database of the Republic of China (Taiwan), 2023. [Standards for Pesticide Residue Limits in Foods](#), accessed December 2023.

¹⁵ Electronic Code of Federal Regulations (eCFR), 2023. [USA Electronic Code of Federal Regulations](#). eCFR website, accessed December 2023.

Commodity	Tolerance for residues arising from the use of fluxapyroxad (mg/kg)						
	Australia	EU ¹⁰	Codex ¹¹	Japan ¹²	Korea ¹³	Taiwan ¹⁴	USA ¹⁵
							except corn, pop, grain; except corn, kernels plus cobs with husks removed; except rice; except wheat]
Rape seed [canola]	T0.2 (current) 0.2 (proposed)	0.9	0.8 (oilseed)	0.9	0.8	0.8	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	Codex	EU	Japan	Korea	USA
Residue definition	Mefentrifluconazole	(proposed mefentrifluconazole for compliance with MRLs, 2022 JMPR) ¹⁶	Mefentrifluconazole	Mefentrifluconazole	–	Mefentrifluconazole
Edible offal (mammalian)	T0.3 (current) 0.3 (proposed)	(proposed 2, 2022 JMPR)	0.4 (bovine liver) 0.15 (bovine kidney)	0.3 (cattle liver, kidney)		1.5 (cattle meat byproducts)

¹⁶ Food and Agricultural Organization of the United Nations (FAO) and the World Health Organisation (WHO), 2022. [Joint Meeting on Pesticide Residues – Pesticide Residues in Food 2022 – Mefentrifluconazole](#), WHO website, accessed December 2023.

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Commodity	Tolerance for residues arising from the use of mefentrifluconazole (mg/kg)					
	Australia	Codex	EU	Japan	Korea	USA
Meat (mammalian) [in the fat]	T0.2 (current)	(proposed 0.15 for meat, 1.5 for fats, 2022 JMPR)	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)	(proposed 0.1, 2022 JMPR)	0.03 (cattle milk)		0.03	0.15 (milk)
	0.03 (proposed)					4 (milk fat)
	0.4 (fats, proposed)					
Barley	T0.2 (current)	(proposed 3, 2022 JMPR)	0.6	4	3	4 (Grain, cereal, group 15, except wheat and corn)
	0.2 (proposed)					
Oats	T0.2 (current)	(proposed 3, 2022 JMPR)	0.6	4 (other cereal grains)		4 (Grain, cereal, group 15, except wheat and corn)
	0.2 (proposed)					
Wheat	T0.03 (current)	(proposed 0.4, 2022 JMPR)	0.05	0.3	0.3	0.3
	0.03 (proposed)					
Rape seed [canola]	T0.05 (current)	(proposed 1, small seed oilseeds, 2022 JMPR)	0.06	1		1
	0.05 (proposed)					
Oaten hay	T20 (forage and fodder of cereal grains – current)	(proposed 50, Straw and hay of cereal grains, dry weight, 2022 JMPR)	–	–		15 (Grain, cereal, forage, fodder, and straw, group 16, hay)
	20 (forage and fodder of cereal grains – proposed)					

MRLs for mefentrifluconazole have not been established for animal commodities, cereals or canola in Taiwan. The applicant indicated that import tolerances for mefentrifluconazole for barley and oats (each at 4 mg/kg), wheat (0.3 mg/kg), canola (1 mg/kg) and cereal forage/fodder (30–40 mg/kg) are expected to be established in Taiwan in Q4 2024.

Current and proposed Australian MRLs for fluxapyroxad and mefentrifluconazole

Table 7: Current MRL Standard – Table 1

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
GC 0647	Oats	T0.2
PM 0110	Poultry meat [in the fat]	*0.01
PO 0111	Poultry, edible offal of	*0.01
SO 0495	Rape seed [canola]	T0.2
GC 0654	Wheat	0.1
CM 0654	Wheat bran, unprocessed	0.2
Mefentrifluconazole		
GC 0640	Barley	T0.2
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
GC 0647	Oats	T0.2
PM 0110	Poultry meat [in the fat]	*0.01
PO 0111	Poultry, edible offal of	0.02

Compound	Food	MRL (mg/kg)
SO 0495	Rape seed [canola]	T0.05
GC 0654	Wheat	T0.03

Table 8: Current MRL Standard – Table 4

Compound	Animal feed commodity	MRL (mg/kg)
Fluxapyroxad		
	Almond hulls	30
AB 0226	Apple pomace, dry	5
	Forage and fodder of cereal grains	20
	Primary feed commodities {except Forage and fodder of cereal grains}	1
Mefentrifluconazole		
	Almond hulls	7
AB 0226	Apple pomace, dry	5
	Forage and fodder of cereal grainsT20	
AB 0269	Grape pomace, dry	5
	Rape seed [canola] forage and fodder	T2
	Tomato pomace, dry	15

Table 9: Proposed MRL Standard – Table 1

Compound	Food	MRL (mg/kg)
Fluxapyroxad		
Delete:		
GC 0647	Oats	T0.2
SO 0495	Rape seed [canola]	T0.2
Add:		
GC 0647	Oats	0.2
SO 0495	Rape seed [canola]	0.2
Mefentrifluconazole		

Compound	Food	MRL (mg/kg)
Delete:		
GC 0640	Barley	T0.2
MO 0105	Edible offal (mammalian)	T0.3
MM 0095	Meat (mammalian) [in the fat]	T0.2
ML 0106	Milks	*0.01
GC 0647	Oats	T0.2
SO 0495	Rape seed [canola]	T0.05
GC 0654	Wheat	T0.03
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 – Table 4

Compound	Animal feed commodity	MRL (mg/kg)
Mefenitruconazole		
Delete:		
	Forage and fodder of cereal grains	T20
	Rape seed [canola] forage and fodder	T2
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 by Codex, the EU, Japan, and the USA, however no mefentrifluconazole milk MRL is established by 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 in the EU. Higher MRLs for these commodities have also been proposed by the 2022 JMPR and were expected to be adopted by Codex in November 2023.

In 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 feeds¹⁷. However, relevant Codex MRLs have or will be established for both fluxapyroxad and mefentrifluconazole as indicated in Tables 5 and 6.

¹⁷ Ministry of Agriculture and Forestry Japan. [Ministerial Ordinance on the Specifications and Standards of Feeds and Feed Additives](#), Food and Agricultural Materials Inspection Center (FAMIC) website, accessed December 2023

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.