Australian Government

Australian Pesticides and Veterinary Medicines Authority

Trade Advice Notice

on mefentrifluconazole and pyraclostrobin in the product Balaya Fungicide for use on barley, oats, wheat and pulses

APVMA product number 94799

September 2025

ISSN 2200-3894 (electronic)

Ownership of intellectual property rights in this publication

Creative Commons licence

Photographic credits

Use of the Coat of Arms

Disclaimer

Comments and enquiries regarding copyright:

Assistant Director, Communications
Australian Pesticides and Veterinary Medicines Authority
GPO Box 574
Canberra ACT 2601 Australia

Telephone: +61 2 6770 2300
Email: communications@apvma.gov.au.

This publication is available from the APVMA website.

Contents

List of tables

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 to register Balaya 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 10 October 2025 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, Agricultural Chemicals
Australian Pesticides and Veterinary Medicines Authority
GPO Box 574
Canberra ACT 2601 Australia

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 Balaya Fungicide, containing 100 g/L mefentrifluconazole and 100 g/L pyraclostrobin Emulsifiable Concentrate, for use on barley, oats, wheat and pulses.

Mefentrifluconazole

The registered use of mefentrifluconazole on wheat, barley, oats and oaten hay (Revystar Fungicide, Emulsifiable Concentrate, P93947) involves a maximum of 2 applications per crop, applied when conditions favour disease development and no later than Z59, at a rate of 75 g ai/ha per crop in conjunction with a harvest withholding period (WHP) of 'Not required when used as directed' and a grazing WHP of 4 weeks.

The current mefentrifluconazole Maximum Residue Limits (MRLs) for GC 0640 Barley and GC 0647 Oats (0.2 mg/kg each) and GC 0654 Wheat at 0.03 mg/kg were established in 2024 based on 8 Australian trials on wheat (4), barley (2) and oats (2) and 16 European trials on wheat (8) and barley (8).

No mefentrifluconazole MRL for any pulse crop is currently established in the MRL Standard for Residues of Chemical Products.

Mefentrifluconazole MRLs for barley, oats and wheat higher than the current mefentrifluconazole MRLs for these commodities and the establishment of a finite mefentrifluconazole MRL of 1.5 mg/kg for VD 0070 Pulses are proposed which therefore requires further consideration with respect to trade.

Pyraclostrobin

The registered use of pyraclostrobin on wheat, barley, oats and oaten hay (4Farmers Pyraclostrobin 250 EC Fungicide, P90309) involves application when conditions favour disease development and a repeat application when necessary but no later than Z59, at a rate of 62.5 g ai/ha for oats and oaten hay and up to 85 g ai/ha for wheat and barley, in conjunction with a harvest WHP of 'Not required when used as directed' and a grazing WHP of 3 weeks.

The current pyraclostrobin MRL for GC 0080 Cereal grains at *0.01 mg/kg was established in 2009 based on 83 Australian trials on wheat (28), barley (27) and oats (28).

A registered use of pyraclostrobin on pulses has not been previously considered by the APVMA. The current proposal is for the first registration of pyraclostrobin in pulses.

The previously permitted use of pyraclostrobin on chickpeas and lentils under permit PER82995 (28/07/2016 - 30/11/2016) involved a maximum application rate of 162.5 g ai/ha in conjunction with a harvest WHP of 30 days and a grazing WHP of 5 weeks. The previously permitted use of pyraclostrobin on mung bean under permit PER13604 (04/12/2012 - 30/06/2015) involved 2 sprays each at a rate of 100 g ai/ha with 21 day harvest and grazing WHPs.

Pyraclostrobin MRLs for barley, oats and wheat higher than the current pyraclostrobin MRL for GC 0080 Cereal grains and the establishment of a finite pyraclostrobin MRL of 1 mg/kg for VD 0070 Pulses are proposed which therefore requires further consideration with respect to trade.

Trade considerations

Commodities exported

Wheat, barley, oats (including hay) and pulses 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 grains/seeds, forages and fodders. Residues in these commodities resulting from the use of Balaya Fungicide may have the potential to unduly prejudice trade.

Destination and value of exports

Cereal grains

Total exports of barley were estimated at 8323 kt in the 2023 fiscal year, valued at $3.32 billion. Major export destinations for Australian barley were China, Japan, Thailand, Vietnam, Korea, Philippines, Taiwan and United Arab Emirates (ABARES).

Total exports of wheat were 22454 kt in the 2023 fiscal year, valued at $9.87 billion. Major export destinations for Australian wheat were China, Indonesia, Philippines, Vietnam, Yemen, Korea, Japan, Malaysia, New Zealand, Thailand, Kuwait, United Arab Emirates, Papua New Guinea, Myanmar, South Africa, Taiwan, Fiji, Oman, Iraq, India and Singapore (ABARES).

Total exports of oats were 368 kt in the 2023 fiscal year, valued at $198 million (ABARES). Major export destinations for Australian oats were China, Mexico, India, Japan, Malaysia, Sri Lanka, United Arab Emirate and Philippines (DAFF). Key export markets for Australian fodder crops (including oaten hay) include Japan, Korea, China and Taiwan[1].

Pulses

Total exports of pulses were estimated at 3699 kt in the 2023 fiscal year, valued at $2.97 billion. Total exports of specific pulse crops were estimated at 635 kt valued at $341 million (lupins), 115 kt valued at $71 million (field peas) and 607 kt valued at $517 million (chickpeas) (ABARES).

The main export markets for Australian pulses include Asia, North Africa, Middle East and the Indian sub-continent[2]. For the year 2023, major export destinations (in terms of volume) for Australian pulses are shown below[3].

[1] AgriFutures Australia, *AgriFutures Australia - Export Fodder*, AgriFutures Australia website, accessed July 2025.

[2] Pulse Australia, *Pulses: Understanding Global Markets*, Pulse Australia website, accessed July 2025.

[3] Department of Agriculture, Fisheries and Forestry (DAFF), *Australian agriculture trade - reference tables*, DAFF website, accessed July 2025.

Dried shelled lentils - India, South Africa, Mauritius, New Zealand, China, South Korea, Bangladesh, Yemen, Lebanon, Sri Lanka, United Arab Emirates, Türkiye and Thailand

Dried shelled chickpeas – Syria, Singapore, South Korea, Yemen, Egypt, Pakistan, Bangladesh, United Arab Emirates and Nepal

Dried shelled beans – Kenya, New Zealand, Cambodia and Japan

Proposed Australian use pattern

Table 1: Proposed use pattern – Balaya Fungicide (100 g/L mefentrifluconazole + 100 g/L pyraclostrobin, Emulsifiable Concentrate)

Crop	Disease	Rate	Critical comments
Wheat	Septoria tritici blotch (*Zymoseptoria tritici*) Septoria nodorum blotch (*Parastagonospora nodorum*) Powdery mildew (*Blumeria graminis f.sp.tritici*) Stripe rust (*Puccinia striiformis*) Leaf rust (*Puccinia triticina*)	500 to 750 mL/ha (50-75 g ai/ha mefentrifluconazole + 50-75 g ai/ha pyraclostrobin)	Monitor crops from mid tillering and on susceptible varieties. Apply at the first sign of infection. Aim to protect the three top leaves or upper canopy of the plant from disease. Use a higher rate (up to 750 mL/ha) on susceptible cultivars or where conditions favour severe disease development. Continue to monitor crops after application, further fungicide applications may be required if initial application is made before the flag leaf has emerged. A maximum of two applications of Balaya Fungicide may be made per crop. DO NOT apply after Z75 (Medium milk).
	Yellow leaf spot (*Pyrenophora tritici-repentis*)	750 mL/ha (75 g ai/ha mefentrifluconazole + 75 g ai/ha pyraclostrobin)	Monitor crops from mid tillering and on susceptible varieties. Apply at the first sign of infection. Aim to protect the three top leaves of the plant from disease. Continue to monitor crops after application, further fungicide applications may be required if initial application is made before the flag leaf has emerged. A maximum of two applications of Balaya Fungicide may be made per crop. DO NOT apply after Z75 (Medium milk).

Crop	Disease	Rate	Critical comments
	Eyespot (*Oculimacula yallundae*)	750 mL/ha (75 g ai/ha mefentrifluconazole + 75 g ai/ha pyraclostrobin)	Monitor crops from mid tillering and spray by Z31 (first node detectable) before canopy density prevents good spray coverage of the lower canopy. In dense crops an earlier application may be required. Aim to protect the base of the crop from disease. A maximum of two applications of Balaya Fungicide may be made per crop. DO NOT apply after Z75 (Medium milk).
Barley	Net form of net blotch (*Pyrenophora teres* f. sp. *teres*) Spot form of net blotch (*Pyrenophora teres* f. sp. *maculata*) Powdery mildew (*Blumeria graminis* f. sp. *hordei*) Leaf scald (*Rhynchosporium commune*) Leaf rust (*Puccinia hordei*)	500 to 750 mL/ha (50-75 g ai/ha mefentrifluconazole + 50-75 g ai/ha pyraclostrobin)	Monitor crops from mid-tillering and on susceptible varieties. Apply at the first sign of infection. Aim to protect the three top leaves or upper canopy of the plant from disease. Use a higher rate (up to 750 mL/ha) on susceptible cultivars or where conditions favour severe disease development. Continue to monitor crops after application, further fungicide applications may be required if initial application is made before the flag leaf has emerged. A maximum of two applications of Balaya Fungicide may be made per crop. DO NOT apply after Z75 (Medium milk).
	Ramularia leaf spot (*Ramularia collo-cygni*)	500 to 750 mL/ha (50-75 g ai/ha mefentrifluconazole + 50-75 g ai/ha pyraclostrobin)	Monitor crops from mid-tillering. Apply as a preventative spray on susceptible crops when conditions favour disease. Use a higher rate (up to 750 mL/ha) on susceptible cultivars or where conditions favour severe disease development. Continue to monitor crops after application, further fungicide applications may be required if initial application is made before the flag leaf has emerged. A maximum of two applications of Balaya Fungicide may be made per crop. DO NOT apply later than Z75 (Medium milk).
Oats and Oaten Hay	Red leather leaf (*Spermospora avenae*) Septoria avenae blotch (*Parastagonospora avenae*) Leaf rust (*Puccinia coronata f.sp avenae*)	500 to 750 mL/ha (50-75 g ai/ha mefentrifluconazole + 50-75 g ai/ha pyraclostrobin)	Monitor crops from mid-tillering. Apply as a preventative spray on susceptible crops when conditions favour disease. Use a higher rate (up to 750 mL/ha) on susceptible cultivars or where conditions favour severe disease development.

Crop	Disease	Rate	Critical comments
	Stem rust (*Puccinia graminis* f.sp *avenae*)	750 mL/ha (75 g ai/ha mefentrifluconazole + 75 g ai/ha pyraclostrobin)	Continue to monitor crops after application, further fungicide applications may be required if initial application is made before the flag leaf has emerged. A maximum of two applications of Balaya Fungicide may be made per crop. DO NOT apply later than Z75 (Medium milk).
Pulses crops	Ascochyta blight (*Ascochyta* spp.)	500 mL/ha to 1 L/ha (50-100 g ai/ha mefentrifluconazole + 50-100 g ai/ha pyraclostrobin)	Balaya fungicide is most effective when applied before an infection event (e.g. prior to rain) and dependant on the disease prior to canopy closure.
	Botrytis grey mould and Chocolate spot (*Botrytis* spp.) Sclerotinia (*Sclerotinia sclerotiorum*)	750 mL/ha to 1 L/ha (75-100 g ai/ha mefentrifluconazole + 75-100 g ai/ha pyraclostrobin)	For best results apply at first sign of disease prior to significant disease expression. Use a higher rate (up to 1 L/ha) on susceptible cultivars or where conditions favour severe disease development.
Faba Beans and Broad Beans	Cercospora leaf spot (*Cercospora zonata*)	500 mL/ha to 1 L/ha (50-100 g ai/ha mefentrifluconazole + 50-100 g ai/ha pyraclostrobin)	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.
	Rust (*Uromyces viciae-fabae*)	750 mL/ha to 1 L/ha (75-100 g ai/ha mefentrifluconazole + 75-100 g ai/ha pyraclostrobin)	Further fungicide application may be required if seasonal conditions are conducive for continued disease development or when the risk of disease is high. A maximum of two applications of Balaya Fungicide may be made per crop. Apply up to the end of pod development (BBCH 79) provided that leaves are green and plants are actively growing. DO NOT apply after the end of pod development (BBCH 79), or earlier if plants are senescing. DO NOT apply less than 14 days before harvest.

Withholding periods

Harvest: Not required when used as directed

Grazing:

Wheat, barley and oats: Do not graze or cut for stock food for 4 weeks after application.

Pulses: Do not graze or cut for stock food for 7 days after application.

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) 15 days

Livestock that has grazed on or been fed treated crops should be placed on clean feed for 15 days prior to slaughter.

Results from residues trials presented to the APVMA

Cereal grains

The critical use pattern for barley, oats and wheat is for up to 2 foliar applications each, applied no later than Z75 (medium milk), at 75 g mefentrifluconazole/ha + 75 g pyraclostrobin/ha in conjunction with a harvest withholding period (WHP) of 'Not required when used as directed' and a grazing WHP of 4 weeks.

A total of 8 Australian and 70 overseas residue trials (13 Argentina, 12 Brazil, 8 Europe, 9 New Zealand and 28 USA) for mefentrifluconazole and pyraclostrobin on barley (25 trials), oats (6 trials) and wheat (47 trials) were considered relevant to the proposed use of mefentrifluconazole and pyraclostrobin on barley, oats and wheat.

Barley grains

Mefentrifluconazole

In 2 Australian trials, mefentrifluconazole residues in barley grain at 35-52 days after last application (DALA), following 2 foliar applications of mefentrifluconazole + pyraclostrobin at BBCH 69-77 at 90.8-97.1 g ai/ha mefentrifluconazole (~1.2-1.3 × the proposed rate), were in ranked order: 0.032 and 0.106 mg/kg (n=2).

In 8 Argentinean trials, mefentrifluconazole residues (scaled to the proposed rate) in barley grains at 30 days after application (DAA) (or later if higher residues are observed), following one foliar application of mefentrifluconazole + pyraclostrobin at BBCH 71-85 at 133.3-200 g ai/ha mefentrifluconazole (~1.8-2.7 x the proposed rate) plus adjuvant, were in ranked order: < 0.01 (< LOQ), 0.014, 0.046, 0.05, 0.08, 0.14 (2), and 0.17 mg/kg (n=8).

In 3 trials on barley conducted in New Zealand, mefentrifluconazole residues (scaled to the proposed rate) in barley grains at 35 DALA (or later if higher residues are observed), following 2 foliar applications of mefentrifluconazole + fluxapyroxad at BBCH 69-83 at 122-129 g ai/ha mefentrifluconazole (~1.6-1.7 x the proposed rate), were in ranked order: 0.60, 0.81 and 0.88 mg/kg (n=3).

In 8 European trials, mefentrifluconazole residues in barley grains (scaled to the proposed rate) at 34-46 DALA following 2 foliar applications of mefentrifluconazole (either alone or in combination with pyraclostrobin) at BBCH 49-69 at 138-155 g ai/ha mefentrifluconazole (~1.8-2.1 × the proposed rate), were in ranked order: 0.026, 0.031, 0.032, 0.06 (3), 0.07, 0.08 and 0.13 mg/kg (n=8).

The Australian and overseas trials were combined for MRL estimation. The combined dataset suitable for the estimation of an MRL, is, in ranked order: < 0.01 (< LOQ), 0.014, 0.026, 0.031, 0.032, 0.046, 0.05, 0.06 (3), 0.07, 0.08, 0.08, 0.106, 0.13, 0.14 (2), 0.17, 0.60, 0.81 and 0.88 mg/kg (n=21). The OECD MRL calculator estimates an MRL of 1.5 mg/kg. The STMR is 0.07 mg/kg.

Based on the available data, a mefentrifluconazole MRL of 1.5 mg/kg for GC 0640 Barley is considered appropriate for the proposed use in conjunction with a harvest WHP of 'Not required when used as directed'. The current mefentrifluconazole MRL of 0.2 mg/kg for GC 0640 Barley should be changed to 1.5 mg/kg.

Pyraclostrobin

In 2 Australian trials, pyraclostrobin residues (scaled to the proposed rate as necessary) in barley grain at 35-52 DALA, following 2 foliar applications of mefentrifluconazole + pyraclostrobin at BBCH 69-77 at 90.8-97.1 g ai/ha pyraclostrobin (~1.2-1.3 × the proposed rate), were in ranked order: 0.031 and 0.039 mg/kg (n=2).

In 8 Argentinean trials, pyraclostrobin residues (scaled to the proposed rate) in barley grains at 30 DAA (or later if higher residues are observed), following one foliar application of mefentrifluconazole + pyraclostrobin at BBCH 71-85 at 150-200 g ai/ha pyraclostrobin (~2-2.7 × the proposed rate), were in ranked order: < 0.01 (< LOQ, n=2), 0.05 (2), 0.06 (3) and 0.10 mg/kg (n=8).

In 4 Brazilian trials, pyraclostrobin residues (scaled to the proposed rate) in barley grains at 30 DAA, following one foliar application of pyraclostrobin at BBCH 73-86, at 200 g ai/ha (~2.7 × the proposed rate), were in ranked order: 0.02 and 0.03 (3) mg/kg (n=4).

In 8 European trials, pyraclostrobin residues (scaled to the proposed rate) in barley grains at 34-46 DALA, following 2 foliar applications of mefentrifluconazole + pyraclostrobin at BBCH 49-69 at 138-159 g ai/ha pyraclostrobin (~1.8-2.1 × the proposed rate), were in ranked order: 0.021, 0.026, 0.032, 0.034, 0.037, 0.05 and 0.06 (2) mg/kg (n=8).

The Australian and overseas trials were combined for MRL estimation. The combined dataset suitable for the estimation of an MRL, is, in ranked order: < 0.01 (< LOQ, n=2), 0.02, 0.021, 0.026, 0.03 (3), 0.031, 0.032, 0.034, 0.037, 0.039, 0.05 (3), 0.06 (5) and 0.10 mg/kg (n=22). The OECD MRL calculator estimates an MRL of 0.15 mg/kg. The STMR is 0.036 mg/kg.

Based on the available data, a pyraclostrobin MRL of 0.2 mg/kg for GC 0640 Barley is considered appropriate for the proposed use in conjunction with a harvest WHP of 'Not required when used as directed'.

As discussed below, the establishment of finite pyraclostrobin MRLs for wheat and oats are also recommended. Noting that the current pyraclostrobin MRL of *0.01 mg/kg for GC 0080 Cereal grains was established based on wheat, barley and oats data and that the updated APVMA Crop Groups also require sorghum grain, maize and sweet corn data (on top of wheat, barley and oats) for the establishment of a

group MRL for GC 0080 Cereals, the current pyraclostrobin MRL of *0.01 mg/kg for GC 0080 should be deleted, noting also that there are currently no approved use of pyraclostrobin in cereal grains other than wheat, barley and oats.

Oats grains

Mefentrifluconazole

In 2 Australian trials, mefentrifluconazole residues (scaled to the proposed rate) in oats grains at 38-50 DALA, following 2 foliar applications of mefentrifluconazole + pyraclostrobin/fluxapyroxad at BBCH 69-75 at 98.2-106.5 g ai/ha mefentrifluconazole (~1.3-1.4 × the proposed rate) were in ranked order: 0.023 and 0.354 mg/kg (n=2).

The 2 Australian trials in oats were combined with the 21 mefentrifluconazole trials in barley discussed above to estimate an MRL. The combined dataset suitable for MRL estimation, is, in ranked order: < 0.01 (< LOQ), 0.014, 0.023, 0.026, 0.028, 0.031, 0.046, 0.05, 0.06 (3), 0.07, 0.08 (2), 0.106, 0.13, 0.14 (2), 0.17, 0.354, 0.60, 0.81 and 0.88 mg/kg (n=23). The OECD MRL calculator estimates an MRL of 1.5 mg/kg. The STMR is 0.07 mg/kg.

Based on the available data, a mefentrifluconazole MRL of 1.5 mg/kg for GC 0647 Oats is considered appropriate for the proposed use in conjunction with a harvest WHP of 'Not required when used as directed'. The current mefentrifluconazole MRL of 0.2 mg/kg for GC 0647 Oats should be changed to 1.5 mg/kg.

Pyraclostrobin

In 2 Australian trials, pyraclostrobin residues (scaled to the proposed rate) in oats grains at 38-50 DALA, following 2 foliar applications of mefentrifluconazole + pyraclostrobin at BBCH 69-75 at 98.8-107.6 g ai/ha pyraclostrobin (~1.3-1.4× the proposed rate), were in ranked order: 0.011 and 0.089 mg/kg (n=2).

In 4 Brazilian trials, pyraclostrobin residues (scaled to the proposed rate) in oats grains at 30 DAA, following one foliar application of pyraclostrobin at BBCH 72-82, at 200 g ai/ha pyraclostrobin (~2.7 × the proposed rate), were in ranked order: < 0.02, 0.02, 0.05 and 0.16 mg/kg (n=4).

The Australian and Brazilian trials in oats were combined with the 22 pyraclostrobin trials on barley discussed above. The combined dataset suitable for the estimation of an MRL, is, in ranked order: < 0.01 (< LOQ, n=2), 0.011, < 0.02, 0.02, 0.02, 0.021, 0.026, 0.03 (3), 0.031, 0.032, 0.034, 0.037, 0.039, 0.05, 0.05 (3), 0.06 (5), 0.089, 0.10 and 0.16 mg/kg (n=28). The OECD MRL calculator estimates an MRL of 0.2 mg/kg. The STMR is 0.036 mg/kg.

Based on the available data, a pyraclostrobin MRL of 0.2 mg/kg for GC 0647 Oats is considered appropriate for the proposed use, conjunction with a harvest WHP of 'Not required when used as directed'. As discussed above, the current pyraclostrobin MRL of *0.01 mg/kg for GC 0080 should be deleted.

Wheat grains

Mefentrifluconazole

In 3 Australian trials considered relevant to the proposed use, mefentrifluconazole residues (scaled to the proposed rate) in wheat grains at 37-44 DALA, following 2 foliar applications of mefentrifluconazole + fluxapyroxad at BBCH 69-75 at 87.4-108.2 g ai/ha mefentrifluconazole (~1.2-1.4 × the proposed rate), were in ranked order: 0.013, 0.016 and 0.286 mg/kg (n=3)

In 6 New Zealand trials, mefentrifluconazole residues (scaled to the proposed rate) in wheat grains at 35 DALA (or later if higher residues are observed), following 2 foliar applications of mefentrifluconazole + fluxapyroxad at BBCH 69-87 at 124-130.8 g ai/ha mefentrifluconazole (~1.7 x the proposed rate), were in ranked order: < 0.01 (< LOQ), 0.011, 0.012, 0.019, 0.14 and 0.23 mg/kg (n=6).

In 5 Argentinean trials considered relevant to the proposed use, mefentrifluconazole residues (scaled to the proposed rate) on wheat grains at 30 DAA (or later if higher residues are observed), following one foliar application of mefentrifluconazole + pyraclostrobin plus adjuvant at BBCH 75-77 at a rate of 216.66-232.2 g ai/ha mefentrifluconazole (~2.9-3.1 × the proposed rate), were in ranked order: < 0.01 (< LOQ, n=4) and 0.012 mg/kg (n=5).

The 3 Australian and 11 overseas trials were combined to estimate an MRL. The combined dataset suitable for MRL estimation, is, in ranked order: < 0.01 (5), 0.011, 0.012 (2), 0.013, 0.016, 0.019, 0.14, 0.23 and 0.286 mg/kg (n=14). The OECD MRL calculator estimates an MRL of 0.5 mg/kg (unrounded MRL = 0.427 mg/kg). The STMR is 0.01 mg/kg.

Based on the available data, a mefentrifluconazole MRL of 0.4 mg/kg on GC 0654 Wheat is considered appropriate for the proposed use, in conjunction with a harvest withholding period of 'Not required when used as directed'. The current mefentrifluconazole MRL of 0.03 mg/kg for GC 0654 Wheat should be changed to 0.4 mg/kg.

Pyraclostrobin

In 4 Australian trials, pyraclostrobin residues (scaled to the proposed rate as necessary) in wheat grains at 37-44 DALA, following 2 foliar applications of mefentrifluconazole + pyraclostrobin at BBCH 69-75 at 93.0-105.7 g ai/ha pyraclostrobin (~1.2-1.4 × the proposed rate), were, in ranked order: < 0.010 (< LOQ), 0.016, 0.018 and 0.100 mg/kg (n=4).

In 28 North American trials, pyraclostrobin residues (scaled to the proposed rate) in wheat grains at 24-60 DALA, following 2 foliar applications of pyraclostrobin at BBCH 59-69 at ~217-232 g ai/ha (~2.9-3.1 × the proposed rate), were in ranked order: < 0.02 (< LOQ, n=25), 0.025, 0.035 and 0.036 mg/kg (n=28).

The Australian and USA trials were combined to estimate an MRL. The combined dataset suitable for the estimation of an MRL, is, in ranked order: < 0.010, < 0.02 (25), 0.016, 0.018, 0.025, 0.035, 0.036 and 0.100 mg/kg (n=32). The OECD MRL calculator estimates an MRL of 0.1 mg/kg, noting the high uncertainty of MRL estimate due to the high level of censoring. The STMR is 0.02 mg/kg.

Based on the available data and noting a HR of 0.100 mg/kg, a conservative pyraclostrobin MRL of 0.2 mg/kg for GC 0654 Wheat is considered appropriate for the proposed use in conjunction with a harvest WHP of 'Not required when used as directed'. As discussed above, the current pyraclostrobin MRL of *0.01 mg/kg for GC 0080 should be deleted.

Cereal forage

Mefentrifluconazole

In 8 Australian trials, mefentrifluconazole residues (scaled to the proposed rate as necessary) in barley (2 trials), oats (2 trials) and wheat (4 trials) forage at 27-29 DALA, following 2 applications of mefentrifluconazole + pyraclostrobin/fluxapyroxad at BBCH 69-77 at 83.0-108.2 g ai/ha mefentrifluconazole (~1.1-1.4 × the proposed rate), were, in ranked order: 0.837, 1.482, 1.562, 3.726, 3.785, 3.847, 4.765 and 5.288 mg/kg on a dry weight (DW) basis (n=8)

In 9 New Zealand trials, mefentrifluconazole residues (scaled to the proposed rate) in barley (3 trials) and wheat (6 trials) forage at 28 DALA (or later if higher residues are observed), following 2 applications of mefentrifluconazole (alone or in combination with fluxapyroxad) at BBCH 69-87 at 122-130.8 g ai/ha mefentrifluconazole (~1.6-1.7 x the proposed rate), were in ranked order: 1.2, 1.4, 1.7, 1.8, 1.9 (2), 2.3, 2.4 and 3.7 mg/kg DW (n=9).

In 8 European trials, mefentrifluconazole residues (scaled to the proposed rate and converted to a DW basis using a dry matter content of 30%) in barley forage at 27-42 DALA (or later if higher residues are observed), following 2 applications of mefentrifluconazole (either alone or in combination with pyraclostrobin) at BBCH 49-69 at 138-155 g ai/ha mefentrifluconazole (~1.8-2.1 × the proposed rate), were in ranked order: 1.17, 1.28, 2.1, 2.7, 2.8, 3.7, 4.8 and 5.2 mg/kg DW (n=8).

The cereals forage data (0.837, 1.17, 1.2, 1.28, 1.4, 1.482, 1.562, 1.7, 1.8, 1.9 (2), 2.1, 2.3, 2.4, 2.7, 2.8, 3.7 (2), 3.726, 3.785, 3.847, 4.765, 4.8, 5.2 and 5.288 mg/kg DW, n=25) is similar to the cereals straw data below and are therefore combined for MRL estimation. The combined cereals forage and straw dataset suitable for the estimation of an MRL, is, in ranked order: 0.837, 0.9 (2), 1.0, 1.035, 1.054, 1.17, 1.2, 1.28, 1.3, 1.4, 1.482, 1.562, 1.7, 1.8, 1.9, 1.9, 1.9, 2.1, 2.289, 2.3, 2.3, 2.4, 2.4, 2.7, 2.8, 3.131, 3.7 (2), 3.726, 3.785, 3.847, 4.067, 4.321, 4.765, 4.8, 4.870, 5.023, 5.1, 5.2 and 5.288 mg/kg DW (n=41). The OECD MRL calculator estimates an MRL of 9 mg/kg. The STMR is 2.3 mg/kg.

Based on the available data, a mefentrifluconazole MRL of 9 mg/kg for Cereals forage and fodder, dry is considered appropriate for the proposed use, in conjunction with the proposed grazing WHP of 4 weeks. The current mefentrifluconazole MRL of 20 mg/kg for Forage and fodder of cereal grains remains appropriate and is expected to cover potential mefentrifluconazole residues arising from the proposed use on barley, oats and wheat.

Pyraclostrobin

In 8 Australian trials, pyraclostrobin residues (scaled to the proposed rate as necessary) in barley (2 trials), oats (2 trials) and wheat (4 trials) forage at 27-29 DALA, following 2 applications at BBCH 69-77 at 90.8-107.6 g ai/ha pyraclostrobin (~1.2-1.4 × the proposed rate), were in ranked order: 0.096, 0.615, 0.633, 0.701, 0.782, 0.827, 0.913 and 0.933 mg/kg DW (n=8)

In 8 European trials, pyraclostrobin residues (scaled to the proposed rate and converted to a DW basis using a dry matter content of 30%) in barley forage at 27-28 DALA (or later if higher residues are observed), following 2 applications at BBCH 49-69 at 138-159 g ai/ha pyraclostrobin (~1.8-2.1 × the proposed rate), were in ranked order: 0.44, 0.67, 0.71, 0.78, 0.97, 1.07, 2.0 and 2.4 mg/kg DW (n=8).

The Australian trials on barley, oats and wheat are combined with the European trials on barley to estimate an MRL. Based on a combined dataset (0.096, 0.44, 0.615, 0.633, 0.67, 0.701, 0.71, 0.78, 0.782, 0.827, 0.913, 0.933, 0.97, 1.07, 2.0 and 2.4 mg/kg DW, n=16), the OECD MRL calculator estimates an MRL of 4 mg/kg. The STMR is 0.781 mg/kg.

Based on the available data, the current pyraclostrobin MRL for Cereal forage, green at 5 mg/kg remains appropriate and will cover the proposed use on barley, oats and wheat.

Cereal straw

Mefentrifluconazole

In 8 Australian trials, mefentrifluconazole residues (scaled to the proposed rate as necessary) in barley (2 trials), oats (2 trials) and wheat (4 trials) straw at 35-52 DALA, following 2 applications of mefentrifluconazole + pyraclostrobin/fluxapyroxad at BBCH 69-77 at 83.0-108.2 g ai/ha mefentrifluconazole (~1.1-1.4 × the proposed rate), were, in ranked order: 1.035, 1.054, 2.289, 3.131, 4.067, 4.321, 4.870 and 5.023 mg/kg DW (n=8).

In 8 European trials, mefentrifluconazole residues (scaled to the proposed rate and converted to a DW basis using a dry matter content of 89%) in barley straw at 34-46 DALA (or later if higher residues are observed), following 2 applications of mefentrifluconazole (either alone or in combination with pyraclostrobin) at BBCH 49-69 at 138-155 g ai/ha mefentrifluconazole (~1.8-2.1 × the proposed rate), were in ranked order: 0.9 (2), 1.0, 1.3, 1.9, 2.3, 2.4 and 5.1 mg/kg DW (n=8).

As discussed above, the combined Australian and European cereals straw data (0.9 (2), 1.0, 1.035, 1.054, 1.3, 1.9, 2.289, 2.3, 2.4, 3.131, 4.067, 4.321, 4.870, 5.023 and 5.1 mg/kg DW) (n=16) is similar to the cereals forage data discussed above and are therefore combined for MRL estimation. Based on the available data, the current mefentrifluconazole MRL of 20 mg/kg for Forage and fodder of cereal grains remains appropriate and is expected to cover potential mefentrifluconazole residues arising from the proposed use on barley, oats and wheat.

Pyraclostrobin

In 8 Australian trials, pyraclostrobin residues (scaled to the proposed rate as necessary) in barley (2 trials), oats (2 trials) and wheat (4 trials) straw at 35-52 DALA, following 2 applications at BBCH 69-77 at 90.8-107.6 g ai/ha pyraclostrobin (~1.2-1.4 × the proposed rate), were in ranked order: 0.605, 0.650, 0.749, 0.761, 0.781, 0.872, 1.406 and 1.924 mg/kg DW (n=8).

In 8 European trials, pyraclostrobin residues (scaled to the proposed rate and converted to a DW basis using a dry matter content of 89%) in barley straw at 34-46 DALA, following 2 applications at BBCH 49-69 at 138-159 g ai/ha pyraclostrobin (~1.8-2.1 × the proposed rate), were in ranked order: 0.6 (3), 0.9 (2), 1.4 (2) and 1.7 mg/kg DW (n=8).

In 28 North American trials, pyraclostrobin residues (scaled to the proposed rate and converted to a DW basis using a dry matter content of 88%) in wheat straw at 24-60 DALA, following 2 applications at BBCH 59-69 at ~217-232 g ai/ha pyraclostrobin (~2.9-3.1 × the proposed rate), were in ranked order: 0.220, 0.222, 0.281, 0.286, 0.352, 0.380, 0.462, 0.509, 0.521, 0.605, 0.611, 0.626, 0.642, 0.662, 0.681, 0.789, 0.845, 0.850, 0.974, 1.167, 1.188, 1.496, 1.501, 1.632, 1.665, 1.724, 2.251 and 2.252 mg/kg DW (n=28).

The Australian trials on wheat, barley and oats are combined with the overseas trials on wheat and barley to estimate an MRL. The combined dataset suitable for MRL estimation, is in ranked order: 0.220, 0.222, 0.281, 0.286, 0.352, 0.380, 0.462, 0.509, 0.521, 0.6 (3), 0.605 (2), 0.611, 0.626, 0.642, 0.650, 0.662, 0.681, 0.749, 0.761, 0.781, 0.789, 0.845, 0.850, 0.872, 0.9 (2), 0.974, 1.167, 1.188, 1.4 (2), 1.406, 1.496, 1.501, 1.632, 1.665, 1.7, 1.724, 1.924, 2.251 and 2.252 mg/kg DW (n=44). The OECD MRL calculator estimates an MRL of 3 mg/kg. The STMR is 0.771 mg/kg.

Based on the available data, a pyraclostrobin MRL of 3 mg/kg for AS 0081 Straw and fodder (dry) of cereal grains is considered appropriate for the proposed use, in conjunction with the proposed grazing WHP of 4 weeks. The current pyraclostrobin MRL for AS 0081 Straw and fodder (dry) of cereal grains at 0.5 mg/kg should be changed to 3 mg/kg.

Pulses

The critical use pattern for pulses is for up to 2 foliar applications per crop, applied at first sign of disease up to no later than BBCH 79 (end of pod development) and at least 14 days before harvest, at rates of up to 100 g mefentrifluconazole/ha + 100 g pyraclostrobin/ha in conjunction with a harvest withholding period (WHP) of 'Not required when used as directed' and a grazing WHP of 7 days.

Ten (10) Australian trials involving the use of an EC formulation containing mefentrifluconazole + pyraclostrobin/fluxapyroxad and 23 European trials involving the use of an SC or WG formulation containing mefentrifluconazole (SC) and pyraclostrobin (WG) on broad beans (7), chickpeas (2), field peas (13) and lupins (4) were considered relevant to the proposed use on pulses.

Pulse grains

Mefentrifluconazole

In 10 Australian trials, mefentrifluconazole residues in pulse grains at 13-14 DALA , following 2 foliar applications of mefentrifluconazole + pyraclostrobin/fluxapyroxad between BBCH 69-89 at a rate of 90.7-113.6 g ai/ha mefentrifluconazole (~0.9-1.1× the proposed rate), were in ranked order:

- chickpeas: < 0.005 (< LOD) and 0.055 mg/kg (n=2)
- field peas: 0.015, 0.028, 0.036 and 0.163 mg/kg (n=4)
- lupins:< 0.010 (< LOQ), 0.160 (2) and 1.098 mg/kg (n=4)

The chickpeas, field peas and lupins data were combined to estimate a group MRL for pulses. The combined dataset suitable for MRL estimation, is in ranked order: < 0.010 (< LOQ, n=2), 0.015, 0.028, 0.036, 0.055, 0.160 (2), 0.163 and 1.098 mg/kg (n=10). The OECD MRL calculator estimates an MRL of 1.5 mg/kg. The STMR is 0.046 mg/kg.

Based on the available data, a mefentrifluconazole MRL of 1.5 mg/kg for VD 0070 Pulses is considered appropriate to support the proposed use of mefentrifluconazole on pulses in conjunction with a harvest withholding period of 'Not required when used as directed'

Pyraclostrobin

In 10 Australian trials, pyraclostrobin residues in pulse grains at 14 DALA, following 2 foliar applications (12-17 days apart) of mefentrifluconazole + pyraclostrobin between BBCH 69-89 at a rate of 95.2-113.4 g ai/ha pyraclostrobin (~1-1.1× the proposed rate) using spray volumes of 91.9-120.0 L/ha, were in ranked order:

- chickpeas: < 0.005 (< LOD) and 0.022 mg/kg (n=2)
- field peas: < 0.010 (< LOQ), 0.014, 0.031, and 0.079 mg/kg (n=4)
- lupins: <0.005 (< LOD), 0.093, 0.185 and 0.667 mg/kg (n=4)

The chickpeas, field peas and lupins data were combined to estimate a group MRL for pulses. The combined dataset suitable for MRL estimation, is in ranked order: < 0.010 (< LOQ, n=3), 0.014, 0.022, 0.031, 0.079, 0.093, 0.185 and 0.677 mg/kg (n=10). The OECD MRL calculator estimates an MRL of 1 mg/kg. The STMR is 0.027 mg/kg.

Based on the available data, a pyraclostrobin MRL of 1 mg/kg for VD 0070 Pulses is considered appropriate to support the proposed use of pyraclostrobin on pulses in conjunction with a harvest withholding period of 'Not required when used as directed'

Pulse straw

Mefentrifluconazole

In 10 Australian trials, mefentrifluconazole residues in pulse straw at 13-14 DALA, following 2 foliar applications of mefentrifluconazole + pyraclostrobin/fluxapyroxad between BBCH 69-89 at a rate of 92.9-113.6 g ai/ha mefentrifluconazole (~0.9-1.1 × the proposed rate), were in ranked order:

- chickpeas: 2.331 and 7.323 mg/kg DW (n=2)
- field peas: 5.714, 12.161, 15.671 and 16.132 mg/kg DW (n=4)
- lupins: 0.022, 1.432, 4.615 and 4.757 mg/kg DW (n=4)

The combined dataset suitable for MRL estimation, is, in ranked order: 0.022, 1.432, 2.331, 4.615, 4.757, 5.714, 7.323, 12.161, 15.671 and 16.132 mg/kg DW (n=10). The OECD MRL calculator estimates an MRL of 30 mg/kg. The STMR is 5.236 mg/kg.

Based on the available data at 14 DALA and the pulse forage dataset below [1.03, 1.43, 2.37, 2.54, 3.04 and 6.4 (2) mg/kg DW (n=7)], a mefentrifluconazole MRL for Pulse forage and fodder at 30 mg/kg is considered appropriate for the proposed use of mefentrifluconazole on pulses, in conjunction with a recommended grazing WHP of 14 days.

Pyraclostrobin

In 10 Australian trials, pyraclostrobin residues in pulse straw at 14 DALA, following 2 foliar applications of mefentrifluconazole + pyraclostrobin between BBCH 69-89 at a rate of 95.2-113.4 g ai/ha pyraclostrobin (~1-1.1× the proposed rate), were in ranked order:

- chickpeas: 1.110 and 3.702 mg/kg DW (n=2)
- field peas: 3.440, 5.025, 7.232 and 8.134 mg/kg DW (n=4)
- lupins: 0.027, 1.739, 4.185 and 4.478 mg/kg DW (n=4)

The combined dataset suitable for MRL estimation, is, in ranked order: 0.027, 1.110, 1.739, 3.440, 3.702, 4.185, 4.478, 5.025, 7.232 and 8.134 mg/kg DW (n=10). The OECD MRL calculator estimates an MRL of 15 mg/kg. The STMR is 3.944 mg/kg.

Based on the available data at 14 DALA and the pulse forage dataset below [1.52, 1.64, 1.72, 1.94, 2.24, 2.40, 2.52 (2), 2.56, 2.76, 3.04, 3.20, 4.0, 4.9 and 8.0 (2) mg/kg DW (n=16)], a pyraclostrobin MRL for Pulse forage and fodder at 15 mg/kg is considered appropriate for the proposed use of pyraclostrobin on pulses, in conjunction with a recommended grazing WHP of 14 days.

Pulse forage

A 7 day grazing WHP was considered in order to extrapolate residues data from SC/WG to the proposed EC formulation, noting that the EC trials in the submitted studies are not considered relevant to the proposed GAP (either the study targeted a 21 day PHI or no field phase was provided).

Mefentrifluconazole

In 7 European trials considered relevant to the proposed use, mefentrifluconazole residues (converted to a dry weight basis based on a 35% dry matter for bean vines and 25% dry matter for pea vines) in pulse forage at 6-7 DALA (BBCH 79, 7-42 days before harvest to reflect a failed crop scenario), following 2 foliar applications of mefentrifluconazole between BBCH 61-71 and 72 at a rate of 95-102 g ai/ha (~1× the proposed rate), were in ranked order:

- broad beans:1.03, 1.43, 2.37 and 2.54 mg/kg DW (n=4)
- peas: 3.04 and 6.4 (2) mg/kg DW (n=3)

The combined dataset suitable for MRL estimation, is in ranked order: 1.03, 1.43, 2.37, 2.54, 3.04 and 6.4 (2) mg/kg DW (n=7). The OECD MRL calculator estimates an MRL of 15 mg/kg. The STMR is 2.54 mg/kg.

Based on the available data at 7 DALA and the pulse straw dataset above [0.022, 1.432, 2.331, 4.615, 4.757, 5.714, 7.323, 12.161, 15.671 and 16.132 mg/kg DW (n=10)] and noting that residues in forage at a shorter PHI would not be expected to be less than those in straw on a dry weight basis, a mefentrifluconazole MRL for Pulse forage and fodder at 30 mg/kg is considered appropriate for the proposed use, in conjunction with a recommended grazing WHP of 7 days.

Pyraclostrobin

In 16 European trials considered relevant to the proposed use, pyraclostrobin residues (converted to a dry weight basis based on a 35% dry matter for bean vines and 25% dry matter for pea vines) in pea forage and broad bean forage at 7 DALA (BBCH 79-85), following 2 foliar applications of pyraclostrobin between BBCH 69-75 and 76-83 at a nominal rate of 100.5-120.6 g ai/ha (~1-1.2× the proposed rate), were in ranked order: 1.52, 1.64, 1.72, 1.94, 2.24, 2.40, 2.52 (2), 2.56, 2.76, 3.04, 3.20, 4.0, 4.9 and 8.0 (2) mg/kg DW (n=16). The OECD MRL calculator estimates an MRL of 15 mg/kg. The STMR is 2.54 mg/kg.

Based on the available data at 7 DALA and the pulse straw dataset above [0.027, 1.110, 1.739, 3.440, 3.702, 4.185, 4.478, 5.025, 7.232 and 8.134 mg/kg DW (n=10)], a pyraclostrobin MRL for Pulse forage and fodder at 15 mg/kg is considered appropriate for the proposed use, in conjunction with a recommended grazing WHP of 7 days.

Animal commodities

Mefentrifluconazole

Cattle

Based on the proposed use on pulses (field peas straw HR = 16.132 mg/kg DW), the existing dietary burden of 9.0 ppm each for dairy cattle and beef cattle will increase to 16.1 ppm each. A dairy cattle transfer study for mefentrifluconazole has been previously considered. Estimated residues in tissues and milk from a dietary burden of 16.1 ppm are summarised below.

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

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)	0.110	0.105	1.40	0.505	0.900
16.1 (estimated burden)	0.036	0.035	0.46	0.166	0.296
Established MRLs	0.03 (milks)	0.2 (meat in the fat)	0.3 (offal)		–
Recommended MRLs	0.05	0.4	0.7		–

To account for the potential transfer of mefentrifluconazole residues to livestock commodities which may occur as a result of the proposed use on pulses, it is recommended that the current mefentrifluconazole MRLs be increased to 0.05 mg/kg for ML 0106 Milks, 0.4 mg/kg for MM 0095 Meat (mammalian) [in the fat] and 0.7 mg/kg for MO 0105 Edible offal (mammalian).

Consideration of an Export Slaughter Interval (ESI)

No animal commodity MRLs for mefentrifluconazole 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 residue decline and is the driver for consideration of an Export Slaughter Interval (ESI). Based on an estimated residue in fat of 0.296 mg/kg and a half-life of 3 days, it would take approximately 15 days on clean feed for residues to decline to below the LOQ (0.01 mg/kg). A 15 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 10 day ESI required for mefentrifluconazole on a product currently registered for use on canola, wheat, barley and oats (Revystar Fungicide, 93947).

Poultry

Based on the proposed use on barley (barley grain STMR = 0.07 mg/kg), the existing dietary burden of 0.36 ppm for poultry (based on a diet consisting of 20% grape pomace and 80% cereal grain) will increase to 0.38 ppm. A laying hen transfer study for mefentrifluconazole has been previously considered. Estimated residues in tissues and eggs from a dietary burden of 0.38 ppm are summarised below.

Table 3: Estimated residues in poultry tissues and eggs and required MRLs

Feeding level (ppm)	Eggs	Muscle	Liver	Fat	Skin with fat
	Mefentrifluconazole residue (mg/kg)				
1.74 (observed)	<0.01	<0.01	0.017	<0.01	<0.01
0.18 (observed)	–	<0.01	<0.01	<0.01	<0.01
0.38, 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 existing animal commodity mefentrifluconazole MRLs at *0.01 mg/kg (eggs), *0.01 mg/kg (meat [in the fat]) and 0.02 mg/kg (offal) remain appropriate for the proposed uses. No changes to the current mefentrifluconazole animal commodity MRLs are required.

Pyraclostrobin

Cattle

Based on the proposed use on pulses (field peas straw HR = 8.134 mg/kg DW), the existing dietary burden of 4.1 ppm each for dairy cattle and beef cattle will increase to 8.1 ppm each. A dairy cattle transfer study for pyraclostrobin has been previously considered. Estimated residues in tissues and milk from a dietary burden of 8.1 ppm are summarised below.

Table 4: Estimated residues in mammalian tissues and milk and required MRLs

Feeding level (ppm)	Milk	Muscle	Liver	Kidney	Fat
	Total pyraclostrobin (based on current residue definition: parent + metabolites hydrolysed to BF 500-5) (mg eq/kg)				
8.8 (observed)	<0.01	<0.05	<0.05	<0.05	0.089*
8.1 (estimated burden)	<0.01	<0.05	<0.05	<0.05	0.059
Established MRLs	*0.01 (milks)	-	0.1 (offal)		*0.05 (meat [in the fat])
Recommended MRLs	No change	No change	No change		0.1

**Pyraclostrobin residues (in accordance with residue definition) in fat in the goat metabolism study is 0.089 and 0.901 mg/kg at 12.2 and 78.1 ppm dose levels, respectively and <0.05 mg/kg in fat in lactating cows at 8.8 ppm and 27.2 ppm dose levels.*

Pyraclostrobin residues are expected to be less than the established animal commodity MRLs in milks and edible offal. However, residues in fat will exceed the pyraclostrobin MRL of *0.05 mg/kg for MM 0095 Meat (mammalian) [in the fat]. it is recommended that the current pyraclostrobin MRL of *0.05 mg/kg for MM 0095 Meat (mammalian) [in the fat] be increased to 0.1 mg/kg.

Consideration of an Export Slaughter Interval (ESI)

No animal commodity MRLs for pyraclostrobin are established in Korea or Taiwan, so the endpoint for an ESI will be taken as the LOQ (0.05 mg/kg). Noting that no finite residues in fat were observed in cattle at any sampling point (including the depuration phase) and that no depuration data is available for lactating goats, the time needed for the estimated residue in fat to be at the LOQ cannot be determined. Given an LOQ of 0.05 mg/kg, it is noted that the estimated residues in liver and kidney are already at or below the LOQ according to the current residue definition.

Noting that an ESI of 15 days is required for mefentrifluconazole, the recommended ESI for the proposed use of Balaya Fungicide will be 15 days, given estimated pyraclostrobin residues in fat were just above the LOQ.

Poultry

Based on the proposed use on barley (barley grain STMR = 0.036 mg/kg), the existing dietary burden of 0.29 ppm for poultry (based on a diet consisting of 20% grape pomace and 80% barley grains) will increase to 0.31 ppm. A laying hen transfer study for pyraclostrobin has been previously considered. Estimated residues in tissues and eggs from a dietary burden of 0.31 ppm are summarised below.

Table 5: Estimated residues in poultry tissues and eggs and required MRLs

Feeding level (ppm)	Eggs	Muscle	Liver	Fat
	Total pyraclostrobin (based on current residue definition: parent + metabolites hydrolysed to BF 500-5) (mg eq/kg)			
3 (observed)	<0.05	<0.05	<0.05	<0.05
0.31, estimated burden	<0.05	<0.05	<0.05	<0.05
Established MRLs	*0.05 (eggs)	*0.05 (meat in the fat)	*0.05 (offal)	
Recommended MRLs	No change	No change	No change	

The existing animal commodity pyraclostrobin MRLs at *0.05 mg/kg (eggs), *0.05 mg/kg (meat [in the fat]) and *0.05 mg/kg (offal) remain appropriate for the proposed uses. No changes to the current pyraclostrobin animal commodity MRLs are required.

Overseas registration and approved label instructions

The Applicant indicated that Balaya Fungicide is registered for use in cereals in the European Union, Russian Federation and Ukraine.

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. Mefentrifluconazole and pyraclostrobin have been considered by Codex. The following relevant Codex CXLs and/or international MRLs have been established for mefentrifluconazole and pyraclostrobin.

Table 6: Overseas MRLs/tolerances for mefentrifluconazole

Commodity	Tolerance for residues arising from the use of mefentrifluconazole (mg/kg)						
	Australia[4]	EU[5]	Japan[6]	Codex[7]	USA[8]	Korea[9]	Taiwan[10]
Residue definition	Mefentrifluconazole	Mefentrifluconazole	Mefentrifluconazole	Mefentrifluconazole	Mefentrifluconazole	Mefentrifluconazole	Mefentrifluconazole
Barley	0.2 (current) 1.5 (proposed)	3	4	3	4 (Grain, cereal, group 15, except wheat and corn)	3.0	2.0
Edible offal (mammalian)	0.3 (current) 0.7 (proposed)	0.15 (kidney), 0.4 (liver), 0.1 (edible offals (other than liver and kidney))	2 (Cattle, liver), 2 (Cattle, kidney), 2 (Cattle, edible offal)	2	1.5 (Cattle, meat byproducts)	-	-

[4] Agricultural and Veterinary Chemicals Code (MRL Standard for Residues of Chemical Products) Instrument 2023, accessed July 2025.

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

[6] The Japan Food Chemical Research Foundation, *Maximum Residue Limits (MRLs) List of Agricultural Chemicals in Foods*, The Japan Food Chemical Research Foundation website, accessed July 2025.

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

[8] Electronic Code of Federal Regulations, *USA Electronic Code of Federal Regulations*, eCFR website, accessed July 2025.

[9] Food Safety Korea, *Import tolerance application status*, Food Safety Korea website, accessed July 2025.

[10] Food and Drug Administration, *Standards for Pesticide Residue Limits in Foods*, Taiwan Food and Drug Administration website, accessed July 2025.

Commodity	Tolerance for residues arising from the use of mefentrifluconazole (mg/kg)						
	Australia[4]	EU[5]	Japan[6]	Codex[7]	USA[8]	Korea[9]	Taiwan[10]
Meat (mammalian) [in the fat]	0.2 (current) 0.4 (proposed)	0.2 (fat) 0.04 (muscle)	1 (Cattle, fat) 0.2 (cattle muscle)	1.5 (Mammalian fats (except milk fats)) 0.15 Meat (from mammals other than marine mammals)	1 (Cattle, fat) 0.15 (Cattle meat)	-	-
Milks	0.03 (current) 0.05 (proposed)	0.03 (Milk - Cattle)	0.2 (Milk)	0.1	0.15 (Milk)	-	-
Oaten Hay	20 (current – Forage and fodder of cereal grains)	-	-	50 (straw and hay of cereal grains (excluding pseudocereals) (subgroup)	15 (Grain, cereal, forage, fodder, and straw, group 16, hay)	-	-
Oats	0.2 (current) 1.5 (proposed)	0.6 (Oat)	4 (Other cereal grains)	3	4 (Grain, cereal, group 15, except wheat and corn)	3.0 (Oat)	-
Pulses	1.5 (proposed)	0.07 (Beans), 1.5 (Lentils), 0.2 (Lupins, Peas)	2 (Beans, dried), 0.2 (Broad beans, Peas), 0.2 (Other legumes/pulses)	0.07 [Dry beans (subgroup)], 0.15 [Dry peas (subgroup)], 1.5 [Lentil (dry)], 0.4 soya bean (dry)	2 (Lentil, dry seed), 0.4 Soybean seed, 0.15 Vegetable, legume, group 6, except lentil and soybean seed	0.4 (Soybean)	0.4 (Soybean)
Wheat	0.03 (current) 0.4 (proposed)	0.4	0.3	0.4	0.3 (Wheat, grain)	0.3	0.3

Note: No mefentrifluconazole MRLs are established in China.

Table 7: Overseas MRLs/tolerances for pyraclostrobin

Commodity	Tolerance for residues arising from the use of pyraclostrobin (mg/kg)							
	Australia[4]	EU[5]	Japan[6]	Codex[7]	USA[8]	China[11]	Korea[9]	Taiwan[10]
Residue definition	Pyraclostrobin	Pyraclostrobin	Pyraclostrobin	Pyraclostrobin	Pyraclostrobin + its desmethoxy metabolite (methyl-N-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl] phenylcarbamate)	Pyraclostrobin	Pyraclostrobin	Pyraclostrobin
Barley	*0.01 (current – Cereal grains) 0.2 (proposed)	1	1	1	1.4 (Barley, grain)	1	-	0.4
Meat (mammalian) [in the fat]	*0.05 (current) 0.1 (proposed)	0.05* (Bovine, fat, muscle)	0.5 (Cattle, fat, muscle)	0.5 (Mammalian fats (except milk fats) 0.5 (Meat (from mammals other than marine mammals)	0.1 (Cattle, fat, meat)	0.05* (Meat from mammals (with the exception of marine mammal), calculated by residue in the fat)	-	-
Oateh hay	0.5 (current – Straw and	-	-	30 (Straw and hay of cereal	18 (Oat, hay)	-	-	-

[11] USDA Foreign Agricultural Service, *Translation of Maximum Residue Limits for Pesticides in Foods*, USDA website, accessed July 2025.

Commodity	Tolerance for residues arising from the use of pyraclostrobin (mg/kg)							
	Australia[4]	EU[5]	Japan[6]	Codex[7]	USA[8]	China[11]	Korea[9]	Taiwan[10]
	fodder (dry) of cereal grains) 3 (proposed – Oats straw and fodder, dry)			grains (excluding pseudocereals) (subgroup))				
Oats	*0.01 (current – Cereal grains) 0.2 (proposed)	1 (Oat)	1 (Other cereal grains)	1	1.2 (Oat, grain)	1 (Oat)	-	1.0 (Oat)
Pulses	1 (proposed)	0.5 (Lentils), 0.3 (Beans, Peas), 0.05 (Lupins)	0.5 (Beans, dried, Broad beans), 0.3 (Peas), 0.3 (Other legumes/pulses), (0.05 Soybeans, dried)	0.2 [Beans (dry)], 0.3 [Dry peas (subgroup)], 0.5 [Lentil (dry)], 0.05 Soya bean (dry)	0.5 (Pea and bean, dried shelled, except soybean, subgroup 6C), 0.04 (Soybean seed)	0.5 (Mung bean, Lentils), 0.3 (Pea),	0.05 (Mung bean, Soy bean))	0.5 (Chickpea), 0.2 (Other dry beans (except peanut, lentil, snap bean, soybean, sunflower seed, pea), 0.1 (English pea (dry), Green pea (dry), Field pea (dry)), 0.1 (Kidney bean (dry), Field bean (dry)), 0.5 (Lentil (dry)), 0.04 (Soybeans)
Wheat	*0.01 (current – Cereal grains) 0.2 (proposed)	0.2	0.2	0.2	0.02 (Wheat, grain)	0.2	0.09	0.02

Current and proposed Australian MRLs for mefentrifluconazole and pyraclostrobin

Table 8: Current MRL Standard – Table 1

Compound	Food	MRL (mg/kg)
Mefentrifluconazole		
GC 0640	Barley	0.2
MO 0105	Edible offal (mammalian)	0.3
PE 0112	Eggs	*0.01
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
PM 0110	Poultry meat [in the fat]	*0.01
PO 0111	Poultry, edible offal of	0.02
GC 0654	Wheat	0.03
Pyraclostrobin		
GC 0080	Cereal grains	*0.01
MO 0105	Edible offal (mammalian)	0.1
PE 0112	Eggs	*0.05
MM 0095	Meat (mammalian) [in the fat]	*0.05
ML 0106	Milks	*0.01
GC 0647	Oats	T0.2
PM 0110	Poultry meat [in the fat]	*0.05
PO 0111	Poultry, edible offal of	*0.05

Table 9: Current MRL Standard – Table 4

Compound	Animal feed commodity	MRL (mg/kg)
Mefentrifluconazole		
	Almond hulls	7
AB 0226	Apple pomace, dry	5
	Forage and fodder of cereal grains	20
AB 0269	Grape pomace, dry	5
	Rape seed [canola] forage and fodder	2
	Tomato pomace, dry	15
Pyraclostrobin		
AL 1020	Alfalfa [lucerne] fodder	T1.5
AL 1021	Alfalfa [lucerne] forage (green)	T1.5
	Almond hulls	15
AB 0226	Apple pomace, dry	25
	Cereal forage, green	5
AB 0001	Citrus pulp, dry	5
AB 0269	Grape pomace, dry	10
	Straw and fodder (dry) of cereal grains	0.5
	Tomato pomace, dry	15

Table 10: Proposed MRL Standard – Table 1

Compound	Food	MRL (mg/kg)
Mefentrifluconazole		
Delete:		
GC 0640	Barley	0.2
GC 0647	Oats	0.2
GC 0654	Wheat	0.03
Add:		
GC 0640	Barley	1.5

Compound	Food	MRL (mg/kg)
GC 0647	Oats	1.5
VD 0070	Pulses	1.5
GC 0654	Wheat	0.4
Pyraclostrobin		
Delete:		
GC 0080	Cereal grains	*0.01
Add:		
GC 0640	Barley	0.2
GC 0647	Oats	0.2
VD 0070	Pulses	1
GC 0654	Wheat	0.2

Table 11: Proposed MRL Standard – Table 4

Compound	Food	MRL (mg/kg)
Mefentrifluconazole		
Add:		
	Pulse forage and fodder	30
Pyraclostrobin		
Delete:		
AS 0081	Straw and fodder (dry) of cereal grains	0.5
Add:		
	Pulse forage and fodder	15
AS 0081	Straw and fodder (dry) of cereal grains	3

Potential risk to trade

Export of treated produce containing finite (measurable) residues of mefentrifluconazole and pyraclostrobin may pose a risk to Australian trade in situations where (i) no residue tolerance (import tolerance) is established in the importing country or (ii) where residues in Australian produce are likely to exceed a residue tolerance (import tolerance) established in the importing country.

The recommended 15-day ESI should ensure there are no quantifiable residues of mefentrifluconazole or pyraclostrobin in mammalian animal tissues for export. The risk to trade in these commodities is considered to be low.

Mefentrifluconazole

Plant commodities

The proposed mefentrifluconazole MRLs for barley, oats and wheat are generally lower or equivalent to those established internationally. Whilst the proposed mefentrifluconazole MRLs for oats (1.5 mg/kg) is higher than the EU MRLs for oats (0.6 mg/kg), the EU is not considered a major export market for oats. The proposed MRL for wheat (0.4 mg/kg) is equivalent to Codex and the EU and only slightly higher than other markets set at 0.3 mg/kg.

Whilst the proposed mefentrifluconazole MRL of 1.5 mg/kg for pulses is higher than the Codex MRLs of 0.07 mg/kg for dry beans (subgroups) and 0.15 mg/kg for dry peas (subgroup), it is no greater than the established mefentrifluconazole MRLs for beans in Japan and lentils in the EU and USA. It is noted that mefentrifluconazole MRLs for the proposed crops are currently not established in China.

The current mefentrifluconazole MRL of 20 mg/kg for Forage and fodder of cereal grains is lower than the Codex MRL of 50 mg/kg for Straw and hay of cereal grains (excluding pseudocereals) (subgroup). Whilst it is greater than the USA MRL of 15 mg/kg for Grain, cereal, forage, fodder, and straw, group 16, hay, the USA is not considered a major export market for oaten hay.

Animal commodities

An increase has been proposed to the mefentrifluconazole MRLs for edible offal (mammalian) to 0.7 mg/kg, meat (mammalian) [in the fat] to 0.4 mg/kg and milks to 0.05 mg/kg, all of which are generally lower than those established internationally, except for the EU. However, no mefentrifluconazole MRLs for these animal commodities are established by China, Korea or Taiwan.

Pyraclostrobin

The proposed pyraclostrobin MRLs for barley (0.2 mg/kg) and oats (0.2 mg/kg) are lower than those established internationally. The proposed pyraclostrobin MRL of 0.2 mg/kg for wheat is equivalent to the current MRL of 0.2 mg/kg established internationally, except in the USA. Whilst it is higher than the USA MRL of 0.02 mg/kg for pyraclostrobin on wheat, grain, the USA is not considered a major export market for wheat. The proposed pyraclostrobin MRL for pulses is higher than the internationally established MRLs of pyraclostrobin in beans, peas and lentils.

The recommended pyraclostrobin MRL of 3 mg/kg for Straw and fodder (dry) of cereal grains is lower than the USA MRL of 18 mg/kg for Oat, hay and the Codex MRL of 30 mg/kg for Straw and hay of cereal grains (excluding pseudocereals) (subgroup). It is noted that Japan has not established tolerances for mefentrifluconazole or pyraclostrobin in animal feeds[12].

Animal commodities

An increase has been proposed to the pyraclostrobin MRL for meat (mammalian) [in the fat] to 0.1 mg/kg, which is equivalent to the USA MRL and lower than the Japan and Codex MRLs of 0.5 mg/kg each. However, no pyraclostrobin MRL for meat (mammalian) [in the fat] is established by Korea or Taiwan.

[12] Specifications and Standards of Feeds and Feed Additives

Conclusion

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