



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



**Trade Advice Notice on fluxapyroxad and mefentrifluconazole
in the product Revystar Fungicide**

Submissions received

May 2021



To:

Executive Director, Risk Assessment Capability
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001
Via email: enquiries@apvma.gov.au

Date: 26 April 2021

To whom it may concern

I write in response to a request for comments on an application from BASF Australia Ltd to register Revystar Fungicide, containing fluxapyroxad and mefentrifluconazole, for use on wheat, barley, oats and canola. No comment is made on fodder or forage, nor meat products.

This submission is presented on behalf of the National Working Party on Grain Protection (NWPGP).

1. The NWPGP:

- Is the industry body responsible for providing management and leadership to industry in the areas of post-harvest storage, chemical use, market requirements and chemical regulations.
- Is facilitated by Grain Trade Australia.
- Has members across the entire grain supply chain.
- Hosts an annual forum providing participants with the latest research and developments, in the area of post-harvest storage and hygiene, chemical usage and outturn tolerances, international and domestic market requirements, and regulations.
- Co-ordinates and provides government with industry views on chemicals in use on grain and associated products.
- For further details, refer to <http://www.graintrade.org.au/nwpgp>

2. Industry Views on the Application

On behalf of the NWPGP I advise that based on the information provided by the Australian Pesticides and Veterinary Medicines Authority (APVMA) in the Trade Advice Notice (TAN), industry does not support the proposed registration of Revystar Fungicide on wheat, barley, oats and canola.

2.1 Fluxapyroxad – Cereals and Canola

That view of non-support for the registration of Revystar Fungicide is for mefentrifluconazole only, given that there are suitable cereal fluxapyroxad MRLs in most markets for the commodities listed in the TAN. It is recognised there are a range of suitable MRLs in key export markets and at Codex for



fluxapyroxad, most of which have MRLs higher than the proposed (current) MRL in Australia. Many markets default to that Codex MRL. Industry management systems are available to manage risks for those markets with an MRL lower than that in Australia.

The proposed Australian canola MRL is significantly lower than many overseas markets and not considered a significant market access risk.

2.2 Mefentrifluconazole

This advice for industry not supporting the registration of Revystar Fungicide based on the active ingredient mefentrifluconazole is provided on the following basis:

a) Cereals

Cereals, mainly wheat and barley, are significant export crops from Australia. Oats are becoming an increasingly important export crop. A more comprehensive list of markets by commodity than listed in the TAN is listed in this submission.

There is a current lack of suitable MRLs for mefentrifluconazole in key export markets, with many key markets including Codex applying/having a nil MRL. While the TAN indicates trials showed residues arising were low, there is potential for residues to arise from the proposed usage. Similarly, while the STMR is also relatively low, the risk of residues arising from the use of this compound exists. The risk of residues arising is significantly higher for barley and oats, in comparison to wheat as indicated in the TAN.

Industry employs a range of management systems to reduce the risk of residues in cargoes of grain, that mainly involve blending. Commodity Vendor Declarations, segregation, sampling and testing are also used as required and where applicable. However, there is an extensive container trade of cereals to many markets where the potential to blend grain on outturn ranges from limited to not possible. Hence for smaller consignments low level residues would be a risk to trade where shipments are sampled and tested on discharge.

For barley exports, many exports are to malt markets, requiring a single variety of barley. The malt barley export industry is such that segregation requirements by variety and grade already place significant pressure on grain storage facilities. It is not feasible to have another constraint imposed requiring that treated grain to be excluded from trade sensitive markets where the MRL is lower than the Australian MRL.

It is acknowledged that the TAN states MRLs for cereals will be considered by CCPR (expected to be CCPR52 in July 2021) and that MRLs are expected to be adopted in November 2021 by the Codex Alimentarius Commission. Until that occurs, and a range of markets that adopt Codex MRLs confirm those MRLs, the risk to trade continues, even if relatively limited use of this product were to occur in 2021 – note this is unknown based on the information in the TAN.

Similar to the comments on risk to market access outlined above, risk also apply for markets such as South Korea and Taiwan, where it is known that extensive monitoring of imported consignments



occurs. Detection of residues above the existing default and zero MRL respectively, prior to consideration of an Import Tolerance application and adoption of an MRL, places shipments at risk of rejection.

While industry supports additional tools for growers to manage pathogens, this must be balanced against the ability of industry to manage market access and specifically MRLs for a wide range of chemicals potentially used by growers and present on exported grain. This task is becoming increasingly difficult where the potential exists for residues to arise above market MRLs, albeit at relatively low levels.

b) Canola

Canola is a significant export crop, mainly to various countries in the EU.

Residue results supplied in the TAN indicate relatively low levels arising, with a relatively low STMR for mefentrifluconazole. However, some residues are expected given the proposed usage pattern, in excess of several market MRLs including those with a nil MRL. Note that other canola markets in this category not listed in the TAN include Malaysia and UAE. While the latter defaults to the EU and will be covered by the EU MRL once adopted, the other (and other ad hoc markets) generally adopt Codex and the risk of violating those market MRLs will be determined by the timing and level of the Codex MRL to be adopted.

It is noted the EU is expected to adopt an MRL for mefentrifluconazole that will exceed the proposed Australian MRL. Hence when the EU and Codex MRLs are adopted, the risk to market access for many canola markets will be significantly reduced.

3. Summary

In summary, industry does not have any concerns with the proposed registration and use of fluxapyroxad in the product Revystar Fungicide.

However, the registration of the second chemical in that product, mefentrifluconazole, does pose significant market access risks where there are no MRLs or there is a default MRL in key markets and at Codex. Industry preference is for MRLs to be adopted at Codex and key markets before a new product is registered, rather than register a product and then await MRLs to be adopted.

Should Codex MRLs and an MRL be adopted in key markets then this risk will be significantly reduced, and industry will re-consider its views on this matter if applicable.

Attached are the relevant MRLs for both chemicals for many Australian markets as used in this advice.

Should you have any questions on this submission please do not hesitate to contact me.



Regards

A handwritten signature in black ink, appearing to read 'G McMullen', is positioned below the 'Regards' text.

Gerard McMullen

Chair

National Working Party on Grain Protection

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Fluxapyroxad & Mefentrifluconazole MRLs as at 12Apr21

Commodity	Barley, grain	Australia current	Australia proposed	Bahrain	Bangladesh	Cambodia	Canada	China	Codex	Egypt	European Union	Fiji
Barley	Fluxapyroxad	0.2	0.2	0	2 (Codex)	2 (Codex)	3	2 T	2	2 (Codex)	2	2 (Codex)
Barley	Mefentrifluconazole	0	0.2	0	0	0	4	0	0	0.6 (EU)	0.6	0
Oat	Fluxapyroxad	0.1 AOF	0.2	0	2 (Codex)	2 (Codex)	3	2 T	2	2 (Codex)	2	2 (Codex)
Oat	Mefentrifluconazole	0	0.2	0	0	0	4	0	0	0.6 (EU)	0.6	0
Wheat	Fluxapyroxad	0.1	0.1	0	0.3 (Codex)	0.3 (Codex)	0.3	0.3 T	0.3	0.3 (Codex)	0.4	0.3 (Codex)
Wheat	Mefentrifluconazole	0	0.03	0	0	0	0.3	0	0	0.05 (EU)	0.05	0
Rape seed (canola)	Fluxapyroxad	0.1 AOF	0.2	0	0.8 (Codex)	0.8 (Codex)	0.9	0.8 T	0.8	0.8 (Codex)	0.9	0.8 (Codex)
Rape seed (canola)	Mefentrifluconazole	0	0.05	0	0	0	1	0	0	0.01* (EU)	0.01* (0.06P)	0

Note:

1. P = Proposed to be adopted in the EU, unknown date for adoption
2. EU / USA shown given markets that Default to EU
3. * Limit of Quantification
4. D = Default MRL
5. AOF = All other foods
6. All MRLs in mg/kg
7. AUS food consumption MRLs shown
8. T = Temporary MRL
9. Major markets as listed in the TAN are highlighted in green
10. Processed product MRLs not listed above



Fluxapyroxad & Mefentrifluconazole MRLs as at 12Apr21

Commodity	Barley, grain	Great Britain	Hong Kong	India	Indonesia	Iran	Japan	Jordan	Kenya	Korea	Kuwait	Lebanon
Barley	Fluxapyroxad	2	0	0.01 D	0	2 (Codex)	3	2 (Codex)	2 (Codex)	2 IT	0	2 (Codex)
Barley	Mefentrifluconazole	0.6	0	0.01 D	0	0	4	0	0	0.01 D	0	0
Oat	Fluxapyroxad	2	0	0.01 D	2	2 (Codex)	3	2 (Codex)	2 (Codex)	0.01 D	0	2 (Codex)
Oat	Mefentrifluconazole	0.6	0	0.01 D	0	0	4	0	0	0.01 D	0	0
Wheat	Fluxapyroxad	0.4	0	0.01 D	0.3	0.3 (Codex)	2	0.3 (Codex)	0.3 (Codex)	0.3 IT	0	0.3 (Codex)
Wheat	Mefentrifluconazole	0.05	0	0.01 D	0	0	0.3	0	0	0.01 D	0	0
Rape seed (canola)	Fluxapyroxad	0.9	0	0.01 D	0	0.8 (Codex)	0.9	0.8 (Codex)	0.8 (Codex)	0.8 IT	0	0.8 (Codex)
Rape seed (canola)	Mefentrifluconazole	0.01*	0	0.01 D	0	0	1	0	0	0.01 D	0	0

Fluxapyroxad & Mefentrifluconazole MRLs as at 12Apr21

Commodity	Barley, grain	Libya	Malawi	Malaysia	Mozambique	Myanmar	New Zealand	Nigeria	Oman	Pakistan	Philippines	Qatar
Barley	Fluxapyroxad	2 (Codex)	0	2 (Codex)	2 (Codex)	0						
Barley	Mefentrifluconazole	0	0	0.01 D	0	0	0.1 D	0	0	0	0	0
Oat	Fluxapyroxad	2 (Codex)	0	2 (Codex)	2 (Codex)	0						
Oat	Mefentrifluconazole	0	0	0.01 D	0	0	0.1 D	0	0	0	0	0
Wheat	Fluxapyroxad	0.3 (Codex)	0	0.3 (Codex)	0.3 (Codex)	0						
Wheat	Mefentrifluconazole	0	0	0.01 D	0	0	0.1 D	0	0	0	0	0
Rape seed (canola)	Fluxapyroxad	0.8 (Codex)	0	0.8 (Codex)	0.8 (Codex)	0						
Rape seed (canola)	Mefentrifluconazole	0	0	0.01 D	0	0	0.1 D	0	0	0	0	0



Fluxapyroxad & Mefentrifluconazole MRLs as at 12Apr21

Commodity	Barley, grain	Saudi Arabia	Singapore	South Africa	Sudan	Taiwan	Tanzania	Thailand	Tunisia	United Arab Emirates	United States	Vietnam	Zimbabwe
Barley	Fluxapyroxad	2	2 (Codex)	2 (Codex)	2 (Codex)	2	2 (Codex)	2 (Codex)	2 (Codex)	2 (Codex)	3	2	2 (Codex)
Barley	Mefentrifluconazole	0.6 (EU)	0	0.6 (EU)	0	0	0	0.01 D	0	0.6 (EU)	4	0	0
Oat	Fluxapyroxad	2	2 (Codex)	2 (Codex)	2 (Codex)	2	2 (Codex)	2 (Codex)	2 (Codex)	2 (Codex)	3	2	2 (Codex)
Oat	Mefentrifluconazole	0.6 (EU)	0	0.6 (EU)	0	0	0	0.01 D	0	0.6 (EU)	4	0	0
Wheat	Fluxapyroxad	0.3	0.3 (Codex)	0.4 (EU)	0.3 (Codex)	0.3	0.3 (Codex)	0.3 (Codex)	0.3 (Codex)	0.3 (Codex)	0.3	0.3	0.3 (Codex)
Wheat	Mefentrifluconazole	0.05 (EU)	0	0.05 (EU)	0	0	0	0.01 D	0	0.05 (EU)	0.3	0	0
Rape seed (canola)	Fluxapyroxad	0.8 (Codex)	0.8 (Codex)	0.9 (EU)	0.8 (Codex)	0.3	0.8 (Codex)	0.8 (Codex)	0.8 (Codex)	0.8 (Codex)	0.9	0.8	0.8 (Codex)
Rape seed (canola)	Mefentrifluconazole	0.01 (EU)	0	0.01 (EU)	0	0	0	0.01 D	0	0.01 (EU)	1	0	0



SUBMISSION

**APVMA Trade Advice Notice
on fluxapyroxad and mefentrifluconazole in the product
Revystar Fungicide for use on wheat, barley, oats and canola
APVMA product number 89744**

PO Box 370
Braidwood NSW 2662

27 April 2021

Executive Director, Risk Assessment Capability
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001

Re: Trade Advice Notice on the product Revystar Fungicide for use on wheat, barley, oats and canola

Thank you for the opportunity for Grain Producers Australia (GPA) to provide a response to the **Trade Advice Notice on fluxapyroxad and mefentrifluconazole in the product Revystar Fungicide for use on wheat, barley, oats and canola APVMA product number 89744.**¹

Background

There is a strategic need for new fungicides of a different mode of action as part of an Australian resistance management and disease control strategy. Australian growers urgently require access to new fungicide control technologies in order to maintain crop production. There is currently widespread fungicide resistance of barley powdery mildew and barley net and spot-form of net-blotch to Group 3 demethylation inhibitor (DMI, Group 3) triazole fungicides. Succinate dehydrogenase (SDHI, Group 7) resistance in spot form of net blotch is also an increasing problem in barley crops in the WA grain-belt.² There is also widespread wheat powdery mildew resistance to quinone outside Inhibitor (QoI, Group 11) strobilurin fungicides and increasing concern with DMI Group 3 fungicide resistance to this disease.³ Foliar fungal pathogens remain a major threat to crop production across Australia. It is estimated that under current control systems, the annual average loss from disease in cereals and canola crops is more than \$1.3 billion, while the contributed value of fungicides to the Australian grains industry is estimated at \$1.11 billion.^{4,5,6,7}

GPA supports the establishment of a label for the product Revystar Fungicide for use on wheat, barley, oats and canola as tabled by the APVMA.

GPA has reviewed the APVMA **the Trade Advice Notice for the product Revystar Fungicide for use on wheat, barley, oats and canola.** GPA notes and supports the APVMA in maintaining the current fluxapyroxad MRL of 0.1 mg/kg for fluxapyroxad on GC 0654 wheat grain, GPA also notes and supports the APVMA in maintaining the current fluxapyroxad MRL of 0.2 mg/kg for fluxapyroxad on GC 0640 barley grain and establishing an MRL of 0.2 mg/kg for fluxapyroxad on GC 0647 oat grain. GPA supports the APVMA proposed use of these actives with a withholding period of 'Not required when used as directed and a restraint of 'DO NOT apply after Z59 (ear emergence)'.

GPA notes no changes are required to the current MRL of 20 mg/kg for fluxapyroxad on the forage and fodder of cereal grains and supports the establishment of the APVMA recommended mefentrifluconazole MRL of 20 mg/kg on the forage and fodder of cereal grains, both used in conjunction with a 4 week grazing withholding period.

GPA notes and supports the APVMA in establishing a fluxapyroxad MRL of 0.2 mg/kg on canola, noting the trial data set which had a much lower Supervised Trial Median Residue (STMR) of 0.01 mg/kg on SO 0495 rape seed (canola), also noting as there is a restraint on the label preventing application after 50% flowering, plus the GPA supported harvest withholding period 'Not required when used as directed'. GPA also notes that the combined mefentrifluconazole on canola dataset supports an APVMA MRL recommendation of 0.05 mg/kg, based on a Supervised Trial Median Residue (STMR) of 0.01 mg/kg on SO 0495 rape seed (canola), noting the high residue of 0.03 mg/kg in one trial.

¹ <https://apvma.gov.au/node/83816>

² <https://grdc.com.au/news-and-media/news-and-media-releases/national/2020/september/sdhi-resistance-in-sfnb-of-barley-discovered-for-the-first-time-in-australia>

³ <http://ccdm.com.au/wp-content/uploads/2018/03/Fungicide-resistant-diseases-in-Australian-grains.pdf>

⁴ https://grdc.com.au/__data/assets/pdf_file/0026/203957/disease-loss-wheat.pdf.pdf

⁵ https://grdc.com.au/__data/assets/pdf_file/0025/204748/disease-loss-barley.pdf.pdf

⁶ https://grdc.com.au/__data/assets/pdf_file/0021/82263/grdcreportdiseasecostpulsespdf.pdf.pdf

⁷ https://grdc.com.au/__data/assets/pdf_file/0021/82641/grdcreportdiseasecostoilseedspdf.pdf.pdf

GPA notes no changes are required to the current fluxapyroxad MRL of 1 mg/kg on primary feed commodities and supports the establishment of the APVMA recommended mefentrifluconazole MRL of 2 mg/kg on rape seed (canola) forage and fodder in conjunction with a 4 week grazing withholding period.

GPA notes that the APVMA reports that the recommended 10 day export slaughter interval should ensure there are no quantifiable residues of fluxapyroxad or mefentrifluconazole in mammalian animal tissues for export and that the APVMA proposes an increase to the mefentrifluconazole milk MRL to 0.03 mg/kg, which is similar or lower than those MRLs established or to be established in the EU, Japan, and the USA.

GPA notes that the fluxapyroxad oat and rape seed MRLs proposed by the APVMA are lower than those currently established overseas, including by Codex. GPA notes the mefentrifluconazole wheat, barley, oats and rape seed MRLs proposed by the APVMA are lower than those established in Japan and the USA and lower than those established or to be established in the EU.

GPA notes that the APVMA TAN details that 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 fungicide product containing fluxapyroxad or mefentrifluconazole has however been approved for use on cereals and canola in USA who is a potential export market competitor to Australian producers and is also approved for the EU where Australian canola and barley is exported to. It is essential that Australian producers have access to the same crop protection technologies as potential market competitors.

GPA notes the APVMA TAN reports that the applicant has indicated that mefentrifluconazole import tolerances in line with the US MRLs will be applied for in Korea and an import tolerance application for Taiwan has yet to be finalised. GPA also notes that Codex MRLs are expected to be established for cereals and canola in Q3 2021 (delayed from 2020 due to COVID-19) and that an MRL for wheat in China could potentially be set in 2022. GPA notes that while mefentrifluconazole MRLs have not yet been established by Codex at this time, there is however suitable Australian grain markets for which the resulting residues from the proposed use will be accepted. The Codex MRLs should also be in place by the time the harvested grain is exported in 2022.

GPA considers that the current risk to trade from this product approval is low for a number of key Australian grain markets and will be low for most major markets when the Codex MRLs are established later in 2021. As with a number of other existing grain commodities, any potential trade issues for grain markets can be adequately managed by industry through CVD or vendor declarations at delivery and segregation at receival sites.

If you would like to discuss any of these comments and suggestions further in detail, please contact me on email andrew.weidemann@grainproducers.com.au or 0428 504 544.

Yours sincerely



Andrew Weidemann
Chairman GPA

Background on GPA

Grain Producers Australia (GPA) represents Australia's broadacre, grain, pulse and oilseed producers at the national level. Grain Producers Australia works to foster a strong, innovative, profitable, globally competitive and environmentally sustainable Australian grains industry. Representing 5200 farm businesses, it strives to represent Australian grain farmers nationally and internationally in their contribution to sustainable development and society.

Working with its members – state farm organisations and farmers across the grain production area of Australia - GPA advocates for sound outcomes that deliver a positive commercial result. GPA is a not-for-profit company limited by guarantee. It is governed by a board, elected by its members.

The objectives of GPA are to:

- Provide a strong, independent, national advocate for grain producers based on a rigorous and transparent policy development process.
- Engage all sectors of the Australian grains industry to ensure operation of the most efficient and profitable grain supply chain.
- Facilitate a strategic approach to research, development and extension intended to deliver sound commercial outcomes from industry research.

GPA has a policy council, strategically focused on three pillars of economic development, social responsibility and environmental management. Our policy council is supported by, and engages with, representatives from State Farm Organisations including:

- AgForce Grains
- Grain Producers SA
- NSW Farmers Association
- Victorian Farmers' Federation Grains Group
- Tasmanian Farmers and Graziers Association
- WA Farmers
- WA Grains Group

GPA⁸ manages the biosecurity program for the grains industry through Plant Health Australia and is a joint Representative Organisation (RO) responsible for overseeing the performance of the Grains Research and Development Corporation (GRDC).

⁸ Further information on GPA: <https://www.grainproducers.com.au/>