



Australian Government

**Australian Pesticides and
Veterinary Medicines Authority**



Trade Advice Notice

on metrafenone for use on wheat

Permit number 93198

February 2023

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Preface

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an independent statutory authority with responsibility for assessing and approving agricultural and veterinary chemical products prior to their sale and use in Australia.

The APVMA has a policy of encouraging openness and transparency in its activities and of seeking stakeholder involvement in decision making. Part of that process is the publication of Trade Advice Notices for all proposed extensions of use for existing products where there may be trade implications.

The information and technical data required by the APVMA to assess the safety of new chemical products and the methods of assessment must be undertaken according to accepted scientific principles. Details are outlined in regulatory guidance published on the APVMA website.

About this document

This Trade Advice Notice indicates that the APVMA is considering an application to vary the use of an existing registered agricultural or veterinary chemical.

It provides a summary of the APVMA's residue and trade assessment.

Comment is sought from industry groups and stakeholders on the information contained within this document.

Making a submission

The APVMA invites any person to submit a relevant written submission as to whether the application for a permit for use of metrafenone on wheat should be granted. Submissions should relate only to matters that the APVMA is required by legislation to take into account in deciding whether to grant the application. These grounds relate to the trade implications of the extended use of the product. Submissions should state the grounds on which they are based. Comments received outside these grounds cannot be considered by the APVMA.

Submissions must be received by the APVMA by close of business on 21 February 2023 and be directed to the contact listed below. All submissions to the APVMA will be acknowledged in writing via email or by post.

Relevant comments will be taken into account by the APVMA in deciding whether to grant the application and in determining appropriate conditions of registration and product labelling.

When making a submission please include:

- contact name
- company or organisation name (if relevant)
- email or postal address (if available)
- the date you made the submission.

Please note: submissions will be published on the APVMA's website, unless you have asked for the submission to remain confidential, or if the APVMA chooses at its discretion not to publish any submissions received (refer to the public consultation coversheet).

Please lodge your submission using the public consultation coversheet, which provides options for how your submission will be published.

Note that all APVMA documents are subject to the access provisions of the *Freedom of Information Act 1982* and may be required to be released under that Act should a request for access be made.

Unless you request for your submission to remain confidential, the APVMA may release your submission to the applicant for comment.

Written submissions should be addressed to:

Executive Director, Risk Assessment Capability
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001
Phone: +61 2 6770 2300
Email: enquiries@apvma.gov.au.

Further information

Further information can be obtained via the contact details provided above.

Further information on Trade Advice Notices can be found on the APVMA website: apvma.gov.au.

Introduction

The APVMA has before it an emergency permit application from Grain Producers Australia Limited for the use of metrafenone on wheat, for the control of powdery mildew.

Trade considerations

Commodities exported

Cereal grains (including wheat) are considered to be major export commodities in the APVMA's Part 5B guidelines¹, as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feeds produced from treated wheat. Residues in these commodities resulting from the use of metrafenone may have the potential to unduly prejudice trade.

No changes are required to the established metrafenone mammalian and poultry animal commodity MRLs, so the risk to trade in animal commodities is considered to be low and does not require further consideration. The risk to trade with respect to the proposed use on wheat is considered below.

Destination and value of exports

In 2020–21 and 2021–22 Australia exported 23.7 and 27.51 Mt of wheat grain valued at \$6,805 million and \$11,336 million respectively².

The major export markets in 2020–21 and 2021–22 were China (1711 and 5382 kt respectively), Indonesia (3723 and 3561 kt), Vietnam (2367 and 2684 kt), the Philippines (1437 and 2532 kt), the Republic of Korea (972 and 1196 kt), Japan (945 and 1160 kt), Malaysia (869 and 1110 kt), Yemen (705 and 1009 kt), Thailand (852 and 756 kt) and New Zealand (452 and 561 kt).

¹ Australian Pesticides and Veterinary Medicines Authority, [APVMA Regulatory Guidelines – Data Guidelines: Agricultural data guidelines – Pesticides: Overseas trade \(Part 5B\)](#), APVMA website, 20 July 2020, accessed 16 January 2022.

² Australian Bureau of Agricultural and Resource Economics and Sciences (ABARES), [Agricultural commodities and trade data - ABARES](#), ABARES website, 21 December 2022, accessed 16 January 2023.

Proposed Australian use pattern

Table 1: Proposed use pattern for wheat being considered by the APVMA

Vivando Fungicide (P60987) containing 500 g/L metrafenone as the only active constituent

Crop	Pest	Rate	Critical comments
Wheat	Powdery mildew (<i>Blumeria graminis</i> <i>f. Sp tritici</i>)	300 mL/ha (=150 g a.i./ha)	<p>Apply a maximum of 2 foliar applications per crop by boomspray.</p> <p>Monitor crops regularly from early tillering and apply at or before BBCH 31.</p> <p>Monitor if conditions favour disease development and reapply from 21 to 28 days after the first application and no later than BBCH 61.</p> <p>DO NOT apply after the beginning of flowering, growth stage BBCH 61.</p> <p>Apply in a spray volume of 200 L/ha.</p> <p>Apply metrafenone in accordance with the current CropLife Fungicide Resistance Management Strategy.</p>

Withholding periods

Harvest

Not required when used as directed.

Grazing

DO NOT graze or cut for stock food for 28 days after application.

Restrictions

- DO NOT apply more than 2 applications per crop
- DO NOT apply after the beginning of flowering, growth stage BBCH 61
- DO NOT apply with aircraft
- DO NOT apply with spray droplets smaller than a MEDIUM spray droplet size category according to nozzle manufacturer specifications that refer to the ASAE S572 Standard or the BCPC Guideline

Trade advice

Growers should note that MRLs or import tolerances do not exist in all markets for produce treated with metrafenone. If you are growing produce for export, please check with the permit holder for the latest information on MRLs and import tolerances before using metrafenone.

Results from residues trials presented to the APVMA

Residues data for wheat from trials conducted in Europe in 2000–05, which was evaluated by the 2014 Joint Meeting on Pesticide Residues (JMPR)³, were considered in support of the application.

Residues observed in wheat grain samples taken at 23 to 41 days after the last application (DALA) or later if higher residues were observed, after 2 applications of metrafenone were made at BBCH 69 to 83 at an application rate of 140 to 160 g a.i./ha (0.93 to 1.1× the proposed application rate), in 19 residue trials conducted on wheat in various European countries were, in rank order:

<0.01 (8), 0.01 (6), 0.02, 0.03 (2) and 0.04 (2) mg/kg (STMR= 0.01 mg/kg, n=19).

Based on the available relevant residues data the OECD MRL calculator estimates an MRL of 0.06 mg/kg.

An MRL for GC 0654 Wheat set at 0.06 mg/kg is considered to be appropriate to cover residues in wheat grain arising from the proposed use pattern.

The 2014 JMPR considered processing data for wheat. Residues were observed to concentrate in fine bran after processing. Based on the highest residue (HR) observed in wheat grain of 0.04 mg/kg and the highest processing factor of 5.3× in fine bran, the HR-P in wheat bran is calculated to be 0.21 mg/kg.

A metrafenone MRL at 0.3 mg/kg is recommended for CF 0654 Wheat bran, processed.

Overseas registration and approved label instructions

The Applicant submitted a UK label for Flexity (300 g/L metrafenone, a suspension concentrate) demonstrating a registered use on wheat, which is similar to the proposed use. Two applications are allowed at 150 g a.i./ha up to and including the beginning of flowering (GS 61), in a minimum spray volume of 200 L/ha.

³ Food and Agriculture Organisation of the United Nations, [The Joint FAO/WHO Meeting on Pesticide Residues, The 2014 JMPR evaluation of metrafenone](#), Food and Agriculture Organisation of the United Nations website, accessed 16 January 2023.

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. Metrafenone has been considered by Codex.

Table 2: Relevant international MRLs for metrafenone on wheat

Commodity	Tolerance for residues arising from the use of metrafenone (mg/kg)				
	Australia	EU ⁴	Codex ⁵	Japan ⁶	China ⁷
Residue definition	Parent	Parent	Parent	Parent	Parent
Wheat	T0.06 (proposed)	0.07	0.06	0.06	T0.06
Wheat bran, processed	T0.3 (proposed)	–	0.25	0.3	–

It is noted that no relevant MRLs are established in Korea⁸, the USA⁹ or Taiwan¹⁰.

⁴ European Commission, [EU Pesticide residue\(s\) and maximum residue levels \(mg/kg\)](#), European Commission website, accessed 16 January 2023.

⁵ Food and Agriculture Organisation of the United Nations (FAO), [Codex Alimentarius : 278 - Metrafenone](#), FAO website, accessed 16 January 2023.

⁶ Japanese Food Chemistry Research Promotion Foundation, [Table of MRLs for Agricultural Chemicals](#), JFCRPF website, accessed 16 January 2023.

⁷ United States Department of Agriculture Foreign Agricultural Service, [China: Maximum Residue Limits for Pesticides in Foods, Global Agricultural Information Network report](#), 24 August 2021, accessed 16 January 2023.

⁸ Ministry of Food and Drug Safety Korea, [Pesticide MRLs for agricultural commodities](#), FSK website, accessed 16 January 2023.

⁹ Electronic Code of Federal Regulations, [Tolerances and Exemptions for Pesticide Chemical Residues in Food](#), eCFR website, accessed 16 January 2023.

¹⁰ Food and Drug Administration Taiwan, [Food and Drug Administration Taiwan, Standards for Pesticide Residue Limits in Foods](#), accessed 16 January 2023.

Current and proposed Australian MRLs for metrafenone

Table 3: Current relevant MRLs for metrafenone in Table 1 of the MRL Standard

Compound	Food	MRL (mg/kg)
<i>Metrafenone</i>		
MO 0105	Edible offal (mammalian)	*0.05
PE 0112	Eggs	*0.05
MM 0095	Meat (mammalian) [in the fat]	*0.05
ML 0106	Milks	*0.01
PM 0110	Poultry meat [in the fat]	*0.05
PO 0111	Poultry, edible offal of	*0.05

Table 4: Amendments to Table 1 of the MRL Standard for metrafenone

Compound	Food	MRL (mg/kg)
<i>Metrafenone</i>		
Add:		
GC 0654	Wheat	T0.06
CF 0654	Wheat bran, processed	T0.3

Table 5: Amendments to Table 4 of the MRL Standard for metrafenone

Compound	Food	MRL (mg/kg)
<i>Metrafenone</i>		
Add:		
	Wheat forage	T40
AS 0654	Wheat straw and fodder, dry	T10

Potential risk to trade

Export of treated produce containing finite (measurable) residues of metrafenone 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.

Wheat

The proposed use of metrafenone under emergency permit requires the establishment of a finite temporary MRL for metrafenone on wheat.

The proposed TMRL at 0.06 mg/kg is at the same level as the wheat MRL established by China, Codex and Japan. The Applicant has indicated that the Gulf Cooperation Council (GCC which various Middle Eastern countries defer to in the absence of a national MRL) has an MRL established at 0.06 mg/kg. The European Union has a higher MRL at 0.07 mg/kg.

It is noted that the observed median residue was 0.01 mg/kg and that application in all of the 19 relevant trials was at a later timing (BBCH 69 to 83) than that proposed for the permit. Given that metrafenone MRLs have been established in China, and by Codex, the GCC, Japan and the EU at levels equal to or higher than is proposed in Australia, the potential risk to trade for wheat grain to those markets (and markets covered by those MRLs) is considered to be low.

Conclusion

Grain Producers Australia Limited has applied for a permit for the use of metrafenone on wheat, for the control of powdery mildew.

Comment is sought on the potential for the proposed use to prejudice Australian trade of wheat and the ability of industry to manage any potential trade risk.