



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



TRADE ADVICE NOTICE

on fluxapyroxad in the product Ceriax Fungicide for use on wheat

APVMA Product Number 83267

NOVEMBER 2017

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CONTENTS

PREFACE	IV
About this document	iv
Making a submission	iv
Further information	v
<hr/>	
1 INTRODUCTION	6
2 TRADE CONSIDERATIONS	6
2.1 Commodities exported	6
2.2 Destination and value of exports	6
2.3 Proposed Australian use-pattern	7
2.4 Results from residues trials presented to the APVMA	9
2.5 Overseas registration and approved label instructions	9
2.6 Codex alimentarius commission and overseas MRLs	9
2.7 Current and proposed Australian MRLs for fluxapyroxad	10
2.8 Potential risk to trade	11
<hr/>	
3 CONCLUSIONS	11

LIST OF TABLES

Table 1: Overseas MRLs for fluxapyroxad in wheat	10
Table 2: Current MRL Standard—Table1	10
Table 3: Proposed MRL Standard—Table1	10

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.

In undertaking this task, the APVMA works in close cooperation with advisory agencies, including the Department of Health and Aging, Department of the Environment and Energy, and State Departments of Primary Industry.

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 is a Trade Advice Notice.

It indicates that the Australian Pesticides and Veterinary Medicines Authority (APVMA) is considering an application to vary the use of an existing registered agricultural or veterinary chemical. It provides a summary of the APVMA's residue and trade assessment.

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

Making a submission

The APVMA invites any person to submit a relevant written submission as to whether the application to vary the registration of Ceriax 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 29 November 2017 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 group name (if relevant)
- postal address
- email address (if available)
- the date you made the submission.

All personal and confidential commercial information (CCI)¹ material contained in submissions will be treated confidentially.

Written submissions on the APVMA's proposal to grant the application for registration that relate to the grounds for registration should be addressed in writing to:

Residues and Trade

Scientific Assessment and Chemical Review

Australian Pesticides and Veterinary Medicines Authority

PO Box 6182

Symonston ACT 2609

Phone: +61 2 6210 4701

Email: enquiries@apvma.gov.au

Further information

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

Further information on public release summaries can be found on the APVMA website: www.apvma.gov.au

¹ A full definition of 'confidential commercial information' is contained in the Agvet Code.

1 INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from BASF Australia Ltd, to register the new product Ceriax Fungicide containing epoxiconazole, fluxapyroxad and pyraclostrobin as active ingredients. The product is proposed for use on wheat and barley.

The use patterns for epoxiconazole and pyraclostrobin on wheat and barley and for fluxapyroxad on barley are a lower risk than those currently registered and no changes are required to current MRLs for these actives [see Opera Fungicide (epoxiconazole and pyraclostrobin), Product no. 62753 and Imbrex Fungicide (fluxapyroxad), Product 64104].

Only the use of fluxapyroxad on wheat requires consideration with respect to the risk to trade.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Wheat is considered to be a major export commodity², 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 Ceriax Fungicide may have the potential to unduly prejudice trade.

2.2 Destination and value of exports

Total exports of wheat (including flour) were 15777 kilotonnes in 2015–16, valued at \$5.12 billion (ABARES). Major export destinations are summarised below:

COMMODITY	MAJOR DESTINATIONS
Wheat	Indonesia, Korea, China, Japan, Thailand, Malaysia, Philippines, Egypt, Nigeria, Yemen, Kuwait, New Zealand

The significant export markets for Australian beef, sheep, pig meat and offals are listed in the APVMA Regulatory Guidelines—Data Guidelines: Agricultural—Overseas trade (Part 5B). However, no changes are required to current animal commodity MRLs, and the proposed ESI will mitigate the risk of detectable residues in animal commodities for export. The export risk to animal commodities is low and will not be considered further.

² APVMA Regulatory Guidelines—Data Guidelines: Agricultural—Overseas trade (Part 5B)

2.3 Proposed Australian use-pattern

Cerix Fungicide (42 g/L Fluxapyroxad, 67 g/L Pyraclostrobin, 42 g/L Epoxiconazole)

CROP	DISEASE	RATE	CRITICAL COMMENTS
Wheat	Leaf rust <i>(Puccinia recondita)</i> Stripe rust <i>(Puccinia striiformis)</i> Stem rust <i>(Puccinia graminis f.sp.tritici)</i> Septoria nodorum glume blotch <i>(Phaeosphaeria nodorum)</i> Powdery mildew <i>(Blumeria graminis f.sp.tritici)</i> Septoria leaf blotch <i>(Septoria tritici)</i>	750 mL/ha (31.5 g fluxapyroxad/ha, 50.3 g pyraclostrobin/ha, 31.5 g epoxiconazole/ha)	Apply when conditions favour disease development and at the first signs of disease development. Repeat spraying may be required, particularly if infection occurs early. Regularly monitor the crop from 3–4 weeks after the first application for signs of re-infection. DO NOT apply later than Z59.
Barley	Leaf rust <i>(Puccinia hordei)</i> Spot form of net blotch <i>(Pyrenophora teres f. sp. maculata)</i> Net form of net blotch <i>(Pyrenophora teres f. sp. teres)</i> Leaf scald <i>(Rynchosporium secalis)</i> Powdery mildew <i>(Blumeria graminis f. sp. hordei)</i>		Apply when conditions favour disease development and preferably prior to development of high levels of disease in the crop. Repeat spraying may be required, particularly if infection occurs early. Regularly monitor the crop from 3–4 weeks after the first application for signs of re-infection. DO NOT apply later than Z59.

Restrains:

DO NOT apply more than two foliar applications of Cerix (or any other SDHI or strobilurin or Group 7 or 11 fungicide) in any one season on the same paddock.

DO NOT apply when wind speed is less than 3 or more than 20 kilometres per hour at the application site.

DO NOT apply with spray droplets smaller than a MEDIUM spray droplet size category according to nozzle manufacturer specifications that refer to ASAE S572 standard or the BCPC guideline.

DO NOT apply during surface temperature inversion conditions at the application site.

Users of this product **MUST** make an accurate written record of the details of each spray application within 24 hours following application and **KEEP** this record for a minimum of 2 years. The spray application details that must be recorded are: 1. Date with start and finish times of application; 2. Location address and paddock/s sprayed; 3. Full name of this product; 4. Amount of product used per hectare and number of hectares applied to; 5. Crop/situation and weed/pest; 6. Wind speed and direction during application; 7. Air temperature and humidity; 8. Nozzle brand, type, spray angle, nozzle capacity and spray system pressure measured during application; 9. Name and address of person applying this product. (Additional record details may be required by the State or territory where this product is used.)

MANDATORY NO-SPRAY ZONES

DO NOT apply if there are livestock, pasture or any land that is producing feed for livestock downwind from the application area and within the mandatory no-spray zones shown in Table 2 below.

Table 2—No-Spray Zones for Protection of International Trade

FOR AERIAL APPLICATION

Wind Speed Range at Time of Application Downwind Mandatory No-Spray Zone

from 3 to 8 kilometres per hour 160 metres

from 9 to 20 kilometres per hour 180 metres

FOR GROUND APPLICATION

from 3 to 20 kilometres per hour 10 metres

Withholding periods:

Harvest: Not required when used as directed.

Grazing: Do not graze or cut for stock food for 6 weeks after application.

Trade advice information:

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)

AFTER OBSERVING THE WITHHOLDING PERIOD FOR GRAZING OR CUTTING FOR STOCKFOOD, LIVESTOCK THAT HAVE BEEN GRAZED ON OR FED TREATED CROPS SHOULD BE PLACED ON CLEAN FEED FOR 3 DAYS PRIOR TO SLAUGHTER.

2.4 Results from residues trials presented to the APVMA

The proposed use of fluxapyroxad on wheat is for 2 applications at 31.5 g ai/ha up to growth stage Z59. The harvest withholding period is 'Not required when used as directed', the grazing WHP is 6 weeks.

Residues of fluxapyroxad in wheat grain at harvest after 2 applications at 62.5 g ai/ha (2x proposed) with the last application at Z59–61 were <0.01 (2) and 0.01 (2) mg/kg. Residues of fluxapyroxad in barley grain at harvest after 2 applications at 62.5 g ai/ha (2x proposed) with the last application at Z59–61 were 0.03 and 0.05 mg/kg.

The trials involve a higher rate than proposed. It is considered that an MRL of 0.1 mg/kg for fluxapyroxad on GC 0654 wheat would be appropriate for the proposed use, replacing the current MRL of *0.01 mg/kg which was established for a seed treatment use of fluxapyroxad.

In wheat processing studies residues of fluxapyroxad concentrated 2.90x on processing to bran. Based on a cereal high residue of 0.05 mg/kg, the HR-P is 0.15 mg/kg. An MRL of 0.2 mg/kg is recommended for fluxapyroxad on CM 0654 wheat bran, unprocessed.

No change to the established fluxapyroxad MRL for forage and fodder of cereal grains at 20 mg/kg is required.

2.5 Overseas registration and approved label instructions

The applicant indicated that ceriax or closely similar formulations of fluxapyroxad, pyraclostrobin and epoxiconazole are currently registered in the EU and USA.

2.6 Codex alimentarius commission and overseas MRLs

The Codex Alimentarius Commission (Codex) is responsible for establishing Codex Maximum Residue Limits (CXLs) for pesticides. Codex CXLs are primarily intended to facilitate international trade, and accommodate differences in Good Agricultural Practice (GAP) employed by various countries. Some countries may accept Codex CXLs when importing foods. Fluxapyroxad has been considered by Codex. The following relevant Codex CXLs and overseas MRLs have been established for fluxapyroxad.

Table 1: Overseas MRLs for fluxapyroxad in wheat

COMMODITY	TOLERANCE FOR RESIDUES ARISING FROM THE USE OF FLUXAPYROXAD (mg/kg)				
	AUSTRALIA	EU	JAPAN	CODEX	USA
Residue Definition	Fluxapyroxad (plant commodities)	Fluxapyroxad	Fluxapyroxad	Fluxapyroxad	Fluxapyroxad
Wheat	0.1 (proposed)	0.4	0.3	0.3	0.3
Wheat bran, unprocessed	0.2 (Proposed)	-	1	1	0.6

2.7 Current and proposed Australian MRLs for fluxapyroxad

Table 2: Current MRL Standard—Table1

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

Table 3: Proposed MRL Standard—Table1

COMPOUND	FOOD	MRL (mg/kg)
Fluxapyroxad		
DELETE:		
GC 0654	Wheat	*0.01
ADD:		
GC 0654	Wheat	0.1
CM 0654	Wheat bran, unprocessed	0.2

2.8 Potential risk to trade

Export of treated produce containing finite (measurable) residues of fluxapyroxad 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 proposed increased Australian MRL for fluxapyroxad in wheat of 0.1 mg/kg is below those established by Codex, Japan, the EU and the USA.

3 CONCLUSIONS

BASF Australia Ltd have made an application to register the new product Ceriax Fungicide containing epoxiconazole, fluxapyroxad and pyraclostrobin for use on wheat and barley. The proposed use will require an increase to the current MRL for fluxapyroxad on wheat and the establishment of a wheat bran MRL.

Comment is sought on the potential for Ceriax Fungicide to prejudice Australian trade when used on wheat according to the proposed label directions.