



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



TRADE ADVICE NOTICE

on azoxystrobin and epoxiconazole in the Product Nufarm Tazer Xpert
Fungicide

APVMA Product Number 69803

MARCH 2015

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This publication is available from the APVMA website: www.apvma.gov.au.

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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.

In undertaking this task, the APVMA works in close cooperation with advisory agencies, including the Department of Health and Aging, Office of Chemical Safety and Environmental Health (OCSEH), Department of the Environment, Water, Heritage and the Arts (DEWHA), 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 the APVMA's publication *Ag MORAG: Manual of Requirements and Guidelines*.

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.

Any advice the APVMA receives through this consultation which it relies on to grant this application will be noted in a subsequent Advice Summary.

Advice Summaries can be found on the APVMA website: www.apvma.gov.au

Making a submission

The APVMA invites any person to submit a relevant written submission as to whether the application to vary the registration of **Nufarm Tazer Xpert 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 **Wednesday 8 April 2015** 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. A summary of relevant comments and the APVMA's response will be published on the APVMA website.

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:

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 Nufarm Australia Limited, to register the new product Nufarm Tazer Xpert Fungicide. The product contains 80 g/L azoxystrobin and 31.25 g/L epoxiconazole and will be used to control various diseases on wheat, barley and oats.

Use of epoxiconazole on wheat barley and oats will be the same as currently registered for other products and appropriate MRLs are established. Azoxystrobin is currently registered for use on wheat and barley at the same rates as proposed in conjunction with a 6 week harvest withholding period and a 21 day grazing withholding period. Additional residue data have been provided to support the use of azoxystrobin on oats and allow the establishment of an appropriate MRL.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Wheat, barley, oats and oaten hay are major export commodities, as are animal commodities derived from livestock that have been fed on treated produce. No changes are required to the current animal commodity MRLs. The ESI from epoxiconazole products is to apply to these uses. The risk to trade in animal commodities is unchanged from that which currently exists and will not be considered further.

2.2 Destination and value of exports

Major export markets for wheat and barley are summarised below:

COMMODITY	MAJOR DESTINATIONS
Barley	China, Japan, Korea, Vietnam, Thailand, the Philippines, Taiwan, Saudi Arabia, Kuwait, United Arab Emirates
Wheat	Indonesia, Korea, China, Thailand, Malaysia, Egypt, Yemen, Iraq, New Zealand

In 2012–13 Australia exported 156 kt of oats valued at \$54 million (Australian Commodity Statistics 2013, ABARES). Information on the export destinations is not readily available.

Approximately 720 kilotonne of hay is exported from Australia, to the value of ~\$230–250 million, per annum.² Approximately 85% of exports are oaten hay, while 10% is straw and the balance is predominantly lucerne hay and chaff. Approximately 85% of Australian export hay is destined for Japan, while the volume of hay exported to China and the UAE is increasing.

² Personal communication, AFIA, August 2010

2.3 Proposed Australian use-pattern

Nufarm Tazer Xpert Fungicide (80 g/L azoxystrobin, 31.25 g/L epoxiconazole)

CROP	PEST	RATE	CRITICAL COMMENTS
Wheat	Leaf Rust (<i>Puccinia recondita</i>)	1–2 L/ha	Apply when conditions favour disease development and prior to development of disease in the crop. Aim to apply between early stem elongation and ear emergence (Z32–Z59).
	Stripe Rust (<i>Puccinia Striiformis</i>)	(80 + 31.25 to 160 + 62.5 g ai/ha)	DO NOT apply later than Z59 Use the higher rate specified in the rate column under high infection pressure or when longer residual protection is required. Lower rates are effective under low disease pressure but have a reduced residual effect. Ensure thorough coverage. Addition of Banjo at 1% v/v may improve efficacy at lower rates.
	Stem Rust (<i>Puccinia gramminis f. sp. tritici</i>)		
	Septoria nodorum blotch (<i>Stagonospora nodorum</i>)		
	Tan spot (<i>Pyrenophora tritici-repentis</i>)		
	Powdery mildew (<i>Blumeria gramminis f. sp. tritici</i>)		Apply when conditions favour disease development and prior to development of disease in the crop. Aim to apply between early stem elongation and ear emergence (Z32–Z59). Ensure disease levels do not exceed 5% of leaf area infection on any visible leaf prior to application of Tazer Xpert Fungicide. DO NOT apply later than Z59. Regularly monitor the crop after the first application for signs of re-infection. Repeat applications may be required.
Barley	Stem Rust (<i>Puccinia gramminis f. sp. tritici</i>)	1–2 L/ha (80 + 31.25 to 160 + 62.5 g ai/ha)	Apply when conditions favour disease development and prior to development of disease in the crop. Aim to apply no later than Z59. Use the higher rate specified in the rate column under high infection pressure or when longer residual protection is required. Lower rates are effective under lower disease pressure but have a reduced residual effect. Ensure thorough coverage.
	Leaf Scald (<i>Rhynchosporium secalis</i>)		Apply when conditions favour disease development and prior to development of disease in the crop. Aim to apply between early stem elongation and ear emergence (Z32–Z59). DO NOT apply later than Z59. Use the higher rate specified in the rate column under high infection pressure or when longer residual protection is required. Lower rates are effective under low disease pressure but have a reduced residual effect. Ensure thorough coverage.
	Net Form Net blotch (<i>Pyrenophora teres F. teres</i>)	1–2 L/ha (80 + 31.25 to	Apply when conditions favour disease development and prior to development of disease in the crop. Aim to apply between early stem elongation and ear emergence (Z32–Z59). DO NOT apply later than Z59. Use the higher rate specified in the rate column under high infection pressure or when longer residual protection is required. Lower rates are effective under low disease pressure but have a reduced residual effect. Ensure thorough coverage.
	Spot Form Net blotch		

	(<i>Pyrenophora teres</i> <i>F. maculata</i>) Leaf Rust (<i>Puccinia hordei</i>)	160 + 62.5 g ai/ha)	Addition of Banjo 1% v/v improves disease control especially at lower dose rates.
	Powdery mildew (<i>Blumeria</i> <i>gramminis f. sp.</i> <i>hordei</i>)	OR 500 mL – 1 L/ha + Banjo at 1% v/v (40 + 15.63 to 80 + 31.25 g ai/ha)	Apply when conditions favour disease development and prior to development of disease in the crop. Aim to apply between early stem elongation and ear emergence (Z32–Z59). Ensure disease levels do not exceed 5% of leaf area infection on any visible leaf prior to application of Tazer Xpert Fungicide. DO NOT apply later than Z59. Regularly monitor the crop from 2–3 weeks after the first application for signs of re-infection. Repeat applications may be required. Use the higher rate specified in the rate column under high infection pressure or when longer residual protection is required. Lower rates are effective under low disease pressure but have a reduced residual effect. Ensure thorough coverage. Addition of Banjo 1% v/v improves disease control especially at lower use rates.
Oats	Septoria leaf blotch (<i>Phaeosphaeria</i> <i>avenaria</i>)	500 mL – 1 L/ha + (40 + 15.63 to 80 + 31.25 g ai/ha)	Apply when conditions favour development of disease but before high levels of disease develop in the canopy. Repeat sprays may be needed if infection occurs early in crop development and conditions favour infection. Regularly monitor for signs of re-infection from first application. Use the higher rate specified in the rate column under high infection pressure or when longer residual protection is required. Lower rates are effective under low disease pressure but have a reduced residual effect. Ensure thorough coverage. DO NOT apply later than Z59

Restraints: Do not exceed a total rate of 2 L/ha of Tazer Xpert Fungicide for a growing season

Withholding periods:

Harvest: Not required when used as directed.

Grazing: Do not graze or cut for stock food for 3 weeks after application.

Export Slaughter Interval (ESI):

After observing the withholding period for grazing or cutting of stockfood, livestock that have been grazed on or fed treated crops should be placed on clean feed for 3 days prior to slaughter.

Export of treated produce: MRLs or import tolerances for azoxystrobin and epoxiconazole may not be established in all markets. If you are growing cereals for export, please check with Nufarm Australia Ltd for the latest information.

2.4 Results from residues trials presented to the APVMA

Four Australian GLP residue trials on oats were provided in support of the application. Other Australian and overseas data is available to support the use. Residues of azoxystrobin in oat grain at harvest after the last of 2 applications at the proposed rate up to growth stage Z59 were <0.005 (2), 0.034 and 0.051 mg/kg.

In trials on wheat at 42–87 days after a single application at 160 g ai/ha (1x proposed rate, at BBCH 22–BBCH 61), residues of azoxystrobin in wheat grain were ND (4) and <0.02 (2) mg/kg. For a wheat GAP of 250 g ai/ha, 2-3 applications and a PHI of 35–42 days, residues were <0.01 (13), 0.01 (6), 0.02 (3), 0.03 (3), 0.04 (2) and 0.14 mg/kg. Scaled for the proposed Australian rate of 160 g ai/ha the HR is 0.09 mg/kg.

In trials on barley at 42–87 days after a single application at 160 g ai/ha (1x proposed rate, at BBCH 22–BBCH 61), residues of azoxystrobin in barley grain were ND (3) and 0.03 mg/kg. For a barley GAP of 250 g ai/ha, 2-3 applications and a PHI of 35–42 days, residues were 0.01 (4), 0.02 (6), 0.03 (4), 0.04 (3), 0.05, 0.08 (3), 0.09, 0.10 (2), 0.11 (4), 0.12, 0.13 (3), 0.19, 0.20 and 0.28 mg/kg. Scaled for the proposed Australian rate of 160 g ai/ha the HR is 0.17 mg/kg.

The available data indicate that the current wheat and barley grain azoxystrobin MRLs are no longer appropriate. A new MRL of 0.1 mg/kg will be recommended for azoxystrobin on GC 0647 Oats, while the wheat MRL will be increased to 0.1 mg/kg and the barley MRL will be increased to 0.2 mg/kg.

Residues of azoxystrobin in oat stubble at 44–70 days after the last application at the proposed rate (80 g ai/ha) were 0.18, 0.39, 0.45, 0.94, 1.52 and 1.80 mg/kg on a dry weight basis. An MRL of 3 mg/kg is recommended for azoxystrobin on AS 0647 Oat straw and fodder, dry, in line with current MRLs for wheat and barley straw and fodder.

Residues of azoxystrobin in oat forage at 21 days after the last application at the proposed rate (80 g ai/ha) were 0.74, 0.86, 1.04, 1.35 (2), 2.33, 2.64 and 3.91 mg/kg on a dry weight basis. An MRL of 7 mg/kg is recommended for azoxystrobin on AF 0647 Oat forage (green) in conjunction with a 21 day grazing withholding period.

2.5 Overseas registration and approved label instructions

The applicant indicated that azoxystrobin products are registered in different formulations for use on cereal grains around the world.

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. Azoxystrobin has been considered by Codex. The following relevant Codex CXLs and overseas MRLs have been established for Azoxystrobin.

Table 1: Relevant Codex and overseas MRLs for azoxystrobin

COMMODITY	TOLERANCE FOR RESIDUES ARISING FROM THE USE OF AZOXYSTROBIN (mg/kg)					
	AUSTRALIA	EU ³	JAPAN ⁴	CODEX ⁵	TAIWAN	USA ⁶
Residue Definition	Azoxystrobin	Azoxystrobin	Azoxystrobin	Azoxystrobin	Azoxystrobin and its metabolites	Sum of azoxystrobin, [methyl(<i>E</i>)-2-(2-(6-(2-cyanophenoxy) pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate], and the <i>Z</i> -isomer of azoxystrobin [methyl(<i>Z</i>)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate]
Wheat	0.1 (proposed)	0.3	0.3	0.2	0.2	0.2
Barley	0.2 (proposed)	0.5	0.5	0.5	-	3
Oats	0.1 (proposed)	0.5	0.5 (other cereal grains) ⁷	0.5	-	1.5
Oat straw and fodder	3 (proposed)	-	Not established	15 (as cereal)	-	3
Oat forage	7 (proposed)	-	Not established	-	-	5
Oat hay	-	-	Not established	-	-	10

³ www.ec.europa.eu

⁴ www.mhlw.go.jp/english/topics/foodsafety/positivelist060228/index.html

⁵ www.codexalimentarius.net

⁶ www.ecfr.gov

⁷ 'Other cereal grains' refers to all cereal grains, except rice (brown rice), wheat, barley, rye, corn (maize), and buckwheat; see www.mhlw.go.jp/english/topics/foodsafety/positivelist060228/dl/r04.pdf

2.7 Current and proposed Australian MRLs for azoxystrobin

Table 2: Current MRL Standard - Table1

COMPOUND	FOOD	MRL (mg/kg)
AZOXYSTROBIN		
GC 0640	Barley	*0.02
MO 0105	Edible offal (Mammalian)	*0.01
PE 0112	Eggs	*0.01
MM 0095	Meat (mammalian)	*0.01
ML 0106	Milks	0.005
PO 0111	Poultry, Edible offal of	*0.01
PM 0110	Poultry meat	*0.01
GC 0654	Wheat	*0.02

Table 3: Proposed MRL Standard - Table1

COMPOUND	FOOD	MRL (mg/kg)
AZOXYSTROBIN		
DELETE:		
GC 0640	Barley	*0.02
GC 0654	Wheat	*0.02
ADD:		
GC 0640	Barley	0.2
GC 0647	Oats	0.1
GC 0654	Wheat	0.1

2.8 Potential risk to trade

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

As the changes in wheat and barley MRLs are not associated with a change in use pattern, there is no change to the trade risk associated with the uses on wheat and barley. The risk to trade in oats is considered to be low as the proposed Australian MRL is lower than those established in potential markets.

For oaten hay, standards for azoxystrobin are not established in *The Ordinance of the Standards of Feed Additives* (to May 2010⁸). The trade risk for oaten hay from treated crops is considered to be low.

3 CONCLUSIONS

Nufarm Australia Limited has made an application to register the new product Nufarm Tazer Xpert Fungicide. The product contains azoxystrobin and epoxiconazole as its only active constituents and will be used to control various diseases on wheat barley and oats. Use of epoxiconazole on wheat barley and oats will be the same as currently registered for other products and appropriate MRLs are established. Azoxystrobin is currently registered for use on wheat and barley at the same rates as proposed in conjunction with a 6 week harvest withholding period. It is proposed to establish a new MRL for azoxystrobin on oats and increase the current MRLs for azoxystrobin on wheat and barley.

Comment is sought on the potential for Nufarm Tazer Xpert Fungicide to prejudice Australian trade when used on oats.

⁸ www.famic.go.jp/ffis/feed/obj/shore_eng.pdf