Australian Government

Australian Pesticides and Veterinary Medicines Authority

TRADE ADVICE NOTICE

on Fluxapyroxad in the Product Systiva Seed Treatment Fungicide

APVMA Product Number P62412

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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, Office of Chemical Safety and Environmental Health (OCSEH), Department of the Environment, 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.

Making a submission

The APVMA invites any person to submit a relevant written submission as to whether the application to grant the registration of ***Systiva Seed Treatment Fungicide*** containing the existing active constituent fluxapyroxad 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. In relation to this document, these grounds relate to the **trade implications** of the extended use of the product. Comments received outside these grounds cannot be considered by the APVMA.

Submissions must be received by the APVMA by close of business on 15 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.

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:

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Phone: +61 2 6210 4701
Fax: +61 2 6210 4776
Email: enquiries@apvma.gov.au

Further information

Further information including a more detailed technical assessment report on the evaluation of the trade implications of this chemical can be obtained via the contact details provided above.

[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 product, Systiva Seed Treatment Fungicide, containing 333 g/L fluxapyroxad, in wheat and barley as a seed treatment. The proposed use requires an increase in the fluxapyroxad MRL for milk fats and establishment of a wheat MRL.

Fluxapyroxad is currently registered in Australia for foliar use on barley at the maximum rate of 62.5 g ai/ha with applications made no later than ear emergence (Z59). The harvest WHP is 'Not Required When Used as Directed' and the grazing WHP is 14 days.

The potential for fluxapyroxad residues arising from the proposed use of fluxapyroxad to unduly prejudice trade in wheat and barley animal commodities is discussed below.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Wheat and barley are considered to be major export commodities[2], as are animal commodities from livestock fed on treated crops.

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

The significant export markets for Australian beef, sheep, pig meat and offals are listed in APVMA Regulatory Guidelines—Data Guidelines: Agricultural—Overseas trade (Part 5B)[3].

Total exports of dairy products in 2012–13 were worth $2.17 billion, with key export destinations including Japan, Singapore, China, Indonesia, Malaysia, Thailand, the Philippines, Korea, Russia, and the USA.

[2] apvma.gov.au/node/1017#major_export_food_commodity_groups
[3] APVMA Regulatory Guidelines—Data Guidelines: Agricultural—Overseas trade (Part 5B)

2.3 Proposed Australian use-pattern

The proposed Australian use pattern for fluxapyroxad in wheat and barley is summarised below.

Table 1: Proposed use pattern of Systiva Seed Treatment Fungicide (333 g/L fluxapyroxad) in wheat and barley

CROP	DISEASES	RATE	CRITICAL COMMENTS
Barley	Loose smut (*Ustilago segetum var nuda*) Suppression of Rhizoctonia root rot (*Rhizoctonia solani*)	150 mL/100 kg seed (50 g ai/100 kg)	Apply diluted with sufficient water to ensure even coverage of seed. Apply with an applicator designed for liquid seed treatments. Calibrate application equipment for the flow rate of the grain. Systiva will provide suppression of Rhizoctonia and reduce severity of disease within the crop. Systiva has been shown to improve crop vigour and root development, which will further assist in overcoming disease symptoms.
	Powdery mildew (*Blumeria graminis f.* sp. *hordei)* Net form of net blotch (*Pyrenophora teres f. teres*) Scald (*Rhynchosporium secalis*) Spot form of net blotch (*Pyrenophora teres f. maculata*) Leaf Rust (*Puccinia hordei*		Systiva seed treatment is systemic and will provide ongoing residual activity. Typically, greater control and be seen on newly emerged, younger leaves. Foliar disease will be controlled in the crop canopy, including upper leaves, up to the time when the crop reaches the following growth stages, with good suppression thereafter: Powdery Mildew and Leaf Rust will be controlled to at least flag leaf emergence—BBCH 37, with good suppression thereafter. Net Form of Net Blotch, Spot Form of Net Blotch and Scald will be controlled to at least the middle of heading—BBCH 53 to BBCH 55, with good suppression thereafter.
Wheat	Bunt (*Tellitia* spp.) Rhizoctonia root rot (*Rhizoctonia solani*) Suppression of stripe rust (*Puccinina striiformis*)	150 mL/100 kg seed (50 g ai/100 kg)	Applied diluted with sufficient water to ensure even coverage of seed. Apply with an applicator designed for liquid seed treatments. Calibrate application equipment for the flow rate of the grain. SYSTIVA will provide suppression of Rhizoctonia and reduce severity of disease within the crop. SYSTIVA has been shown to improve crop vigour and root development, which will further assist in overcoming disease symptoms.

WITHHOLDING PERIODS

HARVEST: NOT REQUIRED WHEN USED AS DIRECTED
GRAZING: DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 4 WEEKS AFTER APPLICATION

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 2 days prior to slaughter.

2.4 Results from residues trials presented to the APVMA

The proposed use of fluxapyroxad in wheat and barley involves seed treatment application at a rate 50 g ai/100kg for the control of range of soil, seed and foliar fungal diseases.

A harvest withholding period of 'Not Required When Used as Directed', and a grazing withholding period of 4 weeks is proposed. Fluxapyroxad is currently registered in Australia for foliar use on barley at the maximum rate of 62.5 g ai/ha with applications made no later than ear emergence (BBCH59)[4]. The harvest WHP is 'Not Required When Used as Directed' and the grazing WHP is 14 days.

Details from five Australian trials in wheat (1) and barley (4) and fourteen overseas trials (8 in wheat and 6 in barley) undertaken at various rates with residues analysis of grain and various plant fractions were available for consideration.

Wheat:

At commercial harvest, residues of fluxapyroxad[5] (parent) in wheat grain at 1x and 2x the maximum proposed rate following seed treatment application were below the Limit of Detection (LOD = 0.005 mg/kg; LOQ = 0.01 mg/kg, n=2) in a trial conducted in Australia.

At commercial harvest, residues of fluxapyroxad in wheat grain at rates ranging from 0.8x to 1.5x the maximum proposed were <0.01 (LOQ) mg/kg (n=8) in overseas trials.

*Based on the available information, a permanent MRL of *0.01 mg/kg is considered appropriate for wheat (GC 0654) for the proposed use pattern in conjunction with a harvest WHP of 'Not Required When Used As Directed'.*

Barley:

At commercial harvest, residues of fluxapyroxad (scaled to 1x) in barley grain following seed treatment application were <LOD (LOD = 0.005 mg/kg, n=2, LOD = 0.02 mg/kg, n= 4), 0.016 and 0.02 mg/kg.

At commercial harvest, residues of fluxapyroxad in barley grain following seed treatment application made at a rate of 75g ai/100kg seed (1.5x the maximum proposed rate) and two foliar applications (growth stages no later than BBCH59 as per the label) made at a rate of 62.5 g ai/ha (1x the maximum registered label rate for barley) were in rank order 0.02, 0.02 and 0.04 mg/kg in trials conducted in Australia.

Based on the available data, no amendment to the current fluxapyroxad MRL of 0.2 mg/kg established for barley is proposed in conjunction with a harvest WHP of 'Not Required When Used as Directed'.

[4] Imbrex Fungicide, APVMA No. 64101 (https://portal.apvma.gov.au/pubcris).
[5] In Australia, the residue definition of fluxapyroxad for enforcement purpose is fluxapyroxad.

Cereal forage and fodder

Seed treatment application

At 19–29 days after sowing residues of fluxapyroxad (scaled to 1x the maximum proposed rate) in *barley forage* were in rank order 0.61, 0.74, 0.75, 0.77, 0.95, 1.7, 2.0, 2.8, 2.9, 3.3, 3.7, 5.4 and 6.6 mg/kg on a dry weight basis.

At 19–29 days after sowing residues of fluxapyroxad (scaled to 1x the maximum proposed rate) in *wheat forage* were in rank order 0.76, 1.2, 2.5, 2.9, 3.0, 10.3 and 12.3 mg/kg on a dry weight basis.

At commercial maturity, residues of fluxapyroxad (scaled to 1x the maximum proposed rate) in *barley hay* were in rank order <LOD, 0.02, 0.02, 0.03, 0.03, 0.04, 0.04 and 0.04 mg/kg in trials conducted in Australia.

At commercial maturity, residues of fluxapyroxad (scaled to 1x the maximum proposed rate) in *barley straw* were in rank order <LOD (2), 0.01, 0.02 (2), 0.04, 0.05 and 0.18 mg/kg in trials conducted in Australia.

At commercial harvest, residues of fluxapyroxad in *wheat straw* or *fodder* at rates ranging from 0.8x to 1x the maximum proposed were 0.01, 0.02, 0.06 and 0.08 mg/kg.

Seed treatment and foliar application

At PHIs of 13–14 days after the second foliar application (made at growth stages no later than BBCH59 as per the registered label for barley) at 1x the maximum registered label rate for barley and seed treatment made at 1.5x the maximum proposed rate, residues of fluxapyroxad in *barley forage* were 1.4, 2.5 and 7 mg/kg on a dry weight basis.

The trials which involved seed treatment application (1.5x) and two foliar applications (1x the maximum label rate) resulted in fluxapyroxad residues of 1.9, 2.2 and 4.0 mg/kg in *barley hay* at commercial maturity.

The trials which involved seed treatment application (1.5x) and two foliar applications (1x the maximum label rate) resulted in fluxapyroxad residues of 0.07, 0.7 and 3.0 mg/kg in *barley straw* at commercial maturity.

Based on the available information, the current barley forage, straw and fodder (dry) MRLs established at 7 mg/kg will be replaced by a permanent MRL of 20 mg/kg for Forage and Fodder of Cereal Grains in conjunction with a grazing WHP of 28 days.

Animal feed commodities and MRLs

Wheat forage can form 100% of the diet for beef cattle and 60% for dairy. The estimated maximum livestock dietary burden for fluxapyroxad is approximately 12.3 ppm for beef cattle and approximately 7.4 ppm for lactating cattle.

Based on the feeding studies (18 ppm), the expected residues and established MRLs for ruminants are summarised as:

Cattle

FEEDING LEVEL (ppm)	MILK	MUSCLE	LIVER	KIDNEY	FAT	CREAM
	FLUXAPYROXAD RESIDUE (mg/kg)					
18	0.00631	<0.01	0.0317	<0.01	0.0585	0.0564
12.3—beef, estimated burden		<0.01	0.0217	<0.01	0.040	
7.4—dairy, estimated burden	0.0026	<0.01	0.0130	<0.01	0.024	0.023
Established MRLs	0.005 (milks)		0.03 (offal)		0.05	

For milk fats it is assumed cream is 40% fat, to give a fluxapyroxad residue of 0.06 mg/kg in milk fat. The current milk fat MRL of 0.02 mg/kg will be amended to 0.1 mg/kg.

2.6 Overseas registration and approved label instructions

Registrations for Systiva seed treatment, or similar seed treatment formulations containing fluxapyroxad exist in the following countries.

COUNTRY	BARLEY	USE RATE	WHEAT	USE RATE	OTHER CROPS
Belarus	Yes	50 g ai/100 kg	Yes	50 g ai/100 kg	Triticale
Bulgaria	Yes	50 g ai/100kg	Yes	50 g ai/100 kg	Triticale
Canada	No	-	No	-	soybean
Czech Republic	Yes	33.3–50 g ai/100 kg	Yes	33.3–50 g ai/100 kg	Oats
France	Yes	50 g ai/100 kg	Yes	50 g ai/100 kg	Oats, triticale
Greece	Yes	33.3–50 g ai/100 kg	Yes	33.3–50 g ai/100 kg	Oats, triticale
Italy	Yes	33.3–50 g ai/100 kg	Yes	33.3–50 g ai/100 kg	Oats, triticale
New Zealand	Yes	25–41.6 g ai/100 kg	Yes	25–41.6 g ai/100 kg	-
Poland	Yes	50 g ai/100 kg	Yes	50 g ai/100 kg	Triticale
Romania	Yes	25–50 g ai/100 kg	Yes	25–50 g ai/100 kg	Triticale
Russian Federation	Yes	16.65–33.3 g ai/100 kg	Yes	16.65–33.3 g ai/100 kg	-
Slovakia	Yes	50 g ai/100 kg	Yes	50 g ai/100 kg	-
Ukraine	Yes	50 g ai/100 kg	Yes	50 g ai/100 kg	-
United States	Yes	4.4–43.1 g ai/100 kg	Yes	4.4–43.1 g ai/100 kg	Grain legumes, corn, cotton, sorghum

2.7 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. The following relevant international MRLs have been established for fluxapyroxad:

Table 2: Comparison of fluxapyroxad MRLs (mg/kg) for wheat and barley animal commodities

COUNTRY	COMMODITY	FLUXAPYROXAD TOLERANCE (mg/kg)
Australia[6]	All other foods	0.1
	Barley	0.2
	Barley bran, unprocessed	0.5
	Edible offal (mammalian)	0.03
	Eggs	0.005
	Meat [mammalian][in the fat]	0.05
	Milk fats	0.02 (proposed 0.1)
	Milks	0.005
	Poultry, Edible offal of	*0.01
	Poultry meat [in the fat]	*0.01
Codex[7]	Wheat	0.3
	Barley	2
	Edible offal (mammalian)	0.1
	Eggs	0.02
	Maize	0.01
	Meat (mammalian other than marine mammals)	0.2
	Milk fats	0.5
	Milks	0.02

[6] apvma.gov.au/node/10806

[7] www.codexalimentarius.net/pestres/data/index.html

COUNTRY	COMMODITY	FLUXAPYROXAD TOLERANCE (mg/kg)
	Poultry fats	0.05
	Poultry meat	0.02
	Poultry, Edible offal of	0.02
EU[8]	Barley	2
	Wheat	0.4
	Bovine and sheep muscle	0.02
	Bovine and sheep fat	0.2
	Bovine and sheep liver	0.1
	Bovine and sheep kidney	0.1
	Bovine and sheep edible offal	0.1
	Milk	0.02
Japan[9]	Wheat	0.3
	Barley	3
	Cattle muscle	0.2
	Cattle fat	0.2
	Cattle edible offal	0.1
	Milk	0.02
	Poultry muscle	0.02
	Poultry fat	0.05
	Poultry offal	0.02
Canada[10]	Wheat	0.3
	Barley	3
	Meat of cattle	0.01
	Meat of poultry	0.01
	Milk	0.005
USA[11]	Grain, cereal, group 15 (except corn, field, grain; except corn, pop, grain; except corn	3

[8] ec.europa.eu/food/plant/pesticides/pesticides_database/index_en.htm
[9] www.m5.ws001.squarestart.ne.jp/foundation/agrdtl.php?a_inq=62450
[10] pr-rp.hc-sc.gc.ca/mrl-lrm/index-eng.php

[11] www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title40/40cfr180_main_02.tpl

COUNTRY	COMMODITY	FLUXAPYROXAD TOLERANCE (mg/kg)
	kernels plus cobs with husks removed; except wheat)	
	Wheat	0.3
	Cattle, fat	0.05
	Cattle, meat	0.01
	Cattle, meat byproducts	0.03
	Milk	0.005
	Sheep, fat	0.05
	Sheep, meat	0.01
	Sheep, meat by products	0.03

2.6 Current and proposed Australian MRLs for fluxapyroxad

Current relevant MRLs and the residue definition for fluxapyroxad are presented below. A full listing of MRLs can be found at http://apvma.gov.au/node/10806.

Table 3: Current entries in the MRL Standard

MRL STANDARD: TABLE 1

COMPOUND		FOOD	MRL (mg/kg)
FLUXAPYROXAD			
		All other foods	0.1
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
		Milk fats	0.02
ML	0106	Milks	0.005
PO	0111	Poultry, Edible offal of	*0.01
PM	0110	Poultry meat [in the fat]	*0.01

MRL Standard: Table 3

COMPOUND	RESIDUE
FLUXAPYROXAD	Commodities of plant origin: Fluxapyroxad
	Commodities of animal origin for enforcement: Fluxapyroxad
	Commodities of animal origin for dietary exposure assessment: Sum of fluxapyroxad and 3-(difluoromethyl-N-(3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide (M700F008)

MRL STANDARD: TABLE 4

COMPOUND	FOOD	MRL (mg/kg)
FLUXAPYROXAD		
	Barley forage	7
AS 0640	Barley straw and fodder, dry	7
	Primary feed commodities (except barley forage; barley straw and fodder, dry)	1

The following changes are proposed to Australian fluxapyroxad MRLs:

Table 4: Proposed changes to the MRL Standard—Table1

MRL STANDARD: TABLE 1

COMPOUND	FOOD	MRL (MG/KG)
FLUXAPYROXAD		
DELETE:		
	Milk fats	0.02
ADD:		
	Milk fats	0.1
GC 0654	Wheat	*0.01

Table 5: Proposed changes to the MRL Standard—Table4

MRL STANDARD: TABLE 4

COMPOUND	FOOD	MRL (MG/KG)
FLUXAPYROXAD		
DELETE:		
	Barley forage	7
AS 0640	Barley straw and fodder, dry	7
	Primary feed commodities (except barley forage; barley straw and fodder, dry)	1
ADD:		
	Forage and fodder of cereal grains	20
	Primary feed commodities (except forage and fodder of cereal grains)	1

2.7 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.

Quantifiable residues are not expected to occur in wheat grain after seed treatment. Thus the risk to trade is considered to be low. For barley grain, the current MRL remain appropriate and the risk to trade remains low.

An MRL of 0.1 mg/kg is recommended for milk fats which is lower than Codex MRL, noting that the Australian (whole) milks MRL remains at a level the same as, or below, that of the EU, Japan and the USA.

In the dairy cattle transfer study after dosing with fluxapyroxad for 28 days at approximately 60 ppm in the feed, residues of parent in all tissues fell to below the LOQ after a further 2 days on clean feed. A 2 day export slaughter interval (ESI) the same as on the fluxapyroxad *Imbrex* label is considered appropriate for Systiva Seed Treatment Fungicide, which will result in no quantifiable residues in animal commodities for export.

3 CONCLUSIONS

The proposed use requires an increase to the fluxapyroxad MRL for milk fats and establishment of wheat MRL. Comments are sought on the potential for fluxapyroxad residues resulting from the proposed use of Systiva Seed Treatment Fungicide in wheat and barley to unduly prejudice Australian trade in wheat, barley and milk and milk products, and the ability of industry systems to manage any identified risk.