Australian Government

Australian Pesticides and Veterinary Medicines Authority

TRADE ADVICE NOTICE

on Isoxaflutole in the Product Balance 750 WG Herbicide

APVMA Product Number P49456

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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 the Australian Government regulator 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 proposed extensions of use for existing chemicals where there may be trade implications, as defined in *Ag MORAG: Manual of Requirements and Guidelines* Part 5B.

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 for the extension of use of **Balance 750 WG Herbicide** containing the active constituent isoxaflutole 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 **20 March 2013** 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:

Contact Officer, Pesticides
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Kingston ACT 2604
Phone: 02 6210 4748
Fax: 02 6210 4776
Email: pesticides@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: 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 Bayer CropScience to vary the label of Balance 750 WG Herbicide, containing 750 g/kg isoxaflutole. The product is proposed for use in fallow situations.

A change to the residue definition is proposed as the benzoic acid metabolite (2-methylsulfonyl-4-trifluoromethylbenzoic acid) is a common metabolite with pyrasulfotole, and is not currently included in the residue definition for pyrasulfotole. This change in the residue definition requires a change to the MRL for chickpeas.

New residue data for chickpea forage indicates the need for change to the MRL for isoxaflutole in Edible offal (mammalian). The proposed use also requires establishment of permanent MRLs for isoxaflutole in cereals.

The potential for isoxaflutole residues to unduly prejudice trade is discussed below.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Cereals and chickpeas are primary export commodities, as are commodities from animals that have received feeds containing residues arising from the proposed use. Oaten hay is also a major export commodity.

2.2 Destination and value of exports

Australian exports of wheat totalled 18639 kt and were valued at ~ $5526m in 2010-11[2]. Australian exports of coarse grains totalled 5337 kt and were valued at ~$1493m in 2010-11[2]. Barley was the most significant export (~$1295m) and oat exports were valued at ~$37m. Triticale exports were worth ~$149m in 2010-2011[2].

Major export markets by value are shown below (Australian Commodity Statistics 2011 and other sources).

Table 1: Major export markets for Australian cereal grains

GRAIN	MAJOR DESTINATIONS
Barley	China, Japan, Middle East, Rep. of Korea
Sorghum	Japan
Oats	Statistics not available
Triticale	Statistics not available
Wheat	Asia including Indonesia, Japan, Rep. of Korea, Bangladesh, Malaysia, Thailand, China; Middle East including Iraq, Yemen; Egypt

Australian exports of chick-peas were worth $213 million in 2010-11. Information on the Pulse Australia website indicates the main export markets for Australian chick-peas are India, Bangladesh, Pakistan and the United Arab Emirates.[3]

[2] http://adl.brs.gov.au/data/warehouse/agcstd9abcc002/agcstd9abcc0022011/ACS_2011_1.0.3.pdf

[3] www.pulseaus.com.au/pdf/Australian%20Pulse%20Market%20News/Australian%20Pulse%20Market%20News%20Background%20Facts%202012.pdf

Approximately 720 kilotonne of hay is exported from Australia, to the value of ~$230-250 million, per annum.[4] 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.

The significant export markets for animal commodities are defined in Part 5B of Ag MoRaG.

2.3 Proposed Australian use-pattern

The proposed Australian use pattern for Balance 750 WG Herbicide is summarised below. Balance 750 WG Herbicide is currently approved for use post sowing / pre-emergence on chickpeas.

Table 2: Proposed use pattern

Balance 750 WG Herbicide (750 g/kg isoxaflutole)

Crop	Pest	Rate	Critical Comments
Fallow prior to planting of crops as directed under the *Crop rotation recommendation section*	**Weeds controlled** Fleabane (*Conyza bonariensis*), Sowthistle (*Sonchus oleraceus*), Feathertop Rhodes grass (*Chloris virgate*) **Weeds suppressed** Barnyard grass (*Echinochloa colona*)	100 g/ha (75 g ai/ha)	Balance may be applied following crop harvest but not less than the period specified under **Crop rotation recommendations**. Minimum recropping intervals apply for all crops following Balance application. Best results are obtained where a complete and even application of Balance is applied to weed-free soil prior to weed germination and sufficient rainfall occurs after application and prior to weed emergence to wet soil to allow herbicide uptake by germinating weeds. Cultivation following application may reduce pre-emergence weed control provided by Balance. Balance will not control emerged weeds when applied alone. Emerged weeds must be controlled by prior cultivation or by application of a knockdown herbicide. Refer to the compatible products listed below for an appropriate knockdown herbicide to apply with Balance in this situation. Weed control may be reduced by prolonged wet soil conditions following application. Weed escapes may require follow up application of knockdown herbicides.

[4] Personal communication, AFIA, August 2010

Withholding periods:
Harvest:
Crops planted after summer fallow: NOT REQUIRED WHEN USED AS DIRECTED
Grazing:
DO NOT GRAZE TREATED WEEDS AND STUBBLE IN A SUMMER FALLOW SITUATION
DO NOT GRAZE OR CUT FOR STOCKFOOD A CROP SOWN FOLLOWING A FALLOW SPRAY FOR 6 WEEKS AFTER SOWING

Crop rotation recommendations

Balance 750 WG may be applied to chickpea crops where the following crop will be chickpeas, or when the land will be left fallow. The following recropping instructions apply to following crops other than chickpeas.

- Prolonged dry periods or cold conditions may result in extended re-cropping intervals, even if rainfall exceeds the required amount (listed in the table below). If in doubt contact your local Bayer CropScience representative.
- Heavy rainfall after an extended dry period may result in the reactivation of Balance 750 WG. This can lead to transient bleaching or crop stunting.
- Use on soils with a pH less than 7.0 has not been extensively tested, and may result in extended recropping intervals.
- Cultivation recommended prior to recropping.
- Minimum recropping intervals apply for all crops following Balance application. For advice on crops not listed below, contact the manufacturer, Bayer CropScience Pty Ltd.

CROP	MINIMUM RECROPPING INTERVAL	MINIMUM RAINFALL REQUIREMENT*
Wheat	10 weeks**	100 mm
Barley	10 weeks**	100 mm
Oats	10 weeks**	100 mm
Canola	9 months	350 mm
Faba beans	9 months	250 mm
Field peas	9 months	250 mm
Vetch	9 months	250 mm
Lentils	21 months	500 mm
Clover	21 months	500 mm
Lucerne	9 months	350 mm
Medic	21 months	500 mm
Maize	10 weeks**	100 mm
Mung beans	7 months	250 mm
Sorghum	7 months	250 mm
Soybeans	7 months	250 mm
Sunflowers	7 months	250 mm
Cotton	7 months	350 mm

*Minimum rainfall total from Balance use until planting of the subsequent crop. **Do not include flood or furrow irrigation in the minimum rainfall requirement.**

**If Balance has been tank-mixed with simazine, observe the recropping interval for simazine for wheat, barley, oats and maize.

The Applicant has proposed that the benzoic acid metabolite (2-methylsulfonyl-4-trifluoromethylbenzoic acid) be removed from the residue definition for isoxaflutole. The benzoic acid metabolite is a common metabolite with pyrasulfutole.

OCS have confirmed that the benzoic acid metabolite is not considered to be toxicologically significant in their report for this isoxaflutole evaluation.

The applicant has provided supporting documentation to show that the residue definition for isoxaflutole has already been revised in the EU and NAFTA regions.

The proposal to remove the benzoic acid metabolite from the residue definition for isoxaflutole is acceptable.

This change in residue definition is not expected to impact on the current MRLs for isoxaflutole, with the exception of the chick-pea (dry) MRL.

Validated analytical methods are available for determining isoxaflutole and the diketonitrile metabolite in plant and animal commodities.

2.4 Results from residues trials presented to the APVMA

Plant Commodities:

Chickpeas

The maximum GAP for chickpeas on the draft label is for a fallow application at 75 g ai/ha followed by an application at 75 g ai/ha post sowing, pre emergence.

Residues of isoxaflutole and diketonitrile in chick-pea seed at harvest after application at 75 g ai/ha 4 months before sowing and 75 g ai/ha post sowing, pre-emergence were <0.02 mg/kg (n = 3). Residues in chick-pea seed were also <0.02 mg/kg (n = 3) after application at twice the proposed rate.

It is proposed that the current MRL of *0.03 mg/kg for isoxaflutole on VD 0524 Chick-pea (dry) is changed to *0.02 mg/kg to take account of the recommended change to the residue definition for isoxaflutole.

Residues of isoxaflutole and diketonitrile in chickpea stubble at harvest after application at 75 g ai/ha 4 months before sowing and 75 g ai/ha post sowing, pre-emergence were <0.02 mg/kg (n = 3). Residues in chick-pea stubble were also <0.02 mg/kg (n = 3) after application at twice the proposed rate. It is proposed that the MRL for isoxaflutole on AL 0524 Chick-pea fodder at 0.03 mg/kg is replaced with an MRL at *0.02 mg/kg.

Residues of isoxaflutole and diketonitrile in chickpea forage at 42-49 days after application at 75 g ai/ha 4 months before sowing and 75 g ai/ha post sowing, pre-emergence were <0.02, 0.04 and 0.08 mg/kg (fresh weight). On a dry weight basis residues were <0.1, 0.2 and 0.42 mg/kg. Residues in forage at 42 – 49 days after sowing with application at 2× (150 + 150 g ai/ha) were 0.03, 0.04 and 0.09 mg/kg (fresh weight). The highest dry weight residue for the 2× treatment is estimated to be 0.47 mg/kg.

* Denotes that the maximum residues limit (MRL) has been set ‘at or about the limit of analytical quantification.

It is recommended that the grazing withholding period for chickpeas is increased from 4 weeks to 6 weeks in line with the residue data supplied in support of this application. The current MRL of 0.3 mg/kg for isoxaflutole on Chick pea forage (fresh weight) is proposed to be replaced with an MRL of 0.5 mg/kg for Chick-pea forage, which reflects the new residue definition and residues found after a fallow treatment and treatment at planting.

Cereals

Residues of isoxaflutole and diketonitrile in cereal grain at harvest after a fallow treatment at 75 g ai/ha 4 months prior to sowing were <0.02 mg/kg (n = 6). Residues in grain were also <0.02 mg/kg after fallow treatment at up to 225 g ai/ha (3×). An MRL of *0.02 mg/kg is proposed for isoxaflutole on GC 0080 Cereal grain

Residues of isoxaflutole and diketonitrile in cereal stubble at harvest after a fallow treatment at 75 g ai/ha 4 months prior to sowing were <0.02 mg/kg (n = 6). Residues in stubble were also <0.02 mg/kg after fallow treatment at up to 225 g ai/ha (3×). The moisture content of the stubble samples ranged from 3 – 52%. An MRL of *0.02 mg/kg is proposed for isoxaflutole on AS 0081 Straw and fodder (dry) of cereal grains.

Residues of isoxaflutole and diketonitrile in cereal forage 42 days after sowing with a fallow treatment at 75 g ai/ha 4 months prior to sowing were <0.02 mg/kg (n = 6). Residues in forage were also <0.02 mg/kg in all other samples of forage after fallow treatment at up to 225 g ai/ha (3×). The moisture content of the forage samples ranged from 80 – 89%. An MRL of *0.02 mg/kg is proposed for isoxaflutole on Cereal forage (fresh weight).

Other crops

Other crops which may be planted after a fallow treatment with isoxaflutole include oilseeds (canola, sunflowers and cotton), pulses (faba beans, field peas, lentils, mung beans and soybeans) and vetch, clover, lucerne and medic. Residue data for these crops has not been provided although the minimum re-cropping interval for these crops ranges from 7 – 21 months (compared to 10 weeks for cereals, except sorghum).

Based on the results of a confined accumulation study (supported by a corn metabolism study and soil half lives for parent), residues of parent and the diketonitrile metabolite are not expected to occur in crops planted at ~4 months or more after treatment. It is therefore not considered necessary to establish MRLs for the other crops which will be grown 7 – 21 months after treatment of fallow with isoxaflutole.

Animal Commodities:

The maximum livestock dietary exposure for cattle will be as a result of the consumption of chickpea forage containing a highest residue of 0.42 mg/kg as 100% of the diet as calculated below:

Table 3: Dietary intake modelling for isoxaflutole in cattle- 500 kg bw, 20 kg DM/day

Commodity	% in diet	Feed intake	Residue, mg/kg	% DM	Livestock dietary exposure		
					mg/animal	ppm	mg/kg bw
Chickpea forage	100	20	0.42	100	8.4	0.42	0.0168

A dairy cattle transfer study for isoxaflutole was provided when Balance 750 WG Herbicide was first registered for use on sugar cane.

Lactating Holstein dairy cows (3-6 years old; 445-817 kg bw) were fed isoxaflutole at 0, 4.7, 14.4 and 45.5 ppm in the diet via an oral bolus for 42 days, 2 animals for the control group, 4 animals/dosing group. Milk samples were collected ca. twice a week and consisted of pooled AM and PM samples. Samples of milk were analysed for isoxaflutole and metabolites RPA 202248, RPA 205834 and RPA 203328 by HPLC with UV detection (LOQ 0.02 mg/kg). Tissue samples were analysed for isoxaflutole, RPA 202248, RPA 205834 and RPA 207048 using a LC/MS/MS method (LOQ 0.05 mg/kg).

Residues of isoxaflutole and metabolites in tissues are summarised below.

Table 4: Residues of isoxaflutole and metabolites (mg/kg) in tissues of dairy cows fed at 4.7, 14.4 and 45.5 ppm in the feed for 42 days

Tissue	Dose group (ppm)	Isoxaflutole	RPA 202248 (diketonitrile)	RPA 205834	RPA 207048
Muscle	45.5	ND-0<0.05	<0.05	<0.05	<0.05
Fat	45.5	ND	<0.05	<0.05-0.090	ND-<0.05
Kidney	45.5	ND	0.447-0.505	<0.05-0.060	<0.05
	14.4	-	0.173-0.296	<0.05	<0.05
	4.7	-	0.114-0.166	ND-<0.05	<0.05
Liver	45.5	ND	1.70-1.84	0.560-0.810	<0.05-0.068
	14.4	ND	0.475-1.09	0.210-0.299	<0.05
	4.7	ND	0.499-0.770	0.071-0.105	<0.05

LOQ = 0.05 mg/kg

No changes are required to the current MRLs of *0.05 mg/kg for isoxaflutole in ML 0106 Milks or MM 0095 Meat (mammalian).

The highest residue of the diketonitrile metabolite in offal after feeding at 4.7 ppm was 0.770 mg/kg in liver with parent not detected. Scaled to a 0.42 ppm feeding level the predicted residue in liver is 0.07 mg/kg. The

current MRL of *0.05 mg/kg for isoxaflutole in MO 0105 Edible offal (mammalian) should be increased to 0.1 mg/kg.

No changes are required to the current MRLs for Eggs, Poultry, Edible offal and Poultry meat each established at *0.05 mg/kg.

2.5 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. Isoxaflutole has not been considered by Codex.

The following overseas MRLs / tolerances have been established isoxaflutole.

Table 5: Overseas residue MRLs/tolerances for isoxaflutole

Country/status	Commodity	Tolerance, (expiry date) mg/kg	Residue definition
EU	Peas (Chickpeas, field peas, chickling vetch)	*0.05	Sum of isoxaflutole and RPA 202248, expressed as isoxaflutole
	Cereals	*0.05	
Japan	Wheat	0.05 (2012.12.13)	The MRLs are established for the parent compound isoxaflutole for plant products; and as the sum of isoxaflutole and its metabolite, 2-cyano-3-cyclopropyl-4-(2-methylsulfonyl-4-trifluoromethylphenyl)propane-1,3-dione, expressed as isoxaflutole equivalent, for animal products
	Barley	0.05 (2012.12.13)	
	Corn (maize, including pop corn and sweet corn)	0.02 / 0.1 (2012.12.13)	
	Other cereal grains	0.05 (2012.12.13)	
USA	Corn, field, forage	0.04	Compliance with the tolerance levels specified below is to be determined by measuring only the sum of isoxaflutole ((5-cyclopropyl-4-isoxazolyl) [2-(methylsulfonyl)-4-(trifluoromethyl)phenyl] methanone) and its metabolite 1-(2-methylsulfonyl-4-trifluoromethylphenyl)-2-cyano-3-cyclopropyl propan-1,3-dione (RPA 202248), calculated as the stoichiometric equivalent of isoxaflutole, in or on the commodity
	Corn, field, grain	0.02	
	Corn, field, stover	0.02	
	Grain, aspirated fractions	0.30	
	Soybean, seed	0.05	

The following overseas animal commodity MRLs /tolerances have been established:

Country	Commodity	Tolerance, mg/kg (expiry date)
Japan (Residue definition for animal products: the sum of isoxaflutole and its metabolite,	Cattle, muscle	0.2
	Cattle fat	0.2
	Cattle, liver	0.5
	Cattle kidney	0.1

2-cyano-3-cyclopropyl-4-(2-methylsulfonyl-4-trifluoromethylphenyl)propane-1,3-dione, expressed as isoxaflutole equivalent)	Cattle, edible offal	0.1
	Milk	0.02 / 0.03 (2012.12.13)

Animal commodity MRLs are not established for isoxaflutole in the EU, USA or Taiwan.

2.6 Current and proposed Australian MRLs for isoxaflutole

Current relevant MRLs and the residue definition for isoxaflutole are presented below. A full listing of MRLs can be found at www.apvma.gov.au/residues/standard.php.

Table 6: Current relevant entries in the MRL Standard – Table 1, Table 3 and Table 4

MRL STANDARD: TABLE 1

COMPOUND		FOOD	MRL (mg/kg)
ISOXAFLUTOLE			
VD	0524	Chick-pea (dry)	*0.03
MO	0105	Edible offal (mammalian)	*0.05
PE	0112	Eggs	*0.05
MM	0095	Meat (mammalian)	*0.05
ML	0106	Milks	*0.05
SO	0698	Poppy seed	*0.02
PO	0111	Poultry, Edible offal of	*0.05
PM	0110	Poultry meat	*0.05
GC	0659	Sugar cane	*0.01

MRL Standard: TABLE 3

COMPOUND	RESIDUE
ISOXAFLUTOLE	The sum of isoxaflutole, 2-cyclopropylcarconyl-3-(2-methylsulfonyl-4-trifluoromethylphenyl)-3-oxopropanenitrile and 2-methylsulfonyl-4-trifluoromethylbenzoic acid expressed as isoxaflutole

MRL STANDARD: TABLE 4

COMPOUND		ANIMAL FEED COMMODITY	MRL (mg/kg)
ISOXAFLUTOLE			
AL	0524	Chick-pea fodder	0.03

COMPOUND		ANIMAL FEED COMMODITY	MRL (mg/kg)
		Chick pea forage (fresh weight)	0.3
AM	0659	Sugar cane fodder	*0.01

The following changes are proposed to Australian isoxaflutole MRLs:

Table 7: Proposed changes to the MRL Standard – Table1, Table 3 and Table 4

MRL STANDARD: TABLE 1

COMPOUND		FOOD	MRL (mg/kg)
ISOXAFLUTOLE			
DELETE:			
VD	0524	Chick-pea (dry)	*0.03
MO	0105	Edible offal (mammalian)	*0.05
ADD:			
GC	0080	Cereal grains	*0.02
VD	0524	Chick-pea (dry)	*0.02
MO	0105	Edible offal (Mammalian)	0.1

MRL Standard: TABLE 3

COMPOUND	RESIDUE
DELETE:	
Isoxaflutole	The sum of isoxaflutole, 2-cyclopropylcarconyl-3-(2-methylsulfonyl-4-trifluoromethylphenyl)-3-oxopropanenitrile and 2-methylsulfonyl-4-trifluoromethylbenzoic acid expressed as isoxaflutole
ADD:	
Isoxaflutole	The sum of isoxaflutole and 2-cyclopropylcarbonyl-3-(2-methylsulfonyl-4-trifluoromethylphenyl)-3-oxopropanenitrile expressed as isoxaflutole

MRL STANDARD: TABLE 4

COMPOUND		ANIMAL FEED COMMODITY	MRL (mg/kg)
ISOXAFLUTOLE			
DELETE:			
AL	0524	Chick-pea fodder	0.03
		Chick pea forage (fresh weight)	0.3

COMPOUND		ANIMAL FEED COMMODITY	MRL (mg/kg)
ADD:			
		Cereal forage (fresh weight)	*0.02
AL	0524	Chick-pea fodder	*0.02
		Chick-pea forage	0.5
AS	0081	Straw and fodder (dry) of cereal grains	*0.02

2.7 Potential risk to trade

Export of treated produce containing finite (measurable) residues of isoxaflutole 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 risk to trade in cereal grain and chickpeas is considered to be low as detectable residues are not expected to occur in the grain/seed at harvest. The risk to trade in oaten hay after a fallow treatment is also considered to be low as detectable residues are also not expected to occur.

There is a potential risk to trade in animal commodities as the proposed use as a fallow treatment followed by the registered use on chickpeas would require an increase to the mammalian offal MRL to 0.1 mg/kg. Appropriate MRLs for isoxaflutole are not established in all the export markets for Australian animal commodities. However, the highest predicted residue in liver (0.07 mg/kg) is just above the LOQ for the method (0.05 mg/kg) and is based on the assumption that a fallow treatment will be followed by treatment of chickpeas post sowing / pre-emergent and that the resulting chickpea forage will form 100% of the diet for grazing livestock immediately prior to slaughter. It is also noted that the risk of residues in livestock will likely be less than currently exists as an increase to the grazing withholding period for chickpeas from 4 to 6 weeks has been proposed.

3 CONCLUSIONS

It is proposed to increase the MRL for isoxaflutole on Edible offal (mammalian), amend the MRL for chickpeas and establish MRLs for cereals.

Comments are sought on the potential for isoxaflutole in Balance 750 WG Herbicide to prejudice Australian trade when it is used in fallow situations.