Australian Government

Australian Pesticides and Veterinary Medicines Authority

TRADE ADVICE NOTICE

on Pyraflufen-ethyl in the Product Ecopar Forte Herbicide

APVMA Product Number P65209

JULY 2012

The Manager, Public Affairs
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604
Australia

Email: communications@apvma.gov.au

ISSN: 2200-3894
ISBN: 978-0-9873529-4-1

This document is published by the APVMA. In referencing this document the APVMA should be cited as both author and publisher.

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

CONTENTS

List of tables

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 to vary the registration of **Ecopar Forte Herbicide** containing the existing active constituent pyraflufen-ethyl 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 **7 August 2012** 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 Sipcam Pacific Australia Pty Ltd to vary the registration of the product, *Ecopar Forte Herbicide*, containing 40 g/L pyraflufen-ethyl, to include the control of annual broadleaf weeds in oats. When applied to oaten crops, the product will be mixed with a registered MCPA amine product prior to application (similar to the registered use-pattern for wheat, barley and triticale). The proposed extension of use does not require any MRL changes to the current MRL standards for pyraflufen-ethyl.

The use of MCPA is at no greater rate or later growth stage than currently approved and the use of MCPA will not be considered further.

Cereal grains are exported along with meat and dairy products from animals that have been fed feeds containing residues arising from the proposed use. The potential for pyraflufen-ethyl residues in oat grains and animal commodities to unduly prejudice trade is discussed below.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Oat grains are considered to be a major export commodity, as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock feeding on treated animal feeds. Residues in these commodities resulting from the use of *Ecopar Forte Herbicide* may have the potential to unduly prejudice trade.

2.2 Destination and value of exports

Cereal grains

Export volumes and values for cereals, including oats, are tabulated below.

Table 1: Value of Australian Cereal Exports 2006-07 to 2010-11

COMMODITY	EXPORT VALUE ($ MILLION)				
	2006-07	2007-08	2008-09	2009-10	2010-11
Wheat (including flour)	2315	3354	5116	3778	5867
Barley (including malt)	833	1496	1321	1093	1295
Oats	20	37	64	53	37
Sorghum	13	76	405	116	146
Maize	9	11	30	19	15
Triticale	44	113	93	120	149

Source: Australian Bureau of Agricultural and Resource Economics and Sciences (ABARES), Australian commodity statistics, 2011

Details of the export destination of Australian oats were not presented in the ABARES Australian commodity statistics (2011) due to confidentiality restrictions. However, the following key export destinations from 2008 are available.[2]

[2] faostat.fao.org/site/537/default.aspx

Table 2: Major export markets for Australian oat, 2008

EXPORT COMMODITY	KEY EXPORT MARKET	EXPORTS (TONNE)	EXPORTS ($ MILLION)
Oats	Philippines	6 774	2.19
	Japan	3 865	2.15
	Saudi Arabia	1 400	0.48
	USA	1 100	0.59
	United Arab Emirates	1 032	0.40
Oats, rolled	China	13 751	8.42
	Malaysia	13 607	8.63
	Philippines	10 697	7.42
	India	8 879	5.55
	New Zealand	3 376	3.07

Approximately 720 kilotonne of hay is exported from Australia, to the value of ~$230-250 million, per annum.[3] 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.

[3] Private communication, AFIA, August 2010

Animal Commodities

The significant export markets for Australian meat, kidney and liver are listed in Appendix 3 of Part 5B of Ag MORAG. The destination and value of Australian dairy exports are summarised in Table 1 below.

Table 3: Destination and value of Australian dairy exports

DESTINATION	VALUE OF AUSTRALIAN EXPORTS OF DAIRY PRODUCTS, BY DESTINATION ($ MILLION)						
	2002-03	2003-04	2004-05	2005-06	2006-07	2007-08	2008-09
CHEESE							
Japan	272.0	299.6	378.9	298.5	337.9	426.7	398.9
Saudi Arabia	98.9	69.0	81.5	103.5	86.7	89.7	30.6
United States	36.1	33.9	45.4	54.2	52.7	37.2	59.7
Other	393.3	336.7	370.9	381.0	346.9	414.8	306.9
TOTAL	800.3	739.2	876.7	837.2	824.2	968.4	796.1
BUTTER AND BUTTER FAT							
Egypt	18.9	6.4	10.5	12.5	13.9	5.0	22.0
Malaysia	12.7	13.5	11.6	15.8	11.0	17.4	14.0
Singapore	15.5	18.2	16.8	21.1	14.4	26.2	20.2
Other	176.9	144.8	149.6	175.3	139.3	146.0	175.9
TOTAL	224.0	182.9	188.5	224.7	178.6	194.6	232.1
SKIM MILK POWDER							
Malaysia	51.4	52.7	64.2	77.1	72.2	63.4	49.0
Philippines	71.8	60.1	49.4	72.0	46.1	64.1	99.7
Singapore	38.4	42.4	57.8	56.1	67.1	61.8	54.0
Other	246.9	232.3	248.7	323.7	319.6	343.9	350.2
TOTAL	408.5	387.5	420.1	528.9	505.0	533.2	552.9

CASEIN							
Japan	20.6	23.3	23.1	30.4	31.8	38.4	43.6
United States	81.4	68.8	56.6	27.3	32.4	42.2	29.5
Other	26.4	30.5	36.5	31.3	49.3	44.2	34.4
TOTAL	128.4	122.5	116.2	89.0	113.5	124.8	107.5
WHOLEMILK POWDER							
Malaysia	22.3	28.9	33.1	23.8	14.5	27.3	14.9
Singapore	25.2	21.4	30.9	44.6	41.4	88.9	77.0
Taiwan	44.9	40.0	31.5	22.8	13.5	11.8	9.3
Other	284.4	231.6	228.9	242.4	205.4	264.1	374.2
TOTAL	379.8	321.8	324.4	333.6	274.9	392.2	475.3
OTHER PRODUCTS							
Fresh milk	98.2	104.0	108.8	107.3	96.3	83.6	102.1
Other fresh products	5.6	9.6	9.1	6.3	11.8	12.0	0.4
Condensed milk	133.3	121.0	139.8	147.5	156.9	152.4	158.9
Other powders	274.4	257.3	248.3	241.5	211.0	247.4	249.7
TOTAL	511.5	492.0	506.0	502.6	476.0	495.5	511.1
TOTAL DAIRY PRODUCTS	2,453	2,246	2,432	5,516	2,372	2,709	2,675
Source: ABARES, Australian commodity statistics 2009, Canberra							

2.3 Proposed Australian use-pattern

The proposed Australian use pattern for *Ecopar Forte Herbicide* (40 g/L pyraflufen-ethyl) in oats is summarised below.

Table 4: Proposed use pattern

Ecopar Forte Herbicide (40 g/L pyraflufen-ethyl)

Crop	Weeds Controlled	Rate/Ha	Critical Comments
Oats	Wild radish (*Raphanus raphanistrum*)	150 to 200 mL plus 330 mL Agroxone® 750 (or 500 mL of a 500 g/L amine formulation of MCPA)	Apply as a post-emergence treatment to actively growing weeds up to the 6 leaf stage and when the crop is between 2 leaves and mid-late tillering (Zadoks 12-25). Always tank mix with MCPA amine. Use the higher rates on larger weeds or dense infestations. Under favourable growing conditions some weed regrowth may occur. A follow up application of a suitable herbicide e.g., 2,4-D amine, may be required as part of a good weed management strategy.
	Bedstraw (*Galium tricornutum*), Bifora (*Bifora testiculata*), Capeweed (*Arctotheca calendula*), Indian hedge mustard (*Sisymbrium orientale*), Long storks bill (*Erodium botrys*), Prickly lettuce (*Lactuca serriola*), Volunteer canola (*Brassica napus*), Volunteer lupin (*Lupinus sp*), Wild turnip (*Brassica tournefortii*)	200 mL plus 330 mL Agroxone® 750 (or 500 mL of a 500 g/L amine formulation of MCPA)	

RESTRAINTS:
DO NOT tank mix ECOPAR Forte Herbicide plus MCPA amine with any wetter, crop oil concentrates or blended oil/surfactant adjuvants (see compatibility section).
DO NOT tank mix MCPA LVE with ECOPAR Forte Herbicide.
DO NOT tank mix ECOPAR Forte Herbicide plus MCPA amine treatments with selective grass herbicides.
DO NOT apply the tack mix of ECOPAR Forte Herbicide plus MCPA amine before the two leaf crop stage.
DO NOT apply metsulfuron methyl (ESTEEM) tank mixes on oats.
DO NOT apply with aircraft.
DO NOT apply if rain is expected within 6 hours of application.
DO NOT apply to weeds suffering from stress caused by conditions such as frost, drought, soil water logging etc.

WITHHOLDING PERIOD:
HARVEST: NO WITHHOLDING PERIOD REQUIRED WHEN USED AS DIRECTED.
GRAZING (CEREALS): DO NOT GRAZE OR CUT FOR STOCK FOOD FOR 14 DAYS AFTER APPLICATION.

2.4 Results from residues trials presented to the APVMA

Cereal grains

The proposed use pattern for pyraflufen-ethyl on oats is the same as that approved for wheat, barley and triticale, and involves a single application of pyraflufen-ethyl at a rate of 8 g ai/ha when the crop is between 2 leaves and mid-late tillering (BBCH 12-25).

The Australian trials on oats involved a single application of pyraflufen-ethyl made at a rate of 8 g ai/ha in combination with 250 g MCPA/ha up to BBCH growth stage 23-28. Residues on pyraflufen-ethyl were not detected in oat grain, hay or straw at harvest in all three trials. Oat forage was collected 7 days after application and residues of pyraflufen-ethyl were 0.48, 0.51 and 0.84 mg/kg.

In the ten trials submitted during the original evaluation of *Ecopar 20SC Herbicide*, residues in wheat, barley and triticale grains following the application of pyraflufen-ethyl at a rate of 8 or 20 g ai/ha were not detected at crop maturity. When pyraflufen-ethyl was applied at a rate of 20 g ai/ha (2.5x the proposed use pattern), residues in the forage 14 days after application were 0.4, 0.6, 0.83, 0.94 and 1.1 mg/kg.

From the available data, it is considered that the established cereal grains MRL of *0.02 mg/kg is appropriate to cover the proposed use of pyraflufen-ethyl on oats. Residues in oat forage are unlikely to be significantly different to those in other cereal forage and the previously established cereal straw and forage MRL of 1 mg/kg remains appropriate for this use, in conjunction with a 14 day withholding period.

Animal Commodities

Oat forage can contribute up to 100% of the animal's diet. There is no proposal to amend the pyraflufen-ethyl MRLs associated with cereal straw and fodder and therefore the proposed use should not result in the current animal commodity MRLs being exceeded. No change to the animal commodity MRLs which are established at the LOQ for pyraflufen-ethyl are required at this time. For a full discussion of the potential risk to trade in animal commodities when animals consume treated feeds, please refer to the previous Trade Advice Notice for *Ecopar Herbicide*.[4]

[4] www.apvma.gov.au/registration/assessment/docs/prs_ecopar.pdf
*denotes that the maximum residues limit (MRL) has been set at or about the limit of analytical quantification'.

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.

Pyraflufen-ethyl has not been considered by Codex. The EU have established a MRL for oats of *0.02 mg/kg, while Japan have established a MRL for other cereal grains (which includes oats) of 0.02 mg/kg. Residues of pyraflufen-ethyl are not expected in Australian oat grain following treatment according to the proposed use. Animal feed MRLs for pyraflufen-ethyl have not been established in Japan, the major export market for Australian oaten hay.[5] As this is a negative list there is not considered to be a risk to trade. Additionally, detectable residues of pyraflufen-ethyl are not expected to occur in the tissue or milk of animals that have been fed oat forage or fodder treated according to the proposed use. Therefore, there is no perceived risk to Australian trade.

[5] www.famic.go.jp/ffis/feed/r_safety/r_feeds_safety22.html#pesticides, June 2012

2.6 Current and proposed Australian MRLs for pyraflufen-ethyl

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

Table 5: Current relevant entries in the MRL Standard – Table 1, Table 3 and Table 4

MRL STANDARD: TABLE 1

COMPOUND		FOOD	MRL (mg/kg)
PYRAFLUFEN-ETHYL			
GC	0080	Cereal grains	*0.02
SO	0691	Cotton seed	*0.05
MO	0105	Edible offal (Mammalian)	*0.02
PE	0112	Eggs	*0.02
MM	0095	Meat (mammalian)	*0.02
ML	0106	Milks	*0.02
PO	0111	Poultry, Edible offal of	*0.02
PM	0110	Poultry, meat	*0.02

MRL STANDARD: TABLE 3

COMPOUND	RESIDUE
PYRAFLUFEN-ETHYL	Sum of pyraflufen-ethyl and its acid metabolite (2-chloro-5-(4-chloro-5-difluoromethoxy-1-methylpyrazol-3-yl)-4-fluorophenoxyacetic acid)

MRL STANDARD: TABLE 4

COMPOUND		ANIMAL FEED COMMODITY	MRL (mg/kg)
PYRAFLUFEN-ETHYL			
		Pasture (mixed grass / leguminous)	3
AS	0081	Straw and fodder (dry) of cereal grains	1.0

No changes to the current MRL standards for pyraflufen-ethyl are necessary at this time.

2.7 Potential risk to trade

Export of treated produce containing finite (measurable) residues of pyraflufen-ethyl 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.

Pyraflufen-ethyl has not been considered by Codex or the majority of Australian export markets. However, both the EU and Japan have established MRLs that cover the use of pyraflufen-ethyl on oats at 0.02 mg/kg. Residues of pyraflufen-ethyl are not expected in Australian oat grain following treatment according to the proposed use. Animal feed MRLs for pyraflufen-ethyl have not been established in Japan, the major export market for Australian oaten hay. Additionally, detectable residues of pyraflufen-ethyl are not expected to occur in the tissue or milk of animals that have been fed oat forage or fodder treated according to the proposed use. Therefore, there is no perceived risk to Australian trade.

3 CONCLUSIONS

No changes to the current MRL standards for pyraflufen-ethyl are necessary at this time. Comment is sought on the potential for pyraflufen-ethyl residues to prejudice Australian trade when *Ecopar Forte Herbicide* is used to control annual broadleaf weeds in oats and when treated feeds are fed to animals.

A more detailed technical assessment report on the evaluation of the trade implications of this chemical can be obtained by contacting the APVMA at 02 6210 4748. Alternatively, the reports can be viewed at the APVMA Library, which is located at:

18 Wormald Street
Symonston ACT, 2609

Office hours: 9.00am–5.00pm (EST) Monday to Friday