Australian Government

Australian Pesticides and Veterinary Medicines Authority

TRADE ADVICE NOTICE

on Glufosinate-ammonium in the product Basta Non-Selective Herbicide

APVMA Product Number 39118

FEBRUARY 2013

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ISSN: 2200-3894 (electronic)
ISBN: 978-1-922188-19-9 (electronic)

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The Manager, Public Affairs
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604 Australia
Telephone: +61 2 6210 4701
Email: communications@apvma.gov.au
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 (OCS), Department of Sustainability Environment, Water, Population and Communities (DSEWPaC), 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 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 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 **Basta Non-Selective Herbicide** 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 **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:

Pesticides Contact Officer
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Symonston ACT 2609
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 Pty Ltd, to register Basta Non-Selective Herbicide for control of various weeds in fallow situations prior to sowing cereals, oilseeds or pulses.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Cereal grains, oilseeds (cotton and canola), and pulses, and oaten hay are exported, and are considered major export commodities in Appendix 1 of Part 5B of Manual of Requirements and Guidelines for Agricultural Products. New MRLs are proposed for cereal grains, oilseeds and pulses.

Mammalian or poultry animal commodities derived from stock fed grain or seed, grain or seed byproducts, forage or fodder from treated cereal, pulse and oilseed crops may be exported. No changes are required to existing MRLs for animal commodities, and residues in livestock consuming treated feed connected with the proposed use pattern are expected to be lower than residues arising from existing use patterns. Residues in animal commodities will therefore not be considered further.

2.2 Destination and value of exports of Cereals, Oilseeds and Pulses

Exports of Australian cereals, pulses, canola, and cotton, are detailed below (Agricultural Commodity Statistics 2012, Australian Bureau of Agriculture and Resource Economics and Sciences, Commonwealth of Australia).

Total exports of barley were 6568 kilotonnes in 2011/12, valued at $1.68 billion. Total exports of wheat (including flour) were 23038 kilotonnes in 2011/12, valued at $6.38 billion. Total exports of oats in 2011/12 were 163 kilotonnes, valued at $47 million. Exports of sorghum in 2011/12 were 1112 kilotonnes, valued at $299 million. Maize exports in 2011/12 were 68 kilotonnes, valued at $24 million.

Total oilseed exports in 2011/12 (including canola, cottonseed, linseed, peanuts, safflower, soya bean and sunflower were 2982 kilotonnes, worth $1.55 billion. Total vegetable oil exports (including canola, cottonseed, linseed, palm, peanut, safflower, soya bean, sunflower and olive) were 140 kilotonnes, at a value of $234 million, in 2011/12. Total oilseed meal exports in 2011/12 were 93.8 kilotonnes at a value of $33.5 million.

Total exports of lupin in 2011/12 were 244 kilotonnes, valued at $65.3 million. Total exports of field peas in 2011/12 were 248 kilotonnes, valued at $93.5 million. Total exports of chick peas in 2011/12 were 653 kilotonnes, valued at $385 million. Total pulse exports were 2069 kilotonnes, values at $1.02 billion, in 2011/12.

Table 1 - Major destinations for Australian cereal, pulse and oilseed exports

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
Sorghum	Japan, New Zealand, Taiwan, Papua New Guinea
Cottonseed (including seed, oil, and meal)	Japan, Korea, the USA
Canola (including seed, oil and meal)	Belgium, the Netherlands, Pakistan, Japan

Approximately 720 kilotonnes 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.

2.3 Proposed Australian use-pattern

Table 2 - Proposed use pattern

Situation	Weed	Weed stage	Rate	Critical Comments
Maintenance of summer fallow prior to planting: Cereal grains (including wheat, barley, oats, maize and sorghum) Pulses (including chickpeas, faba beans, field peas, lentils, lupins, and mung beans), Oilseeds (including canola, cotton, soybeans, and sunflowers) Do not sow	Control of: Annual polymeria Bellvine Bladder ketmia Caltrop Dwarf amaranth Field bindweed (European bindweed) Flax-leaf fleabane Paddy melon Peach vine Red pigweed Rhyncho	2-6 leaf	3.75 L/ha (750 g ai/ha) in a minimum of 100 L water	Apply to actively growing weeds. Good coverage is essential. Refer to 'Application' section for details. DO NOT apply more than three applications per season. Basta will have an effect on weeds that are larger than the recommended leaf stage, but speed of activity and level of control may be reduced. CLIMATIC CONDITIONS Best results are achieved when Basta is applied under warm humid conditions (temperatures below 33 °C with a relative humidity above 50%). Under any other conditions, efficacy and speed of action may be

[2] Personal communication, AFIA, August 2010

Situation	Weed	Weed stage	Rate	Critical Comments
crops until 14 days have elapsed after the final application.	(Rhyncosia) Sesbania pea Sowthistle (milk thistle) Volunteer cotton (other than Liberty Link cotton) Yellow vine Suppression of: Chinese lantern (wild gooseberry) Noogoora burr complex			reduced. DO NOT apply onto weeds when dew, fog, or mist is present.

Withholding periods:

Grazing:
DO NOT graze or cut treated areas for stock food for 8 weeks after application.
DO NOT graze or cut for stock food a crop sown following a fallow spray for 6 weeks after sowing.

2.4 Results from residues trials presented to the APVMA

Cereals, pulses and oilseeds:

The applicant provided a series of ten residue trials conducted in Australia (two each in maize, barley, chickpeas, soya beans and mung beans). In these trials, 3 × 750 g ai/ha applications of glufosinate-ammonium were made to bare soil using commercial formulations at an approximate re-treatment interval of 14 days. The crop was sown into the treated soil at various intervals from the day of the last application, to approximately 4 months after the last application. Forage was sampled at a range of intervals from approximately 4 to 8 weeks after sowing, corresponding to 4 to 16 weeks after the last application.

A package of trials conducted in the USA (13 in maize and 28 in soya beans) was provided. In these trials, a single application of glufosinate-ammonium was made around the time of sowing, at application rates ranging from 0.5-7.5 pounds ai/acre, or 561-8414 g ai/ha. In the maize trials, forage was sampled once for each site, typically around 9-12 weeks after application, with plant material for silage product being sampled later, typically around 14-20 weeks after application, and cobs, grain and fodder being sampled at harvest.

In the soya bean trials, seed was collected at harvest at all sites, with forage (at appropriate intervals shortly after application) and straw (at harvest) being collected from two sites. At two sites for soya beans, and at one site for maize, additional seed was processed into various commercial products.

In the Australian trials in barley, maize, soya bean, mung bean and chickpea, which were conducted in accordance with the proposed GAP, residues were below the LOQ (0.10 mg/kg) in all forage, straw, stubble, grain and seed samples, with the exception of a single soya bean stubble sample containing a low level of MPPA (0.14 mg/kg).

In the US trials, a single application of glufosinate-ammonium was made to the soil close to sowing of maize or soya beans at various rates between 0.75x and 11x the proposed application rate. No parent compound was found above the LOQ in any of the samples. No residues of parent or metabolite were found above the LOQ in any maize sample from a plot treated at 1683 g ai/ha (1.5 lb ai/acre) or less (2.2x the proposed application rate). Low levels of MPPA (up to 0.17 mg/kg) were found in a few samples of forage, fodder, silage, cobs and grain from plots treated at 3365 or 8414 g ai/ha (3 or 7.5 lb ai/acre; 4.5x or 11x the proposed application rate). Only two soya bean seed samples, and one soya bean forage sample contained residues of MPPA above the LOQ, at levels up to 0.07 mg/kg, which is below the method LOQ of 0.1 mg/kg for the Australian trials. No residues were found above the LOQ in any of the processed soya bean or maize commodities.

Based on the data package, residues of glufosinate-ammonium and its metabolites NAG and MPPA are not likely to be detected above the limit of quantitation in seed or grain from treated cereal, pulse or oilseed crops. It is therefore proposed to establish group MRLs at the limit of quantitation (*0.1 mg/kg), for glufosinate-ammonium in cereal, pulses and oilseeds.

The residue data package for barley, maize, soya beans, mung beans and chickpeas show that residues of glufosinate-ammonium and its metabolites NAG and MPPA are unlikely to be found above the combined limit of quantitation of 0.3 mg/kg in forages or fodders from cereal, pulse or oilseed crops (one sample of soya bean stubble contained residues of MPPA at 0.14 mg/kg, a level slightly above the LOQ. As the residue trial results for forage and fodder were reported on a fresh weight basis, the MRLs are adjusted to a dry weight basis for cereal, pulse and oilseed forages, for consistency with the convention in Table 4 of the MRL Standard.

Therefore, the proposed MRLs are: 0.5 mg/kg for cereal straw and fodder, oilseed fodder, and pulse fodder, and 2 mg/kg for cereal, pulse and oilseed forages.

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.

Glufosinate-ammonium has been evaluated by Codex. CXLs established are tabulated below.

The following relevant residue tolerances for glufosinate-ammonium in cereal, oilseed and pulse commodities have been established:

Table 3 - Proposed Australian and overseas MRLs/tolerances for glufosinate-ammonium

Country	Commodity	Tolerance, mg/kg	Reference
Australia	Cereal grains	*0.1	Proposed by APVMA.
	Oilseeds	*0.1	
	Pulses	*0.1	
	Cereal forage	2	
	Cereal straw and fodder	0.5	
Codex	Broad bean (dry)	2	www.codexalimentarius.net/pestres/data/index.html
	Common bean (dry)	2	
	Maize	0.1	
	Peas (dry)	3	
	Rape seed	5	
	Rape seed oil, Crude	*0.05	
	Soya bean (dry)	2	
	Sunflower seed	5	
	Sunflower seed oil, Crude	*0.05	
Japan	Corn, grain [maize]	0.1	Japan Ministry of Health, Labour and Welfare, www.mhlw.go.jp; Japan Food Chemical Research Foundation
	Corn, sweet	0.1	
	Wheat	0.2	
	Barley	0.5	
	Buckwheat	0.3	
	Cottonseed	4	
	Rape seed [canola]	5	
	Sunflower seed	5	
	Soya bean	2	
	Beans, dried	2	
	Peas	3	
	Broad beans	2	
	Peanuts, dried	0.1	
	Other legumes/pulses	3	
	Grass	15	Regulation Value of Pesticides, Food and Agricultural Materials Inspection Center
Korea	Cottonseed	3	MRLs for Pesticides in Foods, www.kfda.go.kr
Taiwan	Corn, grain [maize]	0.1	Standards for Pesticide Residue Limits in Foods, www.fda.gov.tw
	Soya bean	2	
USA	Canola meal	1.1	US Code of Federal Regulations Title 40, Chapter I, subchapter E, Part 180, Tolerances and Exemptions from Tolerances for Pesticide Chemicals in Food, 11 January 2013 (www.gpoaccess.gov/cfr/index.html)
	Canola seed	0.4	
	Field corn grain	0.2	
	Sweet corn kernels plus cob with husks removed	0.3	
	Cotton, undelinted seed	4	
	Rice grain	1	
	Soya bean	2	

Country	Commodity	Tolerance, mg/kg	Reference
EU	Beans [dry]	*0.1	EU Pesticides Database.
	Lentils	3	
	Peas [dry]	3	
	Lupins	3	
	Other pulses	3	
	Linseed	1	
	Peanuts	*0.1	
	Poppy seed	1	
	Sesame seed	*0.1	
	Sunflower seed	5	
	Rape seed	5	
	Soya bean	2	
	Mustard seed	*0.1	
	Cotton seed	*0.1	
	Pumpkin seeds	*0.1	
	Safflower	*0.1	
	Borage	*0.1	
	Gold of pleasure	*0.1	
	Hempseed	*0.1	
	Castor bean	*0.1	
	Other oilseeds	*0.1	
	Barley	*0.1	
	Buckwheat	*0.1	
	Maize	0.5	
	Millet	*0.1	
	Oats	*0.1	
	Rice	*0.1	
	Rye	*0.1	
	Sorghum	*0.1	
	Wheat	*0.1	
	Other cereals	*0.1	

2.6 Current and proposed Australian MRLs for glufosinate-ammonium

The Australian residue definition for glufosinate-ammonium is:
The sum of glufosinate-ammonium, *N*-acetyl glufosinate, and 3-[hydroxy(methyl)-phosphinoyl]propionic acid, expressed as glufosinate (free acid).

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

Table 4 - Current Food MRLs in the Maximum Residue Limit Standard (Table 1)

Compound	Food			MRL (mg/kg)
Glufosinate-ammonium	FI	0030	Assorted tropical and sub-tropical fruits – inedible peel	0.2
	FB	0018	Berries and other small fruits	0.1
	FC	0001	Citrus fruits	0.1
	SB	0716	Coffee beans	T*0.05
	SO	0691	Cotton seed	3
	FT	0295	Date	T0.1
	MO	0105	Edible offal (mammalian)	5
	PE	0112	Eggs	*0.05
	DH	1100	Hops, dry	T1
			Lemon myrtle	T20
	MM	0095	Meat (mammalian)	0.1
	ML	0106	Milks	*0.05
			Native foods [except lemon myrtle]	T0.1
	FT	0305	Olives	*0.1
	FP	0009	Pome fruits	*0.1
	PO	0111	Poultry, Edible offal of	*0.1
	PM	0110	Poultry meat	*0.05
	SO	0495	Rape seed	*0.05
			Saffron	T*0.05
	FS	0012	Stone fruits	*0.05
	DT	1114	Tea, Green, Black	T20
	VO	0448	Tomato	*0.05
	TN	0085	Tree nuts	0.1

Table 5 - Current Animal feed Commodities in the Maximum Residue Limit Standard (Table 4)

Compound	Animal feed commodity			MRL (mg/kg)
Glufosinate-ammonium			Canola forage	5
			Canola meal	0.2
			Canola straw and fodder (dry)	3
			Cotton seed meal and hulls	5
	AS	0162	Hay or fodder (dry) of grasses	5
			Mixed pasture (legume/grasses)	15

Table 6 - Proposed changes for Basta Non-Selective Herbicide in the Maximum Residue Limit Standard (Table 1)

Compound	Food			MRL (mg/kg)
Glufosinate-ammonium DELETE:	SO	0495	Rape seed	*0.05
ADD:	GC	0080	Cereal grains	*0.1
	SO	0088	Oilseeds [except cottonseed]	*0.1
	VD	0070	Pulses	*0.1

Table 7 - Proposed changes for Basta Non-Selective Herbicide in the Maximum Residue Limit Standard (Table 4)

Compound	Animal feed commodity			MRL (mg/kg)
Glufosinate-ammonium ADD:	AF	0081	Forage of cereal grains (green)	2
			Forage of pulse crops (green)	2
			Oilseed fodder [except canola straw and fodder (dry)]	0.5
			Oilseed forage [except canola forage]	2
	AS	0081	Straw and fodder (dry) of cereal grains	0.5
			Straw and fodder (dry) of pulse crops	0.5

2.7 Potential risk to trade

Export of treated produce containing finite (measurable) residues of glufosinate-ammonium 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.

Cereals, oilseeds, and pulses

The risk to trade in cereals, oilseeds and pulses is expected to be low, as residues of glufosinate-ammonium are not expected to be found above the limit of quantitation. Many overseas markets for cereals, oilseeds and pulses already have tolerances established, generally at higher levels. Codex MRLs have also been established for a number of pulse and oilseed commodities. There is a chance of finding low level residues in oaten hay, and an MRL of 0.5 mg/kg is proposed for glufosinate-ammonium in cereal straw and fodder. Japan has an MRL of 15 mg/kg for glufosinate-ammonium in ‘grass’.

Stakeholders are requested to provide comment on the potential risks to trade in cereal grains, oilseeds, and pulses, and oaten hay.

3 CONCLUSIONS

The risk to trade in cereals, oilseeds and pulses is expected to be low, as residues of glufosinate-ammonium are not expected to be found above the limit of quantitation. Many overseas markets for cereals, oilseeds and pulses already have tolerances established, generally at higher levels. Codex MRLs have also been established for a number of pulse and oilseed commodities. There is a slight chance of finding low level residues in oaten hay, and an MRL of 0.5 mg/kg is proposed for glufosinate-ammonium in cereal straw and fodder.

Comments are sought on the potential for Basta Non-Selective Herbicide to unduly prejudice Australian export trade in cereal grains, oilseeds and pulses, and oaten hay when it is used for weed control in fallow areas prior to sowing cereal, oilseed, and pulse crops.