Trade Advice Notice

on

Imidacloprid

in the product

Gaucho 350 Flowable Seed Dressing Insecticide
(product number 46226)

October 2009

1. PREFACE

1.1 About this Document

This is a Trade Advice Notice.

It indicates that the Australian Pesticides and Veterinary Medicines Authority (APVMA) is considering an application for registration of an 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 notice.

The APVMA will only consider comment on submissions that relate to the **trade implications** of the extended use of the product. Comments received outside these grounds will not be considered by the APVMA. Comments made on appropriate grounds will be considered with details posted on the APVMA website noting what action has/will be taken in regard to concerns.

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 at:
http://www.apvma.gov.au/registration/data_requirements_subpage.shtml

1.2 Prior to Submission

Please note that subject to the *Freedom of Information Act 1982*, the *Privacy Act 1988* and the Agvet Codes, all submissions received may be made publicly available. They may be listed or referred to in any papers or reports prepared on this subject matter.

The APVMA reserves the right to reveal the identity of a respondent (you) unless a request for anonymity accompanies your submission. If no request for anonymity is made, you will be taken to have consented to the disclosure of your identity for the purposes of Information Privacy Principle 11 of the *Privacy Act 1988.*

The contents of any submission will not be treated as confidential or confidential commercial information unless they are marked as such and you have provided justification such that the material is capable of being classified as confidential or confidential commercial information in accordance with the *Freedom of Information Act 1982* or the Agvet Codes as the case may be.

1.3 About this consultation

The APVMA invites comment on this Trade Advice Notice until 28 November 2009**.**
Submissions should be addressed to:

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2. INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Bayer CropScience Pty Ltd to extend the use of *GAUCHO 350 FLOWABLE SEED DRESSING INSECTICIDE*, containing the active ingredient imidacloprid at 350 g/L, to faba beans, field peas and lentils for control of aphids. As a result of this application, changes are also proposed to the withholding period and MRL associated with the registered use pattern for lupins.

The potential for imidacloprid residues in these commodities to unduly prejudice trade is discussed below.

No changes to animal commodity MRLs are required and they will not be considered further.

3. TRADE CONSIDERATIONS

3.1 Commodities Exported

Faba beans, field peas, lentils and lupins, together with meat and dairy products, are exported in varying quantities. It is proposed to establish a new MRL for imidacloprid in broad beans, field peas, lentils and to increase the current MRL for lupins.

3.2 Destination and Value of Exports

Export volumes and values for various pulse crops are tabulated below (Australian Bureau of Agricultural and Resource Economics figures). Total exports in 2007-08 were valued at $386.7 million.

Australian Pulse Exports (2003-04 to 2007-08)

Commodity	2003-04	2004-05	2005-06	2006-07	2007-08
Lupins					
Total production (kt)	1180.0	937.0	1285.0	470.0	331.0
Exports (kt)	645.6	418.5	469.5	173.7	50.0
Export value ($m)	147.7	88.8	99.4	37.8	21.3
Field Pea					
Total production (kt)	487.0	289.0	585.0	140.0	267.5
Exports (kt) #	209.3	116.1	156.1	247.7	142.2
Export value ($m)	55.6	33.4	43.2	80.1	61.1
Chick Peas					
Total production (kt)	178.0	115.6	122.8	232.4	313.0
Exports (kt)	163.8	151.2	211.4	244.1	218.1
Export value ($m)	70.6	65.3	106.4	168.2	139.0
Total legumes*					
Total production (kt)	2396.1	1683.3	2619.4	1057.8	1250.3
Exports (kt)	2041.7	1328.7	1706.9	1146.7	619.3
Export value ($m)†	588.0	397.1	533.0	483.9	386.7

includes on field peas and cow peas

* includes lupins, field peas, chickpeas, faba beans, mung beans, navy beans, vetch and lentils

The ten largest export markets for Australian lentils, peas (dry) and beans (dry) by quantity in 2005 are shown below (Food and Agriculture Organization of the United Nations figures). Lupins are primarily exported to Korea; with Japan, Spain and The Netherlands other export markets (*pers. comm.* Pulses Australia).

Export Markets for Australian Pulses (2005)

Lentils		Peas, Dry		Beans, Dry	
Destination	**Tonnes**	**Destination**	**Tonnes**	**Destination**	**Tonnes**
Unspecified	29,105	India	49,504	Saudi Arabia	15,590
Pakistan	25,111	Malaysia	23,388	Sri Lanka	7,523
Sri Lanka	23,179	Sri Lanka	22,092	Egypt	5,944
Bangladesh	15,496	Bangladesh	10,500	Philippines	2,939
Egypt	11,965	Belgium	3,764	Taiwan	2,522
Mauritius	1,123	Mauritius	3,241	Malaysia	2,165
Yemen	616	Taiwan	1,884	Yemen	1,929
South Africa	492	Philippines	935	United Kingdom	1,423
UAE	489	Yemen	889	India	1,242
Lebanon	328	Bahrain	864	Belgium	697

3.3 Proposed Australian Use-Pattern

The proposed Australian use patterns for *GAUCHO 350 FLOWABLE SEED DRESSING INSECTICIDE*, are detailed in the table below.

Crop	Pest	Rate	Critical Comments
Faba beans	Aphids	200 mL/100 kg of seed (70 g ai/100 kg of seed)	Gaucho will protect seedlings from early season aphid infestation. Gaucho does not affect the viability of Rhizobia when Gaucho is mixed with inoculant.
Field peas		100 mL/100 kg of seed (35 g ai/100 kg of seed)	
Lentils		400 mL/100 kg of seed (140 g ai/100 kg of seed)	

Withholding periods:
Harvest: Not required when used as directed
Grazing: Do not graze or cut for stock food within 16 weeks of sowing.

Application:
Use a range of 400-600 mL of total volume (e.g. Gaucho plus water) with each 100 kg of seed. Do not use a volume of more than 600 mL with each 100 kg of seed.

Protection of livestock:
Seed treated with this product must not be used for animal consumption or poultry feed or mixed with animal feed. DO NOT allow seed treated with this product to contaminate seed intended for animal consumption.

Export of treated produce:
Growers should note that MRLs or import tolerances do not exist in all markets for edible produce treated with Gaucho. If you are growing edible produce for export, please check with Bayer CropScience Pty Ltd for the latest information on MRLs and import tolerances before using Gaucho.

The currently registered use patterns for imidacloprid use as a seed dressing on lupins are as follows.

Crop	Pest	Rate	Critical Comments
Lupins	Blue oat mite, redlegged earth mite	300 mL/100 kg of seed (180 g ai/100 kg of seed) or 250 g/100 kg of seed (175 g ai/100 kg of seed)	Gaucho will protect emerging seedlings for 3-4 weeks after sowing. Monitoring should commence within this period to ensure gaucho performance and determine the need for supplementary control measures.

Withholding periods:
Harvest: Not required when used as directed.
Grazing: Do not graze or cut for stock food within 6 weeks or 9 weeks (depending on product) of sowing.

3.4 Results from residues trials presented to the APVMA

Ten Australian residue studies for imidacloprid in faba beans (2 studies), field peas (4 studies) and lupins (4 studies) were provided. A single application of imidacloprid was applied to seed prior to sowing at rates of either 72, 105, 144 or 216 g ai/100 kg of seed. Seed was sown at rates ranging from 80 to 150 kg/ha. Samples of forage were taken at various intervals after sowing, and seed and stubble (fodder) samples were collected at the approximate date of commercial harvest.

At the maximum proposed label application rate (for lentils) of 144 g ai/100 kg of seed, residues in seed were <0.02, <0.02, <0.02, <0.02, 0.05 and 0.08 mg/kg. Residues at the proposed application rates for field peas (35 g ai/100 kg of seed) and faba beans (70 g ai/100 kg of seed) were below the LOQ (either <0.02 or <0.05 mg/kg). Residues at 1.2× the currently approved application rate for lupins of 180 g ai/100 kg of seed were <0.02, <0.02, <0.02, 0.03, <0.05, <0.05, <0.05, 0.09 and 0.13 mg/kg. A highest residue of 0.13 mg/kg was observed in a faba bean trial conducted at 216 g ai/100 kg of seed. Data support the recommendation for the establishment of MRLs of *0.05 mg/kg for field peas (dry) and broad beans (dry), and 0.2 mg/kg for lentils (dry) and lupins (dry). A harvest withholding period of not required when the product is used as directed (is recommended).

At the maximum proposed label application rate of 144 g ai/100 kg of seed and at the proposed withholding period of 16 weeks, highest residues in forage on a dry weight basis were <0.38, 0.69, 0.70, 1.62 and 5.19 mg/kg. The highest residue observed in the trials at the proposed withholding period of 16 weeks was 9.75 mg/kg in a lupin trial conducted at an application rate of 216 g ai/100 kg of seed. At an application rate of 144 g ai/100 kg of seed, highest residues in stubble samples taken at harvest were 0.10, 0.13, 0.24, 0.30 and 3.60 mg/kg. At an application rate of 216 g ai/100 kg of seed, highest residues in stubble samples were <0.06, 0.07, 0.10, 0.12, 0.15, 0.15, 0.20, 0.30, 0.38, and 3.60 mg/kg. Data support the recommendation for the establishment of an MRL of 15 mg/kg for legume animal feeds, in conjunction with a 16-week grazing withholding period.

3.5 Overseas registration and approved label instructions

The applicant has indicated that products containing 350 g/L imidacloprid in a liquid concentrate form (FS) are currently registered for use on different commodities in a number of countries including; Italy, Netherlands, Ireland, Spain, South Africa, Germany, Portugal, Guatemala, Israel, France, Botswana, Indonesia, Greece, Kenya, Malawi, Namibia, Philippines, Poland, Tanzania, Uganda, Zambia and Slovenia.

Imidacloprid is registered as a seed dressing for lentils, field peas and faba (broad) beans in the USA at applications rates of 60-120 g ai/100kg of seed, and in Poland for faba (broad) beans at a rate of 175 g ai/100 kg of seed.

3.6 Codex Alimentarius Commission and overseas MRLs

The Codex Alimentarius Commission (Codex) is responsible for establishing Codex Maximum Residue Limits (CXLs) for pesticides. CXLs are primarily intended to facilitate international trade, and accommodate differences in Good Agricultural Practice (GAP) employed by various countries. Some countries may accept CXLs when importing foods. Imidacloprid use on pulse commodities has not been considered by Codex. MRLs established overseas for various pulse commodities are listed below.

OVERSEAS TOLERANCES FOR IMIDACLOPRID IN RELEVANT COMMODITIES

Country	Commodity	Tolerance/ MRL (mg/kg)	Reference
Brazil	Beans, seeds	0.07	Monografias de Produtos Agrotoxicos, http://www.anvisa.gov.br/toxicologia/monografias/i13.pdf , accessed August 2009.
Canada (default)	Pulses	0.1	Health Canada, http://www.hc-sc.gc.ca/cps-spc/pest/index-eng.php.
EU	Beans (broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cow peas)	1	EU Pesticides Database, http://ec.europa.eu, updated on 29 April 2009.
	Lentils	*0.05	
	Peas (chickpeas, field peas, chickling vetch)	1	
	Lupins	*0.05	
	Pulses, dry, others	*0.05	
Japan (provisional)	Beans, dried	4	Ministry of Health, Labour and Welfare, Table in Item 7(1), Section A General Compositional Standards for Food, Provisional MRLs List http://www.mhlw.go.jp/english/topics/foodsafety/positivelist060228/dl/index-1c.pdf
	Broad beans	1	
	Other legumes, pulses	1	

US	Vegetable, legume (succulent or dried), group 6	4	Electronic Code of Federal Regulations, Title 40, Part 180, Section 180.510, http://edocket.access.gpo.gov/cfr_2007/julqtr/pdf/40cfr180.472.pdf, as of 30 April 2009.

The Canadian and US residue definitions for imidacloprid are the same as Australia, while the Brazilian, EU and Japanese definitions only address parent.

3.7 Current and proposed Australian MRLs for imidacloprid

The following changes are proposed to Australian imidacloprid MRLs:

Table 1

Compound	Food		MRL (mg/kg)
Imidacloprid			
REMOVE:	VD 0545	Lupin (dry)	*0.05
ADD:	VD 0523	Broad bean (dry)	*0.05
	VD 0561	Field pea (dry)	*0.05
	VD 0533	Lentil (dry)	0.2
	VD 0545	Lupin (dry)	0.2

*MRL set at the limit of quantitation.

Table 4

Compound	Animal Feed Commodity	MRL (mg/kg)
Imidacloprid		
REMOVE:	Lupin fodder and forage	10
ADD:	Legume animal feeds	15

For full details of Australian imidacloprid MRLs, please refer to the APVMA website http://www.apvma.gov.au and follow the *Chemical residues* link.

3.8 Potential Risk to Trade

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

At the proposed label application rates, quantifiable residues are only expected in lentils and lupins, with highest residues from trials of 0.08 mg/kg and 0.13 mg/kg respectively. Quantifiable residues are not expected in field beans or faba beans at the proposed label application rates. The overall risk to export trade in pulses is considered to be low.

Tolerance or MRLs for imidacloprid in pulses have not been established in the major export markets for Australian pulses. Comment is sought on the likelihood of the

changes in use for *GAUCHO 350 FLOWABLE SEED DRESSING INSECTICIDE* to cause undue prejudice to trade.

4. CONCLUSION

It is proposed to establish MRLs for imidacloprid in faba (broad) beans, field peas, lentils and lupins. Comment is sought on the potential for imidacloprid in *GAUCHO 350 FLOWABLE SEED DRESSING INSECTICIDE* to prejudice Australian trade when it is used on faba (broad) bean, field pea, lentils and lupin seed to control aphids.

A more detailed technical assessment report on the evaluation of the trade implications of this chemical can be obtained by contacting the APVMA at [to be arranged] alternatively, the reports can be viewed at the APVMA Library, which is located at:

18 Wormald Street
Symonston ACT, 2609 Office hours: 9.00 - 5.00 (EST) Monday to Friday