Australian Government

Australian Pesticides and Veterinary Medicines Authority

TRADE ADVICE NOTICE

on Clothianidin in the Product Poncho Plus Insecticidal Seed Treatment

APVMA Product Number 67779

JUNE 2013

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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 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 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 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 for registration of **Poncho Plus Insecticidal Seed Treatment** 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 **5 July 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:

Pesticide Contact Officer
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Australian Pesticides and Veterinary Medicines Authority
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Phone: +61 2 6210 4748
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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 Poncho Plus Insecticidal Seed Treatment, containing clothianidin and imidacloprid as the active constituents, for control of various insect and mite pests in canola, forage brassicas, maize, sorghum, and pasture (grass and broadleaf). No changes to imidacloprid MRLs for major export commodities are required as a result of the application, hence imidacloprid will not be discussed further.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Maize, sorghum and canola are considered major export commodities in Appendix 1 of Part 5B of Manual of Requirements and Guidelines for Agricultural Products. Mammalian or poultry animal commodities derived from stock fed grain, grain byproducts, forage or fodder from treated crops may be exported. As no changes are required to existing MRLs for animal commodities, these are not discussed further. New MRLs are proposed for clothianidin in maize, sorghum, and canola.

2.2 Destination and value of exports of Cereal and Oilseed Products

Australian exports of maize were 68 kilotonnes, worth $24 million in 2011/12.

Australian exports of sorghum were 1112 kilotonnes, worth $299 million in 2011/12. Over 70% of the sorghum exports by volume in 2011/12 were to Japan. Other destinations for Australian sorghum exports include New Zealand, Taiwan, and Papua New Guinea.

Australian exports of canola were 2323 kilotonnes of seed, worth $1344 million, 21.6 kilotonnes of meal, and 117 kilotonnes of oil, in 2011/12. Major export destinations for Australian canola seed are the Netherlands, Belgium, Pakistan, Japan and Bangladesh. Major destinations for Australian canola oil are New Zealand, Malaysia, Korea, China and Japan. The major destination for Australian canola meal is New Zealand.

2.3 Proposed Australian use-pattern

Table 1 - Proposed use pattern

CROP	PEST	RATE	CRITICAL COMMENTS
Canola, forage brassicas	Wireworm	500 mL/100 kg seed (180 g ai clothianidin/100 kg seed + 120 g ai imidacloprid/100 kg seed)	Poncho Plus will provide protection from wireworm for 3–4 weeks after sowing. Poncho Plus will not protect seedlings from heavy wireworm populations and under these conditions, an alternative control option should be considered.
	Cutworm		Poncho Plus will provide protection from cutworm for 3–4 weeks after sowing.
	Aphids		Poncho Plus will provide protection from early season aphid damage for 3–4 weeks after sowing.
	Lucerne flea		Suppression only of lucerne flea.
	Red legged earth mite		Poncho Plus will protect emerging seedlings from mite damage for 3–4 weeks after sowing. Monitoring should commence within this period to determine the need for supplementary control measures. Use Poncho Plus as part of an integrated mite management program which may include: **For autumn sowing:** After a pasture phase sow Poncho Plus treated seed
	Blue oat mite		

CROP	PEST	RATE	CRITICAL COMMENTS
			following a well-timed spring insecticide spray (prior to the development of diapause eggs). After a cropping phase a spring insecticide spray is usually not required, however if monitoring in spring finds moderate mite populations, a spring insecticide spray should be applied. **For spring sowing:** At the end of a pasture phase monitor for mite activity and if necessary apply an insecticide spray prior to sowing Poncho Plus treated seed.
Maize	Wireworm Cutworm Aphids	1.7 mL/1000 seeds (0.61 g ai clothianidin/1000 seeds + 0.41 g ai imidacloprid/1000 seeds)	Poncho Plus will protect emerging seedlings from wireworm, cutworm and early season aphid damage for 3–4 weeks after sowing. Poncho Plus will not protect seedlings from heavy wireworm populations and under these conditions an alternative control option should be considered.
Sorghum	Wireworm Cutworm Aphids	500 mL/100 kg seed (180 g ai clothianidin/100 kg seed + 120 g ai imidacloprid/100 kg seed)	
Pasture (grass and broadleaf)	<u>Grass and broadleaf pasture</u> Lucerne flea Red legged earth mite Blue oat mite Cutworm <u>Grass pasture only</u> Yellow headed pasture cockchafer African black beetle	500 mL/100 kg seed (180 g ai clothianidin/100 kg seed + 120 g ai imidacloprid/100 kg seed)	Suppression only of lucerne flea. Poncho Plus will protect emerging seedlings from mite damage for 3–4 weeks after sowing. Monitoring should commence within this period to determine the need for supplementary control measures. Use Poncho Plus as part of an integrated mite management program – see critical comments under canola and forage brassica. Poncho Plus will provide protection from cockchafer and African black beetle damage for 3–4 weeks after sowing. Ensure that sowing occurs in optimum conditions and be aware of paddock history to avoid sowing into high populations. Poncho Plus will not control heavy infestations of cockchafers or African black beetle.

Withholding periods:
Harvest: Not required when used as directed.
Grazing:
Maize, sorghum: DO NOT graze or cut for stock food for 4 weeks after application.
Grass pasture: DO NOT graze or cut for stock food for 6 weeks after application.
Canola, forage brassicas, broadleaf pasture: DO NOT graze or cut for stock food for 8 weeks after application.

2.4 Results from residues trials presented to the APVMA

Sorghum:

Residues of clothianidin in sorghum grain collected at harvest after sowing seed treated at 180 or 202.5 g ai/100 kg (1× or 1.125× the proposed rate) were <0.01 (5) mg/kg. An MRL of *0.01 mg/kg is proposed for clothianidin in sorghum.

Maize:

Residues of clothianidin in maize grain collected at harvest from crops grown from seed treated at a rate within ±25% of the proposed application rate per 1000 seeds were <0.01 (6) mg/kg. An MRL of *0.01 mg/kg is proposed for clothianidin in maize.

Canola:

Residues of clothianidin in canola seed collected at harvest after application at 1.4-3.3× the proposed application rate were <0.01 (23), and <0.02 mg/kg. All residues were below the limit of quantitation. An MRL of *0.01 mg/kg is therefore proposed for clothianidin in rape seed (canola).

Animal feeds:

New MRLs are proposed for clothianidin in a range of animal feeds, including alfalfa fodder (*0.01 mg/kg), alfalfa forage (green) (0.1 mg/kg), brassica forage crops (3 mg/kg), canola fodder (dry) (0.3 mg/kg), canola forage (green) (3 mg/kg), maize fodder (0.5 mg/kg), maize forage (2 mg/kg), sorghum forage (green) (1 mg/kg), sorghum straw and fodder, dry (0.1 mg/kg), sweet corn fodder (0.5 mg/kg), and sweet corn forage (2 mg/kg). The resultant livestock dietary burden for clothianidin does not require any changes to existing animal commodity MRLs.

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.

Clothianidin has been evaluated by the Joint Meeting on Pesticide Residues (JMPR), and Codex limits have been established (see below).

The following relevant residue tolerances for clothianidin have been established:

Table 2 – Current and proposed Australian and overseas MRLs/tolerances for clothianidin

COUNTRY	COMMODITY	TOLERANCE, MG/KG	REFERENCE
Australia	Maize	*0.01	This evaluation.
	Rape seed (canola)	*0.01	
	Sorghum	*0.01	
Codex	Maize	0.02	Codex Alimentarius Commission, www.codexalimentarius.net
	Oilseed	0.02*	
	Sorghum	0.01*	
Japan	Corn (maize, including popcorn and sweetcorn)	0.02	Japan Food Chemical Research Foundation, Japan Ministry of Health, Labour and Welfare, Food and Agricultural Materials Inspection Centre.
	Other cereal grains	0.02	
	Rapeseed	0.01	
EU	Maize	0.02*	EU Pesticides Database.
	Rape seed	0.02*	
	Sorghum	0.02*	
Taiwan	Sorghum	0.02	Standards for Pesticide Residue Limits in Foods, amended March 14 2013, Taiwan Food and Drug Administration (www.fda.gov.tw).

2.6 Current and proposed Australian MRLs for clothianidin

The Australian residue definition for clothianidin is:
Clothianidin.

Table 3 – Current Relevant Food MRLs in the MRL Standard (Table 1)

COMPOUND	FOOD		MRL (MG/KG)
Clothianidin	MO 0105	Edible offal (Mammalian)	*0.02
	PE 0112	Eggs	*0.02
	GC 0645	Maize	T*0.01
	MM 0095	Meat (mammalian)	*0.02
	ML 0106	Milks	*0.01
	PO 0111	Poultry, Edible offal of	*0.02
	PM 0110	Poultry meat	*0.02
	SO 0495	Rape seed	T*0.01
	GC 0651	Sorghum	T*0.01

Table 4 - Current Relevant Animal Feed Commodities in the MRL Standard (Table 4)

COMPOUND	ANIMAL FEED COMMODITY		MRL (MG/KG)
Clothianidin		Brassica forage crops (kale, rape, turnips and swede)	T3
		Canola fodder (dry)	T0.3
		Canola forage (green) [dry weight]	T3
	AS 0645	Maize fodder	T0.1
	AF 0645	Maize forage	T2
		Pasture (mixed grass/leguminous)	2
	AS 0651	Sorghum straw and fodder, dry	T0.05
	AF 0651	Sorghum forage (green) [dry weight]	T3
		Sweet corn fodder	T0.7
		Sweet corn forage	T2

Table 5 - Proposed changes for Poncho Plus Insecticidal Seed Treatment in the MRL Standard (Table 1)

COMPOUND	FOOD		MRL (MG/KG)
Clothianidin			
DELETE:	GC 0645	Maize	T*0.01
	SO 0495	Rape seed	T*0.01
	GC 0651	Sorghum	T*0.01
ADD:	GC 0645	Maize	*0.01
	SO 0495	Rape seed [canola]	*0.01
	GC 0651	Sorghum	*0.01

Table 6 - Proposed changes for Poncho Plus Insecticidal Seed Treatment in the MRL Standard (Table 4)

COMPOUND	ANIMAL FEED COMMODITY		MRL (MG/KG)
Clothianidin			
DELETE:		Brassica forage crops (kale, rape, turnips and swede)	T3
		Canola fodder (dry)	T0.3
		Canola forage (green) [dry weight]	T3
	AS 0645	Maize fodder	T0.1
	AF 0645	Maize forage	T2
	AF 0651	Sorghum forage (green) [dry weight]	T3
	AS 0651	Sorghum straw and fodder, dry	T0.05
		Sweet corn fodder	T0.7
		Sweet corn forage	T2
ADD:	AL 1020	Alfalfa fodder	*0.01
	AL 1021	Alfalfa forage (green)	0.1
		Brassica forage crops	3
		Canola fodder (dry)	0.3
		Canola forage (green)	3
	AS 0645	Maize fodder	0.5
	AF 0645	Maize forage	2
	AF 0651	Sorghum forage (green)	1
	AS 0651	Sorghum straw and fodder, dry	0.1
		Sweet corn fodder	0.5
		Sweet corn forage	2

2.7 Potential risk to trade

Export of treated produce containing finite (measurable) residues of clothianidin and 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.

Cereals

MRLs for clothianidin in maize and sorghum are proposed at the limit of quantitation (0.01 mg/kg). Codex MRLs are established at 0.02 and 0.01 mg/kg for maize and sorghum respectively. MRLs are also established in Japan and the EU.

No changes to existing MRLs for imidacloprid in maize or sorghum are required.

The risk to trade in maize and sorghum is considered to be low and acceptable.

Stakeholders are requested to provide comment on the potential risks to trade in maize and sorghum.

Canola

An MRL for clothianidin in canola is proposed at the limit of quantitation (0.01 mg/kg). Codex MRLs are established at 0.02 mg/kg for canola. MRLs are also established in Japan and the EU (0.01 and 0.02 mg/kg respectively).

No changes to existing MRLs for imidacloprid in maize or sorghum are required.

The risk to trade in canola is considered to be low and acceptable.

Stakeholders are requested to provide comment on the potential risks to trade in maize and sorghum.

Animal commodities derived from livestock that have been fed treated cereal and oilseed grains, processed fractions, forage, and fodder

No changes to animal commodity MRLs are required.

3 CONCLUSIONS

Comments are sought on the potential for Poncho Plus Insecticidal Seed Treatment to unduly prejudice Australian export trade in maize, sorghum and canola when it is used for control of various insect and mite pests.