



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**



TRADE ADVICE NOTICE

on Emamectin in the Product Affirm Insecticide

APVMA Product Number P51321

MARCH 2012

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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.

In undertaking this task, the APVMA works in close cooperation with advisory agencies, including the Department of Health and Ageing, Office of Chemical Safety (OCS), Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC), and State Departments of Primary Industries.

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 **Affirm Insecticide** containing the existing active constituent emamectin 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 **26 April 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
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: <http://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 Syngenta Crop Protection Pty Limited to vary the registration of the product, Affirm Insecticide, containing 17 g/L emamectin. Syngenta are proposing to add a use on canola with a similar use pattern to that previously approved under permit. The proposed extension of use requires establishment of permanent MRLs for emamectin in canola.

The potential for emamectin residues in canola to unduly prejudice trade is discussed below.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Canola seed and canola oil are exported along with food commodities from animals that have been fed feeds containing residues arising from the proposed use.

Destination and value of exports

Canola is Australia's third largest broadacre crop after wheat and barley, and it is widely grown across south east Australia and Western Australia. During the 2009-10 season, Australia produced 1.92 million tonnes of canola over 1.71 million hectares. Australia exported 1,238,000 tonnes of this production as seed, small quantities of oil (87,000 tonnes) and canola meal (19,000 tonnes). The major export destinations for Australian canola seed and canola oil are summarised in Tables 1 and 2 below.

Table 1: Volume of Australian canola exports by destination

Destination	2004-05	2005-06	2006-07	2007-08	2008-09	2009-10
		(kt)				
Bangladesh	67.95	41.30	15.23	3.55	3.39	75.88
China	39.62	0.00	3.23	0.00	43.54	0.00
Japan	495.23	370.27	190.47	121.54	96.47	214.16
Pakistan	387.24	97.46	25.00	166.78	120.55	552.61
Other	28.53	375.24	3.67	227.27	709.03	395.59
Total	1018.56	884.27	237.60	519.14	972.97	1238.23

Source: Data from Australian commodity statistics 2010, www.abares.gov.au

Table 2: Volume of Australian canola oil exports by destination

Destination	2004-05	2005-06	2006-07	2007-08	2008-09	2009-10
		(kt)				
China	0.26	0.29	0.28	4.21	0.14	0.07
Japan	18.42	9.34	3.10	2.01	4.17	1.84
New Zealand	14.19	15.73	15.49	13.12	20.09	21.24
Other	14.33	9.07	9.47	37.49	51.94	63.98
Total	47.19	34.42	28.33	56.82	76.33	87.13

Source: Data from Australian commodity statistics 2010, www.abares.gov.au

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

2.2 Proposed Australian use-pattern

The proposed Australian use pattern for Affirm Insecticide in canola is summarised below.

Table 3: Proposed use pattern

Affirm Insecticide (17 g/L emamectin present as emamectin benzoate)

CROP	PEST	RATE	CRITICAL COMMENTS
Canola	Diamondback Moth <i>Plutella xylostella</i>	150 to 300 mL/ha (2.6 - 5.1 g ai/ha) Add a non-ionic surfactant at recommended label rate	Apply as soon as larval populations reach threshold numbers. Observe current industry threshold recommendations based on crop growth stage. Use rates towards the lower end of the range to control existing populations. Use the higher rate when conditions favour rapid crop or pest development. Sample crops twice a week after application to determine if a second application is required. Make no more than 2 applications per season.

WITHHOLDING PERIOD

Do not harvest, graze or cut for stockfood for 7 weeks after application.

2.3 Results from residues trials presented to the APVMA

A GLP residue study involving eight emamectin residue trials conducted on canola has been provided in support of the application. The trials were conducted in the main canola producing regions of Australia including central and western Victoria, the northern wheat belt of Western Australia and northern Tasmania. The trials were conducted at four sites in the 2009 season and four sites in the 2010 season.

Canola grain

In the 2009 trials residues of emamectin B_{1a}, emamectin B_{1b} and emamectin B_{1a} 8, 9 Z isomer in grain were all <0.005 mg/kg (n = 4) at 43 – 52 days after the last of 2 applications at the proposed rate (5.1 g ai/ha). In addition residues in grain were also <0.005 mg/kg in 2 of the trials which had applications at double the proposed rate.

In the 2010 trials, residues of emamectin B_{1a}, its 8,9-Z isomer and emamectin B_{1b} were all <0.005 mg/kg in canola grain samples following cutting/windrowing at 7, 14 and 28 days after application at up to double the proposed rate.

After observance of a 7 week harvest withholding period it is unlikely that residues of emamectin B1a, its 8,9-Z isomer or emamectin B1b will be observed in grain above the LOQ (0.005 mg/kg). It is recommended that the current temporary MRL of T*0.005 mg/kg for emamectin on SO 0495 Rape seed [canola] be made permanent.

Canola forage and fodder

In the 2009 Australian trials residues of emamectin B1a, its 8,9-Z isomer and emamectin B1b in straw at harvest at 43–52 days after the last of 2 applications at the proposed rate were all <0.005 mg/kg (n = 4). In addition residues in straw were also <0.005 mg/kg in 2 trials involving application at double the proposed rate (10.2 g ai/ha). This is supported by the 2010 trials which found that two applications of emamectin at a rate of 5.1 g ai/ha resulted in emamectin B1a, its 8,9-Z isomer and emamectin B1b residues below LOQ (<0.005 mg/kg) in straw samples collected 7, 14 and 28 days after the last application.

The only detectable residue in canola forage at 28 or more days after application was a residue of emamectin B1b at 0.003 mg/kg detected at 28 days after 2 applications at the proposed rate (5.1 g ai/ha). As a 7 week grazing withholding period has been requested it is considered unlikely that the proposed use will result in detectable residues in canola forage or fodder.

It is recommended that the current temporary MRL of T*0.005 for emamectin on Canola forage, fodder and straw (fresh weight) be made permanent.

Animal Commodities

Animal commodity MRLs were established previously on the basis of feeding at 0.03 ppm. As livestock are not expected to be fed feeds containing emamectin residues as a result of the proposed use under this application, no changes are considered necessary to existing animal commodity MRLs.

2.4 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.

Emamectin has not been considered by Codex. The emamectin MRL in the EU for canola (rapeseed) is *0.01 mg/kg and there is no MRL established in Japan for emamectin in canola (rape seed) so the default (uniform) limit of 0.01 mg/kg will apply.

2.5 Current and proposed Australian MRLs for emamectin

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

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

MRL STANDARD: TABLE 1

COMPOUND	FOOD	MRL (mg/kg)
EMAMECTIN		
SO 0691	Cotton seed	0.005
MO 0105	Edible offal (mammalian)	0.01
MM 0095	Meat (mammalian)	*0.002
ML 0106	Milks	*0.0005
SO 0495	Rape seed [canola]	T*0.005

MRL Standard: TABLE 3

COMPOUND	RESIDUE
EMAMECTIN	Emamectin B1a, plus its 8,9-Z isomer and emamectin B1b, plus its 8,9-Z isomer

Note: a separate application has been made to change the residue definition of emamectin. The proposed definition is emamectin B1a and emamectin B1b.

MRL STANDARD: TABLE 4

COMPOUND	ANIMAL FEED COMMODITY	MRL (mg/kg)
EMAMECTIN		
	Canola forage, fodder and straw (fresh weight)	T*0.005
	Fodder and forage of sweet corn	0.05

The following changes are proposed to Australian emamectin MRLs:

Table 5: Proposed changes to the MRL Standard—Table 1 and Table 4

MRL STANDARD: TABLE 1

COMPOUND	FOOD	MRL (mg/kg)
EMAMECTIN		
DELETE:		
SO 0495	Rape seed [canola]	T*0.005
ADD:		
SO 0495	Rape seed [canola]	*0.005

MRL STANDARD: TABLE 4

COMPOUND	ANIMAL FEED COMMODITY	MRL (mg/kg)
EMAMECTIN		
DELETE:		
	Canola forage, fodder and straw (fresh weight)	T*0.005
ADD:		
	Canola forage, fodder and straw (fresh weight)	*0.005

2.6 Potential risk to trade

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

Quantifiable residues are not expected to occur in canola or in canola oil. There is unlikely to be undue risk to trade with respect to these commodities.

Exports of animal commodities are significant however the proposed use is not expected to result in detectable residues.

3 CONCLUSIONS

It is proposed to establish a permanent MRL for emamectin on canola. Comment is sought on the potential for emamectin in Affirm Insecticide to prejudice Australian trade when it is used on canola for the control of diamondback moth and the ability of industry systems to mitigate any such risk.

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: 9.00 - 5.00 (EST) Monday to Friday