Australian Government

Australian Pesticides and Veterinary Medicines Authority

TRADE ADVICE NOTICE

on Emamectin in the Product Affirm Insecticide

APVMA Product Number P51321

AUGUST 2013

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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.

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 for the extension of use of **Affirm Insecticide** containing the 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 **13 September 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:

Contact Officer, Pesticides
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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 Syngenta Crop Protection Pty Limited to vary the label of Affirm Insecticide, containing 17 g/L emamectin present as emamectin benzoate.

A change is proposed to reduce the label withholding period (WHP) for canola from 7 weeks to 2 weeks for the control of diamondback moth. This reduction in the WHP requires changes to the emamectin MRLs for animal feed commodities and for animal commodities. The currently established emamectin MRL for Rape seed [canola] of *0.005 mg/kg will be changed to *0.01 mg/kg, in line with the residue definition.

The potential for emamectin residues resulting from the proposed use to unduly prejudice trade is discussed below.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Canola is 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 exposed to feed produced from treated canola[2]. Residues in these commodities resulting from the use of Affirm Insecticide may have the potential to unduly prejudice trade.

2.2 Destination and value of exports

Canola

Australian exports of canola seed, oil and meal totalled 1453 kt (value $802 million), 104kt ($160 million) and 31.50 kt ($10.97 million) respectively in 2010–11.

The major export markets for canola seed in 2008 included Netherlands, Pakistan, Japan, Germany and United Arab Emirates and for canola oil the Republic of Korea and New Zealand.[3]

Animal Commodities

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

[2] www.apvma.gov.au/morag_ag/vol_3/part_05b_trade.php

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

2.3 Proposed Australian use-pattern

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

Table 1: Proposed use pattern

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

Crop	Pest	Rate	Critical Comments
Canola (for grain production)	Diamondback Moth *Plutella xylostella*	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 threshold level populations when crop growth stage or insect activity does not favour rapid population development. Use the higher rate to control threshold level populations when conditions favour rapid crop or pest population development. Sample crops twice a week after application to determine if a second application is required. Make no more than 2 applications per season. If further applications are necessary, rotate to an approved product from a different MOA group. Highly toxic to bees. Refer to the Protection of Livestock statement for notification requirements DO NOT use on canola grown as a forage crop and DO NOT use on dual-use canola prior to grazing

Withholding periods:
Canola: DO NOT harvest, graze or cut for stock food for 2 weeks after application

2.4 Results from residues trials presented to the APVMA

Canola:

Four emamectin residue trials conducted according to GLP on canola were provided in support of this application. The trials were conducted in 2011 in the main canola producing regions of Australia including south-east and western Victoria, eastern South Australia and southern New South Wales. Data from another

8 trials conducted in 2009 and 2010, which were considered at the time of the original registration of use of emamectin (Affirm Insecticide) on canola, were also considered in support of the proposal.

Seed

A summary of the residues found in canola seed is given below in Table 2.

Table 2: Summary of relevant residues data from 2011 and 2010 Australian residue trials. Each observation reports the residue for an individual rate x harvest type combination. Four sites were utilised in 2011, with application at 1× the proposed label rate (5.1 g ai/ha) and 2× the proposed label rate (10.2 g ai/ha) at each site. All sites included direct heading and herbicide desiccation treatments. Windrowing was conducted at 2 sites. Four sites were utilised in 2010, with application at 1× the proposed label rate (5.1 g ai/ha) and 2× the proposed label rate (10.2 g ai/ha) at each site. Windrowing occurred at all sites. Sampling occurred at various times between treatment and full desiccation of the crop and those relevant to the proposal are presented below. In addition, the pod, including seed, from a number of sites was analysed. The Australian residue definition is the sum of emamectin B1a and emamectin B1b.

Commodity	Treatment	Application number and target rate (g ai/ha)	Days Between Treatment and Windrow or Desiccation	Days Between Treatment and Sampling	Residues (mg/kg)	
					Emamectin B_{1a}	Emamectin B_{1b}
Canola seed (2011)	Windrow	2 x 5.1 (proposed)	7	14	<0.005 <0.005	<0.005 <0.005
		2 x 10.2 (double rate)	7	14	<0.005 <0.005	<0.005 <0.005
	Herbicide Desiccation	2 x 5.1	7	14	<0.005 <0.005 <0.005 <0.005	<0.005 <0.005 <0.005 <0.005
		2 x 10.2	7	14	<0.005 <0.005 <0.005 <0.005	<0.005 <0.005 <0.005 <0.005
	Direct Heading	2 x 5.1	-	14	<0.005 <0.005 <0.005 <0.005	<0.005 <0.005 <0.005 <0.005
		2 x 10.2	-	14	<0.005 <0.005 <0.005 <0.005	<0.005 <0.005 <0.005 <0.005
Canola seed (2010)	Cutting/windrowing	2 x 5.1	7	14	<0.005	<0.005
			14	14	<0.005 <0.005 <0.005	<0.005 <0.005 <0.005
		2 x 10.2	7	14	<0.005	<0.005
			7	14	<0.005	<0.005
			14	14	<0.005	<0.005
Canola	Cutting/windrowing	2 x 5.1	7	7	<0.005	<0.005

Commodity	Treatment	Application number and target rate (g ai/ha)	Days Between Treatment and Windrow or Desiccation	Days Between Treatment and Sampling	Residues (mg/kg)	
					Emamectin B_{1a}	Emamectin B_{1b}
seed and pods (2010)			7	14	<0.005	<0.005
			14	14	<0.005	<0.005
		2 x 10.2	7	7	<0.005	<0.005
			7	14	<0.005	<0.005
			14	14	<0.005	<0.005
					<0.005	<0.005
					<0.005	<0.005

In trials involving windrowing or herbicide desiccation, sampling did not occur until 14 days after application, 7 days after windrowing or when the desiccant was applied. A 14 day (2 week) withholding period has been applied for. As such, the data are considered to be conservative as in commercial practice the withholding period should expire before windrowing occurs. The 2011 trials showed that residues of emamectin B1a and emamectin B1b in grain after windrowing, herbicide desiccation or direct heading were all <0.005 mg/kg (n = 10) at 14 days after the last of 2 applications, at approximately the proposed rate (5.1 g ai/ha). In addition residues in grain were also <0.005 mg/kg (n = 10) at double the proposed rate.

The 2010 trials involved two applications applied 7 days apart with the first application being made at 7, 14, 21 or 35 days before cutting, with samples being collected at 0, 7 and 14 days after cutting. The 2010 trials indicate that residues of emamectin B1a and emamectin B1b were all <0.005 mg/kg in canola grain and grain + pod samples collected from canola which was cut/windrowed at 7, 14 and 28 days after application at up to double the proposed rate.

The results of the 2011 and 2010 trials indicate that after the observance of a 2 week harvest withholding period it is unlikely that residues of either emamectin B1a or emamectin B1b will be observed in grain above the LOQ (0.005 mg/kg) for each component of the residue defintion. It is considered that the current MRL of *0.005[4] mg/kg for emamectin on SO 0495 Rape seed [canola] should be changed to *0.01 mg/kg, in line with the residue definition.

Straw

The 2011 trials showed that residues of emamectin B1a and emamectin B1b in straw after windrowing, herbicide desiccation or direct heading were all <0.005 mg/kg (n = 10) at 14 days after the last of 2 applications at approximately the proposed rate (5.1 g ai/ha). In addition residues in straw were also <0.005 mg/kg (n = 10) at double the proposed rate.

[4] * Denotes that the maximum residues limit (MRL) has been set ‘at or about the limit of analytical quantification’.

The 2010 trials showed that two applications of emamectin at the proposed label rate (5.1 g ai/ha) resulted in emamectin B1a and emamectin B1b residues below LOQ (<0.005 mg/kg) in straw samples collected 7, 14, 21 and 28 days after the last application. Finite residues of emamectin B1a (0.011 mg/kg) in straw were observed at a 14-day WHP in one trial carried out at double the proposed rate. The forage, fodder and straw MRL and resulting animal commodity MRLs are set on the basis of residues in forage (see below).

Forage

A summary of the residues found in canola forage in the 2009 and 2010 Australian residue trials is given below in Table 3.

Table 3: Summary of residues in canola forage from 2009 and 2010 Australian residue trials

Commodity	Application number and rate (g ai/ha)	PHI (days)	Residues (mg/kg)	
			Emamectin B_{1a}	Emamectin B_{1b}
Canola forage	2 × 5.1 (proposed label rate)	0	<0.005, <0.005 (0.003), <0.005 (0.003), 0.014	<0.005, 0.014, 0.023, 0.058
		7	<0.005, <0.005, <0.005, <0.005 (0.002)	<0.005, <0.005, <0.005, <0.005
		14	<0.005, <0.005, <0.005, <0.005, <0.005	<0.005, <0.005, <0.005, <0.005 (0.002), <0.005 (0.004)
		21	<0.005	<0.005
		28	<0.005, <0.005, <0.005	<0.005, <0.005, <0.005 (0.003)
		42/3	<0.005, <0.005	<0.005, <0.005
		51	<0.005	<0.005
	2 × 10.2 (double proposed label rate)	0	<0.005, <0.005 (0.004), 0.007, 0.016	<0.005, 0.007, 0.027, 0.065
		7	<0.005, <0.005, 0.009, 0.012	<0.005, <0.005, <0.005, 0.051
		14	<0.005, 0.006	<0.005, 0.016
		28	<0.005, <0.005	<0.005, <0.005
		43	<0.005	<0.005

Data from the 2009 and 2010 trials showed that the only detectable residues in canola forage at 14 or more days after 2 applications at the proposed rate (5.1 g ai/ha) were residues of emamectin B1b (0.002 and 0.004 mg/kg) detected at 14 days and 0.003 mg/kg detected at 28 days.

Residues of 0.006 (emamectin B1a) and 0.016 mg/kg (emamectin B1b) were detected in one sample from one trial conducted in 2009 at double the proposed rate at 14 days. Total residues in that sample expressed according to the residue definition are 0.022 mg/kg or 0.011 mg/kg when scaled to the proposed application rate.

On the basis of the available data the proposed WHP change from 7 weeks to 2 weeks will necessitate a change to the current MRL for canola forage, fodder and straw (fresh weight). As residues were demonstrated to be present in some trials at levels just below the LOQ utilised in the residue trials it is appropriate to establish a canola forage, fodder and straw MRL at the combined LOQ, and to express it on a dry weight basis. The following emamectin MRL is recommended:

Canola forage, fodder and straw 0.05 mg/kg

Animal Commodities:

The maximum livestock burden for beef cattle will be as a result of the consumption of canola forage containing a highest fresh weight residue of 0.011 mg/kg as 100% of the diet[5] as calculated below:

Table 4: Dietary intake modelling for emamectin in beef cattle- 500 kg bw, 20 kg DM/day

Commodity	% in diet	Feed intake (kg/day)	Residue, mg/kg	% DM	Livestock dietary burden		
					mg/animal/day	ppm	mg/kg bw
Canola forage	100	20	0.011	30	0.733	0.0367	0.00147

DM = Dry Matter

The theoretical maximum livestock burden based on beef cattle eating a diet of 100% canola forage is therefore equivalent to 0.0367 ppm in the feed.

The maximum livestock burden for dairy cattle will be as a result of the consumption of canola forage containing a highest fresh weight residue of 0.011 mg/kg at 40% of the diet, sweet corn forage (currently approved use) containing a highest dry weight residue of 0.031 mg/kg at 40% of the diet and tomato pomace from tomatoes (currently approved use) having a residue of 0.024 mg/kg at 10% of the diet[5] as calculated below:

Table 5: Dietary intake modelling for emamectin in dairy cattle- 500 kg bw, 20 kg DM/day

Commodity	% in diet	Feed intake (kg/day)	Residue, mg/kg	% DM	Livestock dietary burden		
					mg/animal/day	ppm	mg/kg bw
Canola forage	40	8	0.011	30	0.293	0.0147	0.00059
Sweet corn forage	40	8	0.031	100	0.248	0.0124	0.00050
Tomato pomace	10	2	0.024 (STMR-P)	100	0.048	0.0024	
Total						0.0295	

DM = Dry Matter

The theoretical maximum livestock burden based on dairy cattle eating a diet of 40% canola forage, 40% sweet corn forage and 10% tomato pomace, is therefore equivalent to 0.0295 ppm for dairy cattle.

[5] The scaled HR from the 2× trial is used. The MRL recommendations would be the same if the combined LOQs of the method were used as the residue estimate.

An animal feeding study has previously been considered in which dairy cows were fed a diet containing emamectin residues at 0.03, 0.09 and 0.30 ppm in the feed for 28 consecutive days. At the 0.03 ppm feed level, residues of emamectin B1a in tissues were: liver (10 µg/kg), kidney (4.0 µg/kg), fat (2.2 µg/kg) and muscle (<2.0 µg/kg). Residues of emamectin B1b were <1.0 µg/kg in all samples at the 0.03 ppm feed level. Residues of emamectin B1a in whole milk were below the limit of quantitation of 0.5 µg/kg and residues of emamectin B1b were non-detectable (<0.1 µg/kg). Cream residues were found to be significantly higher than those observed in the corresponding whole milk samples. Skim milk was found to contain residues slightly lower than those found in whole milk. This indicates partitioning of the residue into the fat phase of milk.

No depuration data were reported with this study.

Table 6: Residues (µg/kg) of emamectin B1a and B1b in tissues

	1× group[a]		3× group[a]		10× group[a]	
Tissue	B1a	B1b	B1a	B1b	B1a	B1b
Liver	10	<1.0	29	2.2	115	9.0
Kidney	4.0	<1.0	13	<1.0	42	3.6
Fat	2.2	<1.0	6.6	<2.0	15	<2.0
Muscle	<2.0	<1.0	<2.0	<1.0	6.4	<1.0

[a] 1, 3 and 10× groups were dosed at 0.03, 0.09 and 0.3 ppm in the feed. LOQ = 2.0 µg/kg; LOD = 1.0 µg/kg. Highest residues from 3 animals in group shown

The results from the feeding study may be used to predict emamectin residues in animal tissues and milk as a result of cattle eating canola forage, sweet corn forage and tomato pomace:

Table 7: Predicted residues (mg/kg) of emamectin B1a and B1b in tissues and milk

Substrate	Residues after dosing at 0.03 ppm		Residues after dosing at 0.09 ppm		Predicted residues after feeding at 0.0367 ppm (interpolation from residues after dosing at 0.03 and 0.09 ppm)		Predicted residues after feeding at 0.0295 ppm (direct extrapolation from residues after dosing at 0.03 ppm)	
	B1a	B1b	B1a	B1b	B1a	B1b	B1a	B1b
Liver	0.01	<0.001	0.029	0.0022	0.012	0.0011		
Kidney	0.004	<0.001	0.013	<0.001	0.005	<0.001		
Fat	0.0022	<0.001	0.0066	<0.002	0.0027	0.0011		
Muscle	<0.002	<0.001	<0.002	<0.001	<0.002	<0.001		
Milk	<0.0005	<0.0001					<0.0005	<0.0001
Cream	0.0021	<0.00025					0.0021	<0.00025
Milk fats (derived from predicted residue in cream and the nominal fat content of cream of 35%)							0.006	0.0007

LOQ = 0.002 mg/kg; LOD = 0.001 mg/kg. Highest residues from 3 animals in group are shown

The current animal commodity MRLs are no longer appropriate. As residues are observed to partition preferentially into fat it is considered appropriate to delete the established MRL for mammalian meat (*0.002 mg/kg) and establish a meat (mammalian) [in the fat] MRL at 0.01 mg/kg. As residues are observed to partition into the fat phase of milk it is considered appropriate to establish a separate milk fats MRL. According to the residue definition the milks MRL should be changed to *0.001 mg/kg. The following MRLs are considered appropriate for the proposed use of emamectin on canola.

MO 0105 Edible offal (mammalian) 0.02 mg/kg
MM 0095 Meat (mammalian)[in the fat] 0.01 mg/kg
ML0106 Milks *0.001 mg/kg
FM 0183 Milk fats 0.01 mg/kg

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. Emamectin has been considered by Codex.

The emamectin MRL in the EU for canola (rapeseed) is *0.01 mg/kg and there is no established MRL in Japan for emamectin in canola (rape seed) so the default (uniform) limit of 0.01 mg/kg will apply.

The following overseas animal commodity MRLs / tolerances have been established for emamectin.

Table 8: Overseas residue MRLs/ tolerances for emamectin

Commodity[α]	Tolerance for residues arising from the use of emamectin (mg/kg)				
	Australia	**Codex***	**EU**	**USA**	**Japan**
Animal Commodities					
Residue Definition	Emamectin Sum of emamectin B1a and emamectin B1b	Emamectin Benzoate Emamectin Benzoate B1a	Emamectin Emamectin Benzoate B1a expressed as emamectin	Emamectin Emamectin (MAB_{1a}+ MAB_{1b} isomers) and the associated 8,9-Z isomers (8,9-ZB1a+ 8,9-ZB1b)	Emamectin Benzoate MRLs for emamectin benzoate are established for the sum of residues of emamectin benzoate (B1a and B1b) and each of emamectin (B1a and B1b), amino-emamectin (B1a and B1b) formylamino- emamectin (B1a and B1b), N-methylformylamino-emamectin (B1a and B1b), 8,9-Z-emamectin B1a, which are individually calculated as emamectin benzoate, on agricultural products; for the sum of residues of emamectin B1a and 8,9-Z-emamectin B1a, which are individually calculated as emamectin benzoate, on animal

					and fishery products.
Edible offal (mammalian)	0.01 (*0.02*)	0.08			
Cattle kidney			*0.01		0.01
Sheep kidney			*0.01		
Cattle liver			*0.01	0.050	0.01
Sheep liver			*0.01	0.050	
Cattle meat by-products, except liver				0.020	
Sheep meat by-products, except liver				0.020	
Sheep, Edible offal			*0.01		
Cattle, edible offal			*0.01		0.01
Meat from mammals other than marine mammals		0.004			
Other terrestrial mammals, muscle					0.002
Other terrestrial mammals, fat					0.002
Other terrestrial mammals, liver					0.01
Other terrestrial mammals, kidney					0.01
Other terrestrial mammals, edible offal					0.01
Cattle fat	(*0.01 Meat, mammalian [in the fat]*)	0.02 (Mammalian fat)	*0.01	0.010	0.002
Sheep fat			*0.01	0.010	
Cattle, muscle					0.002
Cattle, meat	*0.002 (Meat, mammalian) (-)		*0.01	0.003	
Sheep meat			*0.01	0.003	
Milks	*0.0005 (**0.001*)	0.002	*0.01 (Milk and cream)	0.003	0.0005
Milk fats	(*0.01*)				

Note: Proposed Australian MRLs are in brackets and underlined

* MRLs as proposed by the CCPR were adopted by the Codex Alimentarius Commission, Thirty Fifth Session, FAO Headquarters, Rome, Italy, 2-7 July 2012
There are no animal commodity emamectin MRLs established in Taiwan or Korea

2.6 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 www.apvma.gov.au/residues/standard.php.

Table 9: Current relevant entries in the MRL Standard – Table 1, Table 3 and Table 4

MRL STANDARD: TABLE 1

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

MRL STANDARD: TABLE 3

COMPOUND	RESIDUE
EMAMECTIN	Sum of emamectin B_{1a} and emamectin B_{1b}

MRL STANDARD: TABLE 4

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

The following changes are proposed to Australian emamectin MRLs:

Table 10: Proposed changes to the MRL Standard – Table 1 and Table 4

MRL STANDARD: TABLE 1

COMPOUND	FOOD	MRL (MG/KG)
EMAMECTIN		
DELETE:		
MO 0105	Edible offal (mammalian)	0.01
MM 0095	Meat (mammalian)	*0.002
ML 0106	Milks	*0.0005
SO 0495	Rape seed [canola]	*0.005
ADD:		
MO 0105	Edible offal (mammalian)	0.02
MM 0095	Meat (mammalian)[in the fat]	0.01
FM 0183	Milk fats	0.01
ML 0106	Milks	*0.001
SO 0495	Rape seed [canola]	*0.01

MRL STANDARD: TABLE 4

COMPOUND	ANIMAL FEED COMMODITY	MRL (MG/KG)
EMAMECTIN		
DELETE:		
	Canola forage, fodder and straw (fresh weight)	*0.005
ADD:		
	Canola forage, fodder and straw	0.05

2.7 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.

The MRL for canola will be changed to *0.01 mg/kg to reflect the residue definition of the sum of emamectin B1a and emamectin B1b. The emamectin MRL in the EU for canola (rapeseed) is also *0.01 mg/kg and there is no established MRL in Japan for emamectin in canola (rape seed) so the default (uniform) limit of 0.01 mg/kg will apply. The risk to trade in canola seed and canola oil is considered to be low as the proposed reduction in WHP is not expected to result in detectable residues in the seed at harvest.

Exports of animal commodities are significant and the proposed use may result in detectable residues. Appropriate MRLs for emamectin are not established in all the export markets for Australian animal commodities.

Finite residues could be present in edible offal (proposed MRL 0.02 mg/kg), meat (fat) (proposed MRL 0.01 mg/kg) and milk fats (proposed MRL 0.01 mg/kg) if it is assumed that emamectin is present in canola forage at the highest level estimated from the GLP residue trials, and that animals destined for imminent export slaughter are fed canola forage at 100% of the diet (40% of the diet for milk production). This is unlikely to occur in practice when emamectin is used to control diamondback moth in canola grain crops. The estimated median residue for canola forage, fodder and straw is at or below the combined method limit of detection of 0.004 mg/kg. To further mitigate the risk of unacceptable residues in animal commodities, the following restraint is proposed:

“DO NOT use on canola grown as a forage crop and DO NOT use on dual-use canola prior to grazing”.

The potential trade risk for each of these commodities is briefly discussed below.

Edible offal

The proposed MRL for edible offal of 0.02 mg/kg (based on estimated highest residues in liver of 0.013 mg/kg) is higher than the edible offal MRLs for Japan (0.01 mg/kg for cattle liver and kidney), EU (cattle and sheep edible offal *0.01 mg/kg) but lower than MRLs established in the USA (0.05 mg/kg for cattle and sheep liver and 0.020 mg/kg for cattle and sheep by-products except liver) and the Codex MRL for mammalian edible offal (0.08 mg/kg). It is noted that although the proposed Australian MRLs for offals are higher than those established in some markets the conservatively estimated highest residues approximate the lowest MRLs. Estimated emamectin residues that may arise in offal following feeding of canola forage containing residues at the combined limit of detection of 0.004 mg/kg at 100% of the diet, are estimated to be <0.002 mg/kg. This is below the MRLs established by major trading partners. The risk to trade in offals associated with the proposed use is considered to be low and acceptable.

Meat (mammalian) [in the fat]

The proposed MRL for meat (mammalian)[in the fat] of 0.01 mg/kg (estimated highest residues in fat 0.0038 mg/kg) is higher than the cattle fat MRL for Japan (0.002 mg/kg) and the same magnitude as MRLs

set in the EU (*0.01 mg/kg) and the USA (0.01 mg/kg). It is lower than the Codex MRL for mammalian fat (0.02 mg/kg). Estimated emamectin residues that may arise in meat (fat) following feeding of canola forage containing residues at the conservatively estimated median residue of 0.004 mg/kg are less than the animal commodity method LOQ of 0.001 mg/kg. The risk to trade in meat associated with the proposed use is considered to be low and acceptable.

Milk and Milk fats

The established Australian MRL for milks (*0.0005 mg/kg) will be changed to *0.001 mg/kg, to reflect the residue definition. The proposed MRL for milks is the same or lower than MRLs in most major export markets.

The proposed MRL for milk fats is 0.01 mg/kg (based on estimated highest residues in milk fats of 0.007 mg/kg). An MRL for milk and cream in the EU is set at the same level.

The estimated emamectin residues that may arise in milk fats following feeding of canola forage containing residues at the conservatively estimated median residue of 0.002 mg/kg are less than 0.001 mg/kg. The risk to trade in milk products associated with the proposed use is considered to be low and acceptable.

3 CONCLUSIONS

It is proposed to change the label withholding period (WHP) for canola from 7 weeks to 2 weeks. This change in the WHP requires changes to canola animal feed MRLs and animal commodity MRLs.

Comments are sought on the potential for emamectin in Affirm Insecticide to prejudice Australian trade when it is used on canola according to the proposed use.