Australian Government

Australian Pesticides and Veterinary Medicines Authority

TRADE ADVICE NOTICE

on Spinetoram in the Product Success Neo Insecticide

APVMA Product Number P64109

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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 Ageing, Office of Chemical Safety and Environmental Health (OCSEH), Department of the Environment, Water, Heritage and the Arts (DEWHA), 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 new 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.

Making a submission

The APVMA invites any person to submit a relevant written submission as to whether the application to vary the registration of *Success Neo Insecticide* containing the existing active constituent spinetoram 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 **4 October, 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 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.

[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 Dow AgroSciences to vary the registration of the product, *Success Neo Insecticide* containing 120 g/L spinetoram, for use on canola and forage brassicas for the control of various insects. The proposed use requires the establishment of permanent MRLs for spinetoram on canola seed, canola forage, canola fodder and for forage brassicas.

Meat and dairy products from animals that have been fed feeds containing residues arising from the proposed use may be exported. The potential for spinetoram residues arising from the proposed use in canola, forage brassicas and in animal commodities to unduly prejudice trade is discussed below.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Canola is considered to be a major export commodity[2], as are commodities of animal origin, such as meat, offal and dairy products, which may be derived from livestock fed feed produced from treated canola and forage brassicas.

2.2 Destination and value of exports

Canola is Australia's third largest broad acre 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).

Australian exports of canola seed and oil totalled 1557 kt and were valued at ~$962m in 2010-11.[3]

Major export markets for canola seed and canola oil are presented below.[3]

Table 1: Major destinations for Australian canola exports (selected grains)

GRAIN	MAJOR DESTINATIONS
Canola seeds	Netherlands, Pakistan, Japan, Germany, United Arab Emirates, Bangladesh, Belgium, India, South Africa, Indonesia
Canola oil	Republic of Korea, New Zealand, China, Brazil, Singapore, Japan, Malaysia, Hong Kong, United Arab Emirates, Vietnam

The significant export markets for Australian beef, sheep and pig meat and offals are listed in Appendix 3 of Part 5B of Ag MORAG. Australia exports significant quantities of dairy products (~$2275m in 2010-11) with the main markets being Japan and other countries in Asia. Less significant are exports of poultry meat and eggs. Exports of poultry meat were valued at ~$38m in 2010-11 with the major markets being South Africa, the Philippines, Hong Kong, Singapore and the South Pacific Islands[4]. Exports of eggs were valued at ~$4m in 2005-06 with the major markets being Singapore, the USA and the Philippines[5].

[2] www.apvma.gov.au/morag_ag/vol_3/part_05b_trade.php
[3] faostat.fao.org/site/537/default.aspx
[4] www.daff.gov.au/agriculture-food/meat-wool-dairy/ilg/industries/chicken_meat
[5] www.daff.gov.au/agriculture-food/meat-wool-dairy/ilg/industries/australian_egg_industry

2.3 Proposed Australian use-pattern

The proposed Australian use patterns for *Success Neo Insecticide* are summarised below.

Success Neo Insecticide (containing 120 g/L spinetoram)

CANOLA and FORAGE BRASSICAS			
RESTRAINTS DO NOT make more than 2 applications to any forage brassica or canola crop in any one season (see the RESISTANCE statement).			
CANOLA and ALL FORAGE BRASSICA CROPS: Carefully monitor crops for eggs and larvae of pest species by regular field scouting. Target sprays against mature eggs and newly- hatched larvae when numbers exceed local spray threshold. Any subsequent sprays to control insects in that crop should be made with a product from a different chemical group.			
CROP	PEST	RATE	CRITICAL COMMENTS
Canola	Diamondback moth (cabbage moth), Cabbage cluster caterpillar, Cabbage white butterfly, Centre grub, Corn earworm (heliothis), Native budworm	150 mL + Uptake spraying oil at 100 mL/ha or another non-ionic a wetting agent	Success Neo can be applied once at any time up to 14 days before harvest (windrowing). If initially applied at any time up to early pod formation, then a second application can be made from 7 days after the 1st application or at any time up to 14 days before harvest. If not using Uptake, apply with a non-ionic wetting agent at the manufacturer's recommended rate. Apply in a minimum of 50 L/ha water by ground or 30 L/ha by air. Larvae that are entrenched (hidden in leaves, stems or pods) will not be controlled.
Forage Brassicas including choumoellier, kale, fodder rape, swedes, turnips.	Diamondback moth (cabbage moth),Cabbage cluster caterpillar, Cabbage white butterfly, Centre grub, Corn earworm (heliothis), Native budworm, Soybean looper	100 mL + Uptake spraying oil at 100 mL/ha or another non-ionic a wetting agent	Apply with Uptake spraying oil or with a non-ionic wetting agent at the manufacturer's recommended rate. Apply in a minimum of 50 L/ha water. This treatment will provide knockdown of light infestations of early instar larvae in crops where good spray coverage has been attained. Larvae that are entrenched (hidden in leaves, stems, bulbs or heads) may not be controlled.

PEST NAMES: Cabbage cluster caterpillar: Crocidolomia pavonana; Cabbage centre grub: Hellula hydralis; Cabbage white butterfly: Pieris rapae; Cluster caterpillar: Spodoptera litura; Diamondback moth: Plutella xylostella; Helicoverpa caterpillars, corn earworm, native budworm: Helicoverpa spp.; Soybean looper: Thysanoplusia orichalcea

HARVEST WITHOLDING PERIOD

CANOLA: DO NOT HARVEST FOR 14 DAYS AFTER THE LAST APPLICATION.

GRAZING AND STOCKFOOD WITHHOLDING PERIOD

CANOLA: DO NOT GRAZE OR CUT FOR STOCKFOOD FOR 7 DAYS AFTER TREATMENT.

FORAGE BRASSICAS: DO NOT ALLOW LIVESTOCK TO GRAZE CROPS FOR 7 DAYS AFTER THE LAST APPLICATION

Export Slaughter Interval:
Canola and Forage brassicas: 28 days

2.4 Results from residues trials presented to the APVMA

The proposed use of *Success Neo Insecticide* on canola involves a single foliar application of spinetoram made at a maximum rate of 18 g ai/ha at any time up to 14 days before harvest. If initially applied at any time up to early pod formation, a second application can be made with a retreatment interval of 7 days after the 1st application or at any time up to 14 days before harvest.

For canola, a harvest WHP of 14 days is proposed whereas grazing WHPs of 7 and 14 days are proposed for canola forage and straw respectively.

For forage brassicas, the proposed use of spinetoram involves up to 2 foliar applications made 7 days apart at a rate of 12 g ai /ha. A grazing WHP of 7 days is proposed.

Canola

Field trials involved two foliar applications of spinetoram with a retreatment interval of 7 days, commencing at early pod formation. Alternatively, the field trials involved application of spinetoram at early pod formation, followed by a second application 14 days before harvest (i.e. longer retreatment interval). In each treatment regime, spinetoram was applied at two different application rates of approximately 1x and 1.6x the maximum proposed.

At the proposed WHP of 14 days, the residues of spinetoram were <LOD (0.005 mg/kg, n=24) in canola grain following 2 foliar applications at rates up to 1.6x the maximum proposed in all the 6 trials conducted in Australia. A permanent MRL of *0.01 mg/kg is considered appropriate in conjunction with a harvest WHP of 14 days for canola (SO 0495 Rape seed) for the proposed use pattern.

At the proposed grazing WHP of 7 days, residues of spinetoram on canola forage following 2 foliar applications at a rate approximately 1.1x the maximum proposed were in rank order <0.005 (LOD) (n=4),

0.038 and 0.06 mg/kg on a dry weight basis. For canola straw, at the proposed grazing WHP of 14 days, residues of spinetoram following 2 foliar applications at a rate 1.1x were in rank order <0.005 (LOD) (n=4), 0.01, 0.02 mg/kg on a dry weight basis. Based on the available information, a Table 4 entry of 0.1 mg/kg is considered appropriate for canola forage and straw in conjunction with a 7 day grazing withholding period.

Forage brassicas

At the proposed grazing WHP of 7 days, residues of spinetoram following 2 foliar applications at a rate 1.5x the maximum proposed were between the LOD and LOQ of 0.01 mg/kg (fresh weight basis) whereas at application rate of 2.5x the maximum proposed residues of spinetoram were <0.005 (LOD) (n=2). The residues at the LOQ are considered to approximate 0.08 mg/kg on a dry weight basis. No detectable residues of spinetoram were detected when turnip bulbs were analysed for residues at PHIs ranging from 0 to 13 days. Previously evaluated residue data for leafy vegetables supports the proposed use. Spinetoram applied at approximately 50 to 75 g ai/ha (approximately 4-6x) resulted in residues on a fresh weight basis of 0.004, 0.006, 0.009 and 0.01 mg/kg when scaled for application rate. Based on the available information, a Table 4 MRL of 0.2 mg/kg is considered appropriate for brassica forage crops in conjunction with a 7 day grazing withholding period.

Animal Commodities

Oilseeds may be fed to poultry however detectable residues are not expected in canola seed and hence poultry commodities as a result of the proposed use. An animal feeding study was previously considered for spinetoram[2] where dairy cows were fed a diet containing 37.55 ppm of spinetotram for 28 consecutive days. Based on this study, predicted residues of spinetoram in animal edible commodities such as milk, edible offal and meat (in the fat) following the proposed use are estimated below.

[2] www.apvma.gov.au/registration/assessment/docs/tan_spinetoram.pdf

The estimated dietary burdens[2] of beef or dairy cattle are as follows:

Commodity	% in diet	kg feed/ animal/ day	Residue, mg/kg	% DM	Dietary burden, ppm
Beef cattle, 500 kg bw, 20 kg DM/day					
canola forage	80	16	0.06	100	0.05
forage brassica	80	16	0.08	100	**0.07**
legume animal feed	100	20	0.0325	100	0.03
By-products					
apple pomace	20	4	0.098 (STMR-P)	100	**0.02**
citrus pulp, dry	30	6	0.065 (STMR-P)	100	0.02
grape pomace	20	4	0.053 (STMR-P)	100	0.01
tomato pomace	20	4	0.093 (STMR-P)	100	0.02
Dairy cattle, 500 kg bw, 20 kg DM/day					
forage brassica	50	10	0.08	100	**0.04**
legume animal feed	100	20	0.0325	100	0.03
By-products					
apple pomace	10	2	0.098 (STMR-P)	100	0.01
citrus pulp, dry	30	6	0.065 (STMR-P)	100	**0.02**
grape pomace	20	4	0.053 (STMR-P)	100	0.01
tomato pomace	20	4	0.093 (STMR-P)	100	0.02

The total livestock dietary burden arising from the use of spinetoram on forage brassicas is higher than that of canola as shown above. Thus the estimated residues of spinetoram in edible animal commodities following consumption of forage brassicas are discussed below:

In beef cattle, the estimated residues of spinetoram at the total livestock burden of 0.09 ppm are estimated below:

Beef cattle (mg/kg; Australian residue definition i.e. XDE-175-J and XDE-175-L)

DOSE RATE IN DIET (ppm)	MUSCLE	KIDNEY	LIVER	FAT
37.55	0.54	1.74	2.4	16.5
0.07*	0.001	0.003	0.004	0.03
0.09#	0.001	0.004	0.006	**0.04**

**Predicted feeding level for forage brassicas, # Total livestock burden.*

In dairy cattle, the estimated residues of spinetoram at the total livestock burden of 0.06 ppm are estimated below:

Lactating dairy cattle (mg/kg; Australian residue definition i.e. XDE-175-J and XDE-175-L)

DOSE RATE IN DIET (ppm)	MILK	CREAM
37.55	1.3	6.5
0.04*	0.001	0.007
0.06#	0.002	0.010

**Predicted feeding level for forage brassicas, # Total livestock burden.*

In dairy cattle, the estimated spinetoram residues in milk following a single source exposure of spinetoram as per the proposed use are 0.001 mg/kg. If dairy cattle were fed additional feeds containing spinetoram such as citrus pulp, the maximum total residues (as per the Australian residue definition) of spinetoram in milk would be 0.002 mg/kg. These residue estimates are lower than the current Australian MRL of *0.01 mg/kg for milk. Thus no amendment to the current milk MRL is considered necessary.

However, for MRL establishment multiple sources of exposure to spinetoram must be considered. Thus, for dairy cattle fed at the total livestock burden of 0.06 ppm, the maximum total residues (as per the Australian residue definition) resulting from the uses of spinetoram in cream are 0.010 mg/kg. The fat content of cream is approximately 40%, therefore in milk fats the predicted residues would be 0.02 mg/kg. The current milk fat MRL of 0.02 mg/kg will be amended to 0.03 mg/kg for the proposed use pattern.

In beef cattle, the estimated residues of spinetoram at the total livestock burden of 0.09 ppm are estimated to be 0.006 and 0.04 mg/kg in edible offal and meat (fat) respectively. These residue estimates are below the current Australian MRLs of *0.01 mg/kg and 0.05 mg/kg established for edible offal and meat (mammalian) respectively. Thus no amendment to the current MRL is considered necessary.

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.

Relevant MRLs established in other major export markets and are summarised in the following tables.

Table 2: Comparison of spinetoram MRLs (mg/kg) for animal commodities[3]

		AUSTRALIA	CODEX[4]	USA[5]	EU[6]	JAPAN[7]
Residue definition		XDE-175-J and XDE-175-L	XDE-175-J and XDE-175-L	XDE-175-J, XDE-175-L, *N*-demethyl 175-J and *N*-formyl 175-J	XDE-175-J and XDE-175-L	XDE-175-J and XDE-175-L
Meat (mammalian)		0.05 (fat)	0.2 (fat)			
	Cattle fat			5.5	*0.01	0.2
	Sheep fat			5.5	*0.01	
	Other terrestrial mammals fat					0.2
	Other poultry fat	Poultry, meat [in the fat] *0.01			*0.01 (Poultry fat)	0.10 (Poultry fat)
	Cattle, muscle					0.01
	Cattle meat			0.20	0.20	
	Sheep meat			0.20	0.20	
	Other terrestrial mammals muscle					0.01

[3] Standards are not known to be established in China, Russia or Taiwan
[4] www.codexalimentarius.net/pestres/data/pesticides/details.html?id=233 3 September 2012
[5] www.mrldatabase.com/ 3 September 2012
[6] ec.europa.eu/food/plant/plant_protection_products/pesticides_database/index_en.htm 3 September
[7] www.m5.ws001.squarestart.ne.jp/foundation/search.html 3 September 2012

		AUSTRALIA	CODEX[4]	USA[5]	EU[6]	JAPAN[7]
	Other poultry muscle			0.04 (Poultry meat)	*0.01 (Poultry meat)	
Milk	Whole milk	*0.01	*0.01	0.30	*0.01	0.01
	Milk fat	0.03 (proposed)	0.1	7.5		
Edible offal	Edible offal, mammalian	*0.01	*0.01		*0.01 (Bovine edible offal)	
	Cattle kidney				*0.01	
	Sheep kidney				*0.01	
	Cattle liver			0.85	*0.01	
	Sheep liver			0.85	*0.01	
	Cattle mbyp (except liver)			0.60		
	Sheep mbyp (except liver)			0.60		
Poultry meat		*0.01 [in the fat]			*0.01	
	Poultry byproducts				*0.01	
Poultry offal	Poultry, edible offal of	*0.01				
	Poultry liver	*0.01			*0.01	
	Poultry kidney	*0.01			*0.01	
	Other poultry edible offal			0.04		
Eggs	Eggs	*0.01		0.04	*0.01	

The residue definition for spinetoram in Australia and most major export markets is the parent compound only. In USA, the residue definition for animal commodities includes additional metabolites. The highest livestock burden considering the residue definition appropriate for the USA was 0.22 ppm. The lactating cow feeding study included a feeding level of 1.18 ppm of a spinetoram and metabolite mixture appropriate for addressing the residue definition established in the USA. The maximum residues obtained following administration of the mixture in the feeding study for 28 days at the equivalent of 1.18 ppm in the feed and those estimated at the anticipated dietary burden of 0.22 ppm, are as follows:

	FEEDING LEVEL	
	1.18 ppm	0.22 ppm
Milk	(0.006)[1]	<LOQ
Cream	0.26	0.02
Muscle	(0.007)[1]	<LOQ
Liver	0.011	<LOQ
Kidney	0.006	<LOQ
Subcutaneous fat	0.074	0.01
Mesenterial fat	0.10	0.02
Perirenal fat	0.11	0.02
Composite fat	0.11	0.02

[1] *Concentration is less than the LOQ (0.01 mg/kg) but greater than the LOD (0.003 mg/kg)*

Predicted residues in milk, muscle, liver and kidney are less than the LOQ; however, residues in fat were above the LOQ.

The half-lives of spinetoram in animal tissue range from <3 days in liver to about 7 days in subcutaneous fat. A 28 day ESI (about 4 half-lives) has been proposed to allow residues in animal tissues to decline to below the LOQ. The highest residue in animal tissues at the various livestock burdens considered here was 0.04 mg/kg in fat from a forage brassica based diet at a total dietary burden of 0.09 ppm. Given that half-lives are based on lactating cow feeding studies and that only 2 trials on forage brassicas are available, the applicant proposed export slaughter interval (ESI) of 28 days is considered appropriate for the uses on both canola and forage brassicas.

2.6 Current and proposed Australian MRLs for Spinetoram

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

Table 3: Relevant current entries and proposed changes to Table 1 of the APVMA MRL Standard

COMPOUND		FOOD	CURRENT MRL (mg/kg)	PROPOSED MRL (mg/kg)
SPINETORAM				
VP	0060	Legume vegetables	0.2	
MM	0095	Meat (mammalian) [in the fat]	5	
ML	0106	Milks	*0.01	
FM	0183	Milk fats	0.02	0.03
PO	0111	Poultry, Edible offal of	*0.01	
PM	0110	Poultry meat [in the fat]	*0.01	
SO	0495	Rape seed		*0.01

MRL STANDARD: TABLE 3

COMPOUND	RESIDUE
SPINETORAM	Sum of Ethyl-spinosyn-J and Ethyl-spinosyn-L

Table 4: Relevant current entries and proposed changes to Table 4 of the APVMA MRL Standard

COMPOUND		FOOD	CURRENT MRL (mg/kg)	PROPOSED MRL (mg/kg)
SPINETORAM				
		Canola forage and fodder		0.1
		Forage brassicas		0.2
AL	0157	Legume animal feeds	1	

2.7 Potential risk to trade

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

Detectable residues are not expected to occur in canola seed or oil following the proposed use. Thus there is unlikely to be undue risk to trade with respect to these commodities.

Residues in milk and milk fats are not expected to exceed MRLs in major markets. Residues in animal commodities arising from the proposed use are not expected to exceed the standards established by Codex, the EU, USA or Japan at the proposed WHP. Some significant markets do not have spinetoram MRLs established for animal commodities. Detectable residues in meat (fat) and offals are not expected following an export slaughter interval (ESI) of 28 days. Thus the risk to trade in animal commodities associated with the proposed use of *Success Neo Insecticide* is considered to be low.

3 CONCLUSIONS

It is proposed to establish permanent MRLs for spinetoram in canola and forage brassicas. Comment is sought on the potential for spinetoram residues to prejudice Australian trade when *Success Neo Insecticide* is used on canola and forage brassicas.

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: 9.00am–5.00pm (EST) Monday to Friday