



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



TRADE ADVICE NOTICE

on Spinetoram in the Product Success Neo Insecticide

APVMA Product Number P64109

SEPTEMBER 2013

© Australian Pesticides and Veterinary Medicines Authority 2013

ISSN: 2200-3894 (electronic)

ISBN: 978-1-922188-46-5 (electronic)

Ownership of intellectual property rights in this publication

Unless otherwise noted, copyright (and any other intellectual property rights, if any) in this publication is owned by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

Creative Commons licence

With the exception of the Coat of Arms and other elements specifically identified, this publication is licensed under a Creative Commons Attribution 3.0 Australia Licence. This is a standard form agreement that allows you to copy, distribute, transmit and adapt this publication provided that you attribute the work.



A summary of the licence terms is available from www.creativecommons.org/licenses/by/3.0/au/deed.en. The full licence terms are available from www.creativecommons.org/licenses/by/3.0/au/legalcode.

The APVMA's preference is that you attribute this publication (and any approved material sourced from it) using the following wording:

Source: licensed from the Australian Pesticides and Veterinary Medicines Authority (APVMA) under a Creative Commons Attribution 3.0 Australia Licence.

In referencing this document the Australian Pesticides and Veterinary Medicines Authority should be cited as author, publisher and copyright owner.

Use of the Coat of Arms

The terms under which the Coat of Arms can be used are set out on the Department of the Prime Minister and Cabinet website (see www.dpmc.gov.au/guidelines).

Disclaimer

The material in or linking from this report may contain the views or recommendations of third parties. Third party material does not necessarily reflect the views of the APVMA, or indicate a commitment to a particular course of action.

There may be links in this document that will transfer you to external websites. The APVMA does not have responsibility for these websites, nor does linking to or from this document constitute any form of endorsement.

The APVMA is not responsible for any errors, omissions or matters of interpretation in any third-party information contained within this document.

Comments and enquiries regarding copyright:

The Manager, Public Affairs
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604 Australia

Telephone: +612 6210 4701

Email: communications@apvma.gov.au.

This publication is available from the APVMA website: www.apvma.gov.au.

CONTENTS

List of tables	iii
----------------	-----

PREFACE	1
About this document	1
Making a submission	1
Further information	2
1 INTRODUCTION	3
2 TRADE CONSIDERATIONS	4
2.1 Commodities exported	4
2.2 Destination and value of exports	4
2.3 Proposed Australian use-pattern	4
2.4 Results from residues trials presented to the APVMA	5
2.5 Codex alimentarius commission and overseas MRLs	6
2.6 Current and proposed Australian MRLs for spinetoram	8
The following changes are proposed to Australian spinetoram MRLs:	9
2.7 Potential risk to trade	10
3 CONCLUSIONS	11

List of tables

Table 1: Proposed use pattern of <i>Success Neo Insecticide</i> (120 g/L spinetoram) on sweet corn	4
Table 2: Comparison of spinetoram MRLs (mg/kg) for animal commodities	7
Table 3: Current relevant entries in the MRL Standard – Table 1 and Table 3	8
Table 4: Proposed changes to the MRL Standard – Table1	9

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 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 **Success Neo Insecticide** containing the existing active constituents 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. 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 **7 October 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 Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Symonston ACT 2609

Phone: +61 2 6210 4748

Fax: +61 2 6210 4776

Email: pesticides@apvma.gov.au

Further information

Further information including a more detailed technical assessment report on the evaluation of the trade implications of this chemical 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 Australia Pty Limited to vary the registration of the product, *Success Neo Insecticide*, containing 120 g/L spinetoram, to add a use on sweet corn. The proposed variation of use requires the establishment of an MRL for sweet corn (corn-on-the-cob) and an increase in the animal commodity MRLs for spinetoram.

The potential for spinetoram residues to unduly prejudice trade in animal commodities, arising from the proposed use on sweet corn, is discussed below.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Sweet corn is not considered to be a major export commodity.² Detectable residues of spinetoram are not expected to occur in sweet corn (corn-on-the-cob) when used as per the proposed use and the overall risk to export trade in sweet corn is considered to be negligible.

Animals that have been fed feeds containing residues arising from the proposed use are exported.

2.2 Destination and value of exports

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

2.3 Proposed Australian use-pattern

The proposed Australian use pattern for *Success Neo Insecticide* (120 g/L spinetoram) on sweet corn is summarised below.

Table 1: Proposed use pattern of *Success Neo Insecticide* (120 g/L spinetoram) on sweet corn

CROP	PEST	RATE	CRITICAL COMMENTS
Fruiting vegetables; including Eggplant, Okra, Peppers (Capsicums & Chillies), Sweet corn (see also under separate listing below), Tomatoes	Potato moth (tomato leaf miner)	200-400 mL/ha (24-48 g ai/ha) or Dilute 20-40 mL/100 L (2.4-4.8 g ai/100 L)	Use the per hectare rate when applying to bush tomatoes and sweet corn and the dilute rate (per 100 L) in trellised crops (see the <i>"Dilute Spraying"</i> Section in this booklet). Use the lower rate as part of an IPM program when Helicoverpa is the dominant pest and good crop coverage is possible. Use higher rates during periods of high insect pressure or when crop coverage is difficult. Addition of a non-ionic wetting agent may improve control.
	Helicoverpa		
	Western flower thrips	400 mL/ha (48 g ai/ha) or Dilute 40 mL/100 L (4.8 g ai/100 L)	Use this product as part of the WFT Resistance Management strategy (see end of table for details).
Sweet corn (see also under Fruiting Vegetables above)	Helicoverpa	200-400 mL/ha (24-48 g ai/ha)	Use higher rates during periods of high insect pressure or when crop coverage is difficult.

² Part 5B of the Vet Requirements Series and Ag Requirements Series, Overseas Trade Aspects of Residues in Food Commodities, August 2004.

WITHHOLDING PERIODS**Sweet Corn:****DO NOT HARVEST FOR 3 DAYS AFTER APPLICATION****DO NOT CUT OR GRAZE FOR STOCKFEED FOR 3 DAYS AFTER THE LAST APPLICATION****Export Slaughter Interval:**Forage and fodder of sweet corn: **56 days**

This means that livestock that have grazed on or were fed treated crops or byproducts should be placed on clean feed for at least the periods stated above prior to slaughter.

2.4 Results from residues trials presented to the APVMA

In support of the proposed use the applicant has provided eight Australian trials on sweet corn conducted in 2009 and 2013. Four applications of spinetoram were made 7 days apart, at a rate of 46–48 g ai/ha (~1× the proposed rate).

Total spinetoram residues (sum of XDE-175-J and XDE-175-L expressed as spinetoram) in sweet corn **cobs** three days after the last application were all <LOD (8).

Residues in livestock feeds were all expressed on a dry weight basis. Total spinetoram residues in sweet corn **wrapper leaves** three days after the last application were <0.002, 0.06, 0.11, 0.29, 0.35, 0.42, 0.55 and 0.69 mg/kg.

Total spinetoram residues in sweet corn **forage** (whole plant minus the ear and stover) three days after the last application were 0.53, 0.57 and 0.72 mg/kg.

Total spinetoram residues in sweet corn **stover** from the 2009 trials (whole plant minus the ear, cut off at ground level) three days after the last application (1× the proposed rate) were 0.72, 0.85, 2.31 and 3.11 mg/kg. Total spinetoram residues in sweet corn **stover** from the 2013 trials (stubble) three days after the last application were 0.12, 0.36, 0.36 and 0.42 mg/kg.

It is considered that an MRL for sweet corn (corn-on-the-cob) should be established at *0.01 mg/kg, in conjunction with a 3 day harvest withholding period. An MRL of 5 mg/kg is also recommended for sweet corn forage and fodder (n=7, HR=3.11 mg/kg, STMR=0.72 mg/kg), in conjunction with a 3 day grazing withholding period.

Animal commodities

Potential animal feed commodities derived from crops treated with spinetoram include sweet corn forage and fodder, which may be fed to beef and dairy cattle at up to 80% and 40% of the diet, respectively. The livestock dietary burden for beef and dairy cattle is calculated below:

Beef Cattle- 500 kg bw, 20 kg DM/day

Commodity	% in diet	Feed intake	Residue, mg/kg	% DM	Livestock dietary exposure		
					mg/animal	ppm	mg/kg bw
Sweet corn forage (3 day WHP)	80	16	3.11 (HR)	100	49.76	2.488	0.0995
Apple pomace	20	4	0.093 (STMR-P) ^a	100	0.37	0.019	0.0007
TOTAL (3 day WHP - HR)					50.1	2.50	0.100

^a STMR for spinetoram on apple is 0.01 mg/kg. The median processing value for spinetoram (9.3) was used.

Dairy Cattle- 500 kg bw, 20 kg DM/day

Commodity	% in diet	Feed intake	Residue, mg/kg	% DM	Livestock dietary exposure		
					mg/animal	ppm	mg/kg bw
Sweet corn forage (3 day WHP)	40	8	3.11 (HR)	100	24.88	1.244	0.0498
Apple pomace	20	4	0.093 (STMR-P) ^a	100	0.37	0.019	0.0007
TOTAL (3 day WHP)					25.3	1.26	0.051

^a STMR for spinetoram on apple is 0.01 mg/kg. The median processing value for spinetoram (9.3) was used.

Estimated residues in tissues and milk based on a feeding study involving dosing with spinetoram (XDE-175-J and XDE-175-L) at 37.55 ppm are calculated below:

Predicted residues in animal tissue

Dose Rate in Diet (spinetoram)	Maximum Total Residue (mg/kg)			
	Muscle	Liver	Kidney	Peri-renal Fat
37.55 ppm	0.54	2.4	1.7	17
2.50* ppm	0.036	0.16	0.12	1.1

*Predicted feeding level with 3 day WHP

Predicted residues in milk

Dose Rate in Diet (spinetoram)	Maximum Total Residue (mg/kg)	
	Milk	Cream
37.55 ppm	1.3	6.5
1.26* ppm	0.04	0.2

*Predicted feeding level with 3 day WHP

These results support the establishment of the following animal commodity MRLs for spinetoram: Edible offal (mammalian) 0.2 mg/kg, Meat [mammalian] [in the fat] 2 mg/kg, Milk 0.07 mg/kg and Milk fat 0.7 mg/kg.

The depuration phase of the feeding study indicates that the estimated residues in tissues should decline below detectable limits after 56 days on clean feed. A 56 day Export Slaughter Interval (ESI) is therefore proposed for animals that have consumed sweet corn forage or fodder to ensure there are no detectable residues in animal commodities for export.

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. Spinetoram has been considered by Codex. The following relevant international MRLs have been established for spinetoram:

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

		AUSTRALIA	CODEX	EU	JAPAN	USA
Residue definition		Sum of XDE-175-J and XDE-175-L.	Spinetoram.	XDE-175.	Spinetoram.	Sum of XDE-175-J, XDE-175-L, ND-J and NF-J.
Meat (mammalian)	Meat (mammalian)	2 (fat) (proposed)	0.2 (fat)			
	Cattle fat			*0.01	0.2	5.5
	Sheep fat			*0.01		5.5
	Other terrestrial mammals fat				0.2	
	Cattle meat			0.2	0.01	0.20
	Sheep meat			0.2		0.20
	Other terrestrial mammals muscle				0.01	
Milk	Milk	0.07 (proposed)	*0.01	*0.01	0.01	0.30
	Milk fats	0.7 (proposed)	0.1			7.5
Edible offal	Edible offal, mammalian	0.2 (proposed)	*0.01			
	Cattle kidney			*0.01		
	Sheep kidney			*0.01		
	Cattle liver			*0.01		0.85
	Sheep liver			*0.01		0.85
	Cattle mbyp (except liver)					0.60
	Sheep mbyp (except liver)					0.60

Note: animal commodity MRLs are not established for spinetoram in China, Korea, Russia or Taiwan.

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: Current relevant entries in the MRL Standard - Table 1 and Table 3

MRL STANDARD: TABLE 1

COMPOUND	FOOD	MRL (MG/KG)
Spinetoram		
MO 0105	Edible offal (Mammalian)	*0.01
PE 0112	Eggs	*0.01
VO 0050	Fruiting vegetables, other than Cucurbits [except sweet corn]	0.1
MM 0095	Meat (mammalian) [in the fat]	0.05
ML 0106	Milks	*0.01
FM 0183	Milk fats	0.03
PO 0111	Poultry, Edible offal of	*0.01
PM 0110	Poultry meat [in the fat]	*0.01

MRL Standard: TABLE 3

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

MRL Standard: TABLE 4

COMPOUND	ANIMAL FEED COMMODITY	MRL (MG/KG)
SPINETORAM		
AB 0226	Apple pomace, dry	1
AB 0001	Citrus pulp, dry	0.2
	Canola forage and fodder	0.1
	Forage brassicas (green)	0.2
AB 0269	Grape pomace, dry	2
AL 0157	Legume animal feeds	1
	Tomato pomace, dry	1

The following changes are proposed to Australian spinetoram MRLs:

Table 4: Proposed changes to the MRL Standard - Table1

MRL STANDARD: TABLE 1

COMPOUND	FOOD	MRL (MG/KG)
SPINETORAM		
DELETE:		
MO 0105	Edible offal (Mammalian)	*0.01
MM 0095	Meat (mammalian) [in the fat]	0.05
ML 0106	Milks	*0.01
FM 0183	Milk fats	0.03
ADD:		
MO 0105	Edible offal (Mammalian)	0.2
MM 0095	Meat (mammalian) [in the fat]	2
ML 0106	Milks	0.07
FM 0183	Milk fats	0.7
VO 0447	Sweet corn (corn-on-the-cob)	*0.01

MRL STANDARD: TABLE 4

COMPOUND	ANIMAL FEED COMMODITY	MRL (MG/KG)
SPINETORAM		
ADD:		
	Sweet corn forage and fodder	5

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.

While several overseas countries have established spinetoram MRLs in animal commodities, some key Australian export markets, notably Taiwan, for these commodities have not. As detectable residues are expected to occur when the product is used as directed this creates a potential risk to trade. It is noted that Dow AgroSciences Australia Limited has indicated that an application for import tolerances for animal commodities was lodged for Taiwan in March 2011.

Codex, the EU and Japan have established MRLs for spinetoram in mammalian fat (0.2 mg/kg), offal (*0.01 mg/kg), milk (*0.01 mg/kg) and milk fat (0.1 mg/kg, Codex only), below the proposed Australian MRLs for spinetoram in mammalian fat (2 mg/kg), offal (0.2 mg/kg), milk (0.07 mg/kg) and milk fat (0.7 mg/kg).

For commodities other than milk, observance of the proposed 56 day ESI should ensure there are no detectable residues in animal commodities.

The APVMA is in discussions with the dairy industry about the level of risk associated with the use and management strategies to mitigate the risk.

3 CONCLUSIONS

It is proposed to increase the MRLs for spinetoram in Edible offal (mammalian), Meat [mammalian] [in the fat] and Milk. Comment is sought on the potential for spinetoram residues resulting from the proposed use of *Success Neo Insecticide* on sweet corn to unduly prejudice Australian trade, and the ability of industry systems to manage any identified risk.