Australian Government

Australian Pesticides and Veterinary Medicines Authority

TRADE ADVICE NOTICE

on Spinosad in the Products Conserve™ Grain Protector and Conserve™ On-Farm Grain Protector

APVMA Product Numbers 59914 & 67508

JUNE 2012

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

Email: communications@apvma.gov.au

This document is published by the APVMA. In referencing this document the APVMA should be cited as both author and publisher.

ISSN: 2200-3894
ISBN: 978-0-9873041-9-3

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

Comments and enquiries may be directed to:

Contact Officer
Pesticides Program
Australian Pesticides & Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604
Australia

Telephone: +61 2 6210 4748
Fax: +61 2 6210 4776
Email: pesticides@apvma.gov.au

CONTENTS

List of tables

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 register the products *Conserve™ Grain Protector* or *Conserve™ On-Farm Grain Protector* 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 18 July, 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. A summary of relevant comments and the APVMA's response will be published on the APVMA website.

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 register the new products *Conserve™ Grain Protector* and *Conserve™ On-Farm Grain Protector*. *Conserve™ Grain Protector* contains 120 g/L spinosad and is proposed for use by bulk handlers only for the control of lesser grain borer in stored cereal grain. *Conserve™ On-Farm Grain Protector* is a two-part product (Part A containing 500 g/L chlorpyrifos-methyl and 30 g/L s-methoprene; Part B containing 120 g/L spinosad) for the on-farm control of insect pests in stored grain (except malting barley and rice). The proposed uses will require the establishment of permanent MRLs for spinosad in cereal grains. The use of chlorpyrifos-methyl and s-methoprene in the product *Conserve™ On-Farm Grain Protector* is consistent with currently approved on farm use of products containing these active constituents and no further consideration of these active constituents is required in this Trade Advice Notice.

The proposed registration of *Conserve™ Grain Protector* was discussed in a Trade Advice Notice in May 2006[2]. Responses to that notice did not support registration, citing:

- The lack of suitable Maximum Residue Limits (MRLs) in significant export markets for cereals such as countries of the European Union and Japan.
- The lack of suitable Maximum Residue Limits (MRLs) in significant markets for animal products such as countries of the European Union and Taiwan.

Since publication of the TAN in 2006 residue limits for spinosad have been established that resolve most of the identified issues. Japan has notified the intent to revise maximum residue limits for spinosad in a WTO/SPS notification[3], however the proposed MRLs are yet to come into force. This notice seeks comment on the potential for residues arising from the proposed uses of both products to unduly prejudice trade in cereal grains and in animal commodities.

[2] http://www.apvma.gov.au/registration/assessment/trade.php
[3] G/SPS/N/JPN/285 12 December 2011

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Wheat, rice and coarse grains such as barley, maize, sorghum and triticale are exported along with animal products that may be derived from animals fed treated cereal grains.

2.2 Destination and value of exports

Australian exports of wheat totalled 18639 kt and were valued at ~ $5526m in 2010-11[4].

Australian exports of rice totalled 64.9 kt and were valued at ~$199m in 2010-11[4]. Australian rice production has been significantly lower than the long term average over the last decade owing to prolonged drought.

Australian exports of coarse grains totalled 5337 kt and were valued at ~$1493m in 2010-11[4]. Barley was the most significant export (~$1295m) followed by sorghum (~$146m) and oats (~$37m).

Major export markets for the major Australian cereals by value are shown below (Australian Commodity Statistics 2011 and other sources).

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

GRAIN	MAJOR DESTINATIONS
Barley	China, Japan, Middle East, Rep. of Korea
Sorghum	Japan
Oats	Statistics not available
Rice	Historically includes the Middle East, Hong Kong, Japan
Wheat	Asia including Indonesia, Japan, Rep. of Korea, Bangladesh, Malaysia, Thailand, China; Middle East including Iraq, Yemen; Egypt

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)[4], 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[4] with the major markets being South Africa,

[4] http://adl.brs.gov.au/data/warehouse/agcstd9abcc002/agcstd9abcc0022011/ACS_2011_1.0.3.pdf

the Philippines, Hong Kong, Singapore and the South Pacific Islands[5]. Exports of eggs were valued at ~$4m in 2005-06 with the major markets being Singapore, the USA and the Philippines[6].

2.3 Proposed Australian use-pattern

The proposed Australian use patterns for Conserve™ Grain Protector and Conserve™ On-Farm Grain Protector are summarised below.

Table 2: *Conserve™ Grain Protector* (120 g/L Spinosad) *[proposed for use by bulk handling companies only]*

DIRECTIONS FOR USE: All States
Restraints:
DO NOT treat a consignment or parcel of stored grain more than once
DO NOT move treated grain within 24 hours after treatment.

CROP	PEST	RATE	CRITICAL COMMENT
Cereal grains, post-harvest	Lesser grain borer	400 mL in 50 L of water	Apply at the rate of 1 L diluted spray per ton of grain for up to 9 months' protection *0.96 g ai/t (0.96 ppm)*

NOT TO BE USED FOR ANY PURPOSE OR IN ANY MANNER CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION.

WITHHOLDING PERIOD: NOT REQUIRED WHEN USED AS DIRECTED

[5] http://www.daff.gov.au/agriculture-food/meat-wool-dairy/ilg/industries/chicken_meat 1 June 2012
[6] http://www.daff.gov.au/agriculture-food/meat-wool-dairy/ilg/industries/australian_egg_industry 1 June 2012

Table 3: *Conserve™ On-Farm Grain Protector* (Part B containing 120 g/L Spinosad)

DIRECTIONS FOR USE: All States except WA
Restraints:
DO NOT treat a consignment or parcel of stored grain more than once
DO NOT move treated grain within 24 hours after treatment.

CROP	PEST	RATE	CRITICAL COMMENT
Cereal grains, post-harvest (except for malting barley and rice)	Lesser grain borer, Rice weevil, Granary weevil, Rust-red flour beetle, Confused flour beetle, Saw-toothed grain beetle, Tropical warehouse moth & Maize weevil.	1 L of **Part A** plus 400 mL of **Part B** in 50 L of water	Apply at the rate of 1 L diluted spray per tonne of grain for up to 6 - 9 months' protection *0.96 g spinosad/t (0.96 ppm)*
PEST NAMES: Confused flour beetle: *Tribolium confusum*; Granary weevil*: Sitophilus granarius*; Lesser grain borer*: Ryzopertha dominica*; Maize weevil: *Sitophilus zeamais*; Rice weevil: *Sitophilus oryza*e; Rust-red flour beetle: *Tribolium castaneum;* Saw-tooth grain beetle: *Oryzaephilus* spp.; Tropical warehouse moth: *Cadra cautella.*			

NOT TO BE USED FOR ANY PURPOSE OR IN ANY MANNER CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION

WITHHOLDING PERIOD: NOT REQUIRED WHEN USED AS DIRECTED

Note: For the On-farm product, Part B containing 120 g/L Spinosad is only to be applied with Part A (containing 500 g/L chlorpyrifos-methyl and 30 g/L s-methoprene) to control a broad range of stored product insect pests.

2.4 Results from residues trials presented to the APVMA

The proposed uses of the products *Conserve™ Grain Protector* and *Conserve™ On-Farm Grain Protector* both involve treatment of stored grain with spinosad at a rate of 0.96 ppm. Hence the residues assessment and risks are the same for both products when used according to label directions. Spinosad residues in stored grain (wheat, oats, sorghum, barley and rice) were persistent during the test period (up to 11 months), with little decline, as summarised below.

Table 4. Mean residues of spinosad (total) in stored grains following a single post-harvest treatment at 0.96 g ai/tonne.

	MEAN TOTAL SPINOSAD RESIDUE (mg/kg)				
DAYS POST APPLICATION	1	30	91-97	181-183	269-276
GRAIN					
Wheat	0.89	0.87	0.86	0.80	0.78
Oats	0.47	0.55	0.52	0.43	0.43
Sorghum	0.52	0.50	0.40	0.45	0.46
Sorghum	0.71	0.72	0.80	0.83	0.82
Wheat	0.79	0.80	0.73	0.68	0.66
Barley	0.71	0.66	0.77	0.66	0.74

The data supported a MRL of 1 mg/kg in cereal grains (currently T1 mg/kg), with a withholding period of 'Not Required When Used as Directed'. Processing studies show concentration into wheat bran (×2) and rice hulls (×2.8), and a reduction into brown rice (×0.11). MRLs of 2 mg/kg in wheat bran and 4 mg/kg in rice hulls are recommended.

Animal transfer studies have been undertaken with cattle (lactating cows and beef cattle) and laying hens. When spinosad is fed to beef and dairy cattle at 1 ppm in the feed, residues were highest and most persistent in fat and cream, as summarised below.

Table 5: Highest observed residues (mg/kg) in a 28 day lactating cow feeding study

NOMINAL FEEDING LEVEL (ppm)	MILK	CREAM	SKIM MILK	MUSCLE	KIDNEY	LIVER	FAT
1	0.05	0.22	<0.01	0.03	0.08	0.15	0.66
3	0.15	0.71	0.02	0.07	0.26	0.35	1.72
10	1.32	3.10	0.13	0.30	0.83	1.70	7.48

Beef cattle were dosed with spinosad at levels equivalent to 0.56 and 2.27 ppm in the feed. The decline of residues in cattle fats over 57 days, following feeding of spinosad for 28 days, is summarised in Table 6. Three cattle were included in each treatment group. Body fat residues declined with a half-life of 14 days

Table 6: Decline of spinosad in beef cattle fats.

TISSUE MATRIX	FEEDING LEVEL (ppm)	MEAN (RANGE) SPINOSAD RESIDUES, AT DAYS AFTER CESSATION OF DOSING (mg/kg)						
		1 DAY	8 DAYS	15 DAYS	22 DAYS	29 DAYS	43 DAYS	57 DAYS
Perirenal fat	0.56 ppm	0.154 (0.118-0.219)	0.115 (0.070-0.162)	0.091 (0.048-0.140)	0.040 (0.030-0.052)	0.092 (0.042-0.154)	0.021 (0.012-0.031)	0.008 (0.006-0.009)
	2.27 ppm	0.841 (0.502-1.213)	0.458 (0.448-0.473)	0.313 (0.227-0.403)	0.274 (0.222-0.379)	0.213 (0.130-0.349)	0.069 (0.060-0.077)	0.014 (0.007-0.020)
Subcutaneous fat	0.56 ppm	0.055 (0.024-0.075)	0.085 (0.047-0.125)	0.086 (0.059-0.108)	0.071 (0.060-0.078)	0.102 (0.061-0.182)	0.029 (0.018-0.046)	0.011 (0.008-0.014)
	2.27 ppm	0.212 (0.116-0.307)	0.351 (0.297-0.427)	0.263 (0.105-0.404)	0.312 (0.208-0.499)	0.264 (0.199-0.351)	0.141 (0.099-0.166)	0.016 (0.005-0.026)

A transfer factor of 0.7 was observed in the lactating cow study, from spinosad in feed to cattle fat. .

The estimated maximum livestock burden for cattle (and conservatively other mammalian livestock) is shown below:

Cattle: average 500 kg bw, average feed intake 20 kg DM/day

FEED GROUP	COMMODITY	% IN DIET	FEED INTAKE	RESIDUE, mg/kg	% DM	LIVESTOCK BURDEN		
						mg/animal	ppm	mg/kg bw
Processed grain fraction	Rice hulls	10	2	2.8	100	5.6	0.28	0.011
Grain	Cereal grain	90	18	1	100	18	0.9	0.036
Total		100				23.6	1.18	0.047

If animals were fed spinosad treated grains with residues at 1.2 mg/kg, a reasonable worst case exposure, spinosad residues of 0.85 mg/kg may be found in fat. This compares favourably with the Australian mammalian meat (in the fat) MRL of 2 mg/kg, and is also lower than relevant meat/fat MRLs in significant animal commodity markets, where they are established. For dairy cattle, cereal grains are commonly only fed at up to 50% of the diet[7]. However, the burden for beef cattle approximates that of dairy cattle as other forages or fodders that may be fed with treated cereals may contain similar residues of spinosad as cereal

[7] OECD feeding tables

grains (e.g. the Table 4 entry for spinosad in legume animal feeds is 1 mg/kg). Appropriate MRLs are currently established for Meat (mammalian)[in the fat] and Edible offal (mammalian). The data support establishment of a permanent MRL of 0.1 mg/kg for Milks (currently T0.1 mg/kg) and a MRL for Milk fats of 0.7 mg/kg[8].

The estimated maximum livestock burden for layers and broilers is conservatively estimated to be 1 ppm as rice hulls are not commonly fed to chickens. The burden for turkeys may be higher, as rice hulls may be included in turkey rations[7] with an estimated maximum burden of 1.36 ppm including cereal grain. .

When spinosad was fed to poultry, residues were highest in fats, as summarised in Table 7 and 8.

Table 7: Highest observed residues of spinosad in eggs from hens following feeding at various levels (ND is not detected).

	SPINOSAD RESIDUES (mg/kg)				
NOMINAL FEEDING LEVEL (ppm)	0	0.1	0.3	1	5
DAYS OF FEEDING					
-1	ND	ND	ND	ND	ND
1	ND	-	-	-	ND
4	ND	-	-	-	0.12
7	ND	-	-	-	0.15
10	ND	-	-	-	0.23
13	ND	-	-	-	0.37
20	-	-	-	-	0.23
28	ND	ND	ND	0.02	0.19
35	ND	ND	ND	0.01	0.22

[8] Assumes cream 40% milk fat

Table 8: Highest observed residues of spinosad in poultry tissues from hens following 41 days feeding at various levels

	SPINOSAD RESIDUES (mg/kg)				
NOMINAL FEEDING LEVEL (ppm)	0	0.1	0.3	1	5
MATRIX					
Whole body	ND	<0.01	<0.01	0.03	0.19
Light muscle	ND	ND	ND	ND	0.05
Dark muscle	ND	ND	ND	<0.01	0.07
Abdominal fat	<0.03	0.03	0.05	0.16	1.35
Subcutaneous fat	<0.03	0.05	0.07	0.17	1.63
Liver	ND	ND	ND	0.02	0.11

(ND = not detected).

No decline data were available for spinosad residues in poultry. The data support confirmation of the currently established temporary MRLs for Eggs and Poultry, Edible offal of, at 0.05 mg/kg and 0.05 mg/kg respectively. The data support replacement of the Poultry fat/skin and Poultry meat MRLs with a Poultry meat [in the fat] MRL of 0.5 mg/kg to accommodate the residues that may occur in poultry fed treated cereal grains and rice hulls. Appropriate MRLs are currently established for Meat (mammalian)[in the fat], Edible offal (mammalian) and poultry meat.

2.5 Overseas registration and approved label instructions

The applicant has indicated that Spinosad is registered in 103 countries for treatment of a wide range of horticultural and field crops and in some countries (including Australia) as a direct animal treatment and for mosquito control. The applicant has indicated that spinosad is approved for use as a stored grain protectant in the USA however it is not currently marketed owing to the lack of appropriate MRLs in Japan.

2.6 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. Spinosad has been considered by Codex. The following relevant Codex CXLs have been established for spinosad. Relevant MRLs established in other major export markets and are summarised in the following tables.

Table 9: Comparison of spinosad MRLs (mg/kg) for cereal grains. Residue definitions are sum of spinosyn A and spinosyn D[9]

		WHEAT	WHEAT BRAN (UNPRO-CESSED)	BARLEY	SORGHUM	OATS	RICE	OTHER CEREAL GRAINS	NOTES
Australia	current	T1		T1	T1	T1	T1	T1	as Cereal grains
	proposed	1	2	1	1	1	1	1	as Cereal grains
Codex		1	2	1	1	1	1	1 (Po)	as Cereal grains http://www.codexalimentarius.net/pestres/data/pesticides/details.html?id=203 1 June 2012
EU		1		1	1	1	1	1	As "Others" http://ec.europa.eu/sanco_pesticides/public/index.cfm?event=substance.selection 1 June 2012
Japan		0.02		0.02	1	1	1 (brown)	1	maize/rye 0.02; other cereal grains 1 (all cereal grains, except rice (brown rice), wheat, barley, rye, corn (maize), and buckwheat) http://www.m5.ws001.squarestart.ne.jp/foundation/agrlist.php 1 June 2012
	proposed	2	2	2	1	1	0.1 (brown)	1	"Other cereal grains" refers to all cereal grains, except rice (brown rice), wheat, barley, rye, corn (maize), and buckwheat G/SPS/N/JPN/285; 12 Dec 2011
USA		1.5		1.5	1.5	1.5	1.5	1.5	group 15 CFR180.495 May 24 2012
Taiwan		1		1	1				http://www.fda.gov.tw/eng/people_laws_list.aspx?time=1&classifysn=16 1 June 2012

[9] Spinosad MRLs for cereal grains are not known to be established in China, Hong Kong, India, Indonesia or the Republic of Korea.

Table 10: Comparison of spinosad MRLs (mg/kg) for animal commodities. Residue definitions are Sum of spinosyn A and spinosyn D[10]. MRLs established at the time of the previous TAN for *Conserve™ Grain Protector* are presented in *{parenthesises}*.

		AUSTRALIA (CURRENT/ PROPOSED)	CODEX[11]	USA[12]	EU[13]	JAPAN[14] (CURRENT/ PROPOSED)	TAIWAN[15]
Meat (mammalian)	Cattle meat		3 (fat) *{3 fat}*	2.0	0.3 *{ns}*[16]	2 / 2 (muscle)	2 (muscle) *{ns}*[17]
	Cattle, fat			50	3 *{ns}*	3 / 10	3
	Goat, meat			2.0	0.05 *{ns}*		
	Goat, fat			50	2 *{ns}*		
	Pig meat			0.5	0.05 *{ns}*	2 / 2 (muscle)	1 (muscle) *{ns}*
	Pig, fat			5.0		2 / 10	2
	Pig fat, free of lean meat				1 *{ns}*		
	Hog, meat byproducts			2.0			
	Sheep meat			2.0	0.05 *{ns}*		
	Sheep fat			50	2 *{ns}*		
	Meat (mammalian)	2 (fat)	2 (fat)	*{33 fat}*		0.8 / 2 (muscle) *{20 fat}*	1 (muscle) *{ns}*
	Other terrestrial mammal, fat					2 / 10	2

[10] Spinosad MRLs for animal commodities are not known to be established in China, the Republic of Korea, Russia, Saudi Arabia, Singapore or the UAE
[11] http://www.codexalimentarius.net/pestres/data/pesticides/details.html?id=203 1 June 2012
[12] CFR180.495 24 May 2012
[13] http://ec.europa.eu/sanco_pesticides/public/index.cfm?event=substance.selection 1 June 2012
[14] G/SPS/N/JPN/285; 12 Dec 2011
[15] http://www.fda.gov.tw/eng/people_laws_list.aspx?time=1&classifysn=16 1 June 2012
[16] MRLs were not established at the Community level at the time of the 2006 TAN
[17] MRLs were not established in Taiwan at the time of the 2006 TAN

		AUSTRALIA (CURRENT/ PROPOSED)	CODEX[11]	USA[12]	EU[13]	JAPAN[14] (CURRENT/ PROPOSED)	TAIWAN[15]
	Cattle, goat, sheep, meat byproducts, except liver			5.0			
	Other farm animals				*0.02 *{ns}*		
Milk	Whole milk	T0.1 / 0.1	1 *{1}*	7.0 *{6}*	0.5 *{ns}*	1 / 2 *{3}*	1 *{ns}*
	Milk fat	- / 0.7	5 *{-}*	85			5 *{ns}*
Edible offal	Edible offal, mammalian	0.5	0.5 *{1kidney 2 liver}*	*{8}*		0.5 / 5 *{4}*	0.5 *{ns}*
	Cattle liver		2	10	2 *{ns}*	2 / 5	2 *{ns}*
	Cattle kidney		1		1 *{ns}*	1 / 2	1 *{ns}*
	Bovine, edible offal				0.5 *{ns}*	0.5 / 5	
	Sheep liver			10	0.5 *{ns}*		
	Sheep kidney				0.5 *{ns}*		
	Sheep, edible offal				0.5 *{ns}*		
	Pig liver				0.5 *{ns}*	0.5 / 5	
	Pig kidney				0.3 *{ns}*	0.5 / 2	
	Pig, edible offal				0.5 *{ns}*	0.5 / 5	0.5 *{ns}*
	Other terrestrial mammals, liver					0.5 / 5	
	Other terrestrial mammals, kidney					0.5 / 5	
	Goat liver			10	0.5 *{ns}*		
Poultry meat	Poultry meat [in the fat]	0.5					
	Poultry meat	*0.01 / delete	0.2 (fat) *{0.2}*	0.1 *{0.02}*	0.2 *{ns}*	0.02 / 0.1 (muscle) *{0.02}*	0.02 (muscle) *{ns}*

		AUSTRALIA (CURRENT/ PROPOSED)	CODEX[11]	USA[12]	EU[13]	JAPAN[14] (CURRENT/ PROPOSED)	TAIWAN[15]
	Poultry fat	T0.2 (inc skin) delete		1.3 *{0.5}*	1 *{ns}*	0.4 / 1 *{0.4}*	0.4 *{ns}*
	Poultry, meat byproducts			0.2			
Poultry offal	Poultry, edible offal of	T0.05 / 0.05		*{0.03}*	0.2 *{ns}*	0.04 / 0.2 (chicken; 0.1 other poultry) *{0.04}*	0.05 *{ns}*
Eggs	Eggs	T0.05 / 0.05	0.01 *{0.01}*	0.3 *{0.05}*	0.2 *{ns}*	0.05 / 0.2 (chicken; 0.1 other poultry) *{0.05}*	

{ns} is not set at the time of publication of the 2006 TAN for *Conserve™ Grain Protector*

2.7 Current and proposed Australian MRLs for Spinosad

No changes are proposed to the current Australian residue definition for spinosad which is *Sum of spinosyn A and spinosyn D*. Relevant MRLs and proposed changes to Table 1 and Table 4 the APVMA MRL standard are summarised below. A full listing of Australian MRLs for spinosad can be found at http://www.apvma.gov.au/residues/standard.php.

Table 11: Relevant current entries and proposed changes to Table 1 of the APVMA MRL Standard

COMPOUND		FOOD	CURRENT MRL (mg/kg)	PROPOSED MRL (mg/kg)
SPINOSAD				
GC	0080	Cereal grains	T1	1
MO	0105	Edible offal (mammalian)	0.5	No change
PE	0112	Eggs	T0.05	0.05
MM	0095	Meat (mammalian)[in the fat]	2	No change
ML	0106	Milks	T0.1	0.1
FM	0183	Milk fats	-	0.7
PO	0111	Poultry, Edible offal of	T0.05	0.05
		Poultry fat/skin	T0.2	delete
PM	0110	Poultry meat	*0.01	delete
PM	0110	Poultry meat [in the fat]	-	0.5
CM	0654	Wheat bran, unprocessed	-	2

Table 12: Relevant current entries and proposed changes to Table 4 of the APVMA MRL Standard

COMPOUND		FOOD	CURRENT MRL (mg/kg)	PROPOSED MRL (mg/kg)
SPINOSAD				
AL	0157	Legume animal feeds	1	No change
		Rice hulls	-	4
AF	0651	Sorghum forage (green)	0.5	No change
AS	0651	Sorghum straw and fodder, dry	0.5	No change
		Sweet corn, fodder and forage (dry)	1	No change

2.8 Potential risk to trade

General considerations

Spinosad is being proposed for use both by the bulk handling industry (*Conserve™ Grain Protector*) and on-farm (*Conserve™ On-Farm Grain Protector*). The applicant proposes to control supply of *Conserve™ Grain Protector* to the bulk handling industry, defined as *"Commercial bulk handling entities which are quality assured to receive, store and handle grains for commercial purposes and have, or participate in, residue monitoring programs to ensure industry MRL outturn standards are achieved."* Both products propose to include the following restraint on their respective labels:

DO NOT treat a consignment or parcel of stored grain more than once

Adherence to this restraint is critical to ensure compliance with Australian and international MRLs. On-farm grain storage in Australia is becoming more common, as is trading and export by smaller grain traders and aggregators participating in the bagged and containerised markets.

1. Comment is sought on the ability of the grains industry to comply with the restraint against treating a consignment or parcel of grain more than once. Responses should describe how industry systems can identify and manage the risk of multiple treatments as grains move through the supply chain.

Cereal grains

MRLs for cereal grains at the same level or higher than those proposed for Australia are currently established by Codex and in most major markets that routinely establish MRLs with the exception of Japan. Japan has proposed to increase spinosad MRLs for the major cereal grains from 0.02 mg/kg to 1 or 2 mg/kg, equal to or greater that the proposed Australian MRLs, (Table 9; SPS notification G/SPS/N/JPN/285 of 12 Dec 2011) however these MRLs are not expected to be established until late 2012 or early 2013.

2. Comment is sought on the ability of the grains industry to manage the risk to trade in cereal grains associated with the proposed use of spinosad on stored cereal grains:

   A) Prior to the establishment of the proposed MRLs in Japan and

   B) Following the establishment of the proposed MRLs in Japan.

Animal Commodities

Since publication of the previous TAN for *Conserve™ Grain Protector* in 2006[18] MRLs for animal commodities have been established in the European Union (in 2006 MRLs (import tolerances) were established in the UK only) and in Taiwan significantly reducing the potential risk to trade associated with the

[18] http://www.apvma.gov.au/registration/assessment/trade.php

proposed use. MRLs for animal commodities at the same level or higher than those proposed in Australia are currently established by Codex and in most major markets that routinely establish MRLs for pesticides in animal commodities, with two exceptions. Eggs are considered to be a relatively minor export commodity. The Codex MRL for eggs at 0.01 mg/kg is lower than the Australian MRL of 0.05 mg/kg. The Highest Residue (HR) observed in eggs from the laying hen feeding study was 0.02 mg/kg following feeding at the 1 ppm level. Only one residue above 0.01 mg/kg in eggs was observed over the 35 day feeding period. OECD feed tables indicate that for laying hens, cereals are generally fed at a range of values of up to 15% (barley) to 70% (sorghum) of the diet for layers in Australia. This indicates that the estimate of residues at 1 ppm in a broiler diet is higher than what may be expected in commercial production systems.

Similarly, the MRL for poultry meat [in the fat] is proposed at 0.5 mg/kg, which is marginally higher than the MRL of 0.4 mg/kg established in Taiwan. This MRL is established to account for residues that may occur in turkeys that are fed rice hulls at 20% of the feed ration. Turkeys are not considered to be a major trade commodity and therefore the potential to unduly prejudice Australian trade is considered to be low.

Rice hulls are not considered to be used as a feedstuff in broiler production. The highest likely residue in broiler fat derived from feeding treated cereals at 100% of the ration is <0.2 mg/kg, which compares favourably with the established MRLs for poultry fat. The risk to trade in animal commodities, namely poultry and cattle commodities associated with the proposed uses of *Conserve™ Grain Protector* and *Conserve™ On-Farm Grain Protector* is considered to be low.

3 CONCLUSIONS

The proposed uses of the products *Conserve™ Grain Protector* and *Conserve™ On-Farm Grain Protector* containing spinosad on stored grains are likely to result in residues on treated grain. Comment is sought on the potential for the proposed uses to unduly prejudice Australian trade, specifically:

In regard to export of cereals grains, appropriate standards are not currently established in Japan. As discussed at 2.8:

1. Comment is sought on the ability of the grains industry to comply with the restraint against treating a consignment or parcel of grain more than once. Responses should describe how industry systems can manage the risk of multiple treatments as grains move through the supply chain.

2. Comment is sought on the ability of the grains industry to manage the risk to trade in cereal grains associated with the proposed use of spinosad on stored cereal grains:

   C) Prior to the establishment of the proposed MRLs in Japan and

   D) Following the establishment of the proposed MRLs in Japan.

In relation to animal products, the determination that the risk to trade associated with the proposed use of *Conserve™ Grain Protector* and *Conserve™ On-Farm Grain Protector* are considered to be low.