



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



TRADE ADVICE NOTICE

on Fludioxonil in the Product Scholar Fungicide

APVMA Product Number 63391

FEBRUARY 2010

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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 to grant the registration of **SCHOLAR FUNGICIDE** containing the existing active constituent fludioxonil 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 **9 March 2010** 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:

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Senior Evaluator, 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: <http://www.apvma.gov.au>

¹ A full definition of "confidential commercial information" is contained in the Agvet Code.

1 INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Syngenta Crop Protection Pty Limited to register a new product, SCHOLAR FUNGICIDE, containing 230g/L fludioxonil. The proposed use is as a post-harvest fruit treatment on citrus, pome fruit, stone fruit and kiwi fruit for the control of various storage moulds.

The potential for fludioxonil residues in citrus, pome fruit and stone fruit to unduly prejudice trade is discussed below.

2 TRADE CONSIDERATIONS

2.1 Commodities exported

Citrus fruit, pome fruit and stone fruit are considered to be major export commodities. Animal commodities derived from livestock fed on citrus pulp or pome pomace are also major export commodities. Kiwi fruit are not considered to be a major export commodity and will not be considered further.

2.2 Destination and value of exports

Citrus

Australia exported \$171 million worth of citrus fruits such as oranges, mandarins, lemon, limes, grapefruit and other citrus in the 2007-2008 financial year. The major export markets and value of citrus exported to each country in the 2007-2008 financial year are shown below.

Table 1: Largest Export markets by value for citrus fruits in 2007-2008 financial year

DESTINATION	VALUE, \$ MILLION
United States	52.2
Hong Kong	30.5
Japan	20.1
Malaysia	9.2
United Arab Emirates	8.4
New Zealand	7.9
Singapore	6.6
Indonesia	5.9
United Kingdom	4.5
Canada	4.2
Other	22.1
Total	171.4

Source of data: Australian Bureau of Statistics

Pome Fruit

Pome fruit, principally apples and pears are exported from Australia. Australia exported \$7.1 million worth of apples and \$6.6 million worth of pears in the 2007-2008 financial year. The major export markets and value of apples and pears exported to each major destination in the 2007-2008 financial year are shown below.

Table 2: Largest Export markets by value for pome fruit in 2007-2008 financial year

APPLES		PEARS	
DESTINATION	VALUE, \$'000	DESTINATION	VALUE, \$'000
United Kingdom	2123.5	Canada	2,411.3
Indonesia	1549.9	New Zealand	1,545.5
Papua New Guinea	925.8	New Caledonia	560.5
Taiwan	754.0	Netherlands	329.8
Sri Lanka	486.7	Indonesia	284.4
Malaysia	318.0	Papua New Guinea	272.3
India	227.9	Fiji	252.9
Singapore	151.3	Singapore	190.5
Hong Kong	110.7	Hong Kong	121.6
New Caledonia	97.1	Malaysia	103.4
Other	382.4	Other	569.2
Total	7,127.4	Total	6,641.4

Source of data: Australian Bureau of Statistics

Stone Fruit

Stone fruit, principally apricots, cherries, peaches and plums are exported from Australia. Australia exported \$1.0 million worth of apricots, \$15.2 million worth of cherries, \$3.5 million worth of peaches and \$10.9 million worth of plums in the 2007-2008 financial year. The major export markets and value of apricots, cherries, peaches and plums exported to each major destination in the 2007-2008 financial year are shown below.

Table 3: Largest Export markets by value for stone fruit in 2007-2008 financial year

APRICOTS		CHERRIES	
DESTINATION	VALUE, \$'000	DESTINATION	VALUE, \$'000
Netherlands	306.3	Taiwan	4,407.0
United Arab Emirates	170.1	Hong Kong	3,231.0
Hong Kong	138.2	Singapore	1,707.6
France	112.9	Thailand	1,639.5
Belgium	56.7	Netherlands	1,129.3
Singapore	34.8	United Arab Emirates	562.0
Saudi Arabia	33.9	United States	425.9
Canada	29.9	Malaysia	415.9
Russia	27.2	Japan	220.7
Qatar	20.5	Russia	210.5
Other	116.9	Other	1,282.9
Total	1,046.6	Total	15,232.4
PEACHES		PLUMS	
DESTINATION	VALUE, \$'000	DESTINATION	VALUE, \$'000
United Arab Emirates	859.0	Hong Kong	4,297.6
Singapore	821.7	United Kingdom	2,120.8
Hong Kong	286.8	Singapore	1,649.1
Saudi Arabia	271.5	Malaysia	693.3
Malaysia	163.9	United Arab Emirates	445.2
France	162.4	Thailand	251.2

Kuwait	140.2	Kuwait	246.7
United Kingdom	127.8	India	191.5
Jordan	93.5	Vietnam	174.1
Qatar	83.1	New Caledonia	146.2
Other	449.8	Other	654.0
Total	3,459.6	Total	10,869.8

Source of data: Australian Bureau of Statistics

2.3 Proposed Australian use-pattern

The proposed Australian use pattern for SCHOLAR FUNGICIDE (230 g/L fludioxonil) is summarised below.

Table 4: Proposed use pattern

CROP	DISEASE	RATE		CRITICAL COMMENTS
		DIP AND HIGH VOLUME	LOW VOLUME	
Citrus	Blue Mould (<i>Penicillium italicum</i>), Green Mould (<i>Penicillium digitatum</i>), Diplodia stem end rot	260-520 mL/ 100L water (60-120 g ai/ 100 L water)	87 to 174 mL per 10,000kg fruit applied in 5 to 15 L water (20-40 g ai/ 10,000kg fruit)	Addition of a good buffering agent to achieve a pH above 8 is essential for good efficacy. Raising the temperature of the prepared aqueous solution to a maximum of 50°C may improve the efficacy of this product. Refer to Application section below for application instructions.
Kiwi Fruit	Grey Mould (<i>Botrytis cinerea</i>)	130-260 mL/ 100L water	-	Refer to Application section below for application instructions.
Pome Fruit	Blue Mould (<i>Penicillium expansum</i> & <i>P. solitum</i>), Grey Mould (<i>Botrytis cinerea</i>)	(30-60 g ai/ 100L water)		
Stone Fruit - Except Apricots and Peaches	Brown Rot (<i>Monilinia spp.</i>), Grey Mould (<i>Botrytis cinerea</i>), Rhizopus Rot (<i>Rhizopus</i>)			

Apricots and Peaches	<i>stolonifer</i>)	130 mL/ 100L water (30g ai/ 100L water)	-	
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WITHHOLDING PERIOD

Not Required when Used as Directed

GENERAL INSTRUCTIONS

Scholar is a protective fungicide used as a post-harvest treatment to control certain post-harvest diseases. Scholar may be applied as a post harvest dip, drench, flood or spray in citrus or as a dip or drench in pome, stone and kiwi fruit.

Note: Scholar may be degraded by exposure to direct sunlight, Treated fruit should not be stored in direct sunlight.

Mixing

Clean mixing and spraying equipment before use. Prepare no more treatment solution than is needed for the immediate operation. Shake the container before use to ensure uniform dispersion of contents before measuring quantity required. Half-fill the spray or mixing tank with clean water or wax/oil emulsion (or aqueous dilution of a wax/oil emulsion) and start agitation. While filling the remainder of the spray tank add the required amount of Scholar. Begin application of the solution after Scholar has completely and uniformly dispersed into the mix carrier. Maintain agitation throughout the treatment operation. DO NOT let the treatment mixture stand overnight in the tank. Flush the spray equipment thoroughly after each use.

Application**Dip and High Volume Drench Application**

Dip fruit in prepared solution for 30 to 60 seconds and allow fruit to drain. Ensure fruit is in complete contact with the dipping solution.

High Volume Application

Mix appropriate volume of Scholar (see Directions for Use) in water, wax/oil emulsion or aqueous dilution of a wax/oil emulsion for the fruit being treated. Use T-Jet, flooders or similar application system. Fruit should be treated for approximately 30 seconds. Ensure all parts of fruit are well covered by mixture.

Low Volume Application

Citrus: Apply by low volume application on citrus only. Use properly calibrated low volume application equipment. Ensure all parts of fruit are well covered by the spray solution and application time is as long as practical. Mix the required amount of Scholar in 5 to 15 L of water per 10,000 kg fruit.

2.4 Results from residues trials presented to the APVMA

Citrus

In support of the proposed post harvest uses on citrus fruit, the applicant provided details of three US studies in which orange, grapefruit and lemons were subject to various dip, high volume spray (drench) and low volume fludioxonil treatment regimes.

The citrus studies show that the post harvest application of fludioxonil at the maximum proposed concentration as a dip and low volume spray application resulted in residues of 0.40, 0.46, 0.47, 0.48, 0.49, 0.53, 0.54, 0.61, 0.62, 0.64, 0.85, 0.90, 0.91, 0.92, 0.96, 0.98, 1.0, 1.01, 1.04, 1.09, 1.13, 1.14, 1.28, 1.31, 1.39, 1.41, 1.42, 1.5, 1.5, 1.92, 2.21, 3.02, 3.28, 3.39, 3.43, 3.53, 4.16 & 6.79 mg/kg in citrus. The STMR is 1.07 mg/kg for citrus. An MRL of 10 mg/kg is recommended for FC 0001 Citrus fruits.

A processing factor of 2.6x to dry citrus pulp was derived. The HR-P in dry citrus pulp is estimated to be 18 mg/kg with an STMR-P of 2.8 mg/kg. An MRL of 30 mg/kg is recommended for AB 0001 Citrus pulp, dry.

Pome fruit

In support of the proposed post harvest uses on pome fruit, the applicant provided details of three US studies and a European trial in which apples and pears were subject to various dip and high volume spray (drench) treatments.

The residue studies show that the post harvest application of fludioxonil at the maximum proposed concentration as a dip and high volume spray application resulted in residues of 0.35, 0.50, 0.52, 0.56, 0.59, 0.67, 0.68, 0.71, 0.72, 0.75, 0.76, 0.76, 0.79, 0.93, 1.1, 1.1, 1.1, 1.1, 1.2, 1.3, 1.3, 1.4, 1.6, 2.2, 2.7 & 3.5 mg/kg in pome fruit. The STMR is 0.86 mg/kg for pome fruit. An MRL of 5 mg/kg is recommended for FP 0009 Pome fruits.

A processing factor of 18x to dry apple pomace was derived. The HR-P in dry apple pomace is estimated to be 64 mg/kg with an STMR-P of 16 mg/kg. An MRL of 100 mg/kg is recommended for AB 0226 Apple pomace, dry.

Stone fruit

The applicant has proposed that a maximum concentration of 30 g ai/100L be allowed on apricots and peaches, while a concentration of 30-60 g ai/100L be allowed on stone fruit, other than apricots and peaches.

In support of the proposed post harvest uses on stone fruit, the applicant provided details of two peach, two cherry and two plum studies in which fruit were subject to various dip and high volume spray (drench) treatments in the US.

The cherry and plum data show that the post harvest application of fludioxonil at the maximum proposed concentration as a dip and high volume spray application resulted in 1.1, 1.2, 1.5, 1.6, 1.7, 1.8 & 1.9 mg/kg fludioxonil, with a STMR of 1.55 mg/kg. An MRL of 5 mg/kg is recommended for FS 0012 Stone fruits [except apricots and peaches].

The peach data show that the post harvest application of fludioxonil at the maximum proposed concentration as a dip and high volume spray application resulted in 1.8, 1.8, 2.1, 2.5, 2.5, 3.7, 4.6 & 5.0 mg/kg fludioxonil, with a STMR of 2.5 mg/kg. An MRL of 10 mg/kg is recommended for FS 0240 Apricots and FS 0247 Peaches.

Animal Commodities

The maximum livestock burden is estimated as 3.3 ppm, resulting from feeding apple pomace derived from treated apples and cereal forage derived from treated crops:

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
Apple pomace	20	4	16 (STMR-P)	100	64	3.2	0.128
Cereal forage	80	16	0.02 (MRL)	25	1.3	0.08	0.003
Total					65	3.3	0.129

Quantifiable residues were not observed in tissues of lactating cattle fed at the equivalent of 5.5 ppm fludioxonil in the feed, and quantifiable residues are not expected in milks at the estimated maximum feeding level of 3.3ppm. Currently established animal commodity MRLs remain appropriate.

2.5 Overseas registration and approved label instructions

The applicant indicated that fludioxonil products are registered for use on various crops including citrus, pome, stone and kiwifruit in numerous countries. The countries, in which fludioxonil products are registered for use on relevant crops, are summarised below.

Table 5: Overseas registrations by country and commodity

COUNTRY	COMMODITY
Argentina	Apple, lemon, mandarin, orange, pear
Chile	Cherry, citrus fruit, pome fruit, stone fruit
France	Apricot, cherry, peach, plum
Italy	Apricot, cherry, peach, pear, plum
Japan	Apricot tree (Japanese), citrus fruit, mandarin
Norway	Cherry
Switzerland	Apricot, nectarine, peach, plum, stone fruit
Turkey	Cherry
United States	Citrus fruit, kiwifruit, pome fruit, stone fruit

The 2004 and 2006 JMPR evaluations describes the post harvest fludioxonil use patterns that are registered for use in the USA, and these are described in the table below.

Table 6: Post-harvest fludioxonil use patterns registered in the USA

CROP	APPLICATION					*REF
	FORMULATION	METHOD	RATE	NO.	PHI	
Apricot	50WP	Dip/drench	60 g ai / 100L	1	0	1
Cherry	50WP	Dip/drench	60 g ai / 100L	1	0	1
Citrus	50WP	Dip/drench	60 g ai / 100L	2	0	1
Kiwifruit	50WP	Dip/drench	60 g ai / 100L	NS	NS	1
Nectarine	50WP	Dip/drench	60 g ai / 100L	1	0	1
Pome fruit	50WP	Dip/drench	60 g ai / 100L	2	0	1 & 2
		Spray- low volume	25 g ai / 10,000 kg fruit	2	NS	2

Peach	50WP	Dip/drench	60 g ai / 100L	1	0	1
Plum	50WP	Dip/drench	60 g ai / 100L	1	0	1

*Ref 1: 2004 JMPR evaluation report²

*Ref 2: 2006 JMPR evaluation report³

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. Fludioxonil has been considered by Codex. No changes are proposed to Australian animal commodity MRLs which are currently established at the limit of quantitation. Animal commodity MRLs will not be considered further here. The following relevant Codex CXLs and overseas residue MRLs/ tolerances have been established for fludioxonil in plant commodities:

Table 7: Codex CXLs and overseas residue MRLs/tolerances for fludioxonil

COUNTRY/STATUS	COMMODITY	TOLERANCE, mg/kg
Australia (proposed)	Apricots	10
	Citrus fruits	10
	Kiwifruit	15
	Peaches	10
	Pome fruits	5
	Stone fruits [except apricots and peaches]	5
Canada ⁴	Citrus fruit: all	10
	Citrus oil	500

² Reference: http://www.fao.org/ag/AGP/AGPP/Pesticid/JMPR/Download/2004_eva/FLUDIOXONIL.pdf

³ Reference: http://www.fao.org/ag/AGP/AGPP/Pesticid/JMPR/Download/2006_eva/Fludioxonil%202006%20Evaluation.pdf

⁴ Reference: <http://www.hc-sc.gc.ca/cps-spc/pest/protect-proteger/food-nourriture/mrl-lmr-eng.php>

	Kiwifruit	20
	Pome fruit: all	5
	Stone fruit: all	5
Codex ⁵	Apple pomace, Dry	20
	Citrus fruits	7
	Kiwifruit	15 (Po)
	Pome fruits	5
	Stone fruits	5 (Po) Interim MRL (2005-2009)
EU ⁶	Citrus: Grapefruit	10
	Citrus: Oranges, lemons, limes, mandarins, others	7
	Kiwifruit	20
	Pome fruit: all	5
	Stone fruit: apricots, cherries	5
	Stone fruit: peaches	7
	Stone fruit: plums	0.05
	Stone fruit: others	0.05*
Japan ⁷	Citrus: Lemon, grapefruit	10
	Citrus: Orange, lime, other	1
	Kiwifruit	20
	Pome fruit: all	5
	Stone fruit: all	0.5
United States ⁸	Citrus fruits: all	10

⁵ Reference: http://www.codexalimentarius.net/mrls/pestdes/jsp/pest_q-e.jsp

⁶ Reference: http://ec.europa.eu/sanco_pesticides/public/index.cfm?event=activesubstance.selection&a=1

⁷ Reference: <http://www.m5.ws001.squarestart.ne.jp/foundation/search.html>

	Grapefruit oil	500
	Kiwifruit	20
	Pome fruit: all	5
	Stone fruits: all	5

2.7 Current and proposed Australian MRLs for fludioxonil

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

Table 8: Current relevant entries in the MRL Standard - Table 1, Table 3 and Table 4

MRL STANDARD: TABLE 1

COMPOUND	FOOD	MRL (mg/kg)
FLUDIOXONIL		
MO 0105	Edible offal (mammalian)	*0.05
GC 0645	Maize	*0.02
MM 0095	Meat (mammalian)	*0.01
ML 0106	Milks	*0.01
GC 0651	Sorghum	*0.01

MRL Standard: TABLE 3

COMPOUND	RESIDUE
FLUDIOXONIL	<p><i>Commodities of animal origin:</i> sum of fludioxonil and oxidizable metabolites, expressed as fludioxonil</p> <p><i>Commodities of plant origin:</i> fludioxonil</p>

⁸ Reference: http://www.access.gpo.gov/nara/cfr/waisidx_08/40cfr180_08.html

MRL STANDARD: TABLE 4

COMPOUND	ANIMAL FEED COMMODITY	MRL (mg/kg)
FLUDIOXONIL		
AS 0645	Maize fodder	*0.02
AF 0645	Maize forage	*0.02
AF 0651	Sorghum forage (green)	*0.01
AS 0651	Sorghum straw and fodder, dry	*0.01

The following changes are proposed to Australian fludioxonil MRLs:

Table 9: Proposed changes to the MRL Standard - Table1 and Table 4

MRL STANDARD: TABLE 1

COMPOUND	FOOD	MRL (mg/kg)
FLUDIOXONIL		
ADD:		
FS 0240	Apricots	10
FC 0001	Citrus fruits	10
FI 0341	Kiwifruit	15
FS 0247	Peaches	10
FP 0009	Pome fruits	5
FS 0012	Stone fruits [except apricots and peaches]	5

MRL STANDARD: TABLE 4

COMPOUND	ANIMAL FEED COMMODITY	MRL (mg/kg)
FLUDIOXONIL		
ADD:		
AB 0226	Apple pomace, dry	100
AB 0001	Citrus pulp, dry	30

2.8 Potential risk to trade

Export of treated produce containing finite (measurable) residues of fludioxonil 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 majority of the export destinations for Australian citrus, pome and stone fruit have established fludioxonil MRLs for citrus, pome and stone fruit commodities, or have adopted the established Codex MRLs.

The proposed post harvest uses of fludioxonil on lemons, grapefruit and oranges resulted in a HR and STMR of 6.79 and 1.07 mg/kg respectively. An MRL for FC 0001 Citrus fruits of 10 mg/kg is proposed for Australia, which is equivalent to the MRL established for citrus in Canada, the EU, Japan (for lemon and grapefruit) and the US. Although the established Codex MRL at 7 mg/kg for citrus fruits is lower than the proposed Australian MRL, the observed HR is lower than the codex MRL. The submitted data however suggests that the established Japanese MRL at 1 mg/kg for oranges and limes may be exceeded. Japan was the third most valuable export destination for Australian citrus, including oranges and limes in the 2007/08 financial year.

The proposed post harvest uses of fludioxonil on apples and pears resulted in a HR and STMR at 3.5 and 0.86 mg/kg respectively. An MRL for FP 0009 Pome fruits of 5 mg/kg is proposed for Australia, which is equivalent to the MRL established for pome fruit in Canada, the EU, Japan, and the US and by Codex.

The proposed post harvest uses of fludioxonil on cherries and plums resulted in a HR and STMR at 1.9 and 1.55 mg/kg respectively. An MRL for FS 0012 Stone fruits [except apricots and peaches] of 5 mg/kg is proposed for Australia. The proposed post harvest use of fludioxonil on peaches resulted in a HR and STMR at 5.0 and 2.5 mg/kg respectively. An MRL for FS 0240 Apricot and FS 0247 Peaches of 10 mg/kg is proposed for Australia.

A EU MRL is currently established at 7 mg/kg for peaches, while a MRL is established at 5 mg/kg for apricots and cherries in the EU and for all stone fruit in Canada, the US and by Codex at 5 mg/kg. A MRL is currently established at 0.05 mg/kg for plums and at *0.05 mg/kg for stone fruit other than apricots, cherries, peaches and plums) in the EU, while a Japanese MRL has been established at 0.5 mg/kg for all stone fruit. These MRLs are likely to have been established in support of foliar use of fludioxonil rather than post harvest treatments. The proposed uses on stone fruit may result in the Japanese and EU MRLs (for plums and other stone fruit) being exceeded.

Comment is sought on the likelihood of the changes in use for SCHOLAR FUNGICIDE to cause undue prejudice to trade.

3 CONCLUSIONS

It is proposed to establish MRLs for Apricots, Citrus fruits, Kiwifruits, Peaches, Pome fruit and Stone fruit [except apricots and peaches]. Comment is sought on the potential for fludioxonil in SCHOLAR FUNGICIDE to prejudice Australian trade when it is used on citrus, pome, stone fruit for the control of various storage moulds

A more detailed technical assessment report on the evaluation of the trade implications of this chemical can be obtained by contacting the APVMA at (02) 6210 4748. Alternatively, the reports can be viewed at the APVMA Library, which is located at:

18 Wormald Street

Symonston ACT, 2609 Office hours: 9.00 - 5.00 (EST) Monday to Friday