Trade Advice Notice

on

Chlorothalonil

in the product

Crop care Barrack 720 Fungicide
[APVMA product number 53884]

Date: 19 June 2009

1. PREFACE

1.1 About this Document

This is a Trade Advice Notice.

It indicates that the Australian Pesticides and Veterinary Medicines Authority (APVMA) is considering an application for registration of an 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 notice.

The APVMA will only consider comment on submissions that relate to the **trade implications** of the extended use of the product. Comments received outside these grounds will not be considered by the APVMA. Comments made on appropriate grounds will be considered with details posted on the APVMA website noting what action has/will be taken in regard to concerns.

Any advice the APVMA receives through this consultation which it relies on to grant this application will be noted in a subsequent Advice Summary.

Advice Summaries can be found at:
http://www.apvma.gov.au/registration/data_requirements_subpage.shtml

1.2 Prior to Submission

Please note that subject to the *Freedom of Information Act 1982*, the *Privacy Act 1988* and the Agvet Codes all submissions received may be made publicly available. They may be listed or referred to in any papers or reports prepared on this subject matter.

The APVMA reserves the right to reveal the identity of a respondent (you) unless a request for anonymity accompanies your submission. If no request for anonymity is made, you will be taken to have consented to the disclosure of your identity for the purposes of Information Privacy Principle 11 of the *Privacy Act 1988.*

The contents of any submission will not be treated as confidential or confidential commercial information unless they are marked as such and you have provided justification such that the material is capable of being classified as confidential or confidential commercial information in accordance with the *Freedom of Information Act 1982* or the Agvet Codes as the case may be.

1.3 About this consultation

The APVMA invites comment on this Trade Advice Notice until the 17th July, 2009
Submissions should be addressed to:

Pat Robinson
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Phone: (02) 6210 4756
Fax: (02) 6210 4776

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2. INTRODUCTION

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Crop Care Australasia Pty Ltd to add several new uses to the label of Crop Care Barrack 720 Fungicide, containing 720 g/L chlorothalonil. The applicant is seeking an extension of the approved uses of the product to include the control of Ascochyta blight on chickpeas and lentils and to remove the feeding restraints that currently apply to faba beans and peas.

An initial evaluation of the application was completed in May 2006 and comment was sought on potential impacts on trade in pulses and animal commodities in a Trade Advice Notice that closed on 14 June 2006. In response to comments received during the consultation process at the time, the APVMA considered that further data were required to satisfactorily address the risk to trade in animal commodities resulting from feeding of pulse forages and fodders treated with chlorothalonil. Crop Care Australasia Pty Ltd has subsequently provided a new animal transfer study that included a depuration phase. That study has allowed further risk mitigation measures to be proposed and comment is sought here on the potential for the revised use to unduly prejudice trade in animal commodities. As the potential risks to trade of pulse grains associated with the proposed use were satisfactorily addressed in the previous TAN, these are not considered further here.

A restraint against the feeding of treated forage or fodder to lactating animals producing milk for human consumption is proposed, to ensure that the estimated dietary exposure to chlorothalonil remains acceptable. Comment is sought here on the practicality of that restraint statement.

The proposed Australian use pattern for Crop Care Barrack 720 Fungicide is given below:

Crop Care Barrack 720 Fungicide (720 g/L chlorothalonil)

Crop	Disease	State	Rate	WHP	Critical Comments
Beans - Broad (Faba)	Chocolate spot (*Botrytis fabae*) Rust (*Uromyces viciae-fabae)*	All States	1.4 - 2.3L/ha	14 days Harvest and Grazing	Make the first application as soon as conditions favour the development of the disease. Repeat at 7 - 14 day intervals. Use the higher rate if the crop is dense and disease pressure is high.
Chickpeas	Ascochyta blight (*Ascochyta rabeie*)	Qld, NSW, Vic, SA & WA only	1.0 - 2.0L/ha	14 days Harvest and Grazing	Apply in a minimum total water volume of 100L/ha for ground application and 30 L/ha for aerial application. Use the lower application rate in the following circumstances : 1. At the early stage of crop growth when there is less vegetation to cover and band spraying is possible. 2. In low disease pressure situations, where there is no history of Ascochyta infection in the paddock or adjacent paddocks and/or seasonal conditions are dry. 3. Where a strict 2 week spray interval is practiced in higher disease pressure situations. Use the higher application rate in the following circumstances : 1. In high disease pressure situations, where there is an existing infection or infected stubble is present in the paddock or adjacent paddocks and regular rainfall events are occurring. 2. On highly susceptible varieties, especially where the application interval has extended beyond 2 weeks. Commence application at 3 to 5 weeks after emergence in chickpeas and 8 to 10 weeks after emergence in lentils and make following applications at 2 to 4 week intervals depending on disease presence or prior to rainfall events. Use the shorter spray interval when : 1. In high disease pressure situations (infection present and regular rainfall events) or 2. Highly susceptible varieties are being grown. The longer spray interval may be used when : 1. No rain has occurred since the last application or 2. Where the higher application rate has been used in the previous application and where the variety has low to moderate susceptibility to Ascochyta or Grey Mould infection. If applying prior to rainfall events : 1. Reapply if 2 or more weeks have elapsed since the last application. 2. Apply Barrack at 1L/ha if less than 4 weeks have elapsed since the last application and the variety being grown has low to moderate susceptibility to Ascochyta Blight or Grey Mould or there is no infection in the crop. 3. Apply Barrack at 2 L/ha if 4 or more weeks have elapsed since the last application and a highly susceptible variety is being grown or infection is present in the crop. If Grey Mould is the predominant disease in lentils and infection pressure is high on a susceptible variety, tank mix or alternate Barrack 720 with a Botrytis specific fungicide such as carbendazim, at critical times such as mid flowering to mid pod fill.
Lentils	Ascochyta blight *(Ascochyta lentis)* Grey mould (*Botrytis cinerea, Botrytis fabae)*				
Peas (Processing)	Downy mildew (*Peronospora viciae)*	Qld, WA, NT & Tas. only	1.1 - 1.8L/ha	14 days Harvest and grazing	Make the first application as soon as conditions favour the development of the disease. Repeat at 7 - 14 day intervals. Use the higher rate if the crop is dense and disease pressure is high.
	Ascochyta Rot Disease Complex (*Ascochyta pisi, Mycosohaerella pinodes* and *Phoma pinodella)*				Apply in a protective program commencing at 5 to 6 weeks after sowing in crops with moderate to high risk of infection. Apply two to four applications at 10 to 14 day intervals to provide ongoing suppression of the disease. Use the higher rate if the crop is dense and disease pressure is high.

Withholding periods and Restraints:

HARVEST

Beans, Chickpeas, Lentils and Peas: DO NOT HARVEST FOR 14 DAYS AFTER APPLICATION.

GRAZING

Beans, Chickpeas, Lentils and Peas: DO NOT GRAZE OR CUT FOR STOCKFOOD FOR 14 DAYS AFTER APPLICATION.

DO NOT graze or feed treated forage/fodder to livestock producing milk for human consumption

LIVESTOCK DESTINED FOR EXPORT MARKETS

The grazing withholding period only applies to stock slaughtered for the domestic market. Some export markets apply different standards. To meet these standards, ensure that in addition to complying with the grazing withholding period, the Export Slaughter Interval is observed before stock are sold or slaughtered.

EXPORT SLAUGHTER INTERVAL (ESI) – 60 DAYS

LIVESTOCK THAT HAS BEEN GRAZED ON OR FED TREATED CROPS SHOULD BE PLACED ON CLEAN FEED FOR 60 DAYS PRIOR TO SLAUGHTER.

3. TRADE CONSIDERATIONS

3.1 Commodities Exported

The major export commodities considered here are animal commodities derived from livestock that have been fed treated pulse forage or fodder crops.

3.2 Destination and Value of Exports

The value and destinations of Australian exports of beef, mutton and lamb products are summarised in the tables 1 to 2.[1]

Table 1: Export markets for Australian beef.

Value of Australian exports of beef and veal

	2000 $m	2001 $m	2002 $m	2003 $m	2004 $m	2005 $m	2006 $m	2007 $m
Beef and veal								
Americas								
Canada	148.1	204.4	320.2	110.9	38.1	32.6	43.8	51.2
United States	1 172.8	1 699.7	1 593.6	1 332.3	1 374.4	1 186.4	1 180.7	1 136.3

[1] Australian Commodity Statistics, 2008. ABARE

Asia								
Chinese Taipei	116.7	132.6	152.3	126.7	124.2	148.3	134.6	117.4
Hong Kong, China	18.2	17.8	17.1	15.0	27.3	18.7	13.5	21.5
Indonesia	40.8	37.2	46.1	38.4	26.7	33.5	39.0	83.3
Japan	1 537.3	1 728.2	1 237.7	1 384.4	2 189.9	2 244.7	2 172.1	1 844.0
Korea, Rep. of	221.8	228.9	320.4	250.7	434.4	494.8	734.7	725.6
Malaysia	15.0	16.0	20.2	15.9	12.1	7.8	10.0	17.1
Philippines	34.3	55.8	36.1	23.0	4.3	5.9	3.7	7.2
Singapore	18.5	20.4	20.8	22.5	17.3	15.5	19.2	29.7
Europe								
European Union	37.3	48.4	53.5	49.2	62.8	56.8	77.2	61.6
CIS	3.8	14.4	2.9	0.7	2.0	4.6	61.0	32.2
Eastern Europe	6.3	1.2	9.1	4.5	1.3	0.4	0.4	0.1
Middle East								
Kuwait	0.3	4.6	1.8	9.8	3.4	1.0	0.9	2.3
Saudi Arabia	2.1	23.0	11.6	7.8	3.1	1.7	4.5	3.0
United Arab Emirates	4.4	11.6	10.9	7.8	12.0	13.7	15.6	20.4
Oceania								
New Zealand	11.1	6.3	25.6	15.9	9.8	8.8	8.0	7.8
Pacific Isles	5.2	7.2	7.4	5.4	4.5	4.0	6.3	10.0
Papua New Guinea	14.1	11.5	9.8	4.9	5.2	4.3	5.8	7.6
Total beef and veal	3 464.0	4 357.3	4 002.6	3 475.4	4 390.3	4 346.6	4 604.0	4 258.1

Table 2: Export markets for Australian sheep meat.

Value of Australian exports of sheep meat

	2000	2001	2002	2003	2004	2005	2006	2007
	$m	$m	$m	$m	$m	$m	$m	$m
Mutton								
Canada	4.6	6.8	5.2	3.6	5.8	5.4	7.1	2.9
Chinese Taipei	26.3	36.9	48.9	32.2	41.9	34.8	29.8	23.2
CIS	3.1	3.7	5.4	1.3	5.8	13.5	33.1	23.5
European Union	34.1	42.0	41.4	28.1	43.2	48.3	46.7	40.3
Japan	34.0	42.7	51.1	29.9	47.1	38.1	31.5	29.9
Korea, Rep. of	1.7	2.3	3.3	2.2	3.1	3.1	2.9	2.6
Malaysia	16.5	21.7	22.9	15.9	22.6	18.5	25.1	21.8
Papua New Guinea	6.2	7.4	6.6	6.1	5.1	5.2	4.2	6.5
Saudi Arabia	43.9	90.1	77.5	65.0	53.0	63.9	67.3	58.9
Singapore	18.4	23.4	23.2	20.4	22.0	18.6	19.5	19.3
South Africa	46.3	30.9	17.6	11.1	14.1	18.7	29.2	21.8
United States	43.9	56.4	64.7	67.9	48.6	44.4	50.2	43.2
Other	97.1	146.3	152.0	91.7	113.6	119.7	141.3	135.2
Total	376.4	510.6	519.7	375.3	426.0	432.0	487.9	429.2
Lamb								
European Union b	74.3	105.7	89.3	96.9	93.4	83.9	85.6	82.2
Japan	30.7	37.0	40.8	42.3	53.5	79.1	83.0	56.0
Papua New Guinea	16.0	18.0	15.7	14.4	17.3	19.4	20.0	23.8
South Africa	15.3	5.5	1.2	2.1	3.5	5.3	9.0	7.5
United Arab Emirates	24.2	27.4	31.6	29.9	27.0	32.8	47.1	56.4
United States	150.2	219.9	218.2	257.5	259.9	324.2	319.0	328.4
Other	137.0	165.7	169.5	159.8	184.7	233.1	229.4	268.0
Total	447.7	579.1	566.2	602.9	639.3	777.8	793.2	822.3

3.3 Results from residues trials presented to the APVMA

A new animal transfer study with a significant depuration phase has been considered to allow the estimation of decline of residues in tissues including offal.

Thirty-eight cattle were dosed daily for 28 consecutive days at 3 rates:

[1×] 4 mg/kg bw/day chlorothalonil + 0.032 mg/kg bw/day 4-hydroxy-2,5,6-trichloroisophthalonitrile: equivalent to approximately 165 mg/kg chlorothalonil in the feed.

[3×] 12 mg/kg bw/day chlorothalonil + 0.096 mg/kg bw/day 4-hydroxy-2,5,6-trichloroisophthalonitrile: equivalent to approximately 511 mg/kg chlorothalonil in the feed.

[5×] 20 mg/kg bw/day chlorothalonil + 0.16 mg/kg bw/day 4-hydroxy-2,5,6-trichloroisophthalonitrile: equivalent to approximately 1,211 mg/kg chlorothalonil in the feed.

The dosing regime included the 4-hydroxy-2,5,6-trichloroisophthalonitrile metabolite with parent compound, to reflect the incurred residue in forage and fodder.

Animals in the [5×] group were initially dosed for 5 days at a [10×] rate, however due to low feed intakes they were removed from the study for animal welfare reasons. The animals were re-introduced to the study after 17 days on clean feed and dosed at the [5×] rate for 28 days. As residues were shown to be present in these animals at the start of dosing at the [5×] rate the results for this group are not discussed in this summary. However depuration data from this group were included in the calculations of half lives for chlorothalonil residues in tissues.

Animals were sacrificed at 0, 3, 5 and 10 weeks after removal from dosing and samples of liver, kidney, muscle, peri-renal fat and subcutaneous fat were collected and analysed for chlorothalonil residues.

Residues of the metabolite 4-hydroxy-2,5,6-trichloroisophalonitrile (residue definition for chlorothalonil in animal commodities) were extracted from the bovine tissues with acidic acetone. After purification, extracts were analysed by HPLC with detection by tandem mass spectrometry. The LOQ for the method was 0.01 mg/kg, the LOD was 0.005 mg/kg. Recoveries of 4-hydroxy-2,5,6-trichloroisophalonitrile from fortified samples of bovine tissues were generally within acceptable limits (between 62 and 122%, n=62).

Residues in kidney
Average residues of 4-hydroxy-2,5,6-trichloroisophalonitrile in kidney immediately after the completion of dosing at the 1× and 3× rates were 2.9 and 4.7 mg/kg, respectively. Residues in kidney did not decline to below the LOQ (0.01 mg/kg)

during the depuration phase at any dosing level. For cattle dosed at the 1× rate, average residues in kidney were 0.11 mg/kg after 10 weeks on clean feed.

Residues in liver
Average residues of 4-hydroxy-2,5,6-trichloroisophalonitrile in liver immediately after the completion of dosing at the 1× and 3× rates were 1.7 and 3.5 mg/kg, respectively. Residues in liver did not decline to below the LOQ (0.01 mg/kg) during the depuration phase for any dosing level. For cattle dosed at the 1× rate, average residues in liver were 0.03 mg/kg after 10 weeks on clean feed.

Residues in muscle
Residues of 4-hydroxy-2,5,6-trichloroisophalonitrile in muscle were considerably lower than the levels detected in kidney and liver. Average residues of 4-hydroxy-2,5,6-trichloroisophalonitrile in muscle immediately after the completion of dosing at the 1× and 3× rates were 0.20 and 0.45 mg/kg, respectively. Residues of 4-hydroxy-2,5,6-trichloroisophalonitrile in muscle had declined below the LOD (0.005 mg/kg) for the 1× dosing group after 10 weeks on clean feed. In addition, the average residue in muscle for the 3× dose group was at the LOQ (0.01 mg/kg) after 10 weeks on clean feed.

Residues in peri-renal fat
Residues of 4-hydroxy-2,5,6-trichloroisophalonitrile in peri-renal fat were slightly higher than those in muscle. Average residues of 4-hydroxy-2,5,6-trichloroisophalonitrile in peri-renal fat immediately after the completion of dosing at the 1× and 3× rates were 0.35 and 1.0 mg/kg, respectively. For the 1× dose group residues had declined to below the LOQ (0.01 mg/kg) after 10 weeks on clean feed.

Residues in subcutaneous fat
Residues of 4-hydroxy-2,5,6-trichloroisophalonitrile in subcutaneous fat were also higher than those in muscle. Average residues of 4-hydroxy-2,5,6-trichloroisophalonitrile in subcutaneous fat immediately after the completion of dosing at the 1× and 3× rates were 0.44 and 1.6 mg/kg, respectively. For the 1× dose group, average residues were at the LOQ (0.01 mg/kg) after 10 weeks on clean feed.

Residues in pulse forage and fodder
In overseas trials considered previously, faba beans and chickpeas were treated with 2-3 applications of chlorothalonil at 0.91× the maximum application rate for pulses. Residues in faba bean forage (dry weight basis) at 14 Days After Last Treatment (DALT) were 1.6, 3.6, 4.8, 6.3, 8.6, 11, 12, 18 (n = 2), 20, 21, 25, 27, 29, 32 (n = 2), 33, 41 and 65 mg/kg. For samples of faba bean fodder, including empty pods), collected by mechanical harvest at 14 DALT residues were 9.2, 9.3, 9.7, 15, 16 (n = 2), 17, 22, 32, 38, 46 and 80 mg/kg (DW). Residues in chickpea forage (dry weight basis) at 14 DALT were 9.8, 29, 37 and 89 mg/kg. For samples of chickpea fodder, including empty pods, collected by mechanical harvest at 14 DALT residues were 8.1, 10, 48 and 58 mg/kg.

In the overseas trials the highest chlorothalonil residues (dry weight basis) in faba bean forage / fodder at 14 DALT was 80 mg/kg. The highest residues in chickpea forage / fodder was 89 mg/kg at 14 DALT.

Australian residues data were previously considered for the forage and fodder of broad beans, chickpeas and lentils. Crops were treated with up to 5 applications of chlorothalonil at 0.5-0.6× the maximum rate, followed by a single application at 0.87-1.2× the maximum rate. Residues (dry weight basis) in faba bean forage at 14 DALT were 10, 15 and 24 mg/kg. For chickpea forage residues were 4.7 and 30 mg/kg at 14 DALT. For lentil forage, residues were 34 and 36 mg/kg. Three Australian reverse decline trials were also available and involved a single application to chickpeas and lentils at the proposed rate. At 14 days after treatment, residues in chickpea forage / fodder (dry wt) were 10.3 and 13.3 mg/kg. The residue observed in lentil forage / fodder was 10.6 mg/kg.

In the Australian trials the highest chlorothalonil residues (on a dry weight basis) in faba bean, chick pea and lentil forage / fodder were 24, 30 and 36 mg/kg respectively 14 DALT.

In the initial evaluation, a conservative MRL of 250 mg/kg was proposed for pulse forage and fodder as the re-treatment interval of 11 – 13 days in the trials did not address the shorter minimum re-treatment interval of 7 days for faba beans. The highest residue of 80 mg/kg (from overseas trials) was detected in faba bean forage / fodder at the proposed 14 day withholding period after 2 applications (0.91×) with a 12 day interval. As the residue immediately before the 2nd application was 25 mg/kg it is likely that only the last 2 applications in a spray program would make a significant contribution to the final residue at harvest. It is considered that an MRL of 160 mg/kg for pulse forage / fodder should be adequately conservative to account for the possibility of higher residues resulting from the shorter 7 day re-treatment interval for faba beans.

Residues in pea forage and fodder

Residues data for processing peas that are representative of GAP are based on 4 applications of chlorothalonil, applied at the maximum rate, at the minimum recommended application interval of 7 days. Where peas were harvested 14 DALT residues in the fodder (dry wt basis) were 57, 114, 135 and 219 mg/kg. The recommended MRL for chlorothalonil in pea forage is 250 mg/kg, set in conjunction with a grazing WHP of 14 days.

Anticipated livestock dietary exposure

The anticipated dietary exposure for cattle as a result of the use of chlorothalonil on pulse and legume crops is calculated below. The dietary exposure for pulse forage and fodder is calculated assuming residues of up to the proposed MRL of 160 mg/kg. The dietary exposure for pea forage and fodder is calculated for a highest residue of 219 mg/kg.

Cattle- 500 kg bw, 20 kg DM/day

Feed group	Commodity	% in diet	Feed intake	Residue, mg/kg	% DM	Livestock dietary exposure	
						mg/animal	mg/kg bw
Pulses/legumes	Chickpeas, faba beans, lentils.	100	20	2.4*	100	48	0.096
Forage/Fodder of pulse and legume crops	Chickpeas, faba beans, lentils.	100	20	160	100	3200	6.4
Forage/Fodder of pulse and legume crops	Processing Pea hay/fodder	100	20	219*	100	4380	8.76
Maximum Feeding Level					**100**	**4380**	**8.76**

*based on highest residue rather than the MRL

The maximum predicted intake of chlorothalonil by livestock will be as a result of the consumption of processing pea hay/fodder as 100% of the diet. The maximum intake would be 8.76 mg/kg bw or 219 ppm in the feed. In the new animal transfer study, dosing at 165 ppm gave maximum residues of 3.5 mg/kg in kidney and 0.62 mg/kg in fat. The predicted maximum residues resulting from a chlorothalonil intake of 219 ppm are 3.8 mg/kg in kidney and 1.1 mg/kg in fat (Table 3). An edible offal MRL of 7 mg/kg is recommended. The previously proposed MRL of 3 mg/kg for Meat (mammalian) [in the fat] should be reduced to 2 mg/kg based on the results of the new study.

Table 3: Predicted residues in tissues for an intake of 219 ppm in the feed, and proposed animal commodity MRLs.

Substrate	Highest residue after dosing at 165 ppm (mg/kg)	Predicted residue for an intake of 219 ppm (mg/kg)
Kidney	3.5	3.8
Liver	2.1	2.4
Muscle	0.26	0.3
Peri-renal fat	0.43	0.56
Sub-cutaneous fat	0.62	(1.1
Proposed Animal Commodity MRLs: MO 0105 Edible offal (mammalian) 7 mg/kg MM 0095 Meat (mammalian) [in the fat] 2 mg/kg ML 0106 Milks 0.05 mg/kg (grazing restraint for forage and fodder)		

3.4 Overseas registration and approved label instructions

Chlorothalonil has been used as a fungicide since the late 1960's and is used extensively worldwide in a range of horticultural and agricultural crops. The applicant has indicated that chlorothalonil is registered in over 80 countries including Canada, the USA, South Africa and throughout the EU.

3.5 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.

The following overseas residue MRLs / tolerances have been established:

Commodity[α]	**Tolerance for residues arising from the use of chlorothalonil (mg/kg)**						
	AUS	**Codex**	**Japan**	**USA**	**Republic of Korea**	**EU**	**Taiwan**
Plant Commodities							
Residue Definition	Parent	Parent	Parent	Chlorothalonil (tetrachloroisophthalonitrile) and its metabolite 4-hydroxy-2,5,6-trichloroisophthalonitrile	Parent	Parent	Parent[♠]
Pulses	T7 (3§)						
Peas	10 (vegetable)		0.2				
Broad Beans			0.2				
Soybean			0.2	0.2	0.2	0.01	
Pulses beans						0.01	
Pulses lentils				0.1		0.01	
Pulses peas						0.01	
Pulses others			0.2			0.01	
Beans (dry)		0.2	0.2	0.1	0.1		0.1
Stock feed commodities							
Pulse forage, fodder and hay (DW)	T100 (160§)						
Pea hay or pea fodder (dry)	250§						

Commodity[α]	Tolerance for residues arising from the use of chlorothalonil (mg/kg)						
	AUS	**Codex**	**Japan**	**USA**	**Republic of Korea**	**EU**	**Taiwan**
Animal Commodities							
Residue Definition	4-hydroxy-2,5,6-trichloroisophthalonitrile§		Parent[‡]	4-hydroxy-2,5,6-trichloroisophthalonitrile		Parent	Parent[♠]
Edible offal (mammalian)	T3 (7§)						
Cattle kidney			0.3	0.5		0.01	
Sheep kidney				0.5		0.01	
Cattle liver			0.03			0.01	
Sheep liver						0.01	
Cattle mbyp† except kidney				0.05			
Sheep mbyp† except kidney				0.05			
Edible offal, sheep						0.01	
Chicken liver			0.01				
Other terrestrial mammals, liver			0.03				
Other terrestrial mammals, offal			0.03				
Other terrestrial mammals, kidney			0.3				
Cattle, edible offal			0.03			0.01	
Other poultry liver			0.01				
Chicken kidney			0.01				
Other poultry kidney			0.01				
Chicken edible offal			0.01				
Other poultry edible offal			0.01				

Commodity[α]	Tolerance for residues arising from the use of chlorothalonil (mg/kg)						
	AUS	**Codex**	**Japan**	**USA**	**Republic of Korea**	**EU**	**Taiwan**
Meat (mammalian) [in the fat]	T2 (2§)						
Cattle fat			0.1	0.1		0.01	
Sheep fat				0.1		0.01	
Other terrestrial mammals fat			0.1				
Chicken fat			0.01				
Other poultry fat			0.01				
Cattle, muscle			0.02				
Cattle, meat				0.03		0.01	
Sheep meat				0.03		0.01	
Other terrestrial mammals muscle			0.02				
Chicken muscle			0.01				
Other poultry muscle			0.01				
Milks	T0.05 (0.05§)		0.06	0.1		0.01	
Eggs	*0.05		0.01				

[α] Commodity covered by tolerance. For instance, tolerance may be for bovine liver which covers cattle liver.
§ proposed
† meat by-products
‡ Provisional MRLs based on those of USA & EU
♠ Standard makes the general statement 'The examination of pesticide residues shall include the pesticide itself and its metabolites' Interpretation is unclear.

3.6 Current and proposed Australian MRLs for chlorothalonil.

The following changes to the Australian MRL standard are proposed for chlorothalonil:

Table 1

Compound	Food		MRL (mg/kg)
DELETE:			
Chlorothalonil			
	VD 0070	Pulses	T7
	ML 0106	Milks	T0.05
	MM 0095	Meat (mammalian)[in the fat]	T2
	MO 0105	Edible Offal (mammalian)	T3
ADD:			
Chlorothalonil	VD 0070	Pulses	3
	ML 0106	Milks	0.05
	MM 0095	Meat (mammalian)[in the fat]	2
	MO 0105	Edible Offal (mammalian)	7
	PE 0112	Eggs	*0.05
	PO 0111	Poultry, edible offal of	*0.05
	PM 0110	Poultry meat	*0.05

Table 3

Compound	Residue
DELETE:	
Chlorothalonil	Commodities of plant origin: chlorothalonil Commodities of animal origin: chlorothalonil and the 4-hydroxy-2,5,6-trichloroisophthalonitrile metabolite expressed as chlorothalonil
ADD:	
Chlorothalonil	Commodities of plant origin; chlorothalonil Commodities of animal origin: 4-hydroxy-2,5,6-trichloroisophthalonitrile metabolite, expressed as chlorothalonil.

Table 4

Compound	Animal feed commodity		MRL (mg/kg)
DELETE:			
Chlorothalonil		Pulses, forage and fodder	T100
ADD:			
Chlorothalonil		Pulses, forage and fodder, except pea hay or pea fodder	160
	AL 0072	Pea hay or pea fodder (dry)	250

For full details of current chlorothalonil MRLs, please refer to the APVMA website http://www.apvma.gov.au and follow the Residues link.

3.7 Potential Risk to Trade

Export of treated produce containing finite (measurable) residues of chlorothalonil may pose a risk to Australian trade in situations where no residue tolerance is established in the importing country or where residues in Australian produce are likely to exceed a residue tolerance established in the importing country.

Advice received from Federal and State government departments and peak industry associations in response to the first TAN published for the product indicated that the presence of residues in offal above the standards of trading partners represents an unacceptable risk to the export of this commodity. In addition concerns were raised regarding the possible flow on effects that a detection of chlorothalonil in offal may have on meat exports.

Residues of parent chlorothalonil are not expected in animal commodities. Therefore the standards of Codex, Republic of Korea and the EU where the residue definition for animal commodities is parent compound only are not of concern. The situation for Taiwan is not clear. MRLs have not been established in Taiwan for chlorothalonil in animal commodities, however it is not clear if the residue definition that would be applied would be that of Codex (parent) or if *4-hydroxy-2,5,6-trichloroisophthalonitrile* would be included. For Japan, the residue definition for the provisional MRLs is parent. However as the animal commodity MRLs appear to be established on the basis of the MRLs of the USA this risk assessment assumes the residue definition of *4-hydroxy-2,5,6-trichloroisophthalonitrile* for Japanese MRLs.

The lowest MRLs in markets where animal commodity MRLs are established as the metabolite *4-hydroxy-2,5,6-trichloroisophthalonitrile* are 0.3 mg/kg in kidney (Japan), 0.03 mg/kg in liver (Japan) and 0.1 mg/kg in fat (Japan, USA). To support the proposed uses, it is necessary to recommend an ESI which is long enough to effectively mitigate the risk associated with the trading partner MRLs of 0.3 mg/kg in kidney and 0.1 mg/kg in fat.

An average half life for 4-hydroxy-2,5,6-trichloroisophalonitrile in kidney was calculated to be 15.5 days based on the decline of residues from the 1× dosing group in the new animal transfer study. The calculations assume that the half life is constant and does not depend on concentration.

The decline of the metabolite in kidney for the 1× dosing group is plotted in Figure 1. The decline was represented by the equation $y = 2.531e^{-0.32x}$ (with $R^2 = 0.990$). Based on this equation the half life of the metabolite in kidney would be: $t_{1/2}$ = [ln 0.5]/-0.32 = 2.17 weeks = 15.2 days, which is in good agreement with the calculated average value of 15.5 days.

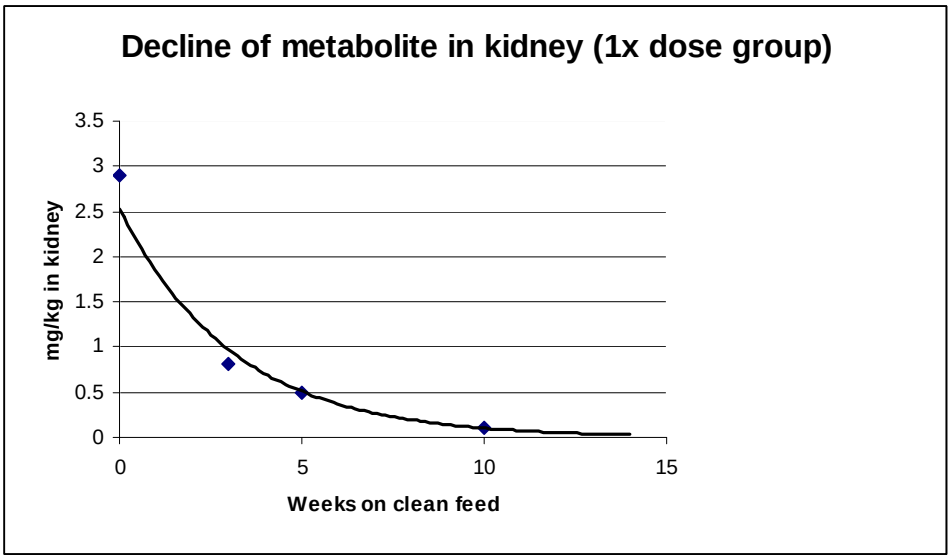

Figure 1

Based on an average half life of 15.5 days for 4-hydroxy-2,5,6-trichloroisophalonitrile in kidney and a predicted high kidney residue of 3.8 mg/kg the maximum predicted residues after the applicants proposed 60 day ESI would be 0.26 mg/kg. As this is approximately equivalent (below) to the Japanese MRL and noting the conservative nature of the calculation it is proposed that a 60 day ESI would be acceptable to address residues in kidney.

For fat an average half life of 11.96 days was calculated, based on the decline of average residues in subcutaneous fat (which had the highest residues) from 0 – 70 days for all 3 feeding levels in the new animal transfer study. From the highest residue of 1.1 mg/kg the maximum predicted residues after the applicants proposed 60 day ESI would be 0.03 mg/kg. As this is below the US/Japanese MRL of 0.1 mg/kg for cattle fat a 60 day ESI would be acceptable for residues in fat.

Japan has established an MRL (provisional) of 0.03 mg/kg for chlorothalonil in cattle liver. An average half life of 13 days was calculated for the metabolite in liver, based on the decline of average residues over 0 – 70 days for all 3 feeding levels. After a 60 day ESI, the predicted highest residue of (2.4) mg/kg in liver would decline to 0.10 mg/kg. In the new animal transfer study average residues of 4-hydroxy-2,5,6-trichloroisophalonitrile in liver from the 1× feeding group declined from 1.7 mg/kg to 0.03 mg/kg after 70 days on clean feed.

Predicted residues at an Export Slaughter Interval of 60 days are summarised in Table 4.

Table 4: Predicted residues in animal tissues at an ESI of 60 days following exposure to feed containing the observed high residue of 219 mg/kg chlorothalonil residues.

Tissue	Predicted HR (mg/kg)	Predicted residue (mg/kg) after a 60 day ESI	Target residue (mg/kg)
Kidney	3.8	0.26	0.3
Liver	2.4	0.10	0.03
Fat	1.1	0.03	0.1

The estimates in Table 4 are based on a maximum feeding level of 219 mg/kg, the maximum residue observed in garden pea forage following 4 applications of chlorothalonil at 7 day intervals at the maximum label rate for peas of 1.3 kg ai/ha. The range of expected residues in feeds is likely to be much less that 219 ppm, hence the 60 days ESI could be considered to be conservative.

Residues in milk and milk products are not considered here as a grazing restraint was previously recommended for lactating animals producing milk for human consumption to ensure that the dietary exposure to chlorothalonil is acceptable. Comment is sought here on the practicality of that restraint statement.

3. CONCLUSION

Crop Care Australasia Pty Ltd has submitted an application to add several new uses to the label of Crop Care Barrack 720 Fungicide, containing 720 g/L chlorothalonil. The applicant is seeking an extension of the approved uses of chlorothalonil to include chickpeas and lentils, for the control of Ascochyta blight. It is also proposed that the feeding restraints that currently apply to use on faba beans and peas be removed.

Comments received in response to an initial Trade Advice Note published for the product in 2006 indicated that the risk to trade arising from residues in edible offal had not been adequately addressed. The advice received was that detectable residues in offal represent an unacceptable risk to trade in this commodity. As the available animal transfer studies did not contain sufficient information to allow the establishment of a suitable ESI to ensure acceptable residues in offal, a new study with a 10 week depuration phase was conducted by Crop Care Australia Pty Ltd.

Based on the maximum proposed use pattern, the intake by animals of chlorothalonil through the consumption of treated forage and fodder of pulse and legume crops is expected to lie between the 1× (165 ppm) and 3× (511 ppm) dose rates in the animal feeding study. At the completion of the depuration period (10 weeks on clean feed), residues were still detectable in the kidney and liver of cattle from all dosing groups. However, observance of a 60 day ESI would significantly reduce the risk of unacceptable residues being detected in animal tissues. A 60 day ESI would result in kidney and fat residues at or below the tolerances of trading partners who have established relevant standards. The calculated maximum predicted residue in liver would be above the Japanese standard for this commodity (for feeding of garden pea forage), which represents a possible trade risk. However in practice residues are expected to be much lower than those estimated here. In addition, results for the 1×

feeding level in the animal depuration study resulted in residue levels in liver much closer to the Japanese standard than those calculated.

Comment is sought on:

1. The ability of a 60 day ESI to adequately mitigate the trade risk associated with the proposed use.
2. The practicality of a restraint statement against feeding treated pulse and pea forage and fodder to lactating dairy animals.

Following advice received on the acceptability of the available residues management options the APVMA will determine if the risk to trade associated with the proposed uses of Crop Care Barrack 720 Fungicide on chick peas and lentils, and removal of the grazing restraints for faba beans and peas is acceptable.

A more detailed technical assessment report on the evaluation of the trade implications of this chemical can be obtained by contacting the APVMA on (02) 6210 4748, or 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