



Australian Government
Australian Pesticides and
Veterinary Medicines Authority



SHEEP ECTOPARASITICIDES

Review Findings

Reconsideration of registration of selected sheep ectoparasiticide
products and approvals of their associated labels

JUNE 2014

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FOREWORD

The Australian Pesticides & Veterinary Medicines Authority (APVMA) is an independent statutory authority with responsibility for the regulation of agricultural and veterinary chemicals in Australia. Its statutory powers are provided in the Agvet Codes scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*.

The APVMA can reconsider the approval of an active constituent, the registration of a chemical product or the approval of a label for a container for a chemical product at any time. This is outlined in Part 2, Division 4 of the Agvet Codes.

The basis for the current reconsideration is whether the APVMA is satisfied that continued use of selected sheep ectoparasiticide products in accordance with the instructions for their use:

- would not be an undue hazard to the safety of people exposed to them during their handling; or people using anything containing their residues;
- would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment; and
- would not unduly prejudice trade or commerce between Australia and places outside Australia.

The APVMA also considers whether product labels carry adequate instructions and warning statements.

A reconsideration may be initiated when new research or evidence has raised concerns about the use or safety of a particular chemical, a product or its label.

The reconsideration process includes a call for information from a variety of sources, a review of that information and, following public consultation, a decision about the future use of the chemical or product.

In undertaking reconsiderations (hereafter referred to as reviews), the APVMA works in close cooperation with advisory agencies including the Office of Chemical Safety (OCS), the Department of the Environment and state departments of agriculture as well as other expert advisers as appropriate.

The APVMA has a policy of encouraging openness and transparency in its activities and community involvement in decision-making. The publication of review reports is a part of that process.

The APVMA also makes these reports available to the regulatory agencies of other countries as part of bilateral agreements. The APVMA recommends that countries receiving these reports not utilise them for registration purposes unless they are also provided with the raw data from the relevant applicant.

This document sets out the review findings relating to selected sheep ectoparasiticide products that have been nominated for review by the APVMA. The review findings and regulatory actions are based on information collected from a variety of sources. The information and technical data required by the APVMA to review the safety of both new and existing chemical products must be

derived according to accepted scientific principles, as must be the methods of assessment undertaken by the APVMA.

The review findings (Volume 1) and technical environment reports (Volume 2) for all registrations relating to selected sheep ectoparasiticide products are available from the APVMA web site:

www.apvma.gov.au/products/review/index.php

CONTENTS

FOREWORD	ii
CONTENTS	iv
List of tables	v
ABBREVIATIONS	vi
<hr/>	
1 EXECUTIVE SUMMARY	1
1.1 Introduction	1
1.2 Public submissions and consultation	1
1.3 Summary of review findings	2
<hr/>	
2 INTRODUCTION	3
Occupational Health and Safety (OHS)	3
Environment	3
Trade	4
Information sources	4
2.1 Scope of the review	5
2.2 Regulatory status of selected sheep ectoparasiticides affected by the review	6
Concurrent Reviews	6
2.3 Application of the review to specialty wool lines	7
2.4 Public consultation on preliminary review findings report (April 2006)	8
<hr/>	
3 DATA ASSESSMENTS	10
3.1 Occupational health and safety (OHS) assessment	10
Introduction	10
Use patterns	10
Health effects relating to occupational exposure	10
Dermal absorption	11
Recommended sheep rehandling interval statements	12
3.2 Environmental assessment	14
Introduction	14
Australian sewage treatment assumptions	14
Effect of plume dilution at ocean outfall	15
Residue levels on wool	16
Australian model assumptions, based on the ocean outfall at Black Rock (Geelong)	16
Revisions to the environmental assessment following consideration of public comments	17
“Hot-spot” scouring scenario	19
Revised environmental assessment outcomes	20
Summary of regulatory findings for Australian environments	27
3.3 Trade assessment	28
Residue levels required by European Union	29
Conclusion	30
<hr/>	
4 ADDITIONAL COMMENTS RECEIVED IN RELATION TO THE PRELIMINARY REVIEW FINDINGS ENVIRONMENTAL ASSESSMENT	32
4.1 AWI Wool Residue Survey Data versus Wool Residue Trial Results for Environmental Risk Analyses of Scouring	32

4.2	Domestic Scouring Model	32
4.3	Model for Overseas Scouring	33
4.4	Specialty Wool Lines	34
4.5	Dicyclanil	35
4.6	Cyromazine	35
4.7	Triflumuron	35
4.8	Diflubenzuron	36
4.9	Cypermethrin/Alpha-Cypermethrin	40
<hr/>		
5	REVIEW FINDINGS	42
5.1	Change in terminology – wool harvest interval	42
5.2	Occupational health and safety findings	42
5.3	Australian environment findings	44
5.4	Trade findings	45
5.5	Recommendations	46
<hr/>		
	APPENDICES	47
	Appendix A – Products affected by the review	48
<hr/>		
	GLOSSARY	60
	REFERENCES	61
	List of tables	
	<i>Table 1 Dermal absorption for sheep ectoparasiticides</i>	11
	<i>Table 2 Recommended sheep rehandling intervals for sheep ectoparasiticides</i>	13
	<i>Table 3: Australian model assumptions used in the environmental risk assessment</i>	17
	<i>Table 4: The revised environmental risk quotients (RQs) for scouring greasy wool in Australia with national average and hot-spot levels of residual ectoparasiticides.</i>	18
	<i>Table 5 Recommended Wool Harvest Intervals (WHI) to manage risks to the Australian environment</i>	28
	<i>Table 6 European Union acceptable sum total content of given chemicals in greasy wool</i>	29
	<i>Table 7 Recommended sheep rehandling intervals</i>	43
	<i>Table 8 Recommended wool harvest intervals</i>	45

ABBREVIATIONS

AF	Assessment factor
APVMA	Australian Pesticides & Veterinary Medicines Authority
AWI	Australian Wool Innovation Limited
ChE	Cholinesterase
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DOM	dissolved organic matter
EC	Emulsifiable concentrate
EC50	Effective concentration 50
EQS	Environmental quality standard
EU	European Union
FAISD	Handbook of first aid instructions, safety directions and warning statements for agricultural and veterinary chemicals.
IGR	Insect Growth Regulator
IPPC	International Pollution Prevention Committee
K_{ow}	n-Octanol/water partitioning coefficient
LC50	Lethal concentration 50
LOEL	Lowest observed effect level
MAC	Maximum acceptable concentration
MAFF	Ministry of Agriculture, Fisheries and Food (UK)
NOEL	No observed effect level
NRA	National Registration Authority for Agricultural and Veterinary Chemicals, now APVMA
NRS	National Registration Scheme
OCS (OHS)	Occupational Health and Safety area within the OCS, previously undertaken by the NOHSC prior to it becoming the OASCC
OCS	Office of Chemical Safety
OASCC	Office of the Australian Safety and Compensation Council
OP	Organophosphate
PEC	Predicted environmental concentration
PNEC	Predicted no effect concentration
PPE	Personal protective equipment
PRF	Preliminary Review Findings
RQ	Risk Quotient
SP	Synthetic pyrethroid
WHI	Wool harvesting interval, synonymous with wool withholding period
WHP	Withholding period
WWP	Wool withholding period, synonymous with wool harvesting interval

Time

h	Hour
---	------

Volume

L	Litre
---	-------

ML	Megalitre
----	-----------

mL	Millilitre
----	------------

Weight

g	Gram
---	------

kg	Kilogram
----	----------

kt	Kilotonne
----	-----------

μ g	Microgram
---------	-----------

mg	Milligram
----	-----------

ng	Nanogram
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Symbols

<<	Much less than
----	----------------

1 EXECUTIVE SUMMARY

1.1 Introduction

The review of selected sheep ectoparasiticide products commenced in September 1999 and addresses the following concerns:

- the occupational health of workers, particularly shearers, who may come into contact with treated wool, primarily during wool harvesting;
- the potential of chemical residues to harm susceptible organisms in the environment, particularly if the chemicals are released in the course of wool processing; and
- the potential of chemical residues on treated wool to prejudice trade, particularly where overseas wool processing plants discharge scour effluent into river ecosystems.

The review covers all sheep ectoparasiticide products that either:

- contain one or more of the 13¹ selected active constituents and / or
- have a claim for treatment of ectoparasites, applied externally, in long wool sheep (six or more week's wool growth).

The review does not cover individual animal treatment products for which the claims are limited to wound treatments and / or fly strike dressings, nor does it include a range of products or active constituents which are only approved for use on short wool (less than six weeks wool growth). It does not consider applicator exposure.

Since the commencement of the review a number of products have discontinued their registration and are being or have been phased out. The current list of registered products affected by the review can be found at Appendix A.

1.2 Public submissions and consultation

The Preliminary Review Findings Report (PRF) was released for public comment in April 2006. The PRF outlined the proposed regulatory action for products covered by the review. Comments in relation to the proposed outcomes of the review were received from product registrants, user groups, state government regulators, industry groups and scientific experts in the field. Some additional data and information was also provided. These addressed issues such as appropriateness of assumptions used in the risk assessment, the enforceability of proposed label amendments, the need for timely regulatory action and the impact of decisions on both the use of chemicals on sheep in Australia and the trade of Australian wool to other countries. These comments and additional information have been taken into consideration in the preparation of the Review Findings Report.

¹ alpha-cypermethrin, chlorfenvinphos, cypermethrin, cyromazine, deltamethrin, diazinon, dicyclanil, diflubenzuron, temephos, triflumuron, propetamphos, ivermectin, spinosad

1.3 Summary of review findings

The APVMA has found that it is not satisfied that the continued use of, or any other dealing with the products that are directly affected by the review of selected sheep ectoparasiticides:

- would not be likely to have an effect that is harmful to the occupational health of workers, particularly shearers, handling treated wool, primarily during wool harvesting

and / or
- would not be likely to have an effect that is harmful to the environment as there is potential for chemical residues to harm susceptible organisms in the environment, particularly if the chemicals are released in the course of wool processing

and / or
- would not have the potential to prejudice trade because of chemical residues on treated wool.

However, the APVMA has found that the current label approvals for these products can be varied to include adequate instructions to enable the APVMA to be satisfied in relation to occupational health and safety, the environment and trade.

2 INTRODUCTION

The Australian sheep blowfly (*Lucilia cuprina*) and the body louse (*Bovicola ovis*) are the main ectoparasites of sheep in Australia. Wool producers depend on the use of registered chemical products to control or prevent disease and production losses associated with ectoparasite infestation. The chemical products approved for external use on sheep are collectively called sheep ectoparasiticide products, or sheep ectoparasiticides.

Sheep ectoparasiticide products are applied by dipping, jetting or backline treatment. Dipping aims to apply a uniform concentration of ectoparasiticide to the whole of the fleece, while jetting and backline treatments deposit the product onto specific areas of the body so that the residue concentration may be substantially higher in those parts of the fleece, compared with that in untreated areas. Some of the chemical groups, such as the organophosphate (OP), synthetic pyrethroid (SP) and macrocyclic lactones, act against specific enzymes involved in neural transmission in the target ectoparasites, while others, such as the triazine and benzyl phenyl urea compounds (the insect growth regulators (IGRs)), interrupt moulting and maturation of juvenile stages.

The use of sheep ectoparasiticides may result in chemical residues on treated wool. When sheep are handled during wool harvesting and when wool is processed, these residues could potentially have an effect that is harmful to workers or an effect that is harmful to the environment.

Many of the currently-used sheep ectoparasiticides were originally assessed and registered before the introduction of the National Registration Scheme (NRS) in 1991. This review considers the risks associated with treated wool.

This review is concerned with three areas of potential risk:

Occupational Health and Safety (OHS)

This review assesses the post-application risks associated with the use of sheep ectoparasiticides. Risks during application of the chemicals are not included in the scope of this review.

Chemical residues on wool might pose an occupational hazard to workers handling sheep, particularly shearers, through dermal absorption (Savage, 1998). There is information indicating that the use of sheep ectoparasiticides, particularly OPs, may be an undue hazard to the safety of people handling wool that contains chemical residues. This undue hazard can continue even after application of the sheep ectoparasiticide to the animal has been completed and the treated wool has dried.

Environment

In Australia, discharge of untreated scouring effluent to surface waters (ponds, rivers and other waterways) is specifically prevented under state legislation, with all effluent receiving some treatment before discharge to the environment (Savage, 1998). Land-based disposal systems use anaerobic and aerobic treatment lagoons and storage dams before treated effluent is sprayed onto pasture. Ectoparasiticide residues are a low environmental risk when managed in this way provided that contamination of streams and groundwater does not occur.

However, scour plants that discharge effluent to sewer systems that end up in ocean outfall have the potential to be an environmental hazard. Models have been used in this review to estimate the maximum mean residue across the Australian wool clip that would generate effluent with levels below the known toxic effect at the ocean outfall.

Trade

Australia produces around 24 % of the world's wool but very little of this is fully processed (scoured, dyed, woven and made up into garments) in Australia. Australia is also the world's leading wool exporter, accounting for two-thirds of the world's wool exports.

Much of Australia's flock is merino; this wool is finer than other breeds (83% of the Australian wool clip, which is predominantly merino, has a diameter of < 24 microns)². The majority of Australian wool is classified as fine apparel, suited to the manufacture of high-quality fashion apparel. Australia supplies 90% of the wool used in the global apparel market (< 19.5 microns)².

Other major wool-producing countries, including New Zealand and the Russian Federation, have a greater proportion of crossbred sheep than merinos. They produce coarser wools, suitable for interior applications such as carpets, upholstery and furnishings, rather than the fine apparel fashion market based in the European Union (EU).

The EU has requirements for levels of residues in any wool that it processes. These levels are reviewed every 3 years and may change at that time. Reference to these levels gives clear guidelines as to the residue levels acceptable for greasy wool processing in Europe. The review considers potential for trade disruption if Australian wool exceeds these guidelines.

Information sources

For this review, the APVMA has sought advice from:

- Office of Chemical Safety (OCS) within the Department of Health and Ageing;
- the Department of the Environment and
- State departments of agriculture.

Assessments undertaken in collaboration with advisory agencies included consideration of data from registrants and special interest groups, public submissions, scientific literature and archival holdings. The APVMA has also received advice from peak industry bodies, including Australian Wool Innovation Limited (AWI) and from the **Commonwealth Scientific and Industrial Research Organisation (CSIRO)**.

In addition to the formal public comment periods at the commencement of the review and at the time of release of the PRF, the APVMA has also liaised with interested parties including the National Farmers

² Australian Wool Innovation Limited: www.wool.com/Fibre-Selection_Australian-Merino-Wool_Quality-Assurance.htm

Federation, Australia Wool Innovations (AWI), the Australian Veterinary Association, the Livestock Contractors Association, WoolProducers, Animal Health Alliance (Australia) Limited, the Australian Wool Industries Secretariat, registrants and overseas regulators, , active constituent approval holders, state regulators and extension officers and other interested individuals.

Technical information, including annual wool residue analysis data and trend analysis has been provided by the CSIRO, with the permission of AWI. This information has formed part of the risk assessments for this review. The APVMA notes that this information was generated by AWI at a direct cost to the industry and that provision of this information to the APVMA has enabled an assessment to be completed that is based on current relevant, albeit limited, information. The APVMA appreciates the generosity of AWI in providing this information and acknowledges the support that has been provided by AWI and its predecessor The Woolmark Company.

The APVMA has liaised with the Wool Residue Management Committee and the NSW Sheep Ectoparasiticide Steering Committee to promote and assist in the development of mechanisms to improve Australia's current wool chemical residue situation.

2.1 Scope of the review

This review was initiated under section 32 of the Agvet Codes, considering whether a chemical residue on treated wool, after application of the product has finished and the wool has dried:

- would be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues;
- would be likely to have an unintended effect that is harmful to animals, plants or things or to the environment; and/or
- would unduly prejudice trade or commerce between Australia and places outside Australia.

The review covers all sheep ectoparasiticide products that either:

- contain one or more of the thirteen active constituents³
and / or
- have a label claim for treatment of ectoparasites, applied externally, in long-wool sheep (six or more weeks wool growth).

³ alpha-cypermethrin, chlorfenvinphos, cypermethrin, cyromazine, deltamethrin, diazinon, dicyclanil, diflubenzuron, temephos, triflumuron, propetamphos, ivermectin, spinosad

The review does not cover individual animal treatment products for which the claims are limited to wound treatments and/or flystrike dressings, nor does it include a range of products/active constituents that are only approved for use on short wool. The products under review were selected on the basis that they are most likely to be a concern because they meet one or more of the above scoping criteria.

Some affected products are also registered for use on cattle, goats, pigs, dogs, cats, horses and deer as well as sheep. However this review does not include consideration of the post-application risks associated with the use of selected sheep ectoparasiticides on animals other than sheep.

Although there is a wide range of product types and methods of application, the post-application risks associated with any chemical residue present on the wool after application has finished and the wool has dried are the subject of this review, not the risks associated with preparation and use.

2.2 Regulatory status of selected sheep ectoparasiticides affected by the review

The active constituents involved in the review of selected sheep ectoparasiticides are:

Alpha-cypermethrin	Cyromazine	Dicyclanil	Propetamphos	Spinosad
Chlorfenvinphos	Deltamethrin	Diflubenzuron	Temephos	
Cypermethrin	Diazinon	Ivermectin	Triflumuron	

At the commencement of the review (September 1999), there were 65 registered products containing one or more of the active constituents affected by the review. Since this time a number of products have discontinued their registration and additional products have been registered. The APVMA has also taken regulatory action to suspend the approvals of diazinon products as part of the review of diazinon on the basis of OH&S risks. The current list of registered products subject to the outcomes of this review is outlined in Appendix A.

Formulation types include topical suspensions/solutions, liquids, topical dusts/powders, topical aerosol sprays and medicated dressings. Products are used on sheep by jetting, dipping, spray-on, pour-on and for use as individual animal treatments/dressings.

Throughout this report, references to products which containing a mixture of diazinon and amitraz, or containing cyhalothrin or lamda-cyhalothrin, including those containing cyhalothrin and rotenone, are for information only because there are no current registrations containing these active constituents for use on sheep. Should an applicant be interested in future registration of a similar sheep ectoparasiticide product containing one or more of these active constituents, the application would need to address any relevant issue highlighted in this report.

Concurrent Reviews

Several chemicals have been or are currently subject to review in their own right. Completed reviews and the outcomes relating to products also covered by this review are listed below.

Chlorfenvinphos -

On the basis that this review OHS identified concerns relating with sheep shearing and wool handling, all dip and jetting products have been cancelled. This review was concluded in October 2011.

Temephos

The Department of the Environment recommended that approved labels be varied to delete all instructions relevant to treatment of long wool sheep. In January 2008, the APVMA approved amended label instructions which were voluntarily requested by the registrant. These amendments addressed the concerns identified in the OHS and environmental review reports.

This review was concluded in June 2009.

Diazinon

This review is ongoing. All long wool uses were suspended May 2007 and subsequently claims for long wool use have been removed or registration has been discontinued.

In May 2007, the APVMA suspended the use of diazinon for sheep dipping and jetting. The decision followed consideration of submissions to the 2006 PRF. Amongst other recommendations, the PRF proposed the discontinuation of uses of diazinon products for sheep dipping and jetting because of evidence showing these practices may have unacceptable impacts on the OH&S of workers.

The outcomes of the diazinon review will reflect the outcomes of the sheep ectoparasiticides review.

This review is ongoing.

Propetamphos

Propetamphos was nominated for review in 1995 as part of the Existing Chemicals Review Program (ECRP), because of concerns over occupational health and safety, toxicity and risk to the environment. Products registered for jetting and dipping were discontinued and it was considered that there was no need to place these products under review. The remaining products are blowfly strike dressing fluids and did not have the same risk. In August 2009 it was removed from the nomination list.

2.3 Application of the review to specialty wool lines

Specialty wool lines such as lambswool, fellmongered⁴ wool and wool crutchings are processed separately from main wool lines but in a similar manner. Because these materials are harvested for human use, the presence of any chemical residues on the wool and any risks posed by chemical residues on the wool are the same as for all other wool lines, therefore they form part of the sheep ectoparasiticide review.

⁴ Fellmongered wool is wool removed from the skin of a dead sheep.

2.4 Public consultation on preliminary review findings report (April 2006)

In April 2006, the APVMA released the PRF report for public consultation.

In the preliminary review findings report, it was proposed that:

- human health risks could be reduced by changing product labels to include 'sheep rehandling intervals' – the interval between applications of the chemical and when sheep can be safely rehandled without the need for protective equipment.
- risks to the Australian environment could be managed by the application of a 'wool harvest interval' (WHI), which defines a minimum interval from when the chemical is applied and when the sheep can be shorn; and
- risks to the trade of Australian wool could be managed if there were changes to the label instructions to provide clear warning of expected changes in EU requirements.
- Human health risks for chlorfenvinphos and deltamethrin could not be adequately managed and the environmental risks associated with the use of temephos on long woolled sheep posed an unacceptable risk to the environment.

In response to the release of the PRF, the APVMA received comments and formal submissions from various groups including registrants, state government departments, industry representatives and chemical users.

There have also been changes in product use patterns, international requirements and availability of wool residue testing.

These submissions included additional data and information for assessment, questions about the appropriateness of assumptions used in the environmental modelling, comments on the impact of the review findings on specialty wool lines and the applicability of WHI to fellmongered and crutched wool, clarification on labelling requirements and comments on the importance of particular chemicals to the sheep industry in Australia.

The additional information has been taken into consideration and revisions made to the assessment and associated conclusions where appropriate.

In summary, continued registration of ectoparasiticides for long wool application to sheep can be supported provided that variations to labels are made as follows:

- addition of sheep rehandling intervals, for all actives including chlofenvinphos, deltamethrin and spinosad
- inclusion of a general advisory statement in relation to trade for all products;
- inclusion of wool harvest intervals for all products;

- restriction of temephos to short wool treatments and requiring a 6 month harvesting interval on environmental grounds.

3 DATA ASSESSMENTS

The data and information received during the public comment period have allowed revisions to be made to the technical aspects of the report and resulting recommendations. Earlier assessment information is presented in the PRF only - the revised assessments and resulting outcomes are discussed below.

3.1 Occupational health and safety (OHS) assessment

Additional data was provided by Schering-Plough in relation to the active constituent temephos, as contained in the product Coopers Assassin Sheep Dip. This study allowed OCS to revise the dermal absorption factor of temephos used in the risk assessment from 100% (on the basis of a lack of data) to 10%. No other information, including suitable wool residue data for deltamethrin or chlorfenvinphos or suitable surrogate active constituents to permit a sheep rehandling interval to be calculated, was provided that would require OCS to revise other aspects of their assessment.

Introduction

The OHS concerns associated with the use of sheep ectoparasiticides relate to the potential for dermal absorption of ectoparasiticide during any rehandling of sheep and harvested wool post-application.

Based on the knowledge that many shearers are likely to shear sheep throughout their working life, any assessment of the risk posed by ectoparasiticide residues on wool should be based on **No Observable Effect Level** (NOELs) taken from long-term repeat-dose studies. In this respect the OHS risk assessment process for shearers, namely to consider life-long exposure, is similar to the process for considering the risk posed to public health from the presence of pesticide residues in food. Hence the NOELs should be the same for both the public health risk assessment of pesticide residues in food and the life-long exposure risk assessment for wool handlers.

Use patterns

This review considered post-application exposure of shearers and other workers engaged in the post-treatment handling of sheep and harvested wool. It did not consider occupational exposure during application of ectoparasiticides. The risks associated with the application of these chemicals have already been assessed as part of the registration process.

Health effects relating to occupational exposure

The risk assessment described in this review is limited to the consideration of the transfer of ectoparasiticide residues to a shearer or other sheep/wool handlers (wool classers, wool processors etc. involved in handling treated sheep and/or wool) via residues on wool. This section describes some adverse health effects experienced by shearers following such an exposure scenario, albeit resulting from an off-label use. In particular, it details a diazinon poisoning incident which was the subject of court proceedings (described below) and the potential of α -cyanopyrethroids (including cypermethrin, alpha-cypermethrin, deltamethrin and cyhalothrin) to cause paraesthesia (described below).

Successful legal action was taken by shearers against a farmer who knowingly exposed shearers to wet diazinon-treated sheep (see section below on diazinon). Therefore an explicit statement should appear on the product label to indicate that the product must be dry before any rehandling can occur. However, such a statement would only be applicable where the margin of exposure for ectoparasiticide residues on wool is acceptable on the day of application (i.e. 'when dry').

There is currently no validated laboratory animal model to permit a dose-response relationship for paraesthesia to be determined. However, since paraesthesia is an acute transient effect with no long-term sequelae, a separate hazard-based safety direction advising users of the potential risk of α -cyanopyrethroid compounds is considered appropriate. This is analogous to the way in which advice is provided for skin sensitising compounds.

Dermal absorption

Only limited information was available on the dermal absorption of most of the sheep ectoparasiticides. Where actual data on dermal absorption were not available, a default dermal absorption value of 100% was adopted. However, if adequate data on the physico-chemical properties of the active constituent such as an octanol/water partition coefficient ($\log K_{ow}$)⁵ of less than 1 or greater than 4 and a molecular weight greater than 500, or other data indicate that the potential for dermal absorption is low, a dermal absorption value of 10% was used. The ratio of a chemical's solubility in n-octanol and water at equilibrium and therefore a measurement of lipophilicity and an indication of its ability to be absorbed across cell membranes. The revised dermal absorption values selected for each of the ectoparasiticides is presented in Table 1.

TABLE 1 DERMAL ABSORPTION FOR SHEEP ECTOPARASITICIDES

ACTIVE CONSTITUENT	DERMAL ABSORPTION	SOURCE
Diazinon	4 %	Wester et al., 1993
Chlorfenvinphos	10%	APVMA 2006a and APVMA 2006b
Propetamphos	10%	Extoxnet PIP, 1996
Temephos	10%	Cross, 2006
Dicyclanil	10%	APVMA 2006a and APVMA 2006b
Cyromazine	5 %	Van de Sandt 1998
Ivermectin	1 %	MAFF 1992
Triflumuron	10%	APVMA 2006a
Cyhalothrin	100%	IPCS No 99

ACTIVE CONSTITUENT	DERMAL ABSORPTION	SOURCE
Diflubenzuron	0.2%	IPCS No 184
Cypermethrin	20%	APVMA 2006a and APVMA 2006b
Deltamethrin	10 %	APVMA 2006a and APVMA 2006b

Recommended sheep rehandling interval statements

The recommended sheep rehandling interval statements for treated sheep are shown in Table 2. If sheep must be handled within the sheep rehandling interval then personal protective equipment (PPE) designed to minimise the transfer of wool grease to bare skin, especially legs and arms, must be worn. Cotton overalls buttoned to the neck and wrist (or equivalent clothing) is recommended for all sheep ectoparasiticides considered in this review.

No specific recommendations for PPE are given as part of this review for the handling of sheep immediately after treatment, i.e., before drying, as this review did not assess the human risk posed by exposure to liquid ectoparasiticides immediately after treatment of sheep.

Chlorfenvinphos is restricted to wound, mulesing and flystrike treatment. The products are included in the review as a consequence of the preventative treatment of entire flocks when mulesing treatments are undertaken. The APVMA has allocated a conservative rehandling interval of 2 weeks.

There is only one product that contains deltamethrin registered for use on sheep. This is a backline product and is for use off-shears. Similar formulations are registered for use in cattle and horses - the recommendation for the rehandling of treated horses is 'do not handle until dry'. As in general there would only be one or a small number of horses treated and handled by the same person, and therefore exposure would be minimal. A conservative rehandling interval applied of 2 weeks, would enhance the products current recommendation that if this product is applied concurrently with other products it should be applied last, to avoid operator contact.

The rehandling interval will be placed under the ADDITIONAL SAFETY INFORMATION heading.

TABLE 2 RECOMMENDED SHEEP REHANDLING INTERVALS FOR SHEEP ECTOPARASITICIDES

ACTIVE CONSTITUENT	RECOMMENDED SHEEP REHANDLING INTERVAL
PRODUCTS CONTAINING OPS	
Diazinon	Sheep Rehandling Interval: Six weeks. If sheep must be handled during this interval, cotton overalls buttoned to the neck and wrist (or equivalent clothing) should be worn
Temephos	Sheep Rehandling Interval: After treatment wait until sheep are dry before rehandling.
Propetamphos.	<p>Sheep Rehandling Interval for dipping: Six weeks. If sheep must be handled during this interval, cotton overalls buttoned to the neck and wrist (or equivalent clothing) should be worn</p> <p>Sheep Rehandling Interval for jetting: Twelve weeks. If sheep must be handled during this interval then cotton overalls buttoned to the neck and wrist (or equivalent clothing) should be worn</p> <p>Sheep Rehandling Interval for spot application: Six weeks. If sheep must be handled during this interval, cotton overalls buttoned to the neck and wrist (or equivalent clothing) should be worn.</p>
PRODUCTS CONTAINING MACROCYCLIC LACTONES	
Ivermectin	Sheep Rehandling Interval: After treatment wait until sheep are dry before rehandling.
PRODUCTS CONTAINING SYNTHETIC PYRETHROIDS	
Cyhalothrin	Sheep Rehandling Interval: After treatment wait until sheep are dry before rehandling.
Alpha-cypermethrin Cypermethrin	Sheep Rehandling Interval: Two weeks. If sheep must be handled during this interval, cotton overalls buttoned to the neck and wrist (or equivalent clothing) should be worn.
PRODUCTS CONTAINING INSECT GROWTH REGULATORS	
Cyromazine Dicyclanil Diflubenzron Triflumuron.	Sheep Rehandling Interval: After treatment wait until sheep are dry before rehandling.
PRODUCTS FOR WHICH SHEEP REHANDLING PERIOD IS SPECIFIED BY APVMA	
Chlorfenvinphos	Sheep Rehandling Interval: Two weeks. If sheep must be handled during this interval, cotton overalls buttoned to the neck and wrist (or equivalent clothing) should be worn.
Deltamethrin.	Sheep Rehandling Interval: Two weeks. If sheep must be handled during this interval, cotton overalls buttoned to the neck and wrist (or equivalent clothing) should be worn.
Spinosad	Sheep Rehandling Interval: After treatment wait until sheep are dry before rehandling.

3.2 Environmental assessment

The environmental assessment for the review of selected sheep ectoparasiticides was undertaken by the Department of the Environment. This assessment considered all the environmental data and information submitted by registrants at the commencement of the review and during the public comment period, as well as information reviewed by the Department of the Environment in previous assessments.

The environmental findings used to formulate both the environmental assessment and the trade assessment for the review of selected sheep ectoparasiticide products are summarised below. The full technical assessments for the active constituents are in Volume 2 of the Preliminary Review Findings.

A consideration of the public comments resulted in changes to the assumptions used in the environmental assessment in relation to:

- the amount of wool scoured per day;
- the efficiency of the scouring process in reducing the level of pesticide discharged at Black Rock sewage treatment plant;
- the future expected level of diazinon use (resulting from APVMA regulatory action); and
- a reduction in the number of scouring facilities operating in Australia.

In addition, the updated average pesticide residues in Australian fleece wool data for the year 2006/07 were used to recalculate the environmental risk quotients for the ectoparasiticides using the modified Australian model.

Introduction

Sheep ectoparasiticide residues on wool raise particular environmental concerns when they are scoured from the wool and discharged to aquatic environments. The approach taken to address concerns related to the potential of chemical residues to harm susceptible organisms in the aquatic environment, particularly if the chemicals are released in the processing of wool, is to first to establish environmental impact thresholds, then to determine whether sheep ectoparasiticide products subject to the review, are below these thresholds, when used in accordance with label instructions.

This risk assessment was based on the results of quantitative modelling of the discharge of scour wastes into the aquatic environment using a slightly modified version of the “Australian Model” introduced by Savage (1998). This simple dilution model was originally developed based on input parameters specific to the scouring industry based in the city of Geelong, Victoria. Modifications to this risk assessment model have been made in response to the information received during the public comment period.

Australian sewage treatment assumptions

In Australia, the discharge of scouring effluent to surface waters is managed under the National Water Quality Management Strategy, Effluent Management Guidelines for Aqueous Wool Scouring and Carbonising in Australia (ANZECC & ARMCANZ 1999). This requires effluent to be at safe levels and of equivalent quality parameters as the receiving waters at the point of discharge to the environment. There are only two scouring plants which discharge into ocean water, both discharge into Port Phillip Bay. A third plant

based in South Australia, recycles a portion of its water and the remaining water is discharged into a wetland.

The assessment undertaken as part of this review to determine the safety of the effluent, is based on short-term outflow data.

Work by Grundy et al. (2000) led to some changes in the assumptions regarding the degree of removal of various chemicals during sewage treatment. This work involved measuring ectoparasiticide residues at entry and exit from the Black Rock sewage treatment plant that services the Geelong catchment. This treatment plant operates in a semi-continuous mode by cyclically directing incoming sewage into separate tanks that operate on a four-hourly cycle, with 10% of the supernatant drawn down after each cycle. Average sewage retention time is 36-48 hours.

Based on this study, removal of diflubenzuron during sewage treatment was assumed to occur with 85% efficiency, rather than the 80% assumed in the review by Savage (1998). Removal efficiencies for diazinon and cypermethrin remain unchanged at 50% and 95%, noting that the latter is a lower limit rather than absolute value.

Since the release of the PRF, the Department of the Environment has also received information on a Commercial-In-Confidence basis regarding the total mass of greasy wool processed at the one remaining scour in Geelong. Based on this information, it is apparent that the nominal daily mass of greasy wool currently being processed in Geelong is now significantly greater than the 50 tonnes/day total assumed by Savage (1998) and the PRF. In the Australian model, the mass of a pesticide entering wool scours on a daily basis is a simple product of the daily mass of greasy wool processed and the average concentration of the pesticide on the fleece in a processing lot. The recent increase in wool processing capacity in Geelong is therefore expected to significantly increase the total mass of all ectoparasiticides entering the first stage of on-site pollution removal at the remaining wool scour, as compared with the quantities calculated in the PRF.

However, the potential for this substantial additional daily pesticide load to reach the aquatic environment has been significantly reduced for all lipophilic ectoparasiticides by the installation of the Sirolan CF pollution control process at the remaining scour. This process efficiently removes lipophilic pesticides in the waste wash water produced in the scour plant by chemical flocculation. The flocculated particles are then removed as solid waste with the sludge fraction of the scour waste stream (Pyper, 2000). The removal efficiency for most lipophilic pesticides including diflubenzuron, the synthetic pyrethroids (SPs), ivermectin and the organophosphates (OPs), is 80%. The removal efficiency for triflumuron with the Sirolan CF process is even higher at 90% (Russell, 2007a). This process is therefore capable of substantially increasing the fraction of lipophilic pesticide inputs that are retained on-site at the scouring plant.

In contrast, the water soluble ectoparasiticides, cyromazine and dicyclanil, are not removed by the Sirolan CF process (Russell, 2007a). Hence, the quantities of these latter two ectoparasiticides discharged to the Black Rock sewage treatment plant as a result of scouring are expected to increase in proportion to the increased mass of wool processed in Geelong.

Effect of plume dilution at ocean outfall

Grundy et al (2000) reported on the commercial scouring of wool treated with diflubenzuron. The report describes the monitoring of diflubenzuron entering and leaving a commercial wool scour for a period of one

week and the subsequent tracking of the discharges through the sewer system and effluent treatment system. The report estimates that the dilution factor in the sewage discharge plume at the surface of the ocean immediately above the outfall diffuser system is at ratio of 1:50, equivalent to a dilution factor of 0.02. This result indicates that the treated effluent undergoes significant dilution in the receiving ocean waters.

Because diflubenzuron is relatively insoluble in water, it is appropriate to consider it as a worst case in comparison with other active constituents subject to the review with respect to its dissolution properties. Therefore, the dilution factor of 0.02, based on the ocean outfall at Black Rock, is used in the environment risk assessment of the other active constituents in the review, as these are more soluble and therefore can be expected to disperse more rapidly.

Residue levels on wool

Mean ectoparasiticide residues in the national clip for particular active constituents were supplied by the AWI as part of the national wool clip monitoring data, although these data are limited. When residue data was available, they were used as the input concentration for the risk calculations and taken into consideration in estimating whether the wool harvest interval (WHI) is acceptable. If data was not available, for example due to the active constituent levels in the national wool clip occurring at levels below reporting or because no testing for the active constituent was undertaken, wool residue data from registrant trials were used.

The evaluation preferred cored bale over sheep band sampling results because the latter generally do not include areas of wool on the sheep which have not been treated. When data from registrant residue trials were used, an adjustment for market share was incorporated into the hazard calculations, as market share is implicit in the AWI national wool clip data.

The AWI survey data for levels of residual ectoparasiticides was preferred by the Department of the Environment as the basis for assessing the environmental risks of scouring because the national average levels of pesticides measured by this survey more closely reflects the levels of pesticides occurring in a typical processing lot at a wool scour. Furthermore, the results of the AWI survey implicitly include the cumulative nationwide results of various registered application methods and application frequencies on wool for a particular active constituent. Hence, AWI survey data, where available, provides a superior predictive tool for calculating the likely discharges of ectoparasiticides from wool scours.

The results of wool residue depletion trials were essential for the environmental risk assessment of active constituents not monitored by the AWI survey such as temephos and ivermectin. The environmental risk assessment for these active constituents was instead based on the results of specific wool residue trials, which allowed projected national average residues in the national clip to be calculated. In the absence of this trial data, the Department of the Environment was not able to adequately assess the environmental risks associated with the use of these active constituents as sheep ectoparasiticides. In this situation, the Department of the Environment has taken a more conservative view of the acceptable WHIs for sheep ectoparasiticides products containing these active constituents.

Australian model assumptions, based on the ocean outfall at Black Rock (Geelong)

Maximum mean residue limits in raw wool were estimated in the PRF from the target concentration at the outfall, based on the assumptions outlined in column 2 of the table below. The new Sirolan CF process and information regarding the amount of wool treated per day has allowed the revision of some of the figures

used in the risk assessment, as shown in column 3 of the following table. The most critical variable in the model, particularly for the highly lipophilic synthetic pyrethroids, is the removal of residues during sewage treatment.

Table 3: Australian model assumptions used in the environmental risk assessment

PARAMETER	ASSUMPTIONS MADE IN PRF	REVISED ASSUMPTIONS
Daily discharge	50ML	50ML
Removal in sewage treatment plant	0% (cyromazine, dicyclanil)	0% (cyromazine, dicyclanil)
	50% (OPs)	80% with Sirolan CF + 50% removed during sewage treatment
	80% (ivermectin, triflumuron)	80% ivermectin and 90% triflumuron with Sirolan CF + 80% removed during sewage treatment
	85% (diflubenzuron)	80% with Sirolan CF + 85% removed during sewage treatment
	95% (SPs)	80% with Sirolan CF + 95% removed during sewage treatment
Recovery with wool grease	30% (OPs, SPs and diflubenzuron)	30% (OPs, SPs and diflubenzuron)
	0% (cyromazine, dicyclanil)	0% (cyromazine, dicyclanil)
	75% (triflumuron)	10% grease removal pathway + 90% dirt-associated removal step (triflumuron)
Retention on scoured wool	4%	4%
Daily scouring load	50 tonnes raw wool	>>50 tonnes raw wool ⁶
Dilution at ocean outfall	1:50 = 0.02	1:50 = 0.02

Revisions to the environmental assessment following consideration of public comments

In response to the PRF (2006), the Department of the Environment considered 12 submissions from industry groups, product registrants and state government departments for further consideration. Of these, 6 contained additional data and/or argument that required further analysis, in the context of the environmental risk assessment framework used in the PRF and, where appropriate, the Department of the Environment's conclusions have been refined.

⁶ The exact tonnage is Commercial-in-confidence

The Australian model has been used to recalculate the Predicted environmental concentration (PEC) and Risk Quotient (RQ) for each ectoparasiticide at the ocean outfall of the Black Rock sewage treatment plant. The calculations described in the PRF have been modified to include the effects of the increased daily mass of wool scoured, the extra removal step afforded by Sirolan CF for lipophilic pesticides and, for triflumuron, a reduction in the nominal removal efficiency in wool wax (as outlined in Table 3: Australian model assumptions). The Predicted no effect concentration (PNEC) for each active constituent was unchanged from the PRF. These revised calculations employ Commercial-In-Confidence information about the total daily processing load at the remaining scour in Geelong. Hence, only upper limits for the revised RQs for each pesticide can be reproduced in this report, as listed in Table 4: The revised environmental risk quotients (RQs) for scouring greasy wool in Australia with national average and hot-spot levels of residual ectoparasiticides.

Table 4: The revised environmental risk quotients (RQs) for scouring greasy wool in Australia with national average and hot-spot levels of residual ectoparasiticides.

ACTIVE CONSTITUENT	RQ (NATIONAL AVERAGE RESIDUES)	RQ (HOT-SPOT SCENARIO)
Diazinon	< 0.5	< 0.5
Propetamphos	< 0.5	< 0.5
Temephos	< 2*	< 4
Dicyclanil	< 0.5	< 1
Cyromazine	<< 0.5	<< 0.5
Ivermectin	< 0.5 [‡]	< 2
Triflumuron	< 0.5	< 0.5
Diflubenzuron	< 0.5	< 0.5
Cypermethrin [†]	< 0.5	< 1
Deltamethrin	< 0.5	< 0.5

*Calculations based on projected national average residues of temephos arising from use on 10% of the national flock with a split in short versus long wool use of 30:70.

[‡]Calculations based on projected national average residues of ivermectin arising from use on 5% of the national flock. [†]Applies also to alpha-cypermethrin.

The revised RQs for all lipophilic pesticides, except for temephos, ivermectin and cypermethrin/alpha-cypermethrin, under the new processing scenario in Geelong are less than the corresponding values calculated in the PRF. The RQs for the water soluble ectoparasiticide, dicyclanil, is greater than the values calculated in the PRF, however the RQs for the water soluble ectoparasiticide, cyromazine, is unchanged. The impact of these changes on the original environmental risk assessments as reported in the PRF, are discussed in more detail for each ectoparasiticide under “Revised environmental assessment outcomes” in this chapter.

“Hot-spot” scouring scenario

In the PRF, the Department of the Environment calculated the RQs for each pesticide for two scenarios: processing lots containing national average residues of ectoparasiticides; and “hot-spot” processing lots containing the ‘mean residue when treated’ level of ectoparasiticides. The latter scenario was used by the Department of the Environment to model the environmental risks of scouring processing lots contaminated with above average levels of residual ectoparasiticides. The ‘mean residue when treated’ figure from the AWI wool survey was used for these calculations because it is a single transparent metric that is based on survey results. However, it is possible to perform a more refined analysis of this scenario by considering the frequency with which highly contaminated sale lots are likely to occur in any given processing lot. This can be achieved by using the actual distribution of measured ectoparasiticide levels on the national clip to calculate probable input loads of pesticides at a scour.

This approach was used by one of the respondents to the PRF to model the predicted discharges of diflubenzuron, cypermethrin and diazinon for the domestic scouring scenario. This new analysis employed a modified version of the Australian model and a numerical simulation technique to calculate the daily discharges of these three pesticides that results from scouring theoretical processing lots over a period of one year. These theoretical processing lots were “constructed” by combining the 2005/2006 AWI survey results for residues of all three active constituents in tested fleece lines with a random selection of quantities of wool from different sale lots. The simulations were run under the assumption that there were two scour mills operating in the Geelong area with a total daily scouring capacity higher than the current figure. The Australian dilution model was modified to incorporate the effects of the use of Sirolan CF at the larger of the two scours on the total load of pesticides discharged to the Black Rock sewage treatment plant, but the other parameters from the PRF were used unchanged.

The results of these simulations for diazinon indicate that unsafe levels of these ectoparasiticides are only discharged on 1 day per year. For diflubenzuron, the level of discharge is not unsafe on any day of processing. For cypermethrin, unsafe discharges occur on 18 days per year. However, this result is likely to be an overestimate because the total load of all pesticides entering the remaining wool scour in Geelong is now significantly less than that calculated for the two scour model used in this analysis.

The approach taken by the respondent is progressive because, by using frequency data for ectoparasiticide levels as an input parameter, the probability of high-residue wool sale lots occurring in a domestic processing lot is implicitly included in the calculation of daily input loads to the scour. Moreover, the analysis focuses on three of the most widely used sheep ectoparasiticides and uses modelling parameters which are based on a realistic (although now conservative) domestic scouring scenario. The respondent’s conclusion that the unsafe threshold for these ectoparasiticides at the Black Rock ocean outfall is rarely exceeded when the likely distribution of pesticides in a processing lot is included is therefore considered acceptable. More generally, this revised analysis indicates that the probability of an adverse environmental effect arising from scouring sale lots of greasy wool contaminated with high levels of ectoparasiticides in Australia is low.

Based on this new analysis, the Department of the Environment now considers the domestic hot-spot scouring scenario to represent a theoretical worst-case event that is unlikely to occur in practice. For this reason, the revised analysis of domestic environmental risks from scouring presented in following sections has been modified to focus on hazards presented by processing lots containing national average levels of ectoparasiticides based on AWI wool residue survey data, where it is available.

However, the Department of the Environment remains concerned that small European scours are vulnerable to contamination of processing lots by sale lots of Australian greasy wool with high levels of residual ectoparasiticides. This concern is based on the fact that these scours discharge aqueous scour wastes into rivers where the possibility for significant dilution of ectoparasiticides in receiving waters is much lower than for the ocean discharge scenario in Australia. Furthermore, the number of high residue sale lots required to contaminate a processing lot in Europe is significantly smaller than in Australia because of the relatively small size of European scours.

Revised environmental assessment outcomes

Taking into consideration the comments and information provided in response to the PRF, revisions to the conclusions made in relation to environmental risk have been made and are discussed below.

Diazinon

The Department of the Environment received a new modelling study relating to the frequency and levels of diazinon discharged from the Black Rock ocean outfall from a respondent. This new study has contributed to the Department of the Environment's revised view about the probability of hot-spot scouring lots occurring in Australia.

In the PRF, the Department of the Environment concluded that there was a potential risk to the Australian environment from scouring greasy wool contaminated with diazinon. However, since this analysis was performed, several important risk factors for the use of diazinon products as sheep ectoparasiticides have changed. The most significant of these has been the decision by the APVMA to suspend the use of diazinon ectoparasiticide products for dipping and jetting sheep (APVMA 2007). This decision, which was based on concerns about the OHS of workers using such products, has resulted in a decline in the average level of residual diazinon in the national wool clip as existing stocks of products used for dipping and jetting sheep were used. The total quantity of diazinon discharged to the Australian environment from wool scouring is therefore expected to decline in line with the reduction in the large scale use of diazinon as a sheep ectoparasiticide.

The use of Sirolan CF in the Geelong scour, which efficiently removes organophosphates from liquid scour wastes, will further reduce the quantities of diazinon being discharged by the Black Rock sewage treatment plant as a result of scouring. Together with the reduction in average residues of diazinon in the national clip, this development will result in a significantly lower Predicted Environmental Concentration (PEC) for diazinon at the Black Rock ocean outfall compared with that calculated for the PRF. In fact, the RQ for processing lots of greasy wool with national average and the RQ for theoretical hot-spot levels of diazinon are now both less than 1, just by incorporating Sirolan CF into the revised risk assessment calculation. Therefore, DEWHA has revised the conclusions provided for diazinon in the PRF as follows:

The Department of the Environment is satisfied that the use of selected sheep ectoparasiticide products containing diazinon in accordance with approved label instructions and the current WHI (2 months) would not be likely to have an effect that is harmful to animals, plants or things or to the Australian environment under Australian scouring conditions.

Propetamphos

The Department of the Environment received no new data from respondents to the PRF to refine the environmental risk assessment of propetamphos.

In the PRF, the Department of the Environment concluded that there was a low risk to the Australian environment from scouring greasy wool contaminated with propetamphos. This was principally due to the very low residues of propetamphos in the national wool clip. These low residues together with pesticide removal steps for the aqueous scour wastes at the wool scours and in the Black Rock sewage treatment plant combined to yield acceptably low concentrations of propetamphos at the ocean outfall. The introduction of Sirolan CF at the remaining wool scour in Geelong is expected to further reduce the quantities of this lipophilic pesticide discharged from the Black Rock ocean outfall. Hence, the PEC of propetamphos resulting from scouring greasy wool in Australia and the environmental risk quotient have both declined with respect to the values calculated in the PRF. Therefore, the Department of the Environment is able to reconfirm the recommendations for propetamphos that were provided in the PRF as follows:

The Department of the Environment is satisfied that the use of selected sheep ectoparasiticide products containing propetamphos in accordance with approved label instructions and the current WHI (2 months) would not be likely to have an effect that is harmful to animals, plants or things or to the Australian environment under Australian scouring conditions.

Temephos

The Department of the Environment received no new data from respondents to the PRF to refine the environmental risk assessment of temephos

Temephos is the active constituent in an ectoparasiticide product that is used for the control of body lice on sheep with short or long wool (Coopers Assassin Sheep Dip 47568). In the PRF, the Department of the Environment concluded that the application of this product on sheep with long wool according to current label instructions could leave residues in fleece that, when scoured, would pose an unacceptable risk to the aquatic environment in Australia.

The hazard posed by long wool applications of temephos on sheep is due to the exceptional ecotoxicity of this active constituent (48 h EC50 for *Daphnia magna*, 7 ng/L) and the approximately 5-fold higher residues remaining in fleece after long wool application as compared with residues from off-shears uses. The risk to the aquatic environment arising from these hazards has been partially mitigated by the introduction of Sirolan CF at the Geelong scour. This process will remove additional quantities of temephos from the strong-flow down liquors of the scour before the aqueous effluent is discharged to the Black Rock sewage treatment plant, as with other organophosphates. However, even when the effect of this new mitigating factor is included, a significant risk to the aquatic environment is still indicated.

Based on this revised analysis, the Department of the Environment remains unsatisfied that the risks to the aquatic environment arising from scouring greasy wool treated with temephos at the long wool stage is acceptable. Therefore, DEWHA reconfirms the advice provided in the PRF as follows:

The Department of the Environment is not satisfied that continued use of the product according to its label instructions on long wool sheep including the current WHI (3 months) would not be likely to be harmful to

aquatic invertebrates inhabiting waters close to the ocean outfall. Use of temephos is to be restricted to short wool applications only and the wool harvest interval has been set at 6 months.

In January 2008, the APVMA approved amended label instructions which were voluntarily requested by the registrant, to restrict the use of the product to short wool only. These amendments addressed the concerns identified in the OHS and environmental review reports. Temephos is only to be used in short wool. (<http://www.apvma.gov.au/products/review/completed/temephos.php>)

Dicyclanil

The Department of the Environment received no new data from respondents to the PRF to refine the environmental risk assessment for dicyclanil. However, the Department of the Environment did receive some comments from a product registrant, which have been considered in section 3.

Dicyclanil is moderately water soluble and therefore not removed from aqueous scour wastes by Sirolan CF. Hence, the quantity of dicyclanil discharged into Bass Strait from the Black Rock sewage treatment plant is expected to increase in proportion to the increased wool processing volume in Geelong. The risk of an adverse effect on the Australian environment arising from scouring greasy wool contaminated with dicyclanil has therefore increased since the analysis for the PRF was carried out. However, the RQ for scouring wool with national average levels of residual dicyclanil remains significantly less than 1.

The domestic environmental risks associated with the use of dicyclanil on wool are considered acceptable on the basis of the following: there is moderate usage of products containing dicyclanil on the national flock; the mitigating effects of effluent dilution at the ocean outfall; and the high PNEC (1100 ng/L). Thus, although the revised domestic environmental risk analysis for dicyclanil indicates that the risks associated with the use of dicyclanil as a sheep ectoparasiticide have increased, they are still acceptable. Therefore, the Department of the Environment is able to reconfirm the recommendations for this active constituent that were provided in the PRF as follows:

The Department of the Environment is satisfied that the use of selected sheep ectoparasiticide products containing dicyclanil in accordance with approved label instructions and the current WHI (3 months) would not be likely to have an effect that is harmful to animals, plants or things or to the Australian environment under Australian scouring conditions.

A single low concentration product has been introduced to the market and WHI was assessed at registration. The WHI for this product has been set at 1 month.

Cyromazine

The Department of the Environment received no new data from respondents to the PRF to refine the environmental risk assessment for cyromazine. However, the Department of the Environment did receive comments from a product registrant, outlined in Section 3.

Cyromazine is readily soluble in water (11 g/L) and is therefore not removed by the Sirolan CF chemical flocculation step in the Geelong scour. The daily quantity of cyromazine being discharged from this scour is therefore expected to increase compared with values calculated in the PRF, in proportion to the increase in the mass of raw wool being scoured. As a result, the mass of cyromazine being discharged daily into Bass

Strait through the ocean outfall of the Black Rock sewage treatment plant and hence the PEC for this active constituent, is expected to increase. The risk quotient for this level of discharge is still $\ll 1$.

The relative insensitivity of the aquatic environment to these increased discharge loads of cyromazine is due to the relatively low ecotoxicity of cyromazine compared with other classes of insect growth regulators and the 1:50 dilution at the ocean outfall. Thus, as with dicyclanil, although the risks from scouring wool treated with cyromazine have increased relative to those calculated for the PRF, they remain acceptably low. Therefore, the Department of the Environment is able to reconfirm the recommendations for cyromazine that were provided in the PRF as follows:

The Department of the Environment is satisfied that the use of selected sheep ectoparasiticide products containing cyromazine in accordance with approved label instructions and the current WHI (2 months) would not be likely to have an effect that is harmful to animals, plants or things or to the Australian environment under Australian scouring conditions.

Ivermectin

In the PRF, Department of the Environment concluded that there was a low risk to the Australian environment from scouring greasy wool contaminated with ivermectin. The relatively low risk quotient calculated for ivermectin (RQ = 0.2) was determined by the very low PEC calculated for ivermectin, which more than offset the low PNEC (1 ng/L). The very low PEC for ivermectin is a product of the very low estimated average residues of this active constituent in the national wool clip (0.076 mg/kg), the efficient removal of this pesticide in the Black Rock sewage treatment plant and dilution effects at the ocean outfall. The Sirolan CF process is expected to further decrease the PEC for ivermectin by removing significant additional quantities of this lipophilic pesticide from the aqueous scour wastes before they are discharged from the Geelong wool scour. Consequently, the calculated RQ for scouring processing lots with projected national average levels of ivermectin is less than the value calculated in the PRF and significantly less than 1. This revised analysis indicates that the risk of scouring greasy wool with projected national average residues of ivermectin remains acceptably low. A 12 week WHI was proposed.

Since PRF new data has become available. Using this data Environment Australia recommend a 6 week WHI for selected sheep ectoparasiticides containing ivermectin.

On this recommendation the APVMA can be satisfied that the use of selected sheep ectoparasiticide products containing ivermectin in accordance with approved label instructions and the WHI (6 weeks) would not be likely to have an effect that is harmful to animals, plants or things or to the Australian environment.

Triflumuron

The Department of the Environment received no new data from respondents to the PRF to refine the environmental risk assessment for triflumuron. However, the Department of the Environment did receive some comments from product registrants, outlined in Section 3.

In the PRF, the Department of the Environment concluded that there was a low risk of an adverse effect on the Australian environment resulting from scouring greasy wool contaminated with triflumuron. The relatively low risk from scouring wool with triflumuron is due to the particularly efficient removal of this pesticide in wool scours (75%), combined with efficient removal in the sewage treatment plant (80%) and the initial 1:50

dilution of treated effluents at the ocean outfall. Thus, even though triflumuron has very high acute toxicity to marine organisms (96 h LC50 = 3.9 µg/L, mysid shrimp), the PEC for triflumuron at the ocean outfall is acceptably low even for a theoretical hot-spot processing lot (RQ = 0.08).

The assumed removal efficiency for triflumuron from the waste wash water stream of a scour plant is 90% with the Sirolan CF process. This higher removal efficiency as compared with other lipophilic pesticides follows from the tendency of triflumuron to behave as water-insoluble particles in a scour plant. In a scour equipped with Sirolan CF, these particles are efficiently separated along with other solids from the waste wash water by chemical flocculation (Russell 2007b). In a conventional scour, these dirt-like particles of triflumuron are removed with other solids in a settling tank or decanter centrifuge. In the PRF, this removal pathway was accounted for by using a default figure of 75% for the removal efficiency for triflumuron with wool grease. However, it appears that relatively little of this removal occurs with the wool grease fraction as is the case with other lipophilic pesticides. Indeed, based on expert advice (Russell 2007b), the association of triflumuron with wool grease appears to be of the order of 10% of incoming pesticide mass as compared with 30% for other lipophilic pesticides. Hence, in the modified Australian model used to model pesticide removal in a scour plant equipped with Sirolan CF, the removal efficiency for triflumuron has been separated into a grease removal pathway with 10% efficiency followed by a dirt-associated removal step with 90% efficiency.

Based on this revised model, the quantities of triflumuron discharged from the upgraded scour in Geelong are expected to be less than those calculated in the PRF. Consequently, the PEC and RQ for triflumuron are lower than those calculated previously. This revised analysis indicates that the risk of scouring greasy wool contaminated with triflumuron in Australia remains acceptably low. Therefore, the Department of the Environment is able to reconfirm the recommendations for triflumuron that were provided in the PRF as follows:

The Department of the Environment is satisfied that the use of selected sheep ectoparasiticide products containing triflumuron in accordance with approved label instructions and the current WHI (2 months) would not be likely to have an effect that is harmful to animals, plants or things or to the Australian environment under Australian scouring conditions.

Diflubenzuron

The Department of the Environment received a considerable quantity of additional data and comment from respondents to the PRF to refine the environmental risk assessment for diflubenzuron.

In the PRF, the Department of the Environment concluded that there was a possible risk to the Australian environment from scouring greasy wool contaminated with higher than average levels of diflubenzuron. This conclusion was based on the relatively high environmental risk quotient calculated for scouring processing lots of greasy wool contaminated with the 'mean residue when treated' level of diflubenzuron (RQ = 0.95). However, the revised RQ for this scenario is now < 0.5, which reflects the relatively efficient removal of diflubenzuron by the Sirolan CF process. Further, new modelling provided by a respondent to the PRF shows that no unsafe discharges of diflubenzuron at the Black Rock ocean outfall are expected to occur when the actual distribution of diflubenzuron residues in the national clip is used to calculate daily input loads of this active constituent at the Geelong scour. Based on this revised analysis, the Department of the Environment concluded that the risk of an adverse effect on the Australian environment arising from scouring processing lots of wool containing sale lots with high levels of residual diflubenzuron is now acceptably low.

A key issue for the use of diflubenzuron as a sheep ectoparasiticide is the adequacy of the 6 month WHI for long wool applications. In the PRF, the Department of the Environment concluded that the current WHI would not be sufficiently protective for the Australian environment. However, this conclusion was based on the domestic hot-spot scouring scenario, which is no longer considered a likely event. Furthermore, an analysis based on scouring wool with national average levels of diflubenzuron shows that the environmental RQ is significantly less than 1. This latter calculation shows that use of registered diflubenzuron ectoparasiticide products according to current label instructions, including the 6 month WHI for long wool applications, yields acceptable average levels of residual diflubenzuron in the national clip. Therefore, the Department of the Environment is able to revise the recommendations for diflubenzuron that were provided in the PRF to the following:

The Department of the Environment **is satisfied that the use of selected sheep ectoparasiticide products containing diflubenzuron in accordance with approved label instructions and the current WHI (6 months) would not be likely to have an effect that is harmful to animals, plants or things or to the Australian environment under Australian scouring conditions.**

Cypermethrin/Alpha-Cypermethrin

The Department of the Environment received new data from respondents to the PRF to refine the environmental risk assessment of cypermethrin/alpha-cypermethrin.

Alpha-cypermethrin is the active constituent in an ectoparasiticide product that is used for the control of body lice and blowfly strike on long wool. In the PRF, the Department of the Environment concluded that the application of this product on sheep with long wool could leave residues in fleece that, when scoured, would pose an unacceptable risk to the aquatic environment in Australia. This conclusion was based on unacceptably high RQ values calculated for hot-spot scouring scenarios (RQs > 2.0) and theoretical RQs arising from scouring wool with national average residues of cypermethrin/alpha-cypermethrin. However, a respondent to the PRF has provided revised modelling results that show that contamination of processing lots with sale lots of greasy wool containing high residues of cypermethrin/alpha-cypermethrin is likely to yield unsafe discharges at the Black Rock ocean outfall only rarely. Hence, the environmental risk arising from scouring processing lots with sale lots contaminated with high levels of cypermethrin/alpha-cypermethrin is no longer considered significant. The risk presented by scouring wool with current and projected national average levels of these active constituents is now also considered acceptable.

The use of alpha-cypermethrin on long wool leaves residues on fleece approximately 50-times greater than those from off-shears applications. The relative levels of use of this product on long wool compared to off-shears application can therefore significantly affect the concentration of cypermethrin/alpha-cypermethrin at shearing and hence the average concentration of these active constituents in the national clip. In the PRF, the Department of the Environment concluded that a rise in long wool usage of alpha-cypermethrin from 1% to 3% of the national flock would be sufficient to increase the PEC of these active constituents to levels in excess of the PNEC (2 ng/L) at the Black Rock ocean outfall. In the revised domestic modelling scenario, the usage level of cypermethrin/alpha-cypermethrin on long wool must rise to more than 8% before the PNEC is exceeded. This rise in acceptable usage levels is a product of the efficient removal of synthetic pyrethroids by Sirolan CF at the upgraded Geelong scour, which will reduce the quantities of these pesticides discharged as a proportion of the input load to the scour.

On the basis of this revised analysis, the Department of the Environment is now satisfied that long-wool treatment with cypermethrin/alpha-cypermethrin should continue to be a registered use, provided that there is not more than an 8-fold increase in the use of cypermethrin/alpha-cypermethrin for late long wool applications. With this condition, the Department of the Environment is able to modify the conclusions for cypermethrin/alpha-cypermethrin that were provided in the PRF as follows:

The Department of the Environment is satisfied that the use of selected sheep ectoparasiticide products containing alpha-cypermethrin or cypermethrin on long wool (more than 6 weeks off shears) in accordance with approved label instructions and the current WHI (2 month) would not be likely to have an effect that is harmful to animals, plants or things or to the Australian environment under Australian scouring conditions.

Deltamethrin

The Department of the Environment received no new data from respondents to the PRF to refine the environmental risk assessment of deltamethrin.

In the PRF, the Department of the Environment concluded that there was unlikely to be a risk to the Australian environment resulting from scouring greasy wool contaminated with levels of deltamethrin. The relatively low risk quotient calculated for this active constituent (RQ = 0.02) was determined by the low PEC for deltamethrin, which more than offset the low PNEC (2 ng/L). The low concentration of deltamethrin at the Black Rock ocean outfall attributable to scouring wool in Geelong is due to the low levels of deltamethrin used in the national flock, the efficient removal of synthetic pyrethroids in the sewage treatment plant and dilution of the treated sewage effluent at the outfall. The Sirolan CF process, which is capable of efficiently removing synthetic pyrethroids from aqueous scour wastes, is expected to further reduce the quantity of deltamethrin reaching the Black Rock plant. Hence, the PEC for deltamethrin at the ocean outfall and the RQ are both less than the values calculated in the PRF. Based on this analysis, the Department of the Environment concludes that the relative risk from scouring greasy wool contaminated with deltamethrin in Australia is lower than that calculated previously. Therefore, the Department of the Environment is able to reconfirm the recommendations for deltamethrin that were provided in the PRF as follows:

The Department of the Environment is satisfied that the use of selected sheep ectoparasiticide products containing deltamethrin in accordance with approved label instructions and the current WHI (2 months) would not be likely to have an effect that is harmful to animals, plants or things or to the Australian environment under Australian scouring conditions.

Chlorfenvinphos

The Department of the Environment did not conduct any assessment as the product is used only in wound treatments and as such is unlikely to be found in scoured wool. The AgVet labelling code currently states *“For wound dressings/fly strike treatments for individual sheep, a default WHP of at least one month applies unless data is supplied to support a shorter WHP.”* A one month default WHI is to be applied for Chlorfenvinphos when it is used for wound treatments in sheep.

Spinosad

Spinosad products were assessed at registration, no withholding period was applied.

Summary of regulatory findings for Australian environments

The findings in the environment assessment have concluded that all product labels apart from those for temephos will require inclusion of a wool harvest interval (WHI) statement in order to ensure that continued use of selected sheep ectoparasiticide products in accordance with existing approved label instructions would not be likely to have an unintended effect that is harmful to the Australian environment. For products containing temephos insufficient data were available to determine an appropriate WHI for long wool use that would ensure protection of the Australian environment. The Department of the Environment was not satisfied that current wool residue levels would be above or around the calculated maximum allowable levels listed that will meet the target PNECs. The use of temephos is not recommended for long wool application. The wool harvest interval is to be placed under the "Withholding Period" heading.

TABLE 5 RECOMMENDED WOOL HARVEST INTERVALS (WHI) TO MANAGE RISKS TO THE AUSTRALIAN ENVIRONMENT

ACTIVE CONSTITUENT	RECOMMENDED WOOL HARVEST INTERVAL (WHI)
Cypermethrin and Alpha-cypermethrin ⁷	2 months
Cyromazine	2 months
Chlorfenvinphos	1 month
Deltamethrin	2 months
Diazinon	2 months
Dicyclanil	3 months
Diflubenzuron	6 months
Ivermectin	6 weeks
Propetamphos	2 months
Temephos	6 months Short wool application only
Triflumuron	2 months
Spinosad	Nil

3.3 Trade assessment

Australia is the world's major wool producer of garment quality wool, with wool being a significant export trade commodity. The economic importance of exports of raw wool is summarised from the Australian Wool Industry web site www.wool.com/Media-Releases.htm?item=7140.htm as follows:

- In 2011/12 Australia produced 367 kt of shorn wool. Total wool production was 429.3 kt.
- In 2011/12, the value of Australian wool exports was \$3.076 billion. The major markets for Australian wool (by value) are China (\$2.319 billion), India (\$197 million) and Italy (\$179 million).

- ABARES, Australian Commodity Statistics, 2012.

The Australian wool producing industry is unique in that most of Australia's greasy wool is exported for full or partial processing overseas. Comparisons with wool production and processing systems in other parts of the world should be viewed in this context.

⁷ For the environmental assessment cypermethrin and alpha-cypermethrin are assessed as indistinguishable. Therefore, although there is only one long wool product (containing alpha-cypermethrin) the recommendations cover label amendments for both cypermethrin and alpha-cypermethrin.

New Zealand is the world's second-largest wool producer and exporter. Although 80–90% of the wool produced in New Zealand is exported as raw fibre, most of this wool is from non-merino breeds. New Zealand wool is largely coarse/strong wool used primarily for interior textiles such as carpets, blankets and upholstery. The dependence of wool producers on ectoparasiticides under New Zealand growing conditions is less than in Australia because of differences in pest pressure associated with climatic conditions and fleece characteristics. China buys about 25 per cent of New Zealand's wool exports (www.wool.com/Media-Releases.htm?item=7140.htm). Other export markets for New Zealand wool include the United Kingdom, India, Belgium, Italy, Australia and Germany.

China is another major world wool producer, in addition to being the major buyer of Australian raw wool. However, China is important as a wool processor, manufacturing textiles and clothing for domestic Chinese as well as export markets. Similarly, South Africa, another significant wool producer, also processes more wool than it produces.

No overseas country is affected in the same way as Australia by the changes in standards for processing raw wool in the EU. There is currently no information to suggest that other countries view the implementation of IPPC Directive 96/61/EC as an imminent threat to trade. Further, there is currently no information available to indicate that any country other than Australia is moving to change the way ectoparasiticides are used on sheep in response to predicted changes to environmental standards in the EU. However, Australia must respond to the changes in market demand for low-residue raw wool to protect Australia's strong primary production position and ongoing dependence on overseas processing of greasy wool.

Rather than attempt to meet the needs of specific scouring plants, it is practical to achieve the standard considered acceptable to the EU market. This potentially may change over time, as the EU will reconsider the levels and chemicals included in that list every 3 years.

Residue levels required by European Union

EU Commission Decision of 9 July 2009 establishes the ecological criteria for the award of the Community Ecolabel for textile products. It specifically addresses greasy wool and other keratin fibers (including wool from sheep, camel, alpaca and goat). The following table indicates the acceptable sum total content of given chemicals.

Table 6 European Union acceptable sum total content of given chemicals in greasy wool

ACTIVE CONSTITUENT	SUM TOTAL CONTENT PPM
cypermethrin, deltamethrin	0.5 ppm
diazinon, propetamphos, chlorfenvinphos, diflubenzuron, triflumuron, dicyclanil	2 ppm

Not all chemicals in the scope of this review are covered by this legislation however the European Commission meets every three years to review these standards and by informing users of the concerns then they are able to ensure appropriate records are kept. A copy of the latest EU Commission rulings in relation to chemical residue limits for raw wool commodities can be found at: [EU Eco-Label site](#) (Section 5. Greasy wool and other keratin fibres).

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:197:0070:01:EN:HTML>).

Conclusion

The APVMA has considered the comparative analysis undertaken by the Department of the Environment of likely scour residues, together with information on relevant environmental international standards and the likely impact of relevant standards in the EU on future exports of Australian raw wool.

The potential for residual ectoparasiticides in greasy wool to prejudice Australia's trade was considered in the PRF based on the release of these active constituents into rivers from small European scours. The presence of chemical residues on certain lots of raw wool may result in harm to the saleability of Australian raw wool to markets including, but not necessarily limited to those in the EU. While markets in the EU are not the sole markets for Australian raw wool, they are significant buyers, particularly for the premium super fine wool lots. Difficulties with the marketing of Australian raw wool to the EU may also impact on the saleability of Australian raw wool to other markets. An important part of Australia's national strategy for international marketing of agricultural commodities is based on the theme of 'clean green'; any violation of residues standards in an overseas market will have a prejudicial effect on this strategy and Australia's international trade reputation.

In the PRF assessment undertaken by the Department of the Environment in relation to processing of wool overseas, it was concluded that chemical residues resulting from the use of a number of sheep ectoparasiticide products in accordance with current approved label instructions could result in an exceedence of overseas environmental standards. This information, taken together with the fact that wool is a significant trade commodity that may be adversely affected by exceeding overseas environmental standards, resulted in the APVMA's recommendation that it would not be satisfied that chemical residues resulting from these uses would not unduly prejudice trade or commerce between Australia and places outside Australia.

Notwithstanding this proposed finding, the following points have been taken into consideration as part of the trade assessment:

1. Environmental Quality Standards (EQSs) have not been published in the EU for all active constituents in products affected by this review;
2. There is no comprehensive model available to translate the EU requirements to corresponding residue levels on treated wool other than the model that has been used for the assessment completed by the Department of the Environment as part of this review;
3. There is no information available to enable the APVMA to evaluate the risk that other countries that purchase Australian raw wool will follow the lead of the EU in imposing environmental standards or the risk that environmental standards will translate to an undue prejudice to trade; and
4. There is no generic mechanism available in Australia to ensure that wool that is unsuitable for processing overseas is identified at the point of sale. However, there is commercial pesticide screening available to wool producers and exporters - services include EU Ecolabel verification which would meet the current EU requirements.

Therefore, the APVMA concludes that there is currently insufficient justification for direct restrictions on long-wool chemical use for existing approved sheep ectoparasiticide products on trade grounds alone. Further, it will not be possible to set specific trade-related WHIs for sheep ectoparasiticide products to ensure that residues on exported wool meet importing country requirements.

However, given that the gap between the point of application of the product to sheep and the processing of harvested wool is at least 18 months, and until overseas requirements are published and pending overseas regulatory action, the APVMA proposes to find that it can be satisfied that the use of these products would not unduly prejudice trade or commerce between Australia and places outside Australia, if approved labels are varied to include advisory information to warn users that overseas regulatory requirements are likely to impact on the use of sheep ectoparasiticide products.

Therefore, the APVMA requires the addition of the following advisory statement to the approved label of all sheep ectoparasiticide products:

Use of this product may result in wool residues that may not comply with European Union environmental quality standards.

Wool treated with this product may contain detectable residues; adequate treatment records should be kept and made available, if requested by wool buyers.

4 ADDITIONAL COMMENTS RECEIVED IN RELATION TO THE PRELIMINARY REVIEW FINDINGS ENVIRONMENTAL ASSESSMENT

Additional information provided in response to the PRF that has not resulted in changes to the environmental risk assessment of scouring greasy wool are discussed below. These have been grouped as general issues related to the environmental risk assessment and more specific issues relevant to each active constituent. A synopsis of these comments or arguments, and additional data (noted in italics) together with the Department of the Environment's responses are presented below.

4.1 AWI Wool Residue Survey Data versus Wool Residue Trial Results for Environmental Risk Analyses of Scouring

Q. Why does the Department of the Environment prefer to use AWI survey data for residual pesticide levels in the national clip for calculating environmental risk quotients rather than the results of specific wool residue trials.

As outlined earlier, the AWI survey data for levels of residual ectoparasiticides is preferred by the Department of the Environment as the basis for assessing the environmental risks of scouring because the national average levels of pesticides measured by this survey will more closely reflect the levels of pesticides occurring in a typical processing lot at a wool scour and the survey results implicitly include the cumulative nationwide results of various registered application methods and application frequencies on wool for a particular active constituent. Hence, AWI survey data, where available, provides a superior predictive tool for calculating the likely discharges of ectoparasiticides from wool scours.

Q. What weighting will the Department of the Environment give to the results of wool residue depletion trials versus AWI survey data when recommending "Wool Harvest Intervals (WHIs)" and trade statements for the labels of sheep ectoparasiticide products in the future?

The results of wool residue depletion trials are essential for the environmental risk assessment of ectoparasiticide active constituents that are not monitored by the AWI survey (temephos and ivermectin). These results allowed projected national average residues in the national clip to be calculated. In the absence of this trial data, the Department of the Environment would be required to take a more conservative view of the acceptable WHIs for sheep ectoparasiticides products containing these active constituents.

Trade statements presented in this review are generic as the time delay between establishment of international regulations, changing labels, product application, wool harvest and wool sale is equates to years.

4.2 Domestic Scouring Model

The Volume of sewage inflow used in the Australian dilution model should be increased from 50 ML to 55 ML

Based on publicly available information (Barwon Water 2002), the Department of the Environment concurred with the respondent that the daily inflow volume to the Black Rock sewage treatment plant is approximately 55 ML. However, the relevant figure for the environmental risk assessment is the volume of sewage effluent discharged daily through the ocean outfall. Based on publicly available information (Barwon Water 2006),

approximately 10% of treated effluent from the Black Rock plant is currently re-used for irrigation, which indicates that the lowest volume of treated effluent discharged to the ocean on a daily basis is 50 ML. The latter figure, which was used in the PRF, has therefore been retained for the highest pesticide output modelling scenario (i.e. worst case), which is used to calculate the PECs of ectoparasiticides near the Black Rock ocean outfall.

Because 10% of effluent is re-used for irrigation, the mass of pesticide discharged through the ocean outfall should be scaled to 90% of the nominal discharge load calculated by the Department of the Environment.

No evidence has been provided that the treated effluent used for irrigation and that destined for the ocean outfall are treated to the same standard, or that they contain the same concentration of ectoparasiticides. In the absence of such data, the Department of the Environment must assume the worst-case calculation (i.e. highest pesticide output load) that all of the pesticides not removed within the sewage plant by means of degradation or adsorption are ultimately discharged through the ocean outfall.

The plume dilution at the ocean outfall used in the Australian dilution model should be increased from 1:50 to 1:100.

In support of this claim, a research article was provided which reported the results of a study to monitor the biotic assemblages (mainly macroalgae) close to the new sub-tidal Black Rock ocean outfall before and after commissioning (Ashton and Richardson, 1995). This article included a citation to a report prepared by one of the authors which apparently provides data in support of the assertion that “The new sub-tidal outfall was designed to achieve a rapid initial mixing (> 100:1)”. However, this report was not provided to the Department of the Environment and the quality of this claim was not assessed. Similarly, the respondent has stated that the operator of the sewage treatment plant has demonstrated that a dilution of 1:100 “was achieved within a few metres of the outfall pipe and was much greater at the surface”, but again the report supporting these claims was not provided and could not be assessed. In the absence of definitive new data, the Department of the Environment has opted to retain the 1:50 plume dilution figure used in the PRF (APVMA 2006a, p. 52), which is also the estimate provided by the design engineer for this sewage treatment plant (Grundy et al., 2000).

4.3 Model for Overseas Scouring

The use of the Spenborough (UK) scour plant was not considered appropriate as the basis for the overseas trade risk assessment for this Review as the Spenborough plant has closed

The closure of the Spenborough scour was acknowledged in Volume 1 of the PRF (APVMA 2006a, p. 54–55), but it was argued that the operational parameters of this scour would serve as a model of small scouring plants discharging treated aqueous scour wastes directly into a riverine environment. The scour discharge model based on the Spenborough plant remains relevant to the operations of scours in mainland Europe because these plants discharge aqueous scour wastes from a single line into small rivers (Savage, 1998, p.15). The Department of the Environment has retained the scour discharge model based on the Spenborough plant because it is currently the only basis for a systematic and consistent quantitative comparison of the relative risks posed by various ectoparasiticides to Australia’s export trade in greasy wool.

The EU has a legislated level for residues of most chemicals for greasy wool. Though the scouring method is of interest it does not affect the levels that must be achieved to meet the EU Ecolabel, which are based on greasy wool residues.

There is no specific modelling of Italian scour plants.

The desirability of developing a specific model for the Italian scouring industry similar to the Geelong-Black Rock system in Australia was noted in the PRF (APVMA 2006a, p. 54–55). However, the Department of the Environment has no information that would allow it to formulate such a model and no new information was supplied by respondents to the PRF that would be useful for this purpose. In this situation, the generic model of a small scour discharging treated aqueous scour wastes into a river has been retained as the most likely scenario for scouring plants in Italy.

Again it is not relevant to determine specific levels of residue allowable in greasy wool. The EU has a legislated level for residues of most chemicals for greasy wool. Though the scouring method is of interest it does not affect the levels that must be achieved to meet the EU Ecolabel, which are based on greasy wool residues.

4.4 Specialty Wool Lines

No “WHP” should apply to ectoparasiticide products that are used on wool intended for fellmongering (an expert report on fellmongering in Australia was provided in support).

The respondents have argued that no “Wool Harvest Interval (WHI)” is necessary for ectoparasiticides products when they are used on sheep intended for fellmongering because all fellmongered wool in Australia is produced by a single processor and is scoured at a single inland scour. However, this argument is not consistent with the expert report supplied which indicates that some of the fellmongered wool produced in Australia is sold into the general wool market. Hence, not all ectoparasiticides released by scouring greasy wool obtained by fellmongering will ultimately be discharged to land, as assumed by the respondents.

As described in this Review, the use of ectoparasiticide products on sheep can leave very high residues of active constituents in greasy wool if insufficient time elapses between application of the product and harvesting of the wool. The proposal from these respondents to eliminate the WHIs for sheep destined for fellmongering is therefore likely to increase the frequency of sale lots of greasy wool with very high residues of ectoparasiticides. The environmental risks arising from scouring these highly contaminated wool lots and discharging the aqueous scour wastes to the aquatic environment cannot be calculated in the absence of detailed data on the volumes of greasy wool from fellmongering entering the national market and the actual residues of pesticides that occurs on fellmongered wool in the absence of WHIs. Hence, the Department of the Environment is unable to calculate the risks to the environment from scouring that would result from this change in label conditions. Therefore, the Department of the Environment cannot support a proposal to exempt ectoparasiticide products from the normal WHIs when used on sheep destined for fellmongering.

The expert’s report also indicates that the majority of wool-on-skins produced in Australia are exported for further processing. A proportion of this wool is expected to be recovered by fellmongering and scoured in overseas scours. The environmental risks from scouring fellmongered wool overseas were not considered by the respondents. However, if this wool were contaminated with high levels of residual pesticides, as may occur if no WHI were applied, there is likely to be an increased risk of adverse environmental effects resulting from hot-spots of Australian greasy wool contaminated with high levels of residual ectoparasiticides. This proposal could therefore potentially prejudice Australia’s trade in greasy wool.

No wool withholding period should be applicable for wool obtained by crutching.

As for the fellmongering proposal above, there is the potential for wool with very high residues to enter the general wool market if this proposal were accepted. The Department of the Environment is unable to calculate the risks to the environment from scouring that would result from this change in label conditions. Therefore, the Department of the Environment cannot support a proposal to exempt wool obtained by crutching from the existing WHIs for ectoparasiticide products.

4.5 Dicyclanil

The PNEC for dicyclanil should be based on chronic toxicity data and an AF of 100 rather than acute toxicity data and an AF of 1000 as used by DEWHA in the PRF.

The derivation of the PNEC for this active constituent is based on the acute toxicity end-point determined for the aquatic invertebrate, *Daphnia magna* (48 h EC₅₀ = 1.1 mg/L). As was indicated in the PRF, the use of the acute daphnia end point for the PNEC derivation requires the use of the maximum assessment factor of 1000 because this is not the most sensitive species and the toxicity of dicyclanil is chronic rather than acute. Further, both the chronic daphnia and chironomid test results were not considered acceptable.

4.6 Cyromazine

There is an inadequate level of instruction to users on the label of one cyromazine ectoparasiticide product for the appropriate disposal of waste dipping/jetting solution and contaminated dip sludge.

The assessment of the environmental risks associated with the disposal of waste ectoparasiticide products is outside the scope of this Review.

4.7 Triflumuron

Q. Why is the toxicity end point of triflumuron to the marine crustacean, mysid shrimp, used in this review 3.9 µg/L, whereas a figure of 3.5 µg/L is used for the acute toxicity to this organism in a previous report on the residue implications of sheep ectoparasiticides (Savage 1998, p. 86)?

The figure of 3.5 µg/L for the acute toxicity of triflumuron to the mysid shrimp cited by Savage is apparently derived from unpublished data from the Bayer. However, the Department of the Environment is uncertain of the exact origin of this figure because the entry in the Savage report is not referenced. In contrast, the figure of 3.9 µg/L for the acute toxicity of triflumuron to mysid shrimp has been used consistently by the Department of the Environment for the assessment of registrations and variations to products containing this active constituent since the early 1990s. This figure was therefore used for the derivation of the PNEC for triflumuron for the Review.

*Q. Why is the toxicity end point for a marine organism (mysid shrimp) used to derive the Maximum Acceptable Concentration (MAC) of triflumuron in rivers in Europe. Instead, the Department of the Environment has suggested a figure of 100 µg/L based on an acute (48 hour) No Effect Level for *Daphnia* from a chronic toxicity test for this species.*

The Department of the Environment has noted that triflumuron is a benzoylurea pesticide and belongs to the same class of insect growth regulators as diflubenzuron. The statutory MAC for diflubenzuron in the UK is 15 ng/L for freshwater and 100 ng/L for saltwater (APVMA 2006a, p. 51). Hence, the MAC proposed by the respondent for triflumuron is 6667 times greater than the statutory limit for diflubenzuron. It is improbable that

two such closely related active constituents could be considered to have such vastly different acute toxicities. The APVMA notes that this has not affected the outcome of the review.

The assessment factor of 10 used for the derivation of the PNEC for triflumuron was insufficiently protective. Instead, the Department of the Environment argued that an AF of 100 should be used because of a relative lack of ecotoxicity data for this active constituent.

This assessment factor has been used by the Department of the Environment for all of its previous assessments of triflumuron and is justified considering the use of the very sensitive marine organism endpoint together with the lack of toxicity to fish and algae.

4.8 Diflubenzuron

The application specific environmental risk assessment carried out for this product by the Department of the Environment employed a more conservative PNEC for diflubenzuron than was used in the PRF. The registrant has sought assurance that this does not disadvantage their product with respect to those of its competitors.

A more conservative PNEC for diflubenzuron was used by the Department of the Environment for the environmental risk assessment of this registrant's product for reasons of data - the ecotoxicology data set available for the registration assessment was smaller than the data set used in the PRF. The larger ecotoxicology data set available in the PRF was sufficient for the Department of the Environment to use the minimum Assessment Factor (10) to derive a PNEC for diflubenzuron (64 ng/L). This has the effect of modestly increasing the PNEC for this active constituent in the PRF compared with the value used in the environmental risk assessment undertaken as part of registration process.

However, the higher PNEC derived in the PRF was used by the Department of the Environment to reassess the domestic environmental risks of all sheep ectoparasiticide products containing diflubenzuron, including the registrant's product. Furthermore, all of these products were reassessed using a common and consistent environmental risk assessment framework. The revised risk assessment as described in Section 12 is therefore equally applicable to all sheep ectoparasiticide products containing diflubenzuron. Hence, the existing WHI for the registrant's product is acceptable. As this WHI is the same as those for the closest comparable products, the Department of the Environment concludes that the registrant's product has not been disadvantaged by the use of a more conservative PNEC than that used in the original environmental risk assessment undertaken as part of active approval.

Diflubenzuron ectoparasiticide products should be restricted to use 7 days after shearing for backline operations or 4 weeks after shearing for low-dose (1 in 2500 dilution) dipping applications. Results from a modelling study in which the loss of mass of diflubenzuron from fleece over time was calculated following application of a low dose formulation of diflubenzuron by dipping were provided in support of this argument and has been described in the literature (Campbell et al., 1998).

The loss of diflubenzuron from fleece treated with the low dose product by dipping was calculated for various scenarios in which the application time period was varied in 1 week intervals up to 6 weeks after shearing. The results of these simulations were compared with the calculated loss of diflubenzuron from fleece following off-shears application of a diflubenzuron backline product. The results of this study indicated that the decay profile and final mass of diflubenzuron in fleece 360 days after shearing are expected to be similar for the backline product applied off-shears and for the low-dose dip product when it is applied 4-weeks off-shears.

The Department of the Environment has revised the environmental risk assessment for registered diflubenzuron sheep ectoparasiticide products provided in the PRF and now supports the use of existing products with the current label instructions. This includes diflubenzuron products registered for the low-dose dipping of sheep up to 6 weeks off-shears. Based on this revised analysis, the Department of the Environment concludes that there is no reason to restrict dipping sheep with low dose diflubenzuron ectoparasiticide products to 4-weeks off-shears.

Change in the default parameters assumed by the Department of the Environment for the plume-dilution, outflow volumes and water re-use strategies at the Black Rock sewage treatment plant.

These arguments were addressed in the assessment.

A new modelling study of the likely discharges of diflubenzuron arising from scouring processing lots composed of wool sale lots with high residues of this active constituent in Australia was provided. The study showed that when the measured distribution of diflubenzuron on the national clip is used to calculate the daily input load of pesticides to the scour, toxic discharges at the Black Rock ocean outfall were not likely to occur on any day of processing over a one year period.

This study was considered by the Department of the Environment in the assessment of diflubenzuron.

Actual quantities of diflubenzuron discharged from the Black Rock ocean outfall as determined by Russell et al. (2001) should be used as the basis for the environmental risk assessment for this active constituent.

The experimental work carried by Russell, Grundy and others in validating certain key assumptions of the Australian dilution model has been of considerable value for this Review. However, these studies were carried out more than 13 years ago and, as indicated in Section 2, the scouring industry in Geelong has undergone some significant changes recently. These changes have the effect of significantly altering the absolute quantities of ectoparasiticides entering the Black Rock sewage treatment plant on a daily basis. Hence, the quantities of ectoparasiticides discharged from the Black Rock sewage treatment plant measured in the various studies by Russell and Grundy cannot form the basis for an assessment of the quantities of pesticides currently discharged from the ocean outfall. In this situation, there is no alternative but to rely on the Australian dilution model which has been modified to account for these recent changes in the local scouring industry.

Separate risk assessments should be carried out for the various application scenarios for diflubenzuron ectoparasiticide products including the following: Short wool plunge and shower dipping and jetting; Long wool plunge and shower dipping and jetting; Off-shears pour-on to adult sheep; Specialty wool lines (lamb's wool, fellmongering and crutching); Long wool pour-on to adult sheep; Repeated Use of pour-on. It is not appropriate to apply one simple model to all situations on the grounds that the residue studies for diflubenzuron in wool show that the depletion is non-linear and varies considerably depending upon the dose applied and the wool length that is applied to.

The Department of the Environment agrees that the concentration of residual ectoparasiticides in the national greasy wool clip is a complex result of the various application methods, formulation types and application timing used for sheep ectoparasiticide products. Despite various attempts to model the relative contributions of these factors to the final measured levels of residual ectoparasiticides in wool, the Department of the Environment is of the view that the only practical way in which to assess the overall environmental risks of residual ectoparasiticides is to use the AWI survey data as the starting point for discharge load calculations, where it is available. This represents the cumulative average of all application

methodologies integrated over the whole national clip. This approach avoids the use of various assumptions about the relative contributions of the different application methodologies and timing that is inherent in the multi-component wool residue depletion models that have been proposed.

For diflubenzuron ectoparasiticide products, "A WHP of 1 month should be implemented for lambs' wool, where lambs are treated at the off-shears rate when less than 3 months of age". In support, the respondent has argued that the treatment of lambs at foot is rare and only a small amount of wool is generated from lambs so treated. In addition, a new study of diflubenzuron residues in merino sheep was provided.

The study provided is for sheep not lambs. Therefore the Department of the Environment is unable to further assess this request and without specific new data the Department is unable to change the analysis provided on p. 145 of Volume 2 of the PRF (APVMA 2006b).

The acute toxicity end point for diflubenzuron was derived from the literature without critical evaluation of the primary experimental data and that this study was not likely to have been carried out according to principles of Good Laboratory Practice (GLP).

The Department of the Environment agrees that it is preferable to review the primary data used to generate ecotoxicology end points, but notes that for older chemicals this is not always feasible. In this latter situation, the standard practice of the Department of the Environment is to consider the reported magnitude of a particular end-point in the context of the overall weight-of-evidence for the ecotoxicology properties of a pesticide. For example, at the time of the PRF, the LC50 figure for exposure of the pre-moult stage of the grass shrimp (*Palaeomonetes pugio*) to diflubenzuron (0.64 µg/L) was the most sensitive reported end-point for a marine crustacean. This result, which was reported as an entry in the United States Environmental Protection Agency (US EPA) database, was used for the derivation of the PNEC because the weight of accumulated aquatic ecotoxicology data for diflubenzuron clearly indicated that this active constituent is acutely toxic to marine crustaceans at concentrations ≤ 2 µg/L. This view was based on both a consideration of other database entries for the acute toxicity of diflubenzuron to marine crustaceans and the critical evaluation of additional ecotoxicology studies supplied to the Department of the Environment for the PRF.

In the interval since the PRF was published, a research article has appeared in the scientific literature which supports the established view regarding the very high acute toxicity of diflubenzuron to Australian marine crustaceans. In this study by Gartenstein *et al* (2006), the embryos and larvae of the brine shrimp, *Artemia salina*, in filtered sea water were exposed to technical grade diflubenzuron present at nominal test concentrations of 0.13, 1 and 10 µg/L. Statistically significant toxic effects were observed for embryos and larvae of *Artemia salina* exposed to the lowest nominal test concentration of diflubenzuron (0.13 µg/L) and the derived 48 h LC50 for *Artemia salina* larvae is 0.37 µg/L. The study also demonstrated that diflubenzuron could cause developmental abnormalities in the larvae of the local sea urchin, *Heliocardaris tuberculata*, at nominal diflubenzuron concentrations of 1 µg/L. The 72 h EC50 derived for this non-crustacean is 2.69 µg/L.

The Department of the Environment also does not accept the respondent's criticism of the use of data from non-GLP ecotoxicology studies to derived PNECs. The available ecotoxicology data set for a well-established active constituent such as diflubenzuron inevitably contains results from some studies that do not conform to the requirements of GLP. This is partly a function of the long use of diflubenzuron as an active constituent in pesticide products which predates the global introduction of the GLP system. These early studies constitute an important part of the weight-of-evidence regarding the aquatic ecotoxicology of diflubenzuron. The Department of the Environment does not consider it appropriate to discard these early studies solely on the basis that they were not conducted in GLP-accredited laboratories or according to GLP criteria, noting this is not a legal requirement in Australia. Rather, the standard approach employed by the

Department of the Environment is to consider and weight all of the available evidence including end-points reported in research articles, review articles, international ecotoxicology databases and, when supplied, new ecotoxicology studies.

Q. Why was the discharge of ectoparasiticides through the Bolivar sewage treatment plant in Adelaide, South Australia, not been evaluated as part of the risk assessment presented in this Review.

The Department of the Environment has received expert advice that a change to a model based on discharges of ectoparasiticides from Bolivar sewage treatment plant is unnecessary. Hence, the Australian model based on scouring in Geelong and discharge of treated effluent through the Black Rock sewage treatment plant has been retained for the environmental risk assessment of domestic scouring. As indicated in Section 2, the model has been modified to incorporate the extra on-site pesticide removal step for diflubenzuron afforded by the Sirolan CF process that is now used at the one remaining scour in Geelong. This change has the effect of significantly decreasing the calculated quantities of diflubenzuron discharged from the Black Rock ocean outfall, as compared with the values calculated in the PRF.

The removal efficiency of diflubenzuron in the Black Rock sewage treatment plant used in the Australian dilution model should be set at a figure of 93% rather than 85% as used by the Department of the Environment in the PRF.

The removal efficiency of 85% for diflubenzuron in the Black Rock sewage treatment plant is derived from the experimental study by Russell *et al.* (2001). This figure corresponds to the removal efficiency measured when only commercial wool sale lots were scoured in Geelong. The Department of the Environment has therefore retained the 85% removal efficiency figure for diflubenzuron in the Black Rock sewage treatment plant for the revised domestic discharge calculations that were carried out for this report.

The environmental fate of diflubenzuron after discharge from the sewage treatment plant should be incorporated into the risk analysis model as a mitigating factor. In support, the respondent provided eight additional studies of the fate and ecotoxicity of diflubenzuron in freshwater mesocosms and field sites.

In freshwater mesocosms and field sites, diflubenzuron is relatively rapidly dissipated from the water column with a half-life in the range 0.4–4.3 days. The main mechanism for dissipation from water appears to be through sorption of the active constituent on suspended organic matter and by absorption in sediment and vegetative matter. However, the active constituent does not persist in the sediment or vegetative compartments, although relatively high transient concentrations can occur in submerged macrophytes. The results of mass balance studies in the lentic ecosystem confirmed that the water column is the main compartment in which exposure of aquatic organisms to diflubenzuron occurs.

The chitinous microcrustacean zooplanktons were consistently the most sensitive to direct toxic effects of diflubenzuron. The most sensitive zooplankton were *cladocera* and *copepoda* for which the lowest observed effect level (LOEL) was as low as 0.7 µg/L (nominal) in a freshwater pond, although more significant effects were observed at nominal concentrations ≥ 2.5 µg/L. The reduction in the abundance of sensitive zooplankton after treatment of freshwater ponds with diflubenzuron sometimes persisted to the end of the observational period. The toxic effects of diflubenzuron on other aquatic invertebrates were generally less severe than for the *cladocera* and *copepoda*. The active constituent did not have direct toxic effects on phytoplankton and fish in a freshwater pond, but indirect effects on fish growth rates resulting from toxicity to zooplankton prey were observed at nominal diflubenzuron concentrations ≥ 7.0 µg/L.

The results of these additional studies confirm the results of studies previously assessed by the Department of the Environment which showed that this active constituent is not persistent in the aquatic environment and that it is relatively rapidly dissipated from the water column by adsorption processes. However, all of these studies were designed to model the application of pesticide formulations of diflubenzuron to aquatic systems as a result of agricultural practices or for mosquito control purposes. Hence, they all involved either a single or, at most, a once repeated application of diflubenzuron pesticide formulations to aquatic environments. In these application scenarios, adsorption of the applied diflubenzuron to suspended particles and sediment can reduce the concentration of diflubenzuron in the water column relatively rapidly because there is no replenishment of the pesticide levels. In such cases, it may be appropriate to include the mitigating effects of pesticide adsorption when assessing the risk of adverse effects on the aquatic environment.

However, the mitigating effects of pesticide adsorption are not likely to be as significant for the environmental risks of pesticides released by scouring greasy wool. This is an industrial process. Hence, pesticides are continuously or semi-continuously discharged to the aquatic environment from a sewage treatment plant or a wool scour. This has the effect of replenishing levels of pesticide in the vicinity of the discharge point which may otherwise decline due to dissipative mechanisms. These mechanisms will include adsorption of pesticides to suspended particles. However, mass transfer processes such as ocean currents, tidal action and river flows are likely to be the dominant dissipative mechanisms in the immediate vicinity of the discharge points.

4.9 Cypermethrin/Alpha-Cypermethrin

A new modelling study of the likely discharges of cypermethrin arising from scouring processing lots composed of wool sale lots with high residues of this active constituent was provided. The study showed that when the measured distribution of cypermethrin on the national clip is used to calculate the daily input load of pesticides to the scour, toxic discharges were only likely on 18 days per year.

This study was considered by the Department of the Environment

The removal efficiency of cypermethrin in the Black Rock sewage treatment plant used in the Australian dilution model should be set at a figure of 97-99% rather than 95% as used by the Department of the Environment in the PRF.

The removal efficiency of 95% for cypermethrin in the Black Rock sewage treatment plant is a lower limit that was estimated in a trial designed to validate assumptions used in the Australian dilution model for sheep ectoparasiticides (Russell *et al.* 2001). A more precise estimate was not possible because cypermethrin was below the detection limit of the analytical method employed (10 ng/L). For this reason, a lower limit for the removal efficiency of this active constituent was calculated based on the assumption that the concentration of cypermethrin in the treated effluent was ≤ 10 ng/L. This approach is appropriate for a worst-case modelling scenario and the 95% figure has therefore been retained for the revised modelling carried out for this report.

Actual quantities of cypermethrin discharged from the Black Rock ocean outfall as determined by Russell *et al.* (2001) should be used as the basis for the environmental risk assessment for this active constituent.

The experimental work carried by Russell, Grundy and others in validating certain key assumptions for the Australian dilution model has been of considerable value for this Review. However, these studies were carried out more than 13 years ago and, as indicated in Section 2, the scouring industry in Geelong has

undergone some significant changes recently. These changes have the effect of significantly altering the absolute quantities of ectoparasiticides entering the Black Rock sewage treatment plant on a daily basis. Hence, the quantities of ectoparasiticides discharged from the Black Rock sewage treatment plant measured in the various studies by Russell and Grundy cannot form the basis for an assessment of the quantities of pesticides currently discharged from the ocean outfall. In this situation, there is no alternative but to rely on the Australian dilution model which has been modified to account for these recent changes in the local scouring industry.

A research article describing the inhibitory effects of suspended solids on the bioavailability of synthetic pyrethroids in water by Yang et al. (2006) was provided.

The effects of suspended solids and Dissolved Organic Matter (DOM) on the bioaccumulation of ^{14}C -labelled permethrin and bifenthrin in *Daphnia magna* were investigated under static conditions. The nominal concentration of both pesticides was $< 1 \mu\text{g/L}$ in each test solution (100 mL). The mass of pesticide absorbed in *D. magna* during the 24 hour exposure period was determined by liquid scintillation counting of the ^{14}C released after combustion of the washed and dried test organisms. The free concentration of the pesticides in the water phase of the test solutions was determined indirectly by liquid scintillation counting of the quantity of each pesticide adsorbed on fibres of polydimethylsiloxane immersed in the test solutions. The test solutions were prepared by dilution of stock solutions of washed and unwashed sediment suspensions in reconstituted hard water.

The bioaccumulation of permethrin and bifenthrin in *D. magna* was inhibited by up to 63% at nominal suspended solid levels of 200 mg (dry-mass equivalent)/L. The inhibitory effect of both pesticides was well described by a simple adsorption model in which bioaccumulation is inversely related to the particulate content of the suspension. Further analysis indicated that both particulate solids and associated dissolved organic matter (DOM) contributed to the adsorption of the pesticides from the aqueous phase. The fraction of added pesticides adsorbed to particulate matter was not available for uptake for *D. magna* over the course of the exposure period. This latter conclusion was based on a statistically significant positive linear correlation between the concentration of pesticides in the bodies of *D. magna* and the free concentration of pesticide in the test solution.

Lipophilic compounds such as synthetic pyrethroids are expected to associate strongly with organic matter and solids. This is reflected in the high removal efficiencies for synthetic pyrethroids in sewage treatment plants, for example. However, this property is not a dominant factor in the environmental risk assessment of synthetic pyrethroids once they are discharged from sewage treatment plants. As outlined above for diflubenzuron, sewage treatment plants discharge treated effluent on a continuous or semi-continuous basis. Hence, dissipation of pesticides from the water column by mechanisms such as adsorption is compensated by the continual renewal of pesticide levels from fresh effluent discharges. The study by Yang *et al.* (2006) therefore does not offer a basis for modifying the assessment of the environmental risks for synthetic pyrethroids (or other ectoparasiticides) discharged from sewage treatment plants.

5 REVIEW FINDINGS

The APVMA has reviewed the registered products and associated label approvals for products that fall within the scope of the review of selected sheep ectoparasiticides. The findings from these investigations, including the consideration of public comments on the PRF Report released for public comment in 2006, are outlined below.

5.1 Change in terminology - wool harvest interval

The APVMA will no longer refer to the wool withholding period (WWP) on labels. It will now be known as the wool harvest interval (WHI) and is the time between the treatment of the animal with the chemical and the harvest of the wool. As outlined in the PRF, this change in terminology will help to distinguish wool residue information from other withholding period statements on the label that pertains to chemical residues in food.

5.2 Occupational health and safety findings

The occupational health and safety assessment of the sheep ectoparasiticides determined that there was sufficient data available to make recommendations on the potential OHS risks associated with the use of sheep ectoparasiticides for all except two of the active constituents, namely deltamethrin and chlorfenvinphos. These actives have both been allocated a rehandling interval of 2 weeks by the APVMA.

In order for the APVMA to be satisfied that the use of sheep ectoparasiticide products in accordance with label instructions would not be an undue hazard to the safety of people exposed to them during their handling or people using anything containing their residues, the labels will be varied to include a sheep rehandling interval statement.

The rehandling interval will be placed under the ADDITIONAL SAFETY INFORMATION heading.

The recommended rehandling intervals for the sheep ectoparasiticides are outlined below:

Table 7 Recommended sheep rehandling intervals

ACTIVE CONSTITUENT	RECOMMENDED SHEEP REHANDLING INTERVAL
Alpha-cypermethrin and Cypermethrin	Sheep Rehandling Interval: Two weeks. If sheep must be handled during this interval, cotton overalls buttoned to the neck and wrist (or equivalent clothing) should be worn.
Chlorfenvinphos	Sheep Rehandling Interval: Two weeks. If sheep must be handled during this interval, cotton overalls buttoned to the neck and wrist (or equivalent clothing) should be worn.
Cyhalothrin	Sheep Rehandling Interval: After treatment wait until sheep are dry before rehandling.
Cyromazine	Sheep Rehandling Interval: After treatment wait until sheep are dry before rehandling.
Deltamethrin	Sheep Rehandling Interval: Two weeks. If sheep must be handled during this interval, cotton overalls buttoned to the neck and wrist (or equivalent clothing) should be worn.
Diazinon	Sheep Rehandling Interval: Six weeks. If sheep must be handled during this interval, cotton overalls buttoned to the neck and wrist (or equivalent clothing) should be worn
Dicyclanil	Sheep Rehandling Interval: After treatment wait until sheep are dry before rehandling.
Ivermectin	Sheep Rehandling Interval: After treatment wait until sheep are dry before rehandling.
Diflubenzuron	Sheep Rehandling Interval: After treatment wait until sheep are dry before rehandling.
Propetamphos	<p>Sheep Rehandling Interval for dipping: Six weeks. If sheep must be handled during this interval, cotton overalls buttoned to the neck and wrist (or equivalent clothing) should be worn</p> <p>Sheep Rehandling Interval for jetting: Twelve weeks. If sheep must be handled during this interval then cotton overalls buttoned to the neck and wrist (or equivalent clothing) should be worn</p> <p>Sheep Rehandling Interval for spot application: Six weeks. If sheep must be handled during this interval, cotton overalls buttoned to the neck and wrist (or equivalent clothing) should be worn</p>
Spinosad	Sheep Rehandling Interval: After treatment wait until sheep are dry before rehandling.
Temephos	Sheep Rehandling Interval: After treatment wait until sheep are dry before rehandling.
Triflumuron	Sheep Rehandling Interval: After treatment wait until sheep are dry before rehandling.

Note – for products with multiple actives, the active with the longest re-handling interval will determine which interval to be used.

No additional data was provided in response to the release of the PRF to complete the OHS risk assessment for deltamethrin or chlorfenvinphos.

Chlorfenvinphos is currently registered for the use as wound, mulesing and flystrike treatments. It is expected that worker exposure during wound dressing and lamb marking would be for relatively short periods, such as marking or intermittent, for example during flystrike risk periods. Considering that the concentration used under such a scenario is low and that the area requiring dressing is not likely to be extensive, the risk to workers during treatment is considered acceptable. Precautions taken while treating animals should be maintained for 2 weeks post treatment, which would include handling at shearing.

Deltamethrin has a pattern of use limited to 'off shears', to limit worker exposure it is recommended that this product be applied last if applying products concurrently. Precautions taken while treating animals should be maintained for 2 weeks post treatment.

5.3 Australian environment findings

The Department of the Environment has assessed the environmental risks associated with the use of sheep ectoparasiticides on wool. With respect to the Australian environment, the APVMA has determined that the active constituents contained in sheep ectoparasiticide products listed in table 8 would not be likely to have an unintended effect that is harmful to the environment under current use patterns. This is based on the condition that labels are varied to include an appropriate WHI.

Table 8 Recommended wool harvest intervals

ACTIVE CONSTITUENT	WOOL HARVEST INTERVAL (WHI)
Alpha-cypermethrin on long wool (six or more weeks off-shears)	2 months
Chlorfenvinphos	1 month
Cypermethrin	2 months
Cyromazine	2 months
Deltamethrin	2 months
Diazinon	2 months
Dicyclanil *	3 months
Diflubenzuron	6 months
Ivermectin	6 weeks
Propetamphos	2 months
Spinosad	Nil
Temephos	6 months Short wool application only.
Triflumuron	2 months

Note – for products with multiple actives, the active with the longest re-handling interval will determine which interval to be used.

Under the “Withholding Period” heading, the wording of the label statement will be: WOOL HARVEST INTERVAL: DO NOT use less than XX months before shearing or fibre collection.

The use of temephos as a long wool treatment for sheep cannot be supported.

Note that an assessment of the impact of residues of chlorfenvinphos on the environment has not been undertaken to date as part of this review because available information was limited. In addition, the separate review of chlorfenvinphos was finalised in October 2011 when the registrant voluntarily amended the product label by removing jetting or dipping of sheep. Use patterns are restricted to wound, mulesing and flystrike treatments. This will limit the amount of product used and the area of wool treated.

* A single low concentration dicyclanil product has been introduced to the market and WHI was assessed at registration. The WHI for this product has been set at 1 month.

5.4 Trade findings

The APVMA has determined that there is currently insufficient justification for direct restrictions on long-wool chemical use for existing approved sheep ectoparasiticide products on trade grounds alone. Further, it will not be possible to set specific trade-related WHIs for sheep ectoparasiticide products to ensure that residues on exported wool meet importing country requirement. The EU environmental quality standards are

assessed on a 3-yearly cycle - to ensure currency these changes would need to reflect the current situation. Recording of product use and testing of lots sold overseas will allow compliance with current international environmental standards.

The APVMA requires the addition of the following advisory statement is to be included under TRADE ADVICE heading:

Use of this product may result in wool residues that may not comply with European Union environmental quality standards.

Wool treated with this product may contain detectable residues; adequate treatment records should be kept and made available, if requested by wool buyers.

5.5 Recommendations

The APVMA has determined that it is not satisfied that the continued use of, or any other dealing with the products listing in Appendix A, directly affected by the review of selected sheep ectoparasiticides:

- would not be likely to have an effect that is harmful to the occupational health of workers, particularly shearers, contacting treated wool, primarily during wool harvesting
and/or
- would not be likely to have an effect that is harmful to the environment as there is the potential for chemical residues to harm susceptible organisms in the environment, particularly if the chemicals are released in the course of wool processing
and/or
- would not have the potential to prejudice trade because of chemical residues on treated wool.

In addition the APVMA is not satisfied that all the labels of the products listed in Appendix A contain adequate instructions in relation to the criteria set out in 14(3) (g) of the Agvet Codes as well as those referred to in Regulations 11 and 12 of the Agvet Code Regulations.

However, the APVMA is satisfied that the conditions of the current label approval for the products in Appendix A can be varied in such a way that so as to contain adequate instructions in accordance with section 14(3) (g) of the Agvet Codes. Once labels are varied as outlined above, the APVMA will affirm the product registrations for products listed in Appendix A.

The APVMA it is not satisfied that previously approved labels for currently registered products affected by this review contain adequate instructions and therefore will cancel these label approvals (see Appendix A for the list of non-current label approval numbers).



APPENDICES

APPENDIX A - PRODUCTS AFFECTED BY THE REVIEW

Table 1: Products registered at the commencement of the review

PRODUCT NO	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBERS	REGULATORY ACTION PROPOSED IN RF
ALPHA-CYPERMETHRIN				
38354	VANQUISH LONG WOOL SPRAY-ON LICE TREATMENT AND BLOWFLY STRIKE PREVENTIVE FOR LONG WOOLLED SHEEP AND UNSHORN LAMBS	INTERVET AUSTRALIA PTY LIMITED	49471	Vary
			0999	Cancel
			02	Cancel
			01	Cancel
38355	DURACIDE SUSTAINED ACTION SPRAY-ON LICE TREATMENT FOR SHORN SHEEP	INTERVET AUSTRALIA PTY LIMITED	0999	Vary
			01	Cancel
CYPERMETHRIN				
39065	WSD SPURT OFF-SHEARS, POUR-ON SHEEP LICE CONTROL	REBOP HOLDINGS PTY LTD T/A WESTERN STOCK DISTRIBUTORS	1200	Vary
			0209	Cancel
47845	OUTFLANK OFF-SHEARS POUR-ON SHEEP LICE TREATMENT	ZOETIS AUSTRALIA PTY LTD	0501	Vary
			01	Cancel
CYPERMETHRIN AND CHLORFENVINPHOS				
45211	BARRICADE 'S' CATTLE DIP AND SPRAY	ZOETIS AUSTRALIA PTY LTD	0509	AFFIRMED
			0999	Cancel
			0204	Cancel
			0101	Cancel
46815	COOPERS BLOCKADE 'S' CATTLE DIP AND SPRAY	INTERVET AUSTRALIA PTY LIMITED	52976	AFFIRMED
			0204	Cancel
			1200	Cancel
			01	Cancel

PRODUCT NO	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBERS	REGULATORY ACTION PROPOSED IN RF
CYROMAZINE				
39979	VETRAZIN SPRAY-ON SHEEP BLOWFLY TREATMENT	NOVARTIS ANIMAL HEALTH AUSTRALASIA PTY. LIMITED	0908	Vary
			0703	Cancel
			0500	Cancel
			0298	Cancel
49852	VETRAZIN LIQUID SHEEP BLOWFLY TREATMENT	NOVARTIS ANIMAL HEALTH AUSTRALASIA PTY. LTD	0908	Vary
			0703	Cancel
			01	Cancel
49995	CYRAZIN LIQUID SHEEP BLOWFLY TREATMENT	ANCARE AUSTRALIA PTY LIMITED	1109	Vary
			0703	Cancel
			0902	Cancel
50179	VITAL CRYSTAL CYROMAZINE 500 SHEEP BLOWFLY TREATMENT	LANGEY HOLDINGS PTY LTD	0510	Vary
			1099	Cancel
DELTAMETHRIN				
36340	COOPERS CLOUT-S BACKLINE LICE TREATMENT	INTERVET AUSTRALIA PTY LIMITED	49456	Vary
			0103	Cancel
			02	Cancel
			01	Cancel
DIAZINON				
38874	VIRBAC DIAZINON SHEEP BLOWFULY DRESSING	VIRBAC (AUSTRALIA) PTY LTD	42422	Vary
			38351	Cancel
			15510	Cancel

PRODUCT NO	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBERS	REGULATORY ACTION PROPOSED IN RF
39572	WSD DIAZINON FOR SHEEP, CATTLE, GOATS AND PIGS	REBOP HOLDINGS PTY LTD T/A WESTERN STOCK DISTRIBUTORS	0607	Vary
			1100	Cancel
DICYCLANIL				
50005	CLIK SPRAY-ON SHEEP BLOWFLY TREATMENT	NOVARTIS ANIMAL HEALTH AUSTRALASIA PTY. LIMITED	61037	Vary
			0310	Cancel
			0509	Cancel
			0802	Cancel
			0899	Cancel
			0998	Cancel
DIFLUBENZURON				
45968	FLEECECARE INSECT GROWTH REGULATOR FOR SHEEP DIPPING AND JETTING	INTERVET AUSTRALIA PTY LIMITED	0407	Vary
			0403	Cancel
			0701	Cancel
			1200	Cancel
			17925	Cancel
			03	Cancel
			02	Cancel
			01	Cancel
			48741	COOPERS STRIKE INSECT GROWTH REGULATOR FOR SHEEP DIPPING AND JETTING
02	Cancel			
01	Cancel			
51359	COOPERS MAGNUM IGR POUR-ON SHEEP LICE DESTROYER	INTERVET AUSTRALIA PTY LIMITED	0407	Vary
			0905	Cancel
			0505	Cancel
			0904	Cancel
			0603	Cancel
			0702	Cancel
			0402	Cancel
			0202	Cancel

PRODUCT NO	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBERS	REGULATORY ACTION PROPOSED IN RF
			0201	Cancel
			0200	Cancel
			0100	Cancel
IVERMECTIN				
45623	JETAMEC JETTING FLUID CONCENTRATE	MERIAL AUSTRALIA PTY LTD	0602	Vary
TEMEPHOS				
47568	COOPERS ASSASSIN SHEEP DIP	INTERVET AUSTRALIA PTY LIMITED	1108	Vary
			0907	Cancel
			18453	Cancel
			0598	Cancel
			0498	Cancel
			02	Cancel
			01	Cancel
TRIFLUMURON				
45636	ZAPP POUR-ON LOUSICIDE FOR SHEEP	BAYER AUSTRALIA LTD (ANIMAL HEALTH)	0209	Vary
			1107	Cancel
			1104	Cancel
			1103	Cancel
			1003	Cancel
			0499	Cancel
			0798	Cancel
			0498	Cancel
			01	Cancel

Table 2: Products registered after the commencement of the review

PRODUCT NO	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBERS	REGULATORY ACTION PROPOSED IN RF
CHLORFENVINPHOS				
39575	WSD AEROSOL SHEEP DRESSING	REBOP HOLDINGS PTY LTD T/A WESTERN STOCK DISTRIBUTORS	1207	Vary
			0704	Cancel
			0201	Cancel
42259	DAVID GRAYS AEROSOL SHEEP DRESSING	DAVID GRAY & CO. PTY LIMITED	0304	Vary
			0899	Cancel
45736	DEFIANCE S INSECTICIDAL FLYSTRIKE, MULES AND WOUND DRESSING	ZOETIS AUSTRALIA PTY LTD	49928	Vary
			0204	Cancel
			0201	Cancel
			02	Cancel
01			01	Cancel
58998	DEFIANCE 'S' AEROSOL INSECTICIDAL FLYSTRIKE, MULES AND WOUND DRESSING	ZOETIS AUSTRALIA PTY LTD	0305	Vary
CYPERMETHRIN				
54370	4FARMERS CYPERMETHRIN 25 OFF-SHEARS, POUR-ON SHEEP LICE CONTROL	4 FARMERS PTY LTD	0801	Vary
CYROMAZINE				
52552	VIRBAC VIRBAZINE SPRAY-ON SHEEP BLOWFLY TREATMENT	VIRBAC (AUSTRALIA) PTY LTD	0608	Vary
			1000	Cancel
52669	VIRBAZINE LIQUID SHEEP BLOWFLY TREATMENT	VIRBAC (AUSTRALIA) PTY LTD	0908	Vary
			0902	Cancel
			0101	Cancel

PRODUCT NO	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBERS	REGULATORY ACTION PROPOSED IN RF
52729	CYRAZIN SPRAY ON SHEEP BLOWFLY TREATMENT	ANCARE AUSTRALIA PTY LIMITED	1109	Vary
			0703	Cancel
			1002	Cancel
			0700	Cancel
52745	VENUS SPRAY-ON SHEEP BLOWFLY TREATMENT	NORBROOK LABORATORIES AUSTRALIA PTY LIMITED	0509	Vary
			0904	Cancel
			0500	Cancel
52967	CYRO-FLY 500 BLOWFLY TREATMENT FOR SHEEP	JUROY PTY LIMITED	61840	Vary
			0509	Cancel
			1200	Cancel
53023	VENUS LIQUID SHEEP BLOWFLY TREATMENT	NORBROOK LABORATORIES AUSTRALIA PTY LIMITED	0509	Vary
			0804	Cancel
			0600	Cancel
54685	COOPERS CLOUT BLOWFLY JETTING/DIPPING LIQUID FOR SHEEP	INTERVET AUSTRALIA PTY LIMITED	0509	Vary
			1101	Cancel
56726	4FARMERS CYROMAZINE 500 SC SHEEP BLOWFLY TREATMENT	4 FARMERS PTY LTD	0706	Vary
58519	YOUNG'S CYROMAZINE SPRAY-ON SHEEP BLOWFLY TREATMENT	NOVARTIS ANIMAL HEALTH AUSTRALASIA PTY. LIMITED	0509	Vary
			0204	Cancel
58810	YOUNG'S CYROMAZINE LIQUID SHEEP BLOWFLY TREATMENT	NOVARTIS ANIMAL HEALTH AUSTRALASIA PTY. LIMITED	0509	Vary
			0604	Cancel
59955	WSD CY-GUARD SC SHEEP BLOWFLY TREATMENT	REBOP HOLDINGS PTY LTD T/A WESTERN STOCK DISTRIBUTORS	0509	Vary
			0806	Cancel
61379	VIRBAZINE SPRAY-ON SHEEP BLOWFLY TREATMENT	VIRBAC (AUSTRALIA) PTY LTD	0509	Vary
			0906	Cancel

PRODUCT NO	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBERS	REGULATORY ACTION PROPOSED IN RF
61444	KFM LIQUID SHEEP BLOWFLY TREATMENT	BAYER AUSTRALIA LTD (ANIMAL HEALTH)	56069	Vary
			0509	Cancel
			0107	Cancel
61516	LUCIFLY SPRAY-ON SHEEP BLOWFLY TREATMENT	NORBROOK LABORATORIES AUSTRALIA PTY LIMITED	0509	Vary
			1106	Cancel
61517	LUCIFLY LIQUID SHEEP BLOWFLY TREATMENT	NORBROOK LABORATORIES AUSTRALIA PTY LIMITED	0509	Vary
			1106	Cancel
61663	WSD CY-GUARD SPRAY ON SHEEP BLOWFLY PROTECTION	REBOP HOLDINGS PTY LTD T/A WESTERN STOCK DISTRIBUTORS	0509	Vary
			1107	Cancel
62845	KFM SPRAY ON SHEEP BLOWFLY PROTECTION	BAYER AUSTRALIA LTD (ANIMAL HEALTH)	56070	Vary
			1009	Cancel
			0208	Cancel
63040	COOPERS CLOUT BLOWFLY DESTROYER SPRAY-ON	INTERVET AUSTRALIA PTY LIMITED	1008	Vary
63041	COOPERS CLOUT BLOWFLY DESTROYER LIQUID	INTERVET AUSTRALIA PTY LIMITED	1008	Vary
64436	STRIKEBACK SC SHEEP BLOWFLY TREATMENT	BAYER AUSTRALIA LTD (ANIMAL HEALTH)	1009	Vary
64437	STRIKEBACK SPRAY ON SHEEP BLOWFLY PROTECTION	BAYER AUSTRALIA LTD (ANIMAL HEALTH)	1009	Vary
65089	INDEPENDENTS OWN URANUS SPRAY-ON SHEEP BLOWFLY TREATMENT	APPARENT PTY. LTD.	61807	Vary
			50128	Cancel
66034	VITAL CYROMAZINE SPRAY-ON SHEEP BLOWFLY TREATMENT	LANGHEY HOLDINGS PTY LTD	52560	Vary

PRODUCT NO	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBERS	REGULATORY ACTION PROPOSED IN RF
66441	CYRO-FLY 60 SPRAY-ON SHEEP BLOWFLY TREATMENT	JUROX PTY LIMITED	62171 53638	Vary Cancel
66589	INDEPENDENTS OWN URANUS SHEEP BLOWFLY TREATMENT	APPARENT PTY. LTD.	61918 53946	Vary Cancel
67540	PROGUARD SPRAY-ON SHEEP BLOWFLY TREATMENT	LANDMARK OPERATIONS LIMITED	56328	Vary
67576	PROGUARD LIQUID SHEEP BLOWFLY TREATMENT	LANDMARK OPERATIONS LIMITED	56378	Vary
69325	SWATTA LIQUID SHEEP BLOWFLY TREATMENT	LANDMARK OPERATIONS LIMITED	60506	Vary
69326	SWATTA SPRAY-ON SHEEP BLOWFLY TREATMENT	LANDMARK OPERATIONS LIMITED	60507	Vary
69738	CRYOFORTE SPRAY ON SHEEP BLOWFLY PROTECTION	ABBAY LABORATORIES PTY LTD	61537	Vary
69737	CRYOFORTE LIQUID SHEEP BLOWFLY TREATMENT	ABBAY LABORATORIES PTY LTD	61636	Vary
DIAZINON				
37640	KFM BLOWFLY DRESSING	BAYER AUSTRALIA LTD (ANIMAL HEALTH)	56068 0407 0805	Vary Cancel Cancel
39572	WSD DIAZINON FOR SHEEP, CATTLE, GOATS AND PIGS	REBOP HOLDINGS PTY LTD T/A WESTERN STOCK DISTRIBUTORS	0209	Vary
39573	WSD FLY STRIKE POWDER TO CONTROL FLYSTRIKE AND FOR WOUND DRESSING FOR ANIMALS	REBOP HOLDINGS PTY LTD T/A WESTERN STOCK DISTRIBUTORS	0209 1202	Vary Cancel

PRODUCT NO	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBERS	REGULATORY ACTION PROPOSED IN RF
39574	WSD MULESING POWDER WOUND DRESSING FOLLOWING MULES OPERATION GENERAL WOUND DRESSING FOR SHEEP, CATTLE AND GOATS	REBOP HOLDINGS PTY LTD T/A WESTERN STOCK DISTRIBUTORS	0309	Vary
			0401	Cancel
46231	COOPERS FLY STRIKE POWDER INSECTICIDE	INTERVET AUSTRALIA PTY LIMITED	0105	Vary
			03	Cancel
			02	Cancel
			01	Cancel
51290	EUREKA GOLD OP SPRAY-ON OFF-SHEARS SHEEP LICE TREATMENT	ZAGRO ANIMAL HEALTH PTE LTD	60541	Vary
			62114	Cancel
			49236	Cancel
			0709	Cancel
			0805	Cancel
62353	COOPERS DIAZINON SHEEP BLOWFLY DRESSING AND CATTLE, GOAT AND PIG SPRAY	INTERVET AUSTRALIA PTY LIMITED	1007	Vary
68253	NUCIDOL GOLD OP SPRAY-ON OFF-SHEARS SHEEP LICE TREATMENT	ZAGRO ANIMAL HEALTH PTE LTD	57843	Vary
DICYCLANIL AND DIFLUBENZURON				
58306	MAGIK SPRAY-ON SHEEP BLOWFLY AND LICE TREATMENT	NOVARTIS ANIMAL HEALTH AUSTRALASIA PTY. LIMITED	0106	Vary
			0505	Cancel
			0804	Cancel
62171	CLIK PLUS SPRAY-ON OFF-SHEARS BLOWFLY AND LICE TREATMENT	NOVARTIS ANIMAL HEALTH AUSTRALASIA PTY. LIMITED	56979	Vary
			55299	Cancel
			0608	Cancel
			0907	

PRODUCT NO	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBERS	REGULATORY ACTION PROPOSED IN RF
DICYCLANIL				
64628	CLIKZIN SPRAY-ON SHEEP BLOWFLY TREATMENT	NOVARTIS ANIMAL HEALTH AUSTRALASIA PTY. LIMITED	58520 48809	Vary Cancel
65651	DEFEND SPRAY-ON SHEEP BLOWFLY TREATMENT	LANDMARK OPERATIONS LIMITED	51498	Vary
65668	YOUNG'S DICYCLANIL 50 SPRAY-ON SHEEP BLOWFLY TREATMENT	NOVARTIS ANIMAL HEALTH AUSTRALASIA PTY. LIMITED	55298 51537	Vary Cancel
66096	DICYCLANIL 50 SPRAY-ON BLOWFLY TREATMENT	NOVARTIS ANIMAL HEALTH AUSTRALASIA PTY. LIMITED	52717	Vary
66896	STRIKEFORCE SPRAY-ON SHEEP BLOWFLY TREATMENT	JUROX PTY LIMITED	54651	Vary
67132	COOPERS STRIKEGUARD SPRAY-ON SHEEP BLOWFLY PROTECTION	INTERVET AUSTRALIA PTY LIMITED	55291	Vary
67594	FLI-GUARD SPRAY ON SHEEP BLOWFLY TREATMENT	ZOETIS AUSTRALIA PTY LTD	56423	Vary
DIFLUBENZURON				
53113	VIRBAC DUODIP TREATMENT FOR SHEEP BODY LICE	VIRBAC (AUSTRALIA) PTY LTD	0107 0600	Vary Cancel
53268	DIFLU OFF-SHEARS IGR POUR-ON FOR SHEEP	INTERVET AUSTRALIA PTY LIMITED	0800	Vary
54279	CRUSADER INSECT GROWTH REGULATOR FOR SHEEP DIPPING	INTERVET AUSTRALIA PTY LIMITED	0701	Vary
61351	COOPERS STAMPEDE POUR-ON LOUSICIDE FOR CATTLE AND SHEEP	INTERVET AUSTRALIA PTY LIMITED	0209 1106	Vary Cancel

PRODUCT NO	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBERS	REGULATORY ACTION PROPOSED IN RF
IVERMECTIN				
53127	COOPERS PARAMAX MULTI-PURPOSE CONCENTRATE FOR SHEEP	INTERVET AUSTRALIA PTY LIMITED	58657 0702 0501	Vary Cancel Cancel
61069	COOPERS BLOWFLY AND LICE JETTING FLUID	INTERVET AUSTRALIA PTY LIMITED	54308 0806	Vary Cancel
61696	ZINJET BLOWFLY AND LICE JETTING FLUID FOR SHEEP	LANDMARK OPERATIONS LIMITED	53814 0807	Vary Cancel
66378	INDEPENDENTS OWN JET AWAY BLOWFLY AND LICE JETTING FLUID FOR SHEEP	APPARENT PTY. LTD.	61192 53536	Vary Cancel
68513	JETGARD BLOWFLY AND LICE JETTING FLUID	THE HUNTER RIVER COMPANY PTY LIMITED	58507	Vary
69327	DUO JET BLOWFLY AND LICE JETTING FLUID FOR SHEEP	LANDMARK OPERATIONS LIMITED	60508	Vary
PROPETAMPHOS				
39554	MULES'N MARK II BLOWFLY DRESSING	BAYER AUSTRALIA LTD (ANIMAL HEALTH)	52451 01	Vary Cancel
40138	YOUNG'S DEADMAG BLOWFLY STRIKE DRESSING FLUID	ARYSTA LIFESCIENCE NORTH AMERICA CORPORATION	53477 0107 0302 0198	Vary Cancel Cancel Cancel
TEMEPHOS				
63311	WHAM SHEEP DIP	LANDMARK OPERATIONS LIMITED	1108	Vary
TRIFLUMURON				

PRODUCT NO	PRODUCT NAME	REGISTRANT	LABEL APPROVAL NUMBERS	REGULATORY ACTION PROPOSED IN RF
52466	EPIC POUR-ON LOUSICIDE FOR SHEEP	JUROY PTY LIMITED	0507	Vary
			0904	Cancel
			1202	Cancel
			0500	Cancel
55485	4FARMERS TRIFLUMURON 25 POUR ON LOUSICIDE FOR SHEEP	4 FARMERS PTY LTD	0105	Vary
			0702	Cancel
56254	WSD COMMAND POUR-ON LOUSICIDE FOR SHEEP	REBOP HOLDINGS PTY LTD T/A WESTERN STOCK DISTRIBUTORS	1207	Vary
			0906	Cancel
			0504	Cancel
			1002	Cancel
58326	TRIFFIK POUR-ON LICE DESTROYER	JUROY PTY LIMITED	0808	Vary
			0507	Cancel
			0306	Cancel
			0704	Cancel
62716	CANNON POUR-ON LOUSICIDE FOR SHEEP	LANDMARK OPERATIONS LIMITED	0909	Vary
SPINOSAD				
56734	ELANCO AH0498 EXTINOSAD AEROSOL FOR WOUNDS	ELANCO ANIMAL A DIV OF ELI LILLY AUST PTY LTD	0804	Vary
			0104	Cancel
56875	ELANCO AH0492 EXTINOSAD LICE, FLY AND MAGGOT ELIMINATOR	ELANCO ANIMAL A DIV OF ELI LILLY AUST PTY LTD	49891	Vary
			0403	Cancel
60117	ELANCO AH0493 EXTINOSAD POUR-ON FOR SHEEP	ELANCO ANIMAL A DIV OF ELI LILLY AUST PTY LTD	58603	Vary
			0210	Cancel
			0708	Cancel
SPINOSAD AND CYROMAZINE				
63384	ELANCO CYREX LIQUID SHEEP BLOWFLY AND LICE TREATMENT	ELANCO ANIMAL HEALTH A DIV OF ELI LILLY AUST PTY LTD	45474	Vary

GLOSSARY

EC50	The concentration of a test substance which results in 50% of the test animals being adversely affected i.e. both mortality and sub-lethal effects
LC50	The concentration of a test substance which results in a 50% mortality of the test species.
LOEL	Lowest observed effect level i.e. the test concentration at which some adverse effect occurs
Long wool	Six or more weeks wool growth
NOEL	No observed effect level i.e. the test concentration at which no adverse effect is observed
Short wool	Less than six weeks wool growth
Sirolan CF	In-line, treatment process, which treats all the strongflow effluent stream from a wool scouring plant
strong-flow down	<p>The waste streams can broadly be defined under three categories:</p> <ul style="list-style-type: none">• Strong flow down which is comprised of flows from the heavy solids loops and wool wax recovery plant. It contains high concentrations of water soluble (suint), solvent soluble (wool wax) and dirt in a stable emulsion.• The rinse water contains primarily low levels of dirt but comprises about two thirds of the liquid waste volume (6 to 7 l/kg greasy wool).• Dry wastes, including the material removed from the wool by the various opening operations and fibre removed by strainers in the contaminant recovery loop such as dirt, short fibres, dag material and some vegetable matter

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