Australian Pesticides &
Veterinary Medicines Authority

The reconsideration of approvals of selected sheep ectoparasiticide products and their associated labels

Preliminary Review Findings

Volume 1 of 2

APRIL 2006

Canberra
Australia

This Preliminary Review Findings report for '*The reconsideration of approvals of selected sheep ectoparasiticide products and their associated labels*' is published by the Australian Pesticides & Veterinary Medicines Authority. For further information about this review contact:

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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
- 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, the Department of the Environment and Heritage, 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 preliminary review findings relating to selected sheep ectoparasiticide products that have been nominated for review by the APVMA. The preliminary review findings and proposed 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: http://www.apvma.gov.au/chemrev/chemrev.html.

COMMENT FROM THE PUBLIC IS INVITED

This Preliminary Review Findings (PRF) report:

- outlines the APVMA review process
- informs interested parties how to respond to the review
- summarises the technical assessments from the reviewing agencies
- outlines the proposed regulatory action to be taken in relation to the continued registration of selected sheep ectoparasiticide products.

The APVMA invites persons and organisations to submit their comments and suggestions on this PRF report directly to the APVMA. These comments will assist the APVMA in preparing the Review Findings report, which is the second report in the three-stage review reporting process. The final report is the Final Review Report and Regulatory Decision.

PREPARING YOUR COMMENTS FOR SUBMISSION

You may agree or disagree with or comment on as many elements of the PRF report as you wish.

When making your comments:

- clearly identify the issue and clearly state your point of view
- give reasons for your comments, supporting them if possible with relevant information and indicate the source of the information you have used
- suggest to the APVMA any alternative solution you may have for the issue.

Please try to structure your comments in point form referring each point to the relevant section in the PRF report. This will help the APVMA to assemble and analyse all of the comments it receives.

Finally, please tell us whether the APVMA can quote your comments in part or in full.

THE CLOSING DATE FOR SUBMISSIONS IS TUESDAY 31 OCTOBER 2006

Your comments should be mailed to:

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GLOSSARY

AA	Annual average
ADI	Acceptable daily intake
AF	Assessment factor
AJR	Automatic jetting race
APVMA	Australian Pesticides & Veterinary Medicines Authority
AR	Applied radioactivity
ARfD	Acute reference dose
Avcare	National Association for Crop Production and Animal Health. From 1 January 2006, Avcare Limited has been known as CropLife Australia Limited. CropLife Australia represents the plant science industry and is responsible for the crop protection and crop biotechnology aspects of Avcare. The animal health aspects will be managed by Animal Health Alliance (Australia) Ltd.
AWI	Australian Wool Innovation Limited
ChE	Cholinesterase
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DEH	Department of the Environment and Heritage
DT50	Time for 50% of the substance to dissipate
EbC50	The concentration of a test substance which results in a 50% inhibition of biomass in an algal test
EC	Emulsifiable concentrate
EC50	The concentration of a test substance which results in 50% of the test animals being adversely affected ie both mortality and sub-lethal effects
EEC	Estimated environmental concentration
EQS	Environmental quality standard
EU	European Union
FAISD	First Aid Instructions and Safety Directions
GC	Gas chromatography
HPLC	High pressure liquid chromatography
IPPC	International Pollution Prevention Committee
K_{oc}	Sorption/desorption coefficient, normalised to organic carbon content
K_{ow}	n-Octanol/water partitioning coefficient
LC0	The concentration of a test substance at which no effect occurred
LC50	The concentration of a test substance which results in a 50% mortality of the test species.
LOEC	Lowest observed effect concentration ie the test concentration at which some adverse effect occurs
LOEL	Lowest observed effect level
Long wool	Six or more weeks wool growth
MAC	Maximum allowable concentration

MAFF	Ministry of Agriculture, Fisheries and Food (UK)
MATC	Maximum acceptable toxicant concentration
MOE	Margin of exposure
NOAEL	No observed adverse effect level
NOEC	No observed effect concentration ie the test concentration at which no adverse effect is observed
NOEL	No observed effect level
NOHSC	National Occupational Health and Safety Commission, now the Office of the Australian Safety and Compensation Council (OASCC)
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
OECD	Organization for Economic Cooperation and Development
OP	Organophosphate
PEC	Predicted environmental concentration
PNEC	Predicted no effect concentration
PPE	Personal protective equipment
PRF	Preliminary Review Findings
Q	Quotient (of EEC/PNEC)
RHI	Sheep rehandling interval
SC	Suspension concentrate (formulation)
Short wool	Less than six weeks wool growth
SP	Synthetic pyrethroid
TLm	Median level toxic concentration ie the test concentration at which 50% effect occurs
USEPA	United States Environmental Protection Agency
WHI	Wool harvesting interval, synonymous with wool withholding period
WHP	Withholding period
WRAS	Wool residue advice scheme
WWP	Wool withholding period, synonymous with wool harvesting interval

Time

d	Day
h	Hour
min	Minute
mo	Month
wk	Week
s	Second
yr	Year

Weight

bw	Body weight
g	Gram
kg	Kilogram
µg	Microgram
mg	Milligram
ng	Nanogram
wt	Weight
m^2	Square metres

Length

cm	Centimetre
m	Metre
µm	Micrometre
mm	Millimetre
nm	Nanometre

Dosing

id	Intradermal
im	Intramuscular
inh	Inhalation
ip	Intraperitoneal
iv	Intravenous
po	Oral
sc	Subcutaneous
mg/kg bw/d	mg/kg body weight/day

Volume

ML	Megalitre
L	Litre
mL	Millilitre
µL	Microlitre

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EXECUTIVE SUMMARY

Introduction

The review of selected sheep ectoparasiticide products 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
- the potential of chemical residues on treated wool to prejudice trade, particularly where overseas wool processing plants discharge scour effluent into river ecosystems.

The September 1999 gazette notice announcing the review of selected sheep ectoparasiticides is at http://www.apvma.gov.au/chemrev/ectoparasiticides.shtml.

As of December 2005 the review covered 13 active constituents in 65 registered products and five discontinued products that are being phased out (see Section 1.2 and Appendix A).

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 which are only approved for use on short wool (less than six weeks wool growth). The review covers all sheep ectoparasiticide products that either:

- contain one or more of the 13 active constituents

  and/or
- have a claim for treatment of ectoparasites, by any method, in long wool sheep (six or more weeks wool growth).

Occupational health and safety

The application of certain sheep ectoparasiticides, particularly organophosphates (OPs), within three to six months before shearing may leave residues on harvested wool that could pose an occupational risk to shearers and other wool handlers, through dermal absorption.

The sheep ectoparasiticide review considered the occupational exposure of shearers and other workers engaged in the handling of sheep following treatment and also the handling of harvested wool following treatment. The review did not consider occupational exposure during application of ectoparasiticides.

Different application methods (eg dipping, jetting) result in retention of different amounts of residue in the fleece. Individual margins of exposure (MOEs) were calculated for different application methods if the data were available. Where data indicated adequate MOEs from week one onwards, the data were extrapolated to determine MOEs for days zero to seven. The aim was to determine whether in such cases it would be safe for shearers to handle treated sheep one or two days after treatment.

The recommended sheep rehandling intervals are shown in Table 5 and recommended label statements for handling treated sheep are shown in Table 6. If sheep must be handled during the sheep rehandling interval, personal protective equipment (PPE) designed to minimise the transfer of wool grease to bare skin, especially legs and arms, should be worn. Cotton overalls buttoned to the neck and wrist (or equivalent clothing) would be appropriate PPE for all sheep ectoparasiticides considered in this review.

Environment and trade

The environmental component of the review focused on the discharge of liquid wool scour effluent directly or indirectly through sewage treatment facilities to land, ocean and riverine discharge points.

Sheep ectoparasiticide residues on wool may be an environmental hazard 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 course of wool processing, is to firstly establish environmental impact thresholds, then to determine whether sheep ectoparasiticide products affected by the review meet these criteria when used in accordance with label instructions.

The worst-case scenario for Australian wool scour effluent discharge is the ocean sewage outlet of Barwon Water's (water authority based in Geelong, Victoria) sewage treatment plant at Black Rock because this has the highest predicted environmental concentration (PEC) of ectoparasiticides associated with scour effluent from two wool scouring plants in the area. The endpoints used in the hazard calculations for the Australian environment are therefore ocean discharge endpoints. The review compares the predicted discharge concentration for treated effluent with the predicted no-effect concentration (PNEC).

Note that although the environmental endpoints at Black Rock focus on the acute toxicity of the ectoparasiticide to the most sensitive species as shown by laboratory testing, in the case of more persistent ectoparasiticides such as insect growth regulators, longer-term chronic toxicity data have also been considered.

The endpoints used in the hazard calculation for overseas environments are termed environmental quality standards (EQS). EQSs are roughly equivalent to no observable effect concentrations (NOEC). Although the majority of these values have not yet been published they are referred to in EU legislation as the set of requirements which must be fulfilled in order to achieve a high level of protection for the environment. The EU is due to finalise the implementation of additional pollution prevention legislation after October 2007. The relevant EU Directive is at http://eippcb.jrc.es/pages/Directive.htm.

The EQSs are likely to be relatively more conservative than the Australian wool scour effluent discharge criteria used in the hazard calculations for the Australian environment because scouring plants in Europe generally discharge into river systems, rather than oceans as is the case in Australia. These river systems have a much more limited dilution capacity; therefore any chemicals in the scour discharge are likely to be a higher risk to the environment. The risks to the environments of overseas countries from too high a level of ectoparasiticide residues on Australia's exported greasy wool may adversely affect Australia's trade in this commodity.

Table 11 summarises the draft regulatory findings based on the environmental assessment. The second column (headed 'Australian environment') lists the conclusion of the Department of the Environment and Heritage (DEH) on whether under Australian scouring conditions and on the assumption that the label includes the current WHI, the 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. The APVMA proposes to add a WHI statement to the labels of all products that fall within the scope of this review, noting that a number of product labels already have a wool withholding period statement on the label.

The third column (headed 'Overseas environment/trade') lists the outcome of a comparative analysis undertaken by the DEH of likely scour residues, together with information on relevant EU environmental standards and the likely impact of those standards on future exports of Australian raw wool.

The assessment undertaken by the DEH in relation to processing of wool overseas concludes that chemical residues that result from the use of a number of sheep ectoparasiticide products in accordance with current approved label instructions could result in a breach of overseas environmental standards. This information, taken together with the fact that raw wool is a significant trade commodity that may be adversely affected by any breach of overseas environmental standards has enabled the APVMA to complete a trade risk assessment for this review.

It should be noted that the proposed findings in Table 11 are based on observed chemical residue levels on wool from sheep ectoparasiticide products[1] over several years until 2004.

Public submissions

The APVMA received comments both before and after announcement of the review of selected sheep ectoparasiticides in 1999. Comments were received from product registrants, an active approval holder, the Woolmark Company and state regulators. Concerns expressed related to the proposed registration requirements for sheep ectoparasiticides, the enforceability of proposed label amendments and the need for timely regulatory action.

The APVMA has liaised with a range of special interest groups throughout the course of this review, including the CSIRO, the National Farmers Federation, Australian Wool Innovation Limited (AWI), the Australian Veterinary Association, the Livestock Contractors Association, WoolProducers, Avcare[2], the Australian Wool Industries Secretariat, overseas registrants and regulators, directly and indirectly-affected product registrants, active constituent approval holders, state regulators and extension officers, and other interested individuals.

[1] Based on national wool clip residue figures collected by Australian Wool Innovation Limited and its predecessors since 1992.

[2] From 1 January 2006, Avcare Limited, the National Association for Crop Production and Animal Health, has been known as CropLife Australia Limited. CropLife Australia represents the plant science industry and is responsible for the crop protection and crop biotechnology aspects of Avcare. The animal health aspects will be managed by Animal Health Alliance (Australia) Ltd.

Proposed review findings

The APVMA proposes to rename wool withholding period (WWP) label statements to wool harvesting interval (WHI) label statements. 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.

OHS

Sufficient data are available to complete the OHS risk assessment for all except two of the active constituents (deltamethrin and chlorfenvinphos) contained in the products that are subject to this review.

The APVMA proposes to find that a sheep rehandling interval statement should be added to the labels of all sheep ectoparasiticide products in order for the APVMA to be satisfied that the use of these 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 sheep rehandling interval will indicate when people can safely handle treated animals after the sheep have been treated with the ectoparasiticide products, which are subject to review.

These sheep rehandling interval statements range from:

> SHEEP REHANDLING INTERVAL: Do not rehandle sheep until dry after treatment

to

> SHEEP REHANDLING INTERVAL 12 WEEKS. If sheep must be handled during this interval, cotton overalls buttoned to the neck (or equivalent clothing) should be worn.

Additional information on each active constituent is given in Table 12.

Insufficient data are available at this stage to complete the OHS risk assessment for deltamethrin and chlorfenvinphos. Prior to completing this component of the review, the APVMA proposes to determine whether adequate wool residue data or other information exist to enable a sheep rehandling interval to be set for these two active constituents. If adequate data are not available it is proposed that the labels for the single registered chlorfenvinphos product be varied to remove all claims for use on sheep, and the two products containing deltamethrin for use on sheep be cancelled on the basis that the APVMA is unable to conclude that the use on sheep of products containing deltamethrin would not be harmful to human health.

Environment

The DEH assessment of the risks associated with the use of sheep ectoparasiticides on wool provides the basis for the APVMA's proposed findings on Australia's environmental risk and Australia's trade risk associated with chemical residues on wool.

With respect to the Australian environment the APVMA proposes to find that most sheep ectoparasiticides would not be likely to have an unintended effect that is harmful to the environment under current use patterns, provided that the label specifies an appropriate WHI. Label WHIs that the APVMA proposes to apply as an outcome of this review are given in Table 12.

The use of products containing **alpha-cypermethrin** on long wool (six or more weeks off shears) has been identified as a source of potentially environmentally harmful residue levels on harvested wool. Therefore the APVMA proposes to find that the continued use of products containing alpha-cypermethrin on long wool cannot be supported because the APVMA is unable to conclude that such use would not be likely to have an unintended effect that is harmful to the Australian environment. It is further proposed that the existing WHI of two months for such products be deleted and a new label restraint statement and amended WHI statement be added that specify that products must not be used on long wool:

> *Do not use this product on sheep that will be shorn with less than 12 months wool growth. Do not use this product on sheep with more than six weeks wool growth at the time of treatment because use of this product in accordance with label instructions will leave residues of alpha- cypermethrin on wool that may be harmful to the environment*

This adjustment in WHI will enable the APVMA to conclude that the use of products containing alpha-cypermethrin in accordance with label instructions would not be likely to have an unintended effect that is harmful to the Australian environment.

With respect to products containing **cypermethrin**, although label instructions for these products currently state that they are approved for use on short wool only, the existing instructions do not make it clear that use on long wool may result in potential environmental harm. Therefore, in order for the APVMA to conclude that the use of products containing cypermethrin would not be likely to have an unintended effect that is harmful to the Australian environment it is proposed that the existing WHI of two months be deleted and a new label restraint statement and amended WHI statement be added that specify these products must not be used on long wool (six or more weeks off shears):

> *Do not use this product on sheep that will be shorn with less than 12 months wool growth. Do not use this product on sheep with more than six weeks wool growth at the time of treatment because use of this product in accordance with label instructions will leave residues of cypermethrin on wool that may be harmful to the environment*

This adjustment in WHI will enable the APVMA to conclude that the use of products containing cypermethrin in accordance with label instructions would not be likely to have an unintended effect that is harmful to the Australian environment.

With respect to products containing **triflumuron**, although label instructions for these products currently state that they are approved only for use up to seven days off shears, this instruction does not make it clear that use on long wool may result in potentially environmentally harmful residue levels on harvested wool. Therefore, in order for the APVMA to conclude that the use of products containing triflumuron would not be likely to have an unintended effect that is harmful to the Australian environment it is proposed that the existing WHI of two months be deleted and a new label restraint statement and amended WHI statement be added that specify that the product must not be used on sheep that are more than seven days off shears:

> *Do not use this product on sheep that will be shorn with less than 12 months wool growth. Do not use this product on sheep with more than seven days wool growth at the time of treatment because use of this product in accordance with label instructions will leave residues of triflumuron on wool that may be harmful to the environment*

This adjustment in WHI will enable the APVMA to conclude that the use of products containing triflumuron in accordance with label instructions would not be likely to have an unintended effect that is harmful to the Australian environment.

With respect to products containing **diazinon**, **diflubenzuron** or **temephos** the DEH has recommended that the APVMA not be satisfied that under Australian scouring conditions and on the assumption that the label includes the current WHI, the continued use of products containing these actives in accordance with existing approved label instructions would not be likely to have an unintended effect that is harmful to the Australian environment. On the basis of the DEH recommendation and in the absence of additional information the APVMA proposes to find that an increase in the WHI will be required for products containing these active constituents to enable the APVMA to conclude that the use of products would not be likely to have an unintended effect that is harmful to the Australian environment.

The APVMA proposes to find that the continued use of products containing **diflubenzuron** on long wool cannot be supported. Therefore the APVMA proposes that label instructions for the continued use of diflubenzuron on wool more than seven days off shears be deleted, the existing WHI of six months be deleted and a new label restraint statement and amended WHI statement be added that specifies that these products must not be used on sheep more than seven days off shears:

> *Do not use this product on sheep that will be shorn with less than 12 months wool growth. Do not use this product on sheep with more than seven days wool growth at the time of treatment because use of this product in accordance with label instructions will leave residues of diflubenzuron on wool that may be harmful to the environment*

The use of products containing **temephos** has been identified as a source of potential environmentally harmful residue levels on harvested wool, notwithstanding the existing three month WHI. This finding is particularly susceptible to market share variation. However, given that products containing temephos for use on sheep are not currently supplied to the market the APVMA proposes to find that the WHI should increase from three months to six months as a precaution. This adjustment in WHI will enable the APVMA to conclude that the use of products containing the active constituent temephos in accordance with label instructions would not be likely to have an unintended effect that is harmful to the Australian environment.

The use of products containing **diazinon** has been identified as a source of potential environmentally harmful residue levels on harvested wool, notwithstanding the existing two month WHI. Should the APVMA find that some uses of sheep ectoparasiticide products containing diazinon may continue to be supportable following finalisation of the diazinon review, the APVMA proposes to find that labels for such products should be amended to increase the WHI from two months to four months in order to be satisfied that the use of sheep ectoparasiticide products containing diazinon would not be likely to have an unintended effect that is harmful to the Australian environment.

Note that an assessment of the impact of residues of **chlorfenvinphos** on the environment and on trade has not been undertaken to date as part of this review because available information is limited. In addition, the separate review of chlorfenvinphos reached the interim outcome stage in 2000. Although regulatory actions were detailed in the interim review report for chlorfenvinphos, a product registrant provided additional data. Thus far the final outcomes for this review have not been proposed by the APVMA. Prior to completing this component of the review the APVMA proposes to determine whether adequate wool residue data or other information exist to enable a sheep rehandling interval to be set for chlorfenvinphos and then to determine if an environment and trade assessment is warranted, before finalising both the review of selected sheep ectoparasiticides and the review of chlorfenvinphos.

Trade

The assessment undertaken by the DEH in relation to processing of wool overseas concludes that chemical residues that result from the use of a number of sheep ectoparasiticide products in accordance with current approved label instructions could result in a breach of overseas environmental standards. This information, taken together with the fact that raw wool is a significant trade commodity that may be adversely affected by any breach of overseas environmental standards, has enabled the APVMA to complete a trade risk assessment for this review.

With respect to the products which are the subject of this review, when used in accordance with current approved label instructions and under current use patterns, the APVMA proposes to find that it is not satisfied that chemical residues resulting from these uses would not unduly prejudice trade or commerce between Australia and places outside Australia.

A number of overseas environmental standards, including the EQSs that will apply in the EU after October 2007, have not yet been published. Given this limitation, the APVMA proposes to find that trade grounds currently provide insufficient justification for direct restrictions on long-wool chemical use for existing approved sheep ectoparasiticide products. This proposed finding is also based on the observation that only predicted

overseas requirements rather than published standards are currently available in many cases and there has been no action taken to date to enforce other published EQSs.

Further, it is unlikely to be possible to set specific trade-related WHIs for sheep ectoparasiticides to ensure that residues on exported wool meet importing country requirements before October 2007 because the EQSs may not be fully implemented prior to October 2007. Until overseas requirements are published, and pending overseas regulatory action, the APVMA proposes to use advisory information on labels to warn stakeholders that overseas regulatory requirements are likely to impact on sheep ectoparasiticide product approvals after October 2007.

The APVMA proposes to require 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 (EQSs) due to be implemented in 2007.*

Summary of proposed findings

The APVMA proposes to find that it is not satisfied that the continued use of, or any other dealing with the products listing in Appendix A 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, 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, particularly where overseas processor plants discharge scour effluent into river ecosystems.

However, the APVMA proposes to find that, with the exception of products containing deltamethrin, the labels for such products can be varied to include adequate statements to enable the APVMA to be satisfied in relation to occupational health and safety, the environment and trade. Therefore, the APVMA proposes that the label approvals for these products be varied to include additional label statements, as specified in Table 12.

In addition, provided that labels are varied as outlined above, with the exception of products containing deltamethrin the APVMA proposes to affirm the product registrations for products listed in Appendix A.

As a consequence of the proposed findings of this review, the APVMA proposes to find that it is not satisfied that the continued use of or any other dealing with the products marked in Appendix A as not directly affected by the review:

- 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, particularly where overseas processor plants discharge scour effluent into river ecosystems.

However, the APVMA proposes to find that, with the exception of products containing deltamethrin the labels for such products can be varied to include adequate statements to enable the APVMA to be satisfied in relation to occupational health and safety, the environment and trade. Therefore, the APVMA proposes that, consistent with the outcomes of the review, the label approvals for these products be varied to include additional label statements, as specified in Table 12.

In addition, provided that labels are varied as outlined above, with the exception of products containing deltamethrin the APVMA proposes to affirm the product registrations for products listed in Appendix A.

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1. INTRODUCTION

Wool production is part of Australia's cultural heritage. Wool is an economically significant primary product although its economic importance has been in decline over recent years.

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), interrupt moulting and maturation of juvenile stages.

The use of sheep ectoparasiticides can result in significant chemical residues on treated wool. When sheep are handled during wool harvesting and when wool is processed, these residues could 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. Therefore, these products and new products imaged off these products may not have been subjected to a comprehensive consideration of all the risks associated with treated wool.

This review is concerned with three areas of potential risk:

Occupational Health and Safety (OHS)

Concern has been raised that 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.

This review assesses the post-application hazards associated with the use of sheep ectoparasiticides.

Environment

In Australia, discharge of untreated scouring effluent to surface waters (ponds, rivers and other waterways) is specifically prevented under state legislation and all effluent receives 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 wastes to sewer systems for ocean outfall have the potential to be an environmental hazard. Models have been used as part of this review to estimate the maximum mean residue across the Australian wool clip that would generate a non-toxic effluent at the ocean outfall.

Trade

Australia produces thirty per cent of the world's wool but very little of this is fully processed (scoured, dyed, woven and made up into garments) in Australia.

Of the raw wool sold in Australia, about 40% is fully processed overseas and the remainder undergoes first-stage scouring in Australia, followed by manufacturing steps that are generally done overseas. Scour plants that discharge wastes to rivers have the potential to cause the greatest environmental hazard, because rivers generally have limited dilution capacity by comparison with inland or ocean discharge scour effluent systems. River scour plants could produce potentially environmentally hazardous by-products if chemical residues are present on wool at significant levels.

Discharge of scour effluent from wool processors to river systems does not occur in Australia but it does occur overseas. Prior to the introduction of the NRS, there was no legislative requirement to determine whether use of any registered products would be likely to cause an adverse impact on trade. One of Australia's key markets, the European Union, is due to finalise the implementation of additional pollution prevention legislation after October 2007. The relevant EU directive is at http://eippcb.jrc.es/pages/Directive.htm. If the current patterns of use of sheep ectoparasiticides in Australia remain unchanged, after October 2007 the potential will exist for treated wool to breach EU environmental standards. This review assesses the trade risks associated with the export of raw wool produced in Australia for processing overseas, particularly processing at scour plants that discharge scour effluent to rivers.

Wool production systems in Australia take time to adjust to changes in market demand. It is anticipated that any amendments to approved labels resulting from this review could take at least 18 months to begin to trigger changes in the level of chemical residues on wool because of the gap between the point of application of the product and the processing of harvested wool. Changes to the use of sheep ectoparasiticides therefore must be developed and implemented ahead of full implementation of the EU standards.

For this review, the APVMA has sought advice from:

- the Toxicology Section of the Office of Chemical Safety (OCS) within the Department of Health and Ageing
- the Occupational Health and Safety Section of OCS
- the Department of the Environment and Heritage (DEH)
- state departments of agriculture.

The APVMA has also received advice from peak industry bodies, including Australian Wool Innovation Limited (AWI), and from the CSIRO.

Assessments undertaken in collaboration with advisory agencies included consideration of data from registrants and special interest groups, public submissions, scientific literature and archival holdings.

1.2 Regulatory status of selected sheep ectoparasiticides affected by the review

As of December 2005, there were 65 registered and five recently-discontinued products affected by the review (see Appendix A). This list includes products that were registered before and after the start of the review.

The review initially involved 14 active constituents and 54 registered products. Products containing cyhalothrin or lamda-cyhalothrin were registered for use on sheep at the commencement of this review, however these registrations have been discontinued and no further registrations have been granted that are relevant to this review. Therefore, changes to product registrations have reduced the original list of directly-affected active constituents to 12:

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

In addition, products for use on sheep containing the active constituent **spinosad** have been registered on the basis that they are also subject to the outcomes of this review. Appropriate regulatory outcomes for products containing spinosad will be determined once this review is finalised.

Throughout this report, references to products containing a mixture of diazinon and amitraz, or containing cyhalothrin/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.

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

1.3 Reasons for the review

The review of selected sheep ectoparasiticide products and their labels addresses the following concerns:

- the occupational health of workers, particularly shearers, contacting 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
- the potential of chemical residues on treated wool to prejudice trade, particularly where overseas wool processing plants discharge scour effluent into river ecosystems.

1.4 Scope of the review

This review was initiated under section 34 of the Agvet Codes, on the basis that chemical residues on treated wool[3]:

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

This review is limited to a subset of all products approved for use as sheep ectoparasiticides (see section 1.2). The products under review were selected on the basis that they are most likely to be a concern because of one or more of the section 34 criteria.

Thus 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 review covers all sheep ectoparasiticide products that either:

- contain one or more of the selected active constituents

  and/or

- have a label claim for treatment of ectoparasites, by any method, in long-wool sheep (six or more weeks wool growth).

As of December 2005, 13 active constituents are affected by this review (12 active constituents from the original scope of the review, plus spinosad). These active constituents are present in 65 registered products currently approved for use on sheep and either subject to the review or subject to the outcomes of the review, plus a further five discontinued products that are being phased out (see Appendix A).

[3] After application of the product has finished and the wool has dried.

Some affected products are also registered for use on cattle, goats, pigs, dogs 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, so that use on cattle, goats, pigs, dogs and deer do not fall within the scope of the review.

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.

1.5 Application of the review to specialty wool lines

Specialty wool lines such as lambswool, fellmongered[4] 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.

1.6 Possible regulatory options

There can be three possible outcomes to the review. Based on the information reviewed the APVMA may be:

1. Satisfied that the products and their labels continue to meet the prescribed requirements for product registration and label approval and therefore affirm the product registrations and label approvals
2. Satisfied that the conditions to which the product registration or label approval are currently subject can be varied in such a way that the requirements for continued product registration and label approval will be complied with and therefore varies the conditions of registration or approval;
3. Not satisfied that the requirements for continued product registration and label approval continue to be met and suspends or cancels the product registration and/or label approval.

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

2. DATA ASSESSMENTS

2.1 Occupational health and safety (OHS) assessment

In 2001 the-then National Occupational Health and Safety Commission (NOHSC) undertook a draft OHS assessment as part of the sheep ectoparasiticide review[5]. The function of the NOHSC was formally transferred to the Office of Chemical Safety (OCS) within the Department of Health and Ageing in April 2004. At that time the APVMA asked the OCS to reconsider the selection of no-observed effect levels (NOELs) and dermal absorption factors that were used in the draft risk assessment for the review. In particular the OCS and the APVMA noted that some of the NOELs, which had been used to assess life-long exposure to ectoparasiticide residues on wool, were different from the NOELs used to establish an acceptable daily intake (ADI) level for life-long exposure to pesticide residues in food. In some cases this difference resulted in a more conservative OHS risk assessment than the dietary intake risk assessment.

Therefore, the OCS undertook a further OHS assessment. The OHS technical assessment from the OCS is as follows.

2.1.1 Introduction

The APVMA is reviewing OHS concerns related to the potential for percutaneous absorption of ectoparasiticide residues to occur 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 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.

A reconsideration of the NOELs and dermal absorption factors used in the 2001 draft risk assessment has resulted in amendments to the recommended sheep rehandling intervals contained in the 2001 risk assessment. However, there were no suitable wool residue data for deltamethrin or chlorfenvinphos to permit a sheep rehandling interval to be calculated.

[5] The draft report was circulated to data providers only.

2.1.2 Use patterns

The formulations and use patterns considered in this review are those shown on product labels and summarised in Table 1. This review considered occupational 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. These issues have been dealt with in other Chemical Review Program reviews or in assessments completed in the course of product registration.

Table 1 Use patterns of selected sheep ectoparasiticides

Active constituent	Application rate/dilution	Frequency of application	Use	Current withholding periods
Products containing OPs				
Diazinon 200 g/L EC	0.1 g/L (reinforced with 0.1 g/L for each 500 L fall in dip volume)	Single treatment usually no later than 6 weeks after shearing	For control of sheep body lice by plunge or shower dipping	Meat 14 days[6] Wool 2 months
	0.2 g/L (reinforced with 0.2 g/L for each 500 L fall in dip sump volume)	Multiple, according to seasonal conditions and severity of parasite pressure	For control of blowfly strike by dipping	
	0.4 g/L	Multiple, according to seasonal conditions and severity of parasite pressure	For control of blowfly strike by jetting or constant replenishment shower dipping	
Diazinon 200 g/L EC combined with Amitraz 125 g/L	0.1 g/L diazinon + 0.125 g/L amitraz reinforced with 0.32 g/L diazinon + 0.4 g/L amitraz for each 500L fall in dip sump volume	Single treatment usually no later than 6 weeks after shearing	For control of sheep body lice, itch mite and blowfly strike by plunge or shower dipping	Meat 21 days
	0.2 g/L diazinon + 0.2 g/L amitraz	Single treatment usually no later than 6 weeks after shearing	For control of lice, itch mite and blowfly strike by constant replenishment shower dipping	
Diazinon 96 g/L combined with cypermethrin 144 g/L in hydrocarbon solvent	Maximum dose 1 g diazinon + 1.5 g cypermethrin applied not later than 3 months before shearing	Multiple, according to seasonal conditions and severity of parasite pressure	For control of sheep body lice and blowfly strike by backline application	Meat 14 days

[6] The meat WHP is for residues in food.

Active constituent	Application rate/dilution	Frequency of application	Use	Current withholding periods
Diazinon 60 g/L + rotenone 15 g/L + piperonyl butoxide 7.5 g/L	0.15 g/L diazinon + 0.038 g/L rotenone + 0.02 g/L piperonyl butoxide	Annual dipping to reduce itch mite	For control of sheep body lice, itch mite and blowfly strike by plunge or shower dipping	Meat 14 days
Chlorfenvinphos 1000 g/L EC	0.5 g/L applied not later than 3 months before shearing	Multiple, according to seasonal conditions and severity of parasite pressure	For control of blowfly strike by jetting	Meat 3 days
Chlorfenvinphos 138g/L combined with cypermethrin 25 g/L	0.55 g/L chlorfenvinphos + 0.10 g/L cypermethrin (dip sump is topped up at a concentration of 0.75 g/L chlorfenvinphos + 0.14 g/L cypermethrin)	Body lice: Usually no more than 2 treatments per year Ticks: Multiple, according to seasonal conditions and severity of parasite pressure	For control of sheep body lice and ticks by plunge or shower dipping and non-recirculating spray races	
Propetamphos 360 g/L EC	0.18 g/L (reinforced with 0.27 g/L for each 1,000 L fall in sump volume)	Single treatment usually no later than 6 weeks after shearing	For control of sheep body lice by plunge or shower dipping	Meat 14 days Wool 2 months
	0.29 g/L (reinforced with 0.45 g/L for each 1,000 L fall in sump volume)	Multiple, according to seasonal conditions and severity of parasite pressure	For control of blowfly strike by dipping	
	0.36 g/L	Multiple, according to seasonal conditions and severity of parasite pressure	For control of blowfly strike by jetting	
Temephos 350 g/L EC	0.35 g/L (reinforced with .08 g/L for each 100 L fall in dip sump volume)	Single treatment usually no later than 6 weeks after shearing	For control of sheep body lice by plunge or shower dipping	Meat 14 days
	0.35 g/L	Single treatment usually no later than 6 weeks after shearing	For control of sheep body lice by constant replenishment shower dipping	

Active constituent	Application rate/dilution	Frequency of application	Use	Current withholding periods
Products containing macrocyclic lactones				
Ivermectin 75 g/L liquid	0.03 g/L, maximum dose 135 mg applied not later than 3 months before shearing	Multiple, according to seasonal conditions and severity of parasite pressure	For control of sheep body lice by hand jetting and blowfly strike by hand jetting or automatic jetting race	Meat 7 days Wool 12 weeks
Products containing synthetic pyrethroids				
Alpha-cypermethrin 20 g/L	Maximum dose 0.3 g	Single treatment no later than 1 day after shearing	For control of sheep body lice by backline application	Meat nil Wool nil
Alpha-cypermethrin 50 g/L	Maximum dose 1 g	Usually no more than 2 treatments per year	For control of sheep body lice and blowfly strike by backline application	Meat nil Wool 8 weeks
Cypermethrin 25 g/L	Maximum dose 0.4 g	Single treatment no later than 24 hours after shearing	Pour-on for control of sheep body lice	Meat 3 days
Cypermethrin 25 g/L + piperonyl butoxide 100 g/L	Maximum dose 0.4 g cypermethrin; 1.6 g piperonyl butoxicide	Single treatment no later than 24 hours after shearing	Pour-on for control of sheep body lice	Meat nil

Active constituent	Application rate/dilution	Frequency of application	Use	Current withholding periods
Cyhalothrin 50 g/L	0.02 g/L (reinforced with 0.02 g/L for each 500 L fall in sump volume)	Single treatment usually no later than 6 weeks after shearing	For control of sheep body lice by plunge or shower dipping	Meat nil
	0.05 g/L	Usually no more than 2 treatments per year	For control of sheep body lice by hand jetting	
Cyhalothrin 16 g/L combined with rotenone 40 g/L	0.02 g/L cyhalothrin + 0.05 g/L rotenone (reinforced with 0.02 g/L cyhalothrin + 0.05 g/L rotenone for each 500 L fall in sump volume)	Single treatment usually no later than 6 weeks after shearing	For control of sheep body lice by plunge or shower dipping	Meat nil
	0.05 g/L cyhalothrin + 0.125 g/L rotenone	Usually no more than 2 treatments per year	For control of sheep body lice by hand jetting	

Active constituent	Application rate/dilution	Frequency of application	Use	Current withholding periods
Deltamethrin 10 g/L	2 mg/kg body weight. A sheep weighing 75 kg would receive 150 mg	Single treatment no later than 1 day after shearing	For control of sheep body lice by backline application	Meat 3 days
	10 g/L in hydrocarbon vehicle for backline application 2 mg/kg body weight. A sheep weighing 75 kg would receive 150 mg	Single treatment no later than 1 day after shearing	For control of sheep body lice by backline application	
Products containing insect growth regulators				
Cyromazine 500 g/L liquid	1 g/L, maximum dose 4 g	Usually no more than 2 treatments per year	For control of blowfly strike by plunge or shower dipping, hand jetting or automatic jetting race	Meat 7 days Wool 2 months
Cyromazine 60 g/L liquid	60 g/L, maximum dose 5 g	Usually no more than 2 treatments per year	For control of blowfly strike by spray-on application	
Dicyclanil 50 g/L liquid	Maximum dose 1.75 g for sheep weighing 50 kg or more	Usually no more than 2 treatments per year	For control of blowfly strike by spray-on application	Meat 28 days Wool 3 months
Dicyclanil 50 g/L + Diflubenzuron 15 g/L	Maximum dose 1.95 g dicyclanil + 0.6 g diflubenzuron for sheep weighing 75 kg	Usually no more than 2 treatments per year	For control of blowfly strike and lice by spray-on application	Meat 21 days Wool 6 months

Active constituent	Application rate/dilution	Frequency of application	Use	Current withholding periods
Diflubenzuron 250 g/L liquid	0.37 g/L applied not later than 6 months before shearing	Single treatment usually no later than 6 weeks after shearing	For control of sheep body lice by plunge or shower dipping	Meat nil Wool 6 months
	0.50 g/L applied not later than 6 months before shearing	Usually no more than 2 treatments per year	For control of blowfly strike by plunge dipping, shower dipping or jetting	
Diflubenzuron 25 g/L	10 mg/kg, maximum dose 1.27 g	Usually no more than 2 treatments per year	For control of sheep body lice and blowfly strike by spray-on back-line application	
Triflumuron 25 g/L	Maximum dose 0.87 g for sheep weighing 85–95 kg	Single treatment usually no later than 4 days after shearing	For control of sheep body lice by spray-on back-line application	Meat 14 days

2.1.3 Selection of NOELs

Although the annual shearing season lasts approximately three to six months, contract shearers may be frequently shearing sheep for nine to 11 months per year (this would include crutching and mulesing between shearing seasons). Moreover, shearers may shear sheep annually over most of their working life. Therefore any OHS risk assessment must consider the hazard which may arise following long-term (chronic) exposure. This is a similar approach to that taken for a dietary risk assessment. Since life-long dermal studies in laboratory animals are not usually done, the oral NOELs used to determine the ADI can be used as a surrogate for life-long dermal studies. However, in order to determine the systemic exposure of workers to ectoparasiticides a dermal absorption factor is needed for each active constituent (see Section 2.1.5). The chronic exposure NOELs for each active constituent are given in Table 2.

Table 2 NOELs used in the risk assessment of sheep ectoparasiticide active constituents

Active constituent	NOEL mg/kg bw/d	Route of administration	Species
Alpha-cypermethrin	4.7	Oral	Dog
Chlorfenvinphos	0.05		Rat
Cyhalothrin	1.5		Rat
Cypermethrin	5.0		Rat
Cyromazine	1.8		Dog
Deltamethrin	1.0		Dog
Diazinon	0.02		Human
Dicyclanil	0.7		Dog
Diflubenzuron	2.0		Rat, dog
Ivermectin	0.1		Mouse
Propetamphos	0.1		Rat
Temephos	1.0		Human
Triflumuron	0.7		Dog

Some products contain more than one active constituent. For example, some diazinon and cypermethrin products also contain piperonyl butoxide or rotenone and amitraz. In such cases, it is the most toxic active constituent (ie diazinon or cypermethrin) that drives the risk assessment for the sheep rehandling interval.

2.1.4 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 handlers 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 (ie day zero).

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 for α-cyanopyrethroid compounds is considered appropriate. This is analogous to the way in which advice is provided for skin sensitising compounds.

Diazinon poisoning

There has been an Australian court case relating to the exposure of shearers to the OP compound diazinon. In the case of *McKenzie and Ors v Harper* (1997, Supreme Court of New South Wales) the plaintiffs were members of a shearing team which sheared sheep that had been recently treated with a mixture containing diazinon, applied as a dressing for the control of blowfly strike. The court heard that the sheep had been treated immediately prior to being shorn, that some sheep which received treatment while on the board were wet with the chemical at the time they were being shorn and that on several occasions the shearers' clothing had become saturated with the mixture as they handled the sheep.

The symptoms reported by the plaintiffs were headaches, general aches and pains, sickness, diarrhoea, vomiting, skin rashes and watering eyes. They subsequently continued to experience some or all of the symptoms and as a result became unfit to continue working as shearers. The judgement in the case acknowledged that, when compared with label directions and the material safety data sheet for diazinon in this context, the use pattern described in evidence was clearly an incorrect application of the product. However, the judge's conclusions have a more general relevance in considering exposure of shearers and other workers involved in handling treated sheep and wool. The judge concluded that the evidence showed that a sufferer of acute symptoms from diazinon poisoning could develop chronic symptoms and that acute exposure could cause chronic symptoms without necessarily passing through a stage of acute symptoms. The judge accepted that the plaintiffs had shown clear and unequivocal signs of acute diazinon poisoning, and had suffered permanently as a result. The effects cited included impaired memory and learning, reduced attention span and a slowed rate of information processing.

Synthetic pyrethroids and paraesthesia

Synthetic pyrethroids are lipophilic insecticides whose biological activity seems to be directly related to their chemical structure. The pyrethroids are divided into two types (I and II) on the basis of differences in signs of neurotoxicity – the Tremor (T) and Choreoathetosis-Salivation (CS) syndromes. The signs of neurotoxicity correspond to particular aspects of the chemical structure of synthetic pyrethroids and originate from a primary action of the pyrethroid (ie sodium channel blocking within the neuronal cell membrane). The CS syndrome is produced by those pyrethroids which contain the α-cyano group (CN) within their chemical structure. All the selected pyrethroid ectoparasiticides considered in this review ie cypermethrin, alpha-cypermethrin, deltamethrin and cyhalothrin are of type II class.

Paraesthesia is a transient sensation of irritation, tingling or numbness in the skin. It occurs with some (mainly type II) pyrethroids and indicates some dermal absorption. It is brought about by transient lowering of the threshold for activation of the sensory nerve fibres or sensory nerve endings and normally does not last more than a few hours. Beyond this there are no abnormal neurological signs to be expected and no ongoing effects once this sensation has subsided. All registered products containing synthetic pyrethroids that are α-cyanopyrethroids should already carry a safety direction advising users of the potential for temporary numbness following skin contact.

2.1.5 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})[7] of less than 1 and greater than 4 and a molecular weight greater than 500, or other data indicate that it is poorly absorbed by the skin, a dermal absorption value of 10% or less was used. The dermal absorption value selected for each of the ectoparasiticides is discussed below:

Organophosphates (OPs)

Diazinon

Diazinon has been shown to be absorbed through the skin of animals and humans, causing a reduction in cholinesterase (ChE) activity. *In vivo* studies using radio-labelled diazinon were conducted in humans to measure the percutaneous absorption rate of diazinon (Wester et al., 1993)**.** Based on the systemic absorption of diazinon a dermal absorption value of 4% was adopted for the risk assessment.

Chlorfenvinphos

No animal studies directly measuring the skin absorption of chlorfenvinphos were available. Dogs, guinea pigs and humans dermally exposed to chlorfenvinphos demonstrated ChE depression, indicating that uptake of the chemical via the skin does occur. Chlorfenvinphos has an octanol/water partition coefficient of approximately 4 and a molecular weight greater than 500 and therefore a dermal absorption value of 10% was used for the risk assessment.

[7] 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.

Propetamphos

No dermal absorption studies are available for propetamphos. Propetamphos is hydrophobic, with a molecular weight of 281 and a log K_{ow} of 5.67. It is moderately toxic by the oral route but slightly to practically non-toxic via the dermal route. In rats, the oral LD_{50} is 75–119 mg/kg bw, while the dermal LD_{50} is 2300–>3100 mg/kg bw (Extoxnet PIP, 1996). Based on this information a dermal absorption value of 10% was used in the OHS risk assessment.

Temephos

The USEPA used a dermal absorption factor of 38% for temephos, based on an unpublished dermal absorption study in rats, rabbits and dogs. On the basis that the full EPA assessment of this study was not available and in the absence of any dermal absorption data submitted to the OCS, a dermal absorption value of 100% was used for the OHS risk assessment for temephos.

Synthetic pyrethroids (SPs)

Alpha-cypermethrin and cypermethrin

Cypermethrin is a highly active type II synthetic pyrethroid insecticide and a permethrin analogue. Chemically it is a racemic mixture of eight stereoisomers based on two asymmetric centres and the technical active constituent contains a cis:trans ratio of 50:50. The cis-isomer is at least 10 times more toxic than the trans-isomer. Alpha-cypermethrin is also a synthetic pyrethroid insecticide containing two of the eight stereoisomers that are present in technical cypermethrin.

Since 80% of an applied radio-labelled dose of alpha-cypermethrin was recovered from a dermal application site four days after dosing, a 20% dermal absorption value for both alpha-cypermethrin and cypermethrin is used for the risk assessment.

Deltamethrin

Deltamethrin is a synthetic dibromo-cyanopyrethroid (type II) insecticide, containing only the d-cis-isomer. The extent of deltamethrin absorption across the skin has not been determined directly. However, using the relative dermal and oral acute toxicity values as a rough guide for dermal absorption yields an estimate of around 10% (ie dermal LD_{50} of 700 mg/kg bw divided by the oral LD_{50} of 67 mg/kg bw). The vehicle[8] may substantially affect dermal absorption but in the absence of an appropriate dermal absorption study this is a 'best guess estimate'. The use of the lower oral LD_{50} value obtained with deltamethrin in peanut oil (ie LD_{50} = 30 mg/kg bw) would yield a lower estimate of dermal absorption. Based on this information a dermal absorption value of 10% was used in the OHS risk assessment.

Cyhalothrin

[8] The solvent or carrier that the chemical is distributed in when applied to the skin. The vehicle is one of several parameters that can potentially affect dermal absorption.

Cyhalothrin is a synthetic type II pyrethroid insecticide that is a mixture of equal amounts of the four Z-cis diastreoisomers. Direct information on dermal absorption is not available, however the median lethal doses by oral and dermal routes indicate that cyhalothrin probably has a high dermal absorption rate (IPCS Environmental Health criterion No.99). In the absence of suitable data a 100% dermal absorption value was assumed.

Insect Growth Regulators (IGRs)

Cyromazine

In vitro percutaneous absorption studies in humans and rats have been submitted (Van de Sandt, 1998). Since the OCS has previously evaluated a rat *in vivo* dermal absorption study, it is possible to estimate the likely human *in vivo* dermal absorption by determining the ratio of flux rates through rat and human epidermis and then using this ratio to derive the likely human *in vivo* absorption. When cyromazine was applied at 0.6, 6 and 60µg.cm^{-2} to rat epidermal membranes the flux rates were 0.0007, 0.0034 and 0.5144µg.cm^{-2}.h^{-1}, respectively. The corresponding flux rates in human epidermal membranes were 0.0001, 0.0012 and 0.0316µg.cm^{-2}.h^{-1} respectively. Hence the ratio of flux rates was 0.14, 0.35 and 0.06 at the low, mid and high dose, respectively.

The *in vivo* dermal absorption study in rats showed that when cyromazine was applied at 10, 100 and 1000µg.cm^{-2}, 14.4%, 9.81% and 8.5% of the applied dose respectively was absorbed. Considering the human/rat flux ratio and the *in vivo* rat dermal absorption rate at similar application concentrations, the estimated cyromazine absorption rate in humans was calculated to be 5% and 0.6% at 10 and 100µg.cm^{-2} respectively. Since the dermal exposure to cyromazine among shearers is anticipated to be low, the higher dermal absorption value (5%) was chosen for the OHS risk assessment.

Diflubenzuron

The IPCS Environmental Health criterion No. 184 (Diflubenzuron) quotes a study in which dermal absorption of ^{14}C-diflubenzuron was only 0.2% when applied to the shaved skin of rabbits as an aqueous micro-suspension of 150mg/kg. The OCS used this value for the OHS risk assessment on the basis that a full evaluation of this study was contained in the IPCS monograph.

Dicyclanil

A comparison of the LOEL from oral (30mg/kg bw/day) and dermal (300mg/kg bw/day) repeat dose studies (28 days) indicates low dermal absorption of dicyclanil (ie much less than 100%). Based on this information, the OCS used a 10% dermal absorption value for the OHS risk assessment.

Triflumuron

Lufenuron, a related compound, has poor dermal penetrating properties as indicated by a dermal NOEL of 1000mg/kg/day and an oral NOEL of 10mg/kg/day in repeat dose studies. Moreover a LOEL for effects following dermal application could not be established for lufenuron. Based on the dermal absorption value of lufenuron, the OCS used a dermal absorption value of 10% for the OHS risk assessment for triflumuron.

Macrocyclic Lactones

A dermal absorption study with avermectin B1a, an ivermectin-related compound, indicated that only 0.1 to 0.5% of the applied dose was absorbed, regardless of the dose and vehicle (MAFF, 1992). Based on this information, the OCS used a dermal absorption value of 1% for the OHS risk assessment.

2.1.6 Exposure following rehandling of treated sheep

Shearers and other workers handling treated sheep and fleeces are exposed to residual ectoparasiticides accumulated in wool grease on an almost daily basis during the peak shearing seasons of winter and spring. For many shearers occasional exposure also occurs throughout the year, because growers may elect to shear flocks at other times for management reasons.

Table 3 presents the concentration of ectoparasiticide residue in wool grease at different times after the treatment of sheep with ectoparasiticides for which data are available. All residue data are presented as mg/kg wool grease. Where product registrants provided data as 'mg/kg wool', they were converted to 'mg/kg of wool grease' on the assumption that all residue is present in the grease fraction of the wool, which constitutes 13% of total wool. The residue values shown are actual measurements made on the wool or in wool grease (Savage, 1998), measurements estimated by mathematical modelling (Campbell & Horton, 2000) or from the estimated amount of residue retained by the sheep fleece immediately after dipping (as in the case of diflubenzuron).

In the study by Avcare and reported by Savage (1998) which was undertaken at Menangle, NSW in November 1992, the data were derived from five sheep per group. An estimate of the amount of ectoparasiticide present at any one sampling interval was made as follows:

$$PR = FW\,[0.3BR + 0.7\,FR]/1{,}000$$

where PR = total amount of residue in greasy wool at the sampling point
FW = fleece weight at the sampling point
BR = backline ectoparasiticide residue
FR = flank ectoparasiticide residue.

The correction factor of 0.3 was used to weight the contribution of the residue found in the backline fleece on the assumption that the contribution of a 30cm wide band of wool taken from the backline of a $1m^2$ fleece would be 30% of the total fleece. The correction factor of 0.7 was applied to the flank ectoparasiticide residue as being representative of the remainder of the fleece.

In a study which investigated the degradation rates of selected OPs in sheep fleece in Wellington New Zealand, it was found that the half-life varied by about two-fold between winter and summer (Rammell & Bentley, 1989). In order to take into account seasonal and regional weather differences in Australia, a two-fold variability factor was included in the residue estimates.

When estimating ectoparasiticide residues on wool, it is normally assumed that sheep with six weeks wool at the time of dipping will retain up to 3 L of dipping solution and sheep dipped 12 weeks or more after shearing will retain up to 4 L of dipping solution after allowing for run-off. This would imply that the amount of the active constituent retained by sheep following dipping would be its concentration in the dipping solution (eg 350 mg/L) multiplied by the volume retained by sheep (350mg x 3L = 1050mg).

In some cases however, actual measurements in wool grease samples have revealed significantly higher amounts of active constituents on the wool immediately after dipping than would be expected from the above calculations (see Table 3). This suggests that a substantial amount of the active constituent partitions into wool grease during dipping operations. The method and duration of application (eg the time sheep spend in the dip) can have a bearing on the amount of ectoparasiticide applied to the sheep and the amount retained on the wool by the time sheep are shorn.

The data in Table 3 demonstrate that, for the same amount of chemical applied, the actual measured residue differs significantly from the modelled value. The authors of one study argued that the difference in values is due to the fact that the modelled values are a geometric mean of values expected from an average flock treated by a given method (Campbell & Horton, 2000). The final measured actual residue results differ from the modelled value with a standard deviation of 0.246 on the log scale, corresponding to a multiplier of 1.76.

Table 3 Ectoparasiticide residue levels in wool grease at various times after treatment with ectoparasiticides

Ectoparasiticide	Measured/ estimated	Amount applied (g/sheep)	Residue level (mg/kg wool grease) Weeks after treatment								Reference
			1	2	4	6	8	12	26	46	
DIPPING											
Diazinon	Measured	1.05	6,160			600		200	10	42	Savage (1998) – Avcare studies
Diazinon (Lice)	Estimated	1.05	4,261	2,308	850	395	215	85	12	1.5	Novartis
Diazinon (Fly)	Estimated	2.10	8,529	4,614	1,702	789	429	171	23	2.3	Novartis
Propetamphos	Measured	0.81	446			385		57	3	2.2	Savage (1998) – Avcare studies
Propetamphos (Lice)	Estimated	0.81	3,108	1,600	546	238	123	46	5	0.8	Novartis
Propetamphos (Fly)	Estimated	1.35	5,175	2,664	909	398	207	77	9	1.0	Novartis
Cyromazine[9]	Measured	3.00	6,815			792		492	76	7.7	Savage (1998) – Avcare studies
Cyromazine[10]	Estimated	3.00	17,446	12,446	6,646	3,754	2,223	877	85	13.0	Novartis
Cyromazine[11]	Estimated	4.00	16,302	13,103	8,698	5,958	4,200	2,247	450	165.0	Novartis
Diflubenzuron	Estimated	1.50	5,244[12]								Schering Plough

[9] Six weeks wool
[10] Six weeks wool
[11] 12 weeks wool
[12] Estimated from the amount of residue in 3L of dipping solution retained by sheep immediately after dipping

Ectoparasiticide	Measured/ estimated	Amount applied (g/sheep)	Residue level (mg/kg wool grease) Weeks after treatment								Reference
			1	2	4	6	8	12	26	46	
JETTING (6 MONTHS WOOL)											
Diazinon	Measured	1.3			1,390		730		60		Savage (1998) – Victorian studies
Cypermethrin	Measured	0.07			92		115		54		Savage (1998) – Victorian studies
Propetamphos	Measured	1.5			1,060		690		30		Savage (1998) – Victorian studies
Cyhalothrin	Measured	0.08			115		100		30		Savage (1998) – Victorian studies
Diflubenzuron	Measured	0.7			2,323		1,615		1,108		Savage (1998) – Victorian studies
Ivermectin	Measured	0.06			38		38		8		Savage (1998) – Victorian studies
JETTING (9 MONTHS WOOL)											
Diazinon	Measured	1.6	2,923			708		370			Savage (1998) – Avcare studies
Diazinon	Estimated	1.6	923	761	531	377	274	152			Novartis
Diazinon	Measured	1.3		1,930	1,246		1,138	860			Savage (1998) – Victorian studies
Propetamphos	Measured	1.5		1,608	592		746	560			Savage (1998) – Victorian studies
Propetamphos	Estimated	1.5	818	664	448	310	220	117			Novartis
Propetamphos	Measured	1.5	3,177			1,300		338			Savage (1998) – Avcare studies
Cyromazine	Measured	4	3,315			1,523		1,060			Savage (1998) – Avcare studies
Cyromazine	Estimated	4	2,100	1,968	1,739	1,548	1,388				Novartis

Ectoparasiticide	Measured/ estimated	Amount applied (g/sheep)	Residue level (mg/kg wool grease) Weeks after treatment								Reference
			1	2	4	6	8	12	26	46	
Cyhalothrin	Measured	0.08		108	100		85	69			Savage (1998) – Victorian studies
JETTING (9 MONTHS WOOL)											
Chlorfenvinphos	Measured	2	2,285			2,654		923			Savage (1998) – Avcare studies
Cypermethrin	Measured	0.07		115	85		85	54			Savage (1998) – Victorian studies
BACKLINE/POUR-ON											
Alpha-cypermethrin (Fly)	Measured	1 (6 months wool)		4,223	3,146		1,230	900			Savage (1998) – Victorian studies
Alpha-cypermethrin (Fly)	Measured	1 (9 months wool)			3,385		1,090		177		Savage (1998) – Victorian studies
Cypermethrin	Measured	1.5 (6 months wool)			6,960		4,890		1,030		Savage (1998) – Victorian studies
Cypermethrin	Measured	1.5 (9 months wool)		9,438	5,430		2,430	1,660			Savage (1998) – Victorian studies
Cyromazine	Estimated	2.04 (6 months wool)	4,415	3,562	2,370	1,620	1,138	602	115		Novartis
Dicyclanil	Estimated	1.2 (9 months wool)	1,867	1,545	1,060	728	502	238			Novartis

Ectoparasiticide	Measured/ estimated	Amount applied (g/sheep)	Residue level (mg/kg wool grease) Weeks after treatment								Reference
			1	2	4	6	8	12	26	46	
Diflubenzuron	Measured	0.5 (off-shears)			7,692		5,476	4,092	1,292		Schering Plough
Triflumuron	Estimated	0.5 (off-shears)					230[13] (130)[14]	130			Bayer
Temephos	Measured	1.4 (9 months wool)	454		366		141	139			Schering Plough

[13] Measured in total fleece
[14] Maximum in wool grease

2.1.7 Occupational exposure of shearers to wool grease

Several studies have attempted to measure the occupational exposure of shearers to wool grease:

- In 1989, a technical working party representing the animal health industry, the CSIRO and NOHSC developed a protocol for assessing the exposure of shearers to ectoparasiticide residues on wool. The protocol assumed that because most ectoparasiticides are soluble in the grease component of the fleece, an estimate could be mode of exposure to specific chemicals if the amount of wool grease transferred to a shearer's skin was known. It was assumed that during the course of a typical working day, a shearer would acquire a covering of 2–3mg/cm^2 over an area of skin equivalent to the front half of the body (9,000cm^2), amounting to a total transfer of 23g of wool grease per day. In the absence of actual transfer data this figure was accepted by the NOHSC, while recognising that it may be an overestimate of the actual exposure.
- A study report prepared by the CSIRO Division of Textile and Fibre Technology on behalf of Avcare was submitted by data providers to this review (Hudson et al., 2000). The report measured wool grease accumulated on the skin of two shearers over 3.5 days of shearing in Victoria during autumn. The effect of washing hands, arms and face during breaks in shearing was measured and the protective effect of shearers' clothing (trousers and singlets) was evaluated. Wool grease measurements were also made on other shed workers involved in handling harvested fleeces.
- In 1999, the NOHSC released Guidelines for Conducting a Health Risk Assessment of Sheep Ectoparasiticides for Wool and Sheep Handlers. The guidelines included formulae for calculating the concentration of a chemical ectoparasiticide applied to sheep, residues of the chemical remaining over time, and exposure of workers to the ectoparasiticide based on the quantity of wool grease transferred to a shearer's body during a typical working day.
- Hudson et al. (2000) concluded that only 140mg of wool grease was transferred to shearers during a typical working day. This was substantially less than the 23g determined from earlier theoretical calculations. Comparisons with data collected from other wool shed workers indicated that as a group, shearers acquired more wool grease than other personnel working in the shed; therefore the results of calculations based on shearer exposure and any recommendations arising from them could be safely applied to all wool handlers. The possibility that larger amounts of grease may be transferred to shearers handling breeds of sheep other than merinos, or shearing sheep in areas with higher ambient temperatures, was discussed in the CSIRO report. The authors contended that, based on Australian Wool Testing Authority pre-sale testing figures, the majority of the sheep are shorn in the winter/spring period and 79% of the wool is produced in relatively temperate high rainfall zones.

  Due to the small sample size and possible seasonal differences, it is considered by the OCS that some degree of variability may occur. Therefore a five-fold variability factor was applied to the value of 140mg, i.e. 700mg of wool grease transfer to account for the likely error in extrapolating from a small sample (n = two shearers) to all shearers; the seasonal variation in the possible uptake of grease from wool (observations were made under mild conditions, with temperatures ranging from 10.5 to 16.0ºC, 12.0 to 17.5ºC, 15.3 to 23.5ºC and 8.5 to 17.5ºC on respective days);

measurement errors inherent in using the analytical tool near its lower limit of detection; and different climatic conditions and sheep strains.

2.1.8 MOE calculation

The margin of exposure (MOE) for workers to ectoparasiticides is given by the ratio:

$$MOE = \frac{NOEL\ (mg/kg\ bw/day)}{E\ (mg/kg\ bw/day)}$$

—where ectoparasiticide exposure (E) is the total daily absorbed dose and is calculated as follows:

Amount of ectoparasiticide residue in wool grease	$2R^{(a)}$mg/kg
Amount of wool grease adsorbed by the shearer/day	$700mg^{(b)}$
Body weight (bw) of shearer	70kg
Dermal absorption value for the ectoparasiticide	X%

(a) The residue values were doubled to account for the likely differences in the rate of degradation within the fleece under different climatic conditions across Australia.

(b) The findings of Hudson et al. (2000) showed that a shearer acquired 140 mg of wool grease in the course of an average working day. This value was increased five-fold to account for variability between individuals and climatic conditions across Australia.

Based on the above assumptions and parameters, the amount of each active constituent absorbed by a shearer was calculated.

$$E\ (mg/kg\ bw/day) = \frac{2R\ mg/kg \times 700mg}{70kg\ bw} \times X\%$$

Calculated MOEs for each active constituent except chlorfenvinphos and deltamethrin are shown in Table 4.

2.1.9 Post-application OHS risk assessment

The post-application occupational risk assessment is the combination of the hazard of the chemical as determined by its toxicological effects, and worker exposure to that chemical during shearing. In order to adequately determine a safe sheep rehandling interval for sheep treated with the ectoparasiticides subject to the review, the MOEs for the ectoparasiticides were calculated by comparing the most appropriate NOEL for the ectoparasiticide with exposure estimates at different time periods post-application.

Residual ectoparasiticides are assumed to be wholly absorbed in the wool grease to which shearers are exposed when handling the treated sheep. Consequently the route of exposure used for the purposes of risk assessment was dermal absorption.

In general an MOE of ≥10 is considered by the OCS to be acceptable where the NOEL is derived from a study using human volunteers and an MOE of ≥100 is acceptable in cases where laboratory animal data have been used. However, for diazinon, where the NOEL was determined in human volunteers, only three subjects per dose level were tested and the two tested dose levels were very close. Hence there was some uncertainty associated with the 'true' NOEL. An MOE of ≥ 20 was considered acceptable for diazinon to account for intra-species (10x) variability, the small number of subjects and closeness of NOEL and LOEL (2x).

Table 4 presents the MOEs calculated for different ectoparasiticides at one to 46 weeks after application. The reason for calculating MOEs at different lengths of time after application was to determine a sheep rehandling interval that would pose minimal risk to shearers and other sheep handlers. Acceptable MOEs (which are >10 for temephos, >20 for diazinon and >100 for the rest of the ectoparasiticides) have been shaded in the table.

The sheep rehandling intervals are determined by the ectoparasiticide residue levels on wool, which in turn depend on their actual application rates rather than their concentration in the products. Consequently, different products containing varying concentrations of an active constituent may have the same sheep rehandling interval if the application rate of the active constituent is also the same.

Analysis of Table 4 shows that generally, ectoparasiticide residues fall to acceptable levels (low risk) either once sheep are dry following application or within two to six weeks after application, irrespective of the method of application (except for diazinon and propetamphos). However, sheep with six months wool and jetted with ectoparasiticides seem to retain chemical residues for longer (four weeks or more) than those with longer wool (nine months wool).

Table 4 MOEs for shearers handling treated sheep[15]

Ectoparasiticide	NOEL (mg/kg bw/d)	Dermal abs. (%)	Acceptable MOE	MOE Weeks after treatment							
				1	2	4	6	8	12	26	46
DIPPING											
Diazinon[m]	0.02	4	20	4		[14]	41		125	>1,000	590
Diazinon[e] (Lice)	0.02	4	20	6	11	29	62	116	294	>1,000	>1,000
Diazinon[e] (Fly)	0.02	4	20	3	5.4	15 [at wk 5–19]	32	58	146	>1,000	>1,000
Propetamphos[m]	0.1	10	100	112			130		862	>1,000	>1,000
Propetamphos[e](Lice)	0.1	10	100	16	32	91	210	400	>1,000	>1,000	>1,000
Propetamphos[e] (Fly)	0.1	10	100	10	19	55	126	241	650	>1,000	>1,000
Cyromazine[m]	1.8	5	100	264			>1,000		>1,000	>1,000	>1,000
Cyromazine[e]	1.8	5	100	103	145	271	479	810	>1,000	>1,000	>1,000
Cyromazine[e]	1.8	5	100	110	137	207	302	429	800	>1,000	>1,000
Diflubenzuron	2.0	0.2	100	>1,000							
JETTING (6 MONTHS WOOL)											
Diazinon[m]	0.02	4	20			18	[24]	34		417	
Cypermethrin[m]	5	20	100	[>1,000]				>1,000		>1,000	
Propetamphos[m]	0.1	10	100			48		71		>1,000	
Cyhalothrin[m]	1.5	100	100	[208]		652		750		>1,000	
Diflubenzuron[m]	2.0	0.2	100	[>1,000]		>1,000		>1,000		>1,000	
Ivermectin[m]	0.1	1.0	100	[>1,000]		>1,000		>1,000		>1,000	

MOE values in square brackets were either interpolated or extrapolated. When included under week 1 they refer to the extrapolated MOE in week 0 (ie immediately after treatment)

Shaded area = acceptable MOE; m = from measured data; e = from estimated data

[15] This table does not include MOE values for chlorfenvinphos or deltamethrin because no adequate wool residue data were provided

Ectoparasiticide	NOEL (mg/kg bw/d)	Dermal abs. (%)	Acceptable MOE	MOE Weeks after treatment							
				1	2	4	6	8	12	26	46
JETTING (9 MONTHS WOOL)											
Diazinon[m]	0.02	4	20	8.5			35		67		
Diazinon[e]	0.02	4	20	27	33	48	67	91	167		
Diazinon[m]	0.02	4	20		13	20		22	29		
Propetamphos[m]	0.1	10	100		31	83		67	91		
Propetamphos[e]	0.1	10	100	61	75	111	161	227	435		
Propetamphos[m]	0.1	10	100	16			38		147		
Cyromazine[m]	1.8	5	100	543			>1,000		>1,000		
Cyromazine[e]	1.8	5	100	857	915	>1,000	>1,000	>1,000			
Cyhalothrin[m]	1.5	100	100	[595]	681	750		882	>1,000		
Chlorfenvinphos[m]	0.05	10	100	2			2		5		
Cypermethrin[m]	5.0	20	100	[>1,000]	>1,000	>1,000		>1,000	>1,000		
BACKLINE/POUR-ON											
Alpha-cypermethrin[m]	4.7	20	100	[107]	278	373		955	>1,000		
Alpha-cypermethrin[m]	4.7	20	100	[209]		348		>1,000		>1,000	
Cypermethrin[m]	5.0	20	100		[109]	180		255		1214	
Cypermethrin[m]	5.0	20	100	[96]	132	230		514	753		
Cyromazine[e]	1.8	5	100	407	505	760	>1,000	>1,000	>1,000	>1,000	
Dicyclanil[e]	0.7	10	100	189	228	329	480	700	>1,000		
Diflubenzuron	2.0	0.2	100	[>1,000]		>1,000		>1,000	>1,000	>1,000	
Triflumuron[e]	0.7	10	100	[>1,000]				>1,000	>1,000		
Temephos[m]	1.0	100	10	109		137		357	357		

2.1.10 Summary of OHS review outcomes

This review has reconsidered the NOELs selected for each of the ectoparasiticides subject to the review. Based on the knowledge that shearers are likely to be exposed to wool grease ectoparasiticide residues throughout their working life, the NOELs used to establish the ADI, drawn from chronic exposure studies, were used in the risk assessment. In the case of diazinon and temephos the same physiological effect, namely cholinesterase inhibition, was observed in both human and animal studies[16]. This common endpoint enabled the human NOEL to be used for risk assessment in conjunction with a five-fold or 10-fold lower safety margin because no extrapolation from animal data to humans was required.

Where suitable data for dermal absorption of chemicals were not available, a default dermal absorption value of 100% was used. However, in cases where adequate data on the physicochemical properties of the active constituent or other data indicated that the potential for dermal absorption is low, a dermal absorption value of 10% or less was used.

Different application methods (eg dipping, jetting) result in retention of different amounts of residue in the fleece. Individual MOEs were calculated for different application methods if the data were available. Where data indicated adequate MOEs from week one onwards, the data were extrapolated to determine MOEs for days zero to seven. The aim was to determine whether in such cases it would be safe for shearers to handle treated sheep one or two days after treatment.

Organophosphates (OPs)

Diazinon

Based on the residue data for diazinon, all MOEs were adequate (ie ≥ 20) from week six onwards for dipping as well as jetting applications.

Propetamphos

Propetamphos data gave different MOE values for dipping and jetting application methods. With dipping, MOEs were adequate (ie ≥ 100) six weeks after treatment. However, following jetting treatment the high levels (ie slow dissipation rate) of propetamphos residues meant that the MOE remained unacceptable until week 12.

Chlorfenvinphos

No wool residue data were provided by registrants for the plunge/shower dip and spray race treatment (for body lice and ticks) and there were inadequate residue data provided to permit a calculation of a plausible MOE for jetting. The data which were provided for jetting (blowflies) suggested that the residue concentrations hardly changed over the 12 weeks following application. This resulted in an unacceptable MOE (five but must be at least 100) even after 12 weeks. Supplementary wool residue data must be considered to confirm these findings. Therefore in the absence of any suitable residue data, no acceptable sheep rehandling interval can be recommended for chlorfenvinphos for any application.

[16] Cholinesterase inhibition was the most sensitive endpoint of a large range of endpoints measured in an extensive set of toxicological studies conducted in laboratory animal species.

Temephos

Based on the measured residue data for temephos the MOE was considered acceptable by day seven for backline/pour-on applications. Since the MOE on day seven after application was 109, and any value equal to or greater than 10 is considered acceptable, an extrapolation of the residue concentration likely to be present on day zero (ie day of application) suggests that it is unlikely to be 11-fold greater than that present on day seven.

Macrocyclic Lactones

Based on the residue data submitted for ivermectin, the MOE was found to be acceptable (ie ≥ 100) from week four onwards. However, extrapolation of data indicated that the MOE was also acceptable on the day of application (ie day zero).

Synthetic pyrethroids (SPs)

With the exception of deltamethrin, pyrethroids are a complex mixture of isomers rather than one single pure compound. These isomers are commonly grouped into four cis- and four trans-isomers, the cis-group being the more powerful insecticide. Cypermethrin is the racemic mixture of all eight isomers. Alpha-cypermethrin contains more than 90%of the insecticidally most active pair of the four cis-isomers of cypermethrin as a racemic mixture.

Despite the close chemical similarity between cypermethrin and alpha-cypermethrin, and the use of a common assay method to measure both racemic mixtures, there was an apparent difference in the dissipation rate for the two chemicals. For cypermethrin used in backline and pour-on applications, the MOE was adequate two weeks after treatment whereas for alpha-cypermethrin an extrapolation of the residue values indicated that an adequate MOE was achieved from week zero onwards (ie the day of application).

For all jetting applications the cypermethrin residue on wool was low and resulted in an acceptable MOE even on day zero. Since there was considerable variability in the measured residues between alpha-cypermethrin and cypermethrin when using the same assay, the data demonstrate that a two-week withholding period should apply for both pyrethroids.

For cyhalothrin the MOE was found to be acceptable on day zero.

There were no wool residue data provided for deltamethrin to permit calculation of an acceptable MOE. Therefore no sheep rehandling interval can apply to products containing deltamethrin.

Insect Growth Regulators

Based on the residue dissipation data for diflubenzuron (dip, jetting and backline/pour-on) and triflumuron (backline/pour-on) the acceptable MOEs (≥ 100) were calculated to be attained on the day of application (ie day zero).

For cyromazine the residue concentration present on the wool after dipping was appreciably higher than that found after jetting or pour-on. However, since dermal absorption of cyromazine was only 5%, acceptable MOEs (≥ 100) were found on the day of treatment for all application types.

The dicyclanil residue data on wool indicated that an acceptable MOE (≥ 100) was present on the day of application (ie day zero).

2.1.11 Recommended sheep rehandling interval statements

The recommended sheep rehandling intervals for treated sheep are shown in Table 5. The recommended label sheep rehandling interval statements are specified in Table 6. If sheep must be handled during 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) are recommended for all sheep ectoparasiticides considered in this review.

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

Table 5 Recommended sheep rehandling intervals for sheep ectoparasiticides

Active constituent	Typical use patterns	Recommended sheep rehandling interval
Products containing OPs		
Diazinon 200 g/L	Dip to control blowflies: sheep with short wool. Dip to control body lice: sheep with short wool. Jet to control blowflies: sheep with long wool.	6 weeks
Diazinon 96 g/L + Cypermethrin 144 g/L	Pour-on to control body lice or blowflies; sheep with long wool	
Diazinon 60 g/L + Rotenone 15 g/L +Piperonyl butoxide 7.5 g/L	Dip to control body lice, keds or blowflies: sheep with short wool.	
Diazinon 200 g/L + Amitraz 125 g/L	Dip to control blowflies or body lice: sheep with short wool.	
Temephos 350 g/L	Dip to control body lice: sheep with short wool. Jet to control blowflies: sheep with long wool.	When sheep are dry following treatment
Propetamphos 360 g/L	Dip to control body lice or blowflies: sheep with short wool. Jet to control blowflies: sheep with long wool.	6 weeks 12 weeks
Products containing macrocyclic lactones		
Ivermectin 75 g/L	Jet to control blowflies: sheep with long wool.	When sheep are dry following treatment

Active constituent	Typical use patterns	Recommended sheep rehandling interval
Products containing synthetic pyrethroids		
Cyhalothrin 50 g/L	Dip to control body lice: sheep with short wool; Jet to control body lice: sheep with long wool	When sheep are dry following treatment
Cyhalothrin 16 g/L + Rotenone	Dip to control body lice: sheep with short wool; Jet to control body lice: sheep with long wool.	
Alpha-cypermethrin 20 g/L	Pour-on to control body lice within 1 day after shearing.	2 weeks
Alpha-cypermethrin 50 g/L	Pour-on to control body lice or blowflies; sheep with long wool.	
Cypermethrin 25 g/L	Jet to control body lice. Pour-on to control body lice or blowflies; sheep with long wool	
Cypermethrin 25 g/L + Piperonyl butoxide 100 g/L	Backline treatment for off-shear control of pyrethroid susceptible lice	
Products containing insect growth regulators		
Cyromazine 60 g/L	Spray-on to control blowflies: sheep with long wool.	When sheep are dry following treatment
Cyromazine 500 g/L	Dip to control blowflies: sheep with long wool. Jet to control blowflies: sheep with long wool	
Dicyclanil 50 g/L	Spray-on to control blowflies: sheep with long wool.	
Dicyclanil 50 g/L + Diflubenzron 15 g/L	Spray-on to control blowflies and lice	
Diflubenzuron 250 g/L	Dip or jet to control body lice or blowflies: sheep with short or long wool.	
Diflubenzuron 25 g/L	Pour-on to control blowflies or body lice: sheep with long wool.	
Triflumuron 25 g/L	Pour-on to control body lice: sheep with short wool.	

Active constituent	Typical use patterns	Recommended sheep rehandling interval
Products for which no sheep rehandling period can be specified		
Chlorfenvinphos 1000 g/L	Jet to control blow flies	**No sheep rehandling interval can be specified due to the absence of any suitable residue data.**
Chlorfenvinphos 138 g/L	Plunge/shower dip spray race (body lice, ticks)	
Chlorfenvinphos 138 g/L + cypermethrin 25 g/L	Dip or spray to control body lice and ticks	
Deltamethrin 10 g/L	Pour-on to control body lice.	

Table 6 Recommended sheep rehandling interval label statements for sheep ectoparasiticides

Active constituent	Recommended sheep rehandling interval label statements
Products containing OPs	
Diazinon 200 g/L	Sheep Rehandling Interval: Six weeks. If sheep must be handled during this interval, cotton overalls buttoned to the neck (or equivalent clothing) should be worn
Diazinon + Rotenone + Piperonyl butoxide	
Diazinon 200 g/L + Amitraz 125 g/L	
Temephos 350 g/L	Sheep Rehandling Interval: Do not rehandle sheep until dry after treatment
Propetamphos 360 g/L	Sheep Rehandling Interval for dipping: Six weeks. If sheep must be handled during this interval, cotton overalls buttoned to the neck (or equivalent clothing) should be worn Sheep Rehandling Interval for jetting: Twelve weeks. If sheep must be handled during this interval then cotton overalls buttoned to the neck (or equivalent clothing) should be worn
Products containing macrocyclic lactones	
Ivermectin 75 g/L	Sheep Rehandling Interval: Do not rehandle sheep until dry after treatment.
Products containing synthetic pyrethroids	
Cyhalothrin 50 g/L	Sheep Rehandling Interval: Do not rehandle sheep until dry after treatment.
Cyhalothrin 16 g/L + Rotenone 40 g/L	
Alpha-cypermethrin 20 or 50 g/L	Sheep Rehandling Interval: Two weeks. If sheep must be handled during this interval, cotton overalls buttoned to the neck (or equivalent clothing) should be worn.
Cypermethrin 25 g/L	
Cypermethrin 25 g/L + Piperonyl butoxide 100 g/L	
Products containing insect growth regulators	
Cyromazine 60 g/L	Sheep Rehandling Interval: Do not rehandle sheep until dry after treatment.
Cyromazine 500 g/L	
Dicyclanil 50 g/L	
Dicyclanil 50 g/L + Diflubenzuron 15 g/L	
Diflubenzuron 250 g/L	
Diflubenzuron 25 g/L	
Triflumuron 25 g/L	

Active constituent	Recommended sheep rehandling interval label statements
Products for which no sheep rehandling period can be specified	
Deltamethrin 10 g/L	**NO SHEEP REHANDLING INTERVAL CAN BE DETERMINED DUE TO THE ABSENCE OF ANY SUITABLE RESIDUE DATA.**
Chlorfenvinphos 1000 g/L & 138 g/L	
Chlorfenvinphos 138 g/L + cypermethrin 25 g/L	

2.2 Summary of the environmental assessment

The environmental assessment for the review of selected sheep ectoparasiticides was undertaken by the DEH, which considered all the environmental data and information submitted by registrants and data in assessment reports previously reviewed by DEH.

The DEH has also provided a comparative analysis of likely scour residues, together with information on relevant international environmental standards and advice on the likely impact of relevant standards applicable in the European Union on future exports of Australian raw wool. This advice has enabled the APVMA to undertake a trade evaluation as part of the sheep ectoparasiticide review. This is detailed in section 2.4.

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 environmental technical assessments for each active constituent are in Volume 2 of the Preliminary Review Report.

2.2.1 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 course of wool processing, is to firstly establish environmental impact thresholds, then to determine whether sheep ectoparasiticide products subject to the review meet these criteria when used in accordance with label instructions.

The worst-case scenario for Australian wool scour effluent discharge is the ocean sewage outlet of Barwon Water's (water authority based in Geelong, Victoria) sewage treatment plant at Black Rock, because this has the highest predicted environmental concentration (PEC) of ectoparasiticides associated with scour effluent from two wool scouring plants in the area. The endpoints used in the hazard calculations for the Australian environment are therefore ocean discharge endpoints. The review compares the predicted discharge concentration for treated effluent with the predicted no-effect concentration (PNEC). Note that although the environmental endpoints at Black Rock focus on the acute toxicity of the ectoparasiticide to the most sensitive species as shown by laboratory testing (see Table 7 in section 2.2.2), in the case of more persistent ectoparasiticides such as insect growth regulators, longer-term chronic toxicity data have also been considered.

The endpoints used in the hazard calculation for overseas environments are termed Environmental Quality Standards (EQS). EQSs are roughly equivalent to no observable effect concentrations (NOEC). Although the majority of these values have not yet been published they are referred to in EU legislation as the set of requirements which must be fulfilled in order to achieve a high level of protection for the environment.

The European Union is due to finalise the implementing of additional pollution prevention legislation after October 2007. The relevant EU directive is at http://eippcb.jrc.es/pages/Directive.htm

The EQSs are likely to be relatively more conservative than the Australian wool scour effluent discharge criteria used in the hazard calculations for the Australian environment because scouring plants in Europe generally discharge into river systems, rather than oceans as is the case in Australia. These river systems have a much more limited dilution capacity than the ocean, therefore any chemicals in the scour discharge are likely to be a higher risk to the environment. The risks to the environments of overseas countries from too high a level of ectoparasiticides residues on Australia's exported greasy wool may adversely affect Australia's trade in this commodity.

This review considers registrants' submitted data and published data for the environmental assessment of the products subject to this review. The review focused on the environmental impact of the effluent discharged into the environment where this effluent contained chemical residues from wool scouring of treated sheep. The review grouped the active constituents into four categories:

1) Organophosphates (OPs)
2) Insect growth regulators
3) Macrocyclic lactones
4) Synthetic pyrethroids (SPs).

Volume 2 details the review's findings. It consists of chapters on each active constituent including a detailed environmental assessment of individual products containing the active constituent.

It should be noted that the proposed findings are based on observed chemical residue levels on wool from sheep ectoparasiticide products[17] over several years until 2004.

[17] Based on national wool clip residue figures collected by AWI and its predecessors since 1992.

2.2.2 Endpoints used in hazard calculations for the Australian environment

The information used to determine these endpoints has been taken from the data submitted by registrants for the review and/or from data in assessment reports previously reviewed by the DEH. In cases where these data were not available, the main sources of LC50 and other endpoint data were sourced from internationally-peer-reviewed documents or the Pesticide Ecotoxicity Database used by the Environmental Fate and Effects Division of the USEPA's Office of Pesticide Programs.

Where sufficient data were available, a statistical approach was adopted as the most robust methodology: toxicity data were manipulated to provide a concentration of the active constituent below which level 95%[18] of organisms in the aquatic environment would not be adversely affected. Where this was not possible due to insufficient data, the assessment factor (AF) approach was used, whereby the most sensitive aquatic toxicity result is divided by 10 or 100 to derive a predicted no effect concentration (PNEC). The AF used (10 or 100) depends on both the extent and quality of the data available. An AF of 10 has predominantly been used in this review.

Table 7 below lists all the endpoints used in this assessment and how they have been derived, together with the most sensitive species.

Table 7 Endpoints derived by the DEH for all active constituents for the Australian risk assessment

Active constituent	Most sensitive species (and result)	Approach used (protection level/AF)	Predicted No effect Concentration (PNEC)
Cypermethrin and Alpha-cypermethrin[19]	Mysid shrimp (4.7 ng/L)	Statistical (95%)	2 ng/L
Cyromazine	Daphnia (92.8 mg/L	AF (100)	928 µg/L.
Deltamethrin	Mysid shrimp (1.7 ng/L)	Statistical (95%)	2 ng/L
Diazinon	Scud (0.2 µg/L)	AF (10)	20 ng/L
Dicyclanil	Daphnia (1.1 µg/L)	AF (1000)	1.1 µg/L
Diflubenzuron	Grass shrimp (0.64 µg/L)	AF (10)	64 ng/L
Ivermectin	Mysid shrimp (26 ng/L)	AF (26[20])	1 ng/L
Propetamphos	Daphnia (3.3 µg/L)	AF (100)	33 ng/L
Temephos	Daphnia (7 ng/L)	AF (10)	0.7 ng/L
Triflumuron	Mysid shrimp (3.9 µg/L)	AF (10)	0.39 µg/L

[18] Other tolerance levels are statistically possible but 95% was used for this assessment as a first approach.
[19] For the environmental assessment cypermethrin and alpha-cypermethrin are assessed as indistinguishable.
[20] As discussed in Volume 2 of the PRF the DEH has adopted the MAC value for this assessment.

2.2.3 Endpoints used in hazard calculations for overseas environments – environmental quality standards (EQS)

International Pollution Prevention Commission (IPPC) Directive 96/61/EC available at http://eippcb.jrc.es/pages/Directive.htm states that

> "The 'environmental quality standard' shall mean the set of requirements which must be fulfilled at a given time by a given environment or particular part thereof, as set out in Community legislation"

and

> "The objective of an integrated approach to pollution control is to prevent emissions into air, water or soil wherever this is practicable, taking into account waste management, and, where it is not, to minimise them in order to achieve a high level of protection for the environment as a whole."

The IPPC Directive applies to a number of potentially polluting industrial activities including waste management facilities. It seeks to prevent or reduce pollution of the air, water and land through a comprehensive permitting system that looks at emissions to all environmental media together. It also covers the generation of waste; the use of energy in industrial activities; and the minimisation of risk of harm to the environment or human health as a whole via source-based control through regulation of installations.

Two types of EQS are generally derived as part of this process: the annual average (AA) and the maximum acceptable concentration (MAC). These are roughly equivalent to chronic and acute NOECs for the ecosystem, although they are more usually derived by application of extrapolation (assessment) factors to LC50 data. MAC is a maximum concentration which is allowable only for short periods of time and which is based on acute toxicity under conditions of low river flow. This contrasts with AA which is an annual average, based on average emissions for scouring plants under average river flows, and takes into account the chronic exposure of aquatic organisms. The AA and MAC values used in this report are UK EQSs but it is anticipated that they will be adopted in other EU countries.

The web site (http://www.sepa.org.uk/guidance/water/index.htm) of the Scottish Environmental Protection Agency contains additional information on the implementation of IPPC Directive 96/61/EC in member states. The web site also includes a list of EQSs for the protection of freshwater and marine life compiled by staff at the WRc-NSF[21] National Centre for Environmental Toxicology in the UK (http://www.sepa.org.uk/pdf/guidance/water/annexes/annex_g.pdf). This list contains EQSs for six of the ectoparasiticides that are the subject of this review:

- the organophosphates: chlorfenvinphos, diazinon and propetamphos
  - (Fresh Water/Salt Water (FW/SW) AA 30ng/L, FW/SW MAC 100ng/L, statutory fresh water values and currently tentative seawater values for the first two, all currently tentative values for propetamphos)
- the synthetic pyrethroid cypermethrin

[21] WRc-NSF provides analysis, testing and consultancy in the areas of public and environmental health in the UK.

- (FW/SW AA 0.2ng/L, FW/SW MAC 2ng/L, all currently tentative except for statutory FW MAC value)

- the insect growth regulator diflubenzuron
  - (FW AA 1ng/L, FW MAC 15ng/L; SW AA 5, SW MAC 100, all values statutory)

- the macrocyclic lactone ivermectin
  - (FW AA 0.1ng/L, FW MAC 1ng/L; SW AA 1ng/L, SW MA 10ng/L, all values currently tentative).

The web site also details AA and MAC limits for total OPs, which includes coumaphos and fenchlorphos. These values are similar AA and MAC limits to the above three OPs.

The former web site http://www.basicweb.fsnet.co.uk/index.htm also included a toxicity database holding UK EQS values. This contained similar values except that the AA for cypermethrin was 0.1ng/L, and some of the tentative/final ratings were different. As this was available 2001 but was removed in mid 2003, the above document (dated October 2004) will be followed in this assessment.

2.2.4 Australian sewage treatment assumptions

Work by Grundy et al. (2000) has 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 is 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.

In Australia, 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 (1997). Therefore effluent should be non-toxic at the point of discharge to the environment.

For non-persistent chemicals, the assessment undertaken as part of this review to determine if the effluent is non-toxic or not has been based on acute data; as although it is sometimes the case that life-cycle tests provide lower end-points, this is balanced by dilution of the treated effluent in receiving ocean waters, as discussed below.

2.2.5 Effect of plume dilution at ocean outfall

Grundy et al. reported on the commercial scouring of wool treated with diflubenzuron (Grundy et al., 2000). 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 a 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 taken into account in the environment hazard assessment of the other active constituents in the review, as these are more soluble and therefore can be expected to disperse more rapidly.

2.2.6 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 were available, they were used as the input concentration for the hazard calculations and taken into consideration in estimating whether the wool withholding period (WWP) is acceptable. If data were 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 had a preference for 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.

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

Maximum mean concentrations of residues that can be tolerated in raw wool can be estimated from the target concentration at the outfall, based on the following assumptions:

Daily discharge	50ML
Removal in sewage treatment plant	0% (cyromazine, dicyclanil)
	50% (OPs)
	80% (ivermectin, triflumuron)
	85% (diflubenzuron)
	95% (SPs)
Recovery with wool grease	30% (OPs, SPs and diflubenzuron)
	0% (cyromazine, dicyclanil)
	75% (triflumuron)
Retention on scoured wool	4%
Daily scouring load	50 tonnes raw wool
Dilution at ocean outfall	1:50 = 0.02

The most critical variable in the model, particularly for the highly lipophilic synthetic pyrethroids, is the removal of residues during sewage treatment. The Black Rock model may require modification to reflect developments in effluent processing (clean-up) methods in the industry. It is likely that the two wool scouring plants in the Geelong area that discharge effluent to Black Rock will also install on-site treatment processes that remove at least 80% of lipophilic residues. Conversely, installation of a third scouring line at one of these plants would add another 20% to overall inputs to the sewer (after on-site treatment). While improvements at Geelong may make the ocean outfall sewage treatment works at Bolivar (Adelaide, South Australia) the worst case situation in Australia, the Black Rock model has been used without further modification for the time being.

2.2.8 Overseas model assumptions, based on discharge to the Spen Beck riverine environment below Spenborough, UK

Maximum mean concentrations of residues that can be tolerated in raw wool can be estimated from the target EQSs and MACs, based on the following assumptions:

Daily river flow	71ML (low flow for MAC)
	149ML (mean flow for AA)
Removal in sewage treatment plant	0% (cyromazine, dicyclanil)
	50% (OPs)
	80% (amitraz, ivermectin, triflumuron)
	85% (diflubenzuron)
	95% (SPs)
Removal as recovered wool grease and by associated on-site effluent treatment processes	0% (cyromazine, dicyclanil)
	80% (OPs, SPs and diflubenzuron)
	90% (triflumuron - associates with dirt)
Retention on scoured wool	4%
Daily scouring load	27.6 tonnes raw wool

Removal of residues during sewage treatment is again an important variable. The assumptions used for on-site treatment may merit further evaluation as higher performance has been demonstrated under some laboratory conditions.

The UK situation also requires updating because the Spenborough plant on which the model is based has now closed. Russell (2000) has developed an alternative and less demanding model based on discharges entering the River Calder below Dewsbury. However, the Spen Beck model will be retained for this review because it is more likely to be representative of scouring plants in Italy discharging to smaller rivers.

2.2.9 The assessment method used for Italian scour plants

There is a rapidly changing situation in the United Kingdom caused by the integrated pollution prevention control (IPPC) policy (an EU Directive) which was introduced on 30 June 2002. Consequently, UK scours are rapidly disappearing and even the model based on Calder rather than Spenborough is rapidly becoming obsolete. This puts the spotlight more and more on Italy, which is one of Australia's major overseas customers for unscoured wool. Details of the Italian scouring practices and their effluent are uncertain but a translation of the 1999 Italian regulation indicates that an effluent sample emanating from a scouring mill and going into public sewerage 'is not acceptable if, after 24 hours, the number of immobile organisms is equal to or higher than 80% of the total' (24 h EC/LC80). In addition to a test on Daphnia, acute toxicity tests can be performed on *Ceriodaphnia dubio*, *Selenastrum capricornutum*, bioluminescent bacteria or organisms such as *Artemia salina*.

While it is very desirable that an Italian model be used for estimating overseas environmental hazard due to the processing of Australian wool, it must be stressed that this is for the testing of the whole effluent. The overall toxicity of whole scouring mill effluent will depend on a number of factors, including the nature and concentrations of chemicals contained within it. These may be ectoparasiticides or other chemicals such as detergents used in scouring. Without undertaking tests such as toxicity identification evaluations (TIE), no assumptions can be made as to the cause of the toxicity. The cause may be just one or two chemicals (as is the case with diazinon/chlorpyrifos in Sydney's sewage) or the result of the combined toxicity from a number of chemicals. It cannot be assumed that each individual chemical is the cause of all the toxicity, or for that matter, that each chemical contributes to the toxicity in a purely additive fashion. Therefore, use of the specific testing methods for effluent toxicity (for example 24 h EC/LC80 discussed above) for individual chemicals based on the Italian regulation is not likely to be helpful.

In summary, while the objective of this review is to ensure that the use of ectoparasiticides on sheep will not produce a toxic effluent, effluents may still be toxic due to other components of the waste product. This becomes complicated if multiple components combine to produce toxicity. The development or use of an appropriate Italian model has not been possible given the way the Italian regulations have been framed.

Therefore, the Spenborough model is currently still the most appropriate model to use for estimating overseas environmental risk assessment because it is based on a rational risk assessment process and relates to the EQSs in EU legislation. However, this model is becoming increasingly difficult to relate to existing scour plant systems overseas because the UK wool scouring system on which the model is based is clearly out-of-date. It is also the case that wool scouring in the United Kingdom is progressively being discontinued. However, insufficient data are available to the DEH to enable a new model to be developed at this stage.

2.2.10 Conceptual model

This is a predictive model that enables the theoretical maximum concentration to be calculated, in mg/kg greasy wool, which will meet the nominated endpoint. Discharge concentrations that meet the target end-points can be converted to predicted target loads in receiving waters by consideration of discharge/river flows. These can in turn be converted to concentration loads in greasy wool by consideration of amounts removed during processing and waste water treatment. The following steps are involved:

1 Calculate the load entering the environment (ENV)

2 Calculate the load entering the sewage treatment plant (STP)

3 Calculate the load entering the on-site treatment plant (OST)

4 Calculate the load entering the wax recovery (WAX)

5 Calculate the load entering the scour on greasy wool (SCR)

By using the above factors, it is possible to calculate the maximum concentrations of ectoparasiticides on wool prior to scouring that correspond to target endpoints. This approach uses, to the extent possible, the AWI wool monitoring data based on national clip residue figures collected by AWI and its predecessors since 1992. These calculations give an indication of the potential trade issues that may arise from the use of the products according to label instructions under Australian conditions prior to export. The results of

the calculations detailed in Volume 2 of the PRF, are summarised in the following tables, which show calculations for Black Rock and Spenborough.

Table 8 Black Rock Model

Ectoparasiticide	Target ng/L (PNEC)	Residue load (g/day) entering:				Wool residue mg/kg[22]
		ENV	STP	WAX	SCR	
Diazinon	20	50	100	142.8	148.7	2.97
Propetamphos	33	83.3	166.6	238	248	4.9
Temephos	0.7	1.75	3.5	5.0	5.2	0.1
Dicyclanil	1,100	2,750	2,750	2,750	2,865	57.3
Cyromazine	9.3×10^5	2.3×10^6	2.3×10^6	2.3×10^6	2.2×10^6	44,640
Ivermectin	1	2.5	12.5	17.9	18.6	0.37
Triflumuron	390	975	4,875	19,500	20,312	406.3
Diflubenzuron	64	160	1,066	1,524	1,587	31.75
Cypermethrin	2	5	100	143	149	2.98
Deltamethrin	2	5	100	143	149	2.98

Table 9 Spenborough Model (AA) EQS

Ectoparasiticide	Target EQS ng/L	Residue load (g/day) entering scour:				Wool residue mg/kg
		ENV	STP	OST	SCR	
Diazinon	30	4.47	8.94	44.7	46.6	1.69
Propetamphos	30	4.47	8.94	44.7	46.6	1.69
Temephos	30*	4.47	8.94	44.7	46.6	1.69
Dicyclanil	200**	29.8	29.8	29.8	21.0	1.12
Cyromazine	5,000**	745	745	745	776	28.1
Ivermectin	0.1	0.0149	0.0745	0.3725	0.39	0.014
Triflumuron	18**	2.68	13.4	134	140	5.06
Diflubenzuron	1	0.149	0.993	4.97	5.17	0.19
Cypermethrin	0.1	0.0149	0.298	1.49	1.55	0.056
Deltamethrin	0.1***	0.0149	0.298	1.49	1.55	0.056

* Assumes UK will adopt the same EQS limits as for total OPs

** Values have no official standing

*** Assumes UK will adopt the same EQS limits as for cypermethrin

[22] Predicted maximum wool residue concentration (mg/kg) that will meet the scour effluent target concentration.

Table 10 Spenborough Model (MAC) EQS

Ectoparasiticide	Target EQS ng/L	Residue load (g/day) entering scour:				Wool residue mg/kg
		ENV	STP	OST	SCR	
Diazinon	100	7.1	14.2	71	74	2.68
Propetamphos	100	7.1	14.2	71	74	2.68
Temephos	100*	7.1	14.2	71	74	2.68
Dicyclanil	1,100**	78.1	78.1	78.1	81.3	2.95
Cyromazine	930,000**	66,030	66,030	66,030	68,781	2,492
Ivermectin	1	0.071	0.355	1.775	1.85	0.067
Triflumuron	390**	27.7	138.5	1,385	1,442.7	52.3
Diflubenzuron	15	1.065	7.1	35.5	37.0	1.34
Cypermethrin	2	0.142	2.84	14.2	14.8	0.54
Deltamethrin	2***	0.142	2.84	14.2	14.8	0.54

* Assumes UK will adopt the same EQS limits as for total OPs
** Values have no official standing
*** Assumes UK will adopt the same EQS limits as for cypermethrin

2.2.11 Summary of proposed regulatory findings for Australian and overseas environments

Table 11 summarises the draft regulatory findings, for both Australia and overseas, based on the findings in the environment assessment part of this report. The second column (headed 'Australian environment') lists the conclusion of the DEH on whether under Australian scouring conditions and on the assumption that the label includes the current WHI the 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 those chemicals where it is indicated that the DEH was not satisfied, i.e. cypermethrin and alpha-cypermethrin, diazinon, diflubenzuron and temephos, this is because current wool residue levels are above or around the calculated maximum allowable levels listed in Table 8 that will meet the target PNECs.

The third column (headed 'Overseas environment/trade') lists the outcome of a comparative analysis undertaken by the DEH of likely scour residues and their likely impact on future exports of Australian raw wool. Again for those chemicals where a potential prejudice to trade is indicated, i.e. cypermethrin and alpha-cypermethrin, cyromazine, diazinon, dicyclanil, diflubenzuron, ivermectin and triflumuron, this is because current wool residue levels are above or around the calculated maximum allowable levels listed in Tables 9 and 10 that will meet the target EQSs. This is the basis upon which the APVMA has been able to complete a trade risk assessment as discussed in section 2.4.

2.3 Consideration of limitations for Australian and overseas environmental assessments

Some product registrants have stated they believe that the assessments in regard to the environment in this review have been too conservative. The APVMA is satisfied that the models used for the Australian and overseas environment assessments, developed by the DEH, are the best independent assessment models available.

Table 11 DEH recommendations on regulatory findings for sheep ectoparasiticides based on active constituents

Active constituent	Australian environment	Overseas environment/ trade	Comments
Cypermethrin and Alpha-cypermethrin[23]	Not satisfied[24]	High potential for prejudice to trade	Australian hazard would change if the remaining long-wool product (alpha-cypermethrin) is removed from the market, but a potential prejudice to trade would remain. Recommend label instructions should be modified to restrict use to short wool only. EQS values[25]: MAC is official, AA is tentative.
Cyromazine	Satisfied[26]	Low potential for prejudice to trade	EQS values are DEH estimates that have no official standing.
Deltamethrin	Satisfied	No potential for prejudice to trade	Based on current low use levels. EQS values are based on cypermethrin.
Diazinon	Not satisfied	Potential prejudice to trade	Safety margins are narrow, both Australian and overseas use are vulnerable to 'hot spots'. EQS values are official.
Dicyclanil	Satisfied	Potential prejudice to trade	Overseas safety margin is narrow, but EQS values are DEH estimates that have no official standing.
Diflubenzuron	Not satisfied	High potential for prejudice to trade	Australian hazard is very vulnerable to 'hot spots'. EQS values are official.
Ivermectin	Satisfied	High potential for prejudice to trade	EQS values are tentative only, and are very low.

[23] 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.
[24] The APVMA should not be satisfied that use of the product in accordance with label instructions would not be likely to have an unintended effect that is harmful to the environment.
[25] EQS values are given in Table 9 and Table 10 and in Volume 2 of the PRF.
[26] The APVMA should be satisfied that the use of the product in accordance with label instructions would not be likely to have an unintended effect that is harmful to the environment.

Active constituent	Australian environment	Overseas environment/ trade	Comments
Propetamphos	Satisfied	No potential prejudice to trade	Based on current low use levels. EQS values are tentative only.
Temephos	Not satisfied	No potential prejudice to trade	Use on long wool with 3 month WWP is the local concern. The overseas situation could change if lower EQS values are adopted based on recent high aquatic invertebrate toxicity
Triflumuron	Satisfied	High potential for prejudice to trade	EQS values are DEH estimates that have no official standing.

2.4 Trade assessment

Wool is a significant export trade commodity. The economic importance of exports of raw wool is summarised from the Australia Now web site at http://www.dfat.gov.au/facts/affaoverview.html as follows:

> Australia is a world leader in the production of high quality wool.
>
> - Australia is the world's largest supplier of wool, producing 42 per cent of the world's greasy wool in 2004–05.
> - In 2004–05 Australia produced around 525 kilotonnes of wool.
> - In 2004–05 Australian wool exports were worth A$2.8 billion.
> - Australia's major wool export markets include China, the EU (including Italy, France, Slovakia, the Czech Republic and Germany), India and Taiwan.

The APVMA has considered the comparative analysis undertaken by the DEH 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 APVMA proposes to find that, given currently applicable and projected overseas environmental standards, if the current use patterns of sheep ectoparasiticides in Australia remain unchanged, the potential will exist for treated wool to cause harm to the environment, particularly if an overseas scour plant discharges waste containing chemical residues from treated wool to rivers. 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.

With respect to the products which are the subject of this review, when used in accordance with current approved label instructions and under current use patterns, the APVMA proposes to find that it is not satisfied that chemical residues resulting from these uses would not unduly prejudice trade or commerce between Australia and places outside Australia. This is because 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 an prejudicial effect on this strategy and Australia's international trading reputation.

3. OVERSEAS REGULATORY STATUS

Australia is the world's major wool producer of garment quality wool. 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.

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. Therefore 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 percent of New Zealand's wool exports. 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 forthcoming 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 forthcoming changes in market demand for low-residue raw wool because of Australia's strong primary production position and ongoing dependence on overseas processing of greasy wool.

4. PUBLIC SUBMISSIONS AND CONSULTATION

The APVMA received comments both before and after the announcement of the review of selected sheep ectoparasiticides in 1999. Comments were received from product registrants, an active constituent approval holder, The Woolmark Company and state regulators. Concerns expressed related to the proposed registration requirements for sheep ectoparasiticides, the enforceability of proposed label amendments and the need for timely regulatory action.

The APVMA has liaised with special interest groups throughout the course of this review, including the CSIRO, the National Farmers Federation, AWI, the Australian Veterinary Association, the Livestock Contractors Association, WoolProducers, Avcare[27], the Australian Wool Industries Secretariat, overseas registrants and regulators, directly and indirectly-affected product registrants, 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.

The APVMA convened and conducted three workshops (1999, 2004 and 2005) and convened or participated in a range of other discussions in the course of this review. These discussions have assisted the APVMA in framing the regulatory approach outlined in this report.

[27] From 1 January 2006, Avcare Limited, the National Association for Crop Production and Animal Health, has been known as CropLife Australia Limited. CropLife Australia represents the plant science industry and is responsible for the crop protection and crop biotechnology aspects of Avcare. The animal health aspects will be managed by Animal Health Alliance (Australia) Ltd.

5. PROPOSED 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.

5.1 Proposed change in terminology

The APVMA proposes to rename wool withholding period (WWP) label statements as wool harvesting interval (WHI) label statements. 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. Although a number of products do not currently carry a withholding period for wool, the APVMA proposes to add a WHI statement to products that are the subject of this review.

5.2 Occupational health and safety findings

Sufficient data are available to complete the OHS risk assessment for all except two of the active constituents (deltamethrin and chlorfenvinphos) contained in the products that are subject to this review.

The APVMA proposes to find that a sheep rehandling interval statement should be added to the label of sheep ectoparasiticides 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 sheep rehandling interval will indicate when people can safely handle treated animals after the sheep have been treated with the ectoparasiticide product.

These sheep rehandling interval statements range from:

> 'SHEEP REHANDLING INTERVAL: Do not rehandle sheep until dry after treatment'

to

> 'SHEEP REHANDLING INTERVAL 12 WEEKS. If sheep must be handled during this interval, cotton overalls buttoned to the neck (or equivalent clothing) should be worn'.

Additional information is given in column two (headed 'Sheep rehandling interval (OHS assessment finding)') of Table 12.

Insufficient data are available at this stage to complete the OHS risk assessment for deltamethrin and chlorfenvinphos. The APVMA proposes to determine whether adequate wool residue data to enable a sheep rehandling interval to be set for these two active constituents exists before finalising this review. If adequate data are not available it is proposed that the labels for the chlorfenvinphos products be varied to remove all claims for use on sheep, and that products containing deltamethrin for use on sheep be cancelled on the basis that the APVMA is not satisfied that the use of products containing deltamethrin on sheep would not be harmful to the safety of people exposed to them during their handling.

5.3 Australian environment findings

The DEH has assessed the risks associated with the use of sheep ectoparasiticides on wool. The DEH assessment provides the basis for the APVMA's proposed findings on Australia's environmental risk and Australia's trade risk associated with chemical residues on wool.

With respect to the Australian environment, the APVMA proposes to find that most sheep ectoparasiticides would not be likely to have an unintended effect that is harmful to the environment under current use patterns, provided that the label specifies an appropriate WHI. Label WHIs that the APVMA proposes to apply as an outcome of this review are given in column three (headed 'Australian WHI statement (Environment assessment finding)') of Table 12.

The use of products containing **alpha-cypermethrin** on long wool (six or more weeks off-shears) has been identified as a source of potentially environmentally harmful residue levels on harvested wool. Therefore the APVMA proposes to find that the continued use of products containing alpha-cypermethrin on long wool cannot be supported because the APVMA is not satisfied that such use would not be likely to have an unintended effect that is harmful to the Australian environment. It is further proposed that the existing WHI of two months for such products be deleted and a new label restraint statement and amended WHI statement be added that specify that products must not be used on long wool:

> *Do not use this product on sheep that will be shorn with less than 12 months wool growth. Do not use this product on sheep with more than six weeks wool growth at the time of treatment because use of this product in accordance with label instructions will leave residues of alpha-cypermethrin on wool that may be harmful to the environment*

This adjustment in WHI will enable the APVMA to conclude that the use of products containing alpha-cypermethrin in accordance with label instructions would not be likely to have an unintended effect that is harmful to the Australian environment

With respect to products containing **cypermethrin**, although label instructions for these products currently state that they are approved for use on short wool only, the existing instructions do not make it clear that use on long wool may result in potential environmental harm. Therefore, in order for the APVMA to conclude that the use of products containing cypermethrin would not be likely to have an unintended effect that is harmful to the Australian environment it is proposed that the existing WHI of two months be deleted and a new label restraint statement and amended WHI statement be added to specify that these products must not be used on long wool (six weeks or more off shears):

> *Do not use this product on sheep that will be shorn with less than 12 months wool growth. Do not use this product on sheep with more than six weeks wool growth at the time of treatment because use of this product in accordance with label instructions will leave residues of cypermethrin on wool that may be harmful to the environment*

This adjustment in WHI will enable the APVMA to conclude that the use of products containing cypermethrin in accordance with label instructions would not be likely to have an unintended effect that is harmful to the Australian environment.

With respect to products containing **triflumuron**, although label instructions for these products currently state that they are approved for use up to seven days off shears only, this instruction does not make it clear that use on long wool may result in potentially environmentally harmful residue levels on harvested wool. Therefore, in order for the APVMA to conclude that the use of products containing triflumuron would not be likely to have an unintended effect that is harmful to the Australian environment, it is proposed that the existing WHI of two months be deleted and a new label restraint statement and amended WHI statement be added that specify that the product must not be used on sheep that are more than seven days off shears

> *Do not use this product on sheep that will be shorn with less than 12 months wool growth. Do not use this product on sheep with more than seven days wool growth at the time of treatment because use of this product in accordance with label instructions will leave residues of triflumuron on wool that may be harmful to the environment*

This adjustment in WHI will enable the APVMA to conclude that the use of products containing triflumuron in accordance with label instructions would not be likely to have an unintended effect that is harmful to the Australian environment.

With respect to products containing **diazinon, diflubenzuron** or **temephos**, the DEH recommends that the APVMA should not be satisfied that under Australian scouring conditions and on the assumption that the label includes the current WHI the continued use of products containing these active constituents in accordance with existing approved label instructions would not be likely to have an unintended effect that is harmful to the Australian environment. On the basis of the DEH recommendation and in the absence of additional information, the APVMA proposes to find that an increase in the WHI will be required for products containing these active constituents to enable the APVMA to conclude that the use of products would not be likely to have an unintended effect that is harmful to the Australian environment.

The APVMA proposes to find that the continued use of products containing **diflubenzuron** on long wool cannot be supported. Therefore the APVMA proposes that label instructions for the continued use of diflubenzuron on wool more than seven days off shears be deleted, that the existing WHI of six months be deleted and a new label restraint statement and amended WHI statement be added that specifies these products must not be used on sheep more than seven days off shears:

> *Do not use this product on sheep that will be shorn with less than 12 months wool growth. Do not use this product on sheep with more than seven days wool growth at the time of treatment because use of this product in accordance with label instructions will leave residues of diflubenzuron on wool that may be harmful to the environment*

For sheep ectoparasiticide products containing **temephos** the APVMA proposes to find that the WHI should be increased from three months to six months. This increase in WHI will enable the APVMA to conclude that the use of products containing the active constituent temephos in accordance with label instructions would not be likely to have an unintended effect that is harmful to the Australian environment.

Should the APVMA find that some uses of sheep ectoparasiticide products containing **diazinon** may continue to be supportable following finalisation of the diazinon review, the APVMA will propose to find that labels for such products be amended to increase the WHI from two months to four months in order to be satisfied that the use of sheep ectoparasiticide products containing diazinon would not be likely to have an unintended effect that is harmful to the Australian environment.

Note that an assessment of the impact of residues of **chlorfenvinphos** on the environment and on trade has not been undertaken to date as part of this review because available information is limited. In addition, the separate review of chlorfenvinphos reached the interim outcome stage in 2000. Although regulatory actions were detailed in the interim review report for chlorfenvinphos, a product registrant provided additional data. Thus far the final outcomes for this review have not been proposed by the APVMA. Prior to completing this component of the review the APVMA proposes to determine whether adequate wool residue data or other information exist to enable a sheep rehandling interval to be set for chlorfenvinphos and then to determine if an environment and trade assessment is warranted, before finalising both the review of selected sheep ectoparasiticides and the review of chlorfenvinphos.

5.4 Trade findings

The assessment undertaken by the DEH in relation to processing of wool overseas concludes that chemical residues that result from the use of a number of sheep ectoparasiticide products in accordance with current approved label instructions could result in a breach of overseas environmental standards. This information, taken together with the fact that wool is a significant trade commodity that may be adversely affected by any breach of overseas environmental standards has enabled the APVMA to complete a trade risk assessment for this review.

With respect to the products which are the subject of this review, when used in accordance with current approved label instructions and under current use patterns, the APVMA proposes to find that it is not 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. 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 DEH as part of this review
3. There is limited information available regarding the implementation of the EU's IPPC directive and no information available regarding enforcement of directive requirements that may apply after October 2007
4. 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
5. There is no mechanism available in Australia to ensure that wool that is unsuitable for processing overseas is identified at point of sale.

Therefore, the APVMA proposes to find 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 before October 2007, because the EQSs may not be fully implemented prior to October 2007.

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 proposes to require 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 (EQSs) due to be implemented in 2007.*

5.5 Supplementary trade findings after October 2007

The APVMA is currently considering more than one possible future regulatory approach that may be applied after October 2007. The regulatory approach that will be adopted will depend on whether a wool residue advice scheme (WRAS) is in operation at that time.

At this stage there is little evidence to show that the wool industry in Australia is developing a WRAS. It may be necessary to consider regulatory label changes as outlined in Table 12, to be implemented if an undue trade prejudice occurs. Any regulatory restrictions of this kind could only be implemented after October 2007.

If a trade prejudice occurs and it is not possible to distinguish between low-residue wool and high-residue wool, all wool produced in Australia would need to contain low residues to be suitable for processing anywhere in the world. In the absence of a WRAS and under circumstances where an undue trade prejudice occurs, the APVMA is unlikely to be able to be satisfied that the continued use of product in accordance with label instructions would not unduly prejudice trade or commerce between Australia and places outside Australia. Column six (headed 'Post-Oct 2007 Environmental Outcome with WRAS (Potential trade assessment findings)') of Table 12 provides additional information on chemicals that may be affected by this finding.

The alternative regulatory approach after October 2007, dependent on an adequate WRAS, is also outlined in column seven of Table 12 (headed 'Post-Oct 2007 Environmental Outcome, without WRAS (Potential trade assessment finding)'). If a WRAS exists, label statements related to the environment and to trade could be more flexibly applied in practice. If an adequate WRAS exists before October 2007 such that any wool that contains significant chemical residues is identified at the point of sale to enable the wool processor to manage the residues on the wool, the APVMA proposes to find that it is satisfied that the use of products in accordance with label instructions would not unduly prejudice trade or commerce between Australia and places outside Australia.

5.6 Overall summary of proposed findings

The APVMA proposes to find that it is not satisfied that the continued use of, or any other dealing with the products listing in Appendix A 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, 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, particularly where overseas processor plants discharge scour effluent into river ecosystems.

However, the APVMA proposes to find that, with the exception of products containing deltamethrin, the labels for such products can be varied to include adequate statements to enable the APVMA to be satisfied in relation to occupational health and safety, the environment and trade. Therefore, the APVMA proposes that the label approvals for these products be varied to include additional label statements, as specified in Table 12.

In addition, provided that labels are varied as outlined above, with the exception of products containing deltamethrin, the APVMA proposes to affirm the product registrations for products listed in Appendix A.

5.7 Proposed findings that apply as a consequence of the review

As a consequence of the proposed findings of this review, the APVMA proposes to find that it is not satisfied that the continued use of or any other dealing with the products marked in Appendix A as not directly affected by the review:

- 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, particularly where overseas processor plants discharge scour effluent into river ecosystems.

However, the APVMA proposes to find that, with the exception of products containing deltamethrin the labels for such products can be varied to include adequate statements to enable the APVMA to be satisfied in relation to occupational health and safety, the environment and trade. Therefore, the APVMA proposes that, consistent with the outcomes of the review, the label approvals for these products be varied to include additional label statements, as specified in Table 12.

In addition, provided that labels are varied as outlined above, with the exception of products containing deltamethrin the APVMA proposes to affirm the product registrations for products listed in Appendix A.

Table 12 Summary of proposed preliminary outcomes for the review of selected sheep ectoparasiticides

Chemical class	Sheep rehandling interval (OHS assessment finding)	Australian WHI[28] statement (Environment assessment finding)	Pre-Oct 2007 Label WHI for trade (current trade assessment finding)	Post-Oct 2007 Environmental Outcome with WRAS[29] (Potential trade assessment finding)	Post-Oct 2007 Environmental Outcome, without WRAS (Potential trade assessment finding)
Alpha-cypermethrin	2 weeks	Delete all long wool claims. Add restraint statement against long wool use	Include general advisory statement on label	Amend advisory statement to specify if use is a potential risk to trade	Cancel all sheep products on trade grounds
Chlorfenvinphos	Delete all sheep claims on OHS grounds	Not completed as part of this review	Not completed as part of this review	Not completed as part of this review	Not completed as part of this review
Cypermethrin	2 weeks	Modify all products to ensure use is restricted to off-shears only. Add restraint statement against long wool use	Include general advisory statement on label. Trade risk will exist after Oct 2007	Amend advisory statement to specify if use is a potential risk to trade	Cancel all sheep products on trade grounds
Cyromazine	When sheep are dry following treatment	Affirm existing 2 months WHI is adequate for Australia, provided use does not increase	Include general advisory statement on label. Trade risk not yet defined	Amend advisory statement to specify use in 2 months before shearing is a potential risk to trade	Exclude use in 2 months before shearing on trade grounds
Deltamethrin	Cancel sheep products on OHS grounds	Add 2 months WHI statement if any uses continue	No label amendments required to address trade. Include nil trade risk statement[30]	No label amendments required to address trade	No label amendments required to address trade

[28] WHI = Wool harvesting interval, synonymous with WWP (Wool Withholding Period) and is the interval between the treatment of the animal with the ectoparasiticide and the harvesting of wool.
[29] WRAS = Wool Residue Advisory Scheme
[30] The proposed Overseas WHI statements are based on existing use levels. Since the APVMA cannot assume use levels will remain static, the APVMA proposes to include the general advisory statement on all labels.

Chemical class	Sheep rehandling interval (OHS assessment finding)	Australian WHI[28] statement (Environment assessment finding)	Pre-Oct 2007 Label WHI for trade (current trade assessment finding)	Post-Oct 2007 Environmental Outcome with WRAS[29] (Potential trade assessment finding)	Post-Oct 2007 Environmental Outcome, without WRAS (Potential trade assessment finding)
Diazinon	6 weeks	Add WHI statement where absent. Increase WHI to 4 months	Include general advisory statement on label. Trade risk not yet defined	Amend advisory statement to specify if use in 4 months before shearing is a potential risk to trade	Exclude use in 4 months before shearing on trade grounds
Dicyclanil	When sheep are dry following treatment	Affirm existing 3 months WHI is adequate for Australia provided use does not increase	Include general advisory statement on label. Trade risk is not yet defined	Amend advisory statement to specify if use in 2 months before shearing is a potential risk to trade	Exclude use in 2 months before shearing on trade grounds
Diflubenzuron	When sheep are dry following treatment	Restrict use to 7 days off shears use on environmental grounds Add restraint statement against use >7 days off shears	Include general advisory statement on label. Trade risk is not yet defined	Amend advisory statement to specify if use is a potential risk to trade	Cancel all sheep products on trade grounds
Ivermectin	When sheep are dry following treatment	Affirm existing 2 months WHI is adequate for Australia provided use does not increase	Include general advisory statement on label. Trade risk is not yet defined	Amend advisory statement to specify if use is a potential risk to trade	Cancel all sheep products on trade grounds
Propetamphos	6 weeks (dipping products) 12 weeks (jetting products)	Affirm existing 2 month WHI is adequate for Australia provided use does not increase	No label amendments required to address trade. Include nil trade risk statement	No label amendments required to address trade	No label amendments required to address trade
Temephos	When sheep are dry following treatment	Increase WHI to 6 months	No label amendments required to address trade. Include nil trade risk statement	No label amendments required to address trade	No label amendments required to address trade

Chemical class	Sheep rehandling interval (OHS assessment finding)	Australian WHI[28] statement (Environment assessment finding)	Pre-Oct 2007 Label WHI for trade (current trade assessment finding)	Post-Oct 2007 Environmental Outcome with WRAS[29] (Potential trade assessment finding)	Post-Oct 2007 Environmental Outcome, without WRAS (Potential trade assessment finding)
Triflumuron	When sheep are dry following treatment	Restrict use to existing approved 7 days off shears on environmental grounds. Add restraint statement against use >7 days off shears.	Include general advisory statement on label. Trade risk is not yet defined	Amend advisory statement to specify if use is a potential risk to trade	Cancel all sheep products on trade grounds

5.8 Application of review outcomes to specialty lines

It has been argued that the collection of lambswool, crutchings and sheepskins for fellmongering should be considered separately and that separate label instructions should be developed to address these special cases. However, such instructions are likely to result in significant complications to label instructions. Given that specialty lines are a minor part of the market, there is insufficient justification to consider separate label instructions to cover these situations. Rather, extra-label ancillary information for workers directly involved in the collection of specialty line wool and skins should be developed by registrants, similar to the way extra information is provided via material safety data sheets or technical notes, to enable appropriate information to be disseminated in such cases. Such ancillary information must be consistent with the findings of this review.

Anyone handling treated animals within the sheep rehandling interval should wear the personal protective equipment recommended on the product label so the use of the ectoparasiticide product will not result in an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues. If this is not practical, the use of the product on sheep intended for special treatment should not occur. In addition, any wool collected within the WHI would be likely to have an unintended effect that is harmful to the Australian environment and could unduly prejudice trade or commerce between Australia and places outside Australia. If such use is unavoidable, lambswool, crutchings or sheepskins should be identified at point of sale by a vendor declaration or certificate of analysis to enable the processor to manage the residues. The processing of specialty lines that have been collected within the WHI can only be supported if mechanisms to manage the identified environment/trade risks are in place.

5.9 Proposed label variations

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.

The APVMA is satisfied that the conditions of current label approval for the products in Appendix 1 can be varied in such a way that they do contain adequate instructions in accordance with section 14(3)(g) of the Agvet Codes (see Table 13 for the list of current label approval numbers).

Accordingly, the APVMA proposes that these labels must be modified.

5.10 Proposed label cancellations

The APVMA proposes to find that it is not satisfied that ‘old’ approved labels for currently registered products affected by this review contain adequate instructions and therefore proposes to cancel these label approvals (see Table 14 for the list of non-current label approval numbers).

The APVMA is now seeking comment on the regulatory approach outlined in this Preliminary Review Report. The closing date for comment is 31 October 2006.

Table 13 Label approval numbers to be varied to contain adequate instructions

Product number	Product name	Label approval number
Alpha-Cypermethrin and Cypermethrin		
38354	Vanquish Long Wool Spray-On Lice Treatment and Blowfly Strike Preventive for Long Wooled Sheep and Unshorn Lambs	0999
38355	Duracide Sustained Action Spray-On Lice Treatment for Shorn Sheep	0999
39065	WSD Spurt Off-Shears, Pour-On Sheep Lice Control	1200
39538	Cypercare Off-Shears Pour-On Sheep Body Lice Treatment	01
46245	Kleenklip Off-Shears High Volume Backline Treatment for Sheep Body Lice	0298
47845	Outflank Off-Shears Pour-On Sheep Lice Treatment	0501
54370	4Farmers Cypermethrin 25 Off-Shears, Pour-On Sheep Lice Control	0801
Cypermethrin + Chlorfenvinphos		
46815	Coopers Blockade 'S' Cattle Dip and Spray	0204
Cyromazine		
39979	Vetrazin Spray-On Sheep Blowfly Treatment	0703
49852	Vetrazin Liquid Sheep Blowfly Treatment	0703
49995	Cyrazin Liquid Sheep Blowfly Treatment	0703
50179	Vital Crystal Cyromazine 500 Sheep Blowfly Treatment	1099
52107	Farmoz Cyromazine 500 SC Sheep Blowfly Treatment	1199
52552	Virbac Virbazine Spray-On Sheep Blowfly Treatment	1000
52669	Virbac Virbazine Liquid Sheep Blowfly Treatment	0902
52729	Cyrazin Spray on Sheep Blowfly Treatment	0703
52745	Venus Spray-On Sheep Blowfly Treatment	0904
52967	Cyro-Fly 500 Blowfly Treatment for Sheep	1200
53023	Venus Liquid Sheep Blowfly Treatment	0804
53393	Jetrite Liquid Sheep Blowfly Treatment	1000
54189	Sprayrite Spray-On Sheep Blowfly Treatment	0501
54685	Coopers Clout Blowfly Jetting/Dipping Liquid for Sheep	1101
56440	Cyro-Fly 60 Spray-On Sheep Blowfly Treatment	1102
57930	Grow Force Cyromazine Liquid Sheep Blowfly Treatment	0603
58519	Young's Cyromazine Spray-On Sheep Blowfly Treatment	0204
58810	Young's Cyromazine Liquid Sheep Blowfly Treatment	0604

Product number	Product name	Label approval number
Diazinon		
33475	Coopers Di-Jet Sheep Dip/Jetting Fluid, Cattle and Pig Spray	01
33867	Coopers Mulesing Powder Insecticide	02
37640	KFM Blowfly Dressing	0805
38874	Virbac Jetdip Sheep Jetting Fluid & Blowfly Dressing	0499
38897	Virbac Mulesing and Fly Strike Powder	0303
39572	WSD Diazinon for Sheep, Cattle, Goats and Pigs	1100
39573	WSD Fly Strike Powder to Control Flystrike and for Wound Dressing for Animals	0401
39574	WSD Mulesing Powder Wound Dressing Following Mules Operation General Wound Dressing for Sheep, Cattle and Goats	0401
42611	Virbac Kleen-Dok with Diazinon an Insecticidal Wound Dressing for Cuts and Abrasions in Sheep and Cattle	1299
46231	Coopers Fly Strike Powder Insecticide	0105
45591	Di-Shield Sheep Dip & Jetting Fluid Cattle Goat and Pig Spray	02
46295	Coopers 4-in-1 Dip	1202
49854	Topclip Blue Shield Sheep Dip, Jetting Fluid and Blowfly Dressing	01
50544	Diprite Constant Concentration Dipping for Sheep	0200
51290	Eureka Gold OP Spray-On Off-Shears Sheep Lice Treatment	0805
Dicyclanil		
50005	Click Spray-On Blowfly Treatment	0802
Dicyclanil + Diflubenzuron		
58306	Magik Spray-On Sheep Blowfly and Lice Treatment	0505

Product number	Product name	Label approval number
Diflubenzuron		
45968	Fleececare Insect Growth Regulator for Sheep Dipping and Jetting	0403
48741	Coopers Strike Insect Growth Regulator for Sheep Dipping and Jetting	02
50036	Backlash Pour On Lousicide for Sheep	1002
51359	Coopers Magnum IGR Pour-On Sheep Lice and Blowfly Destroyer	0505
53113	Virbac Duodip Treatment for Sheep Body Lice and Sheep Blowfly	0600
53268	Diflu Off-Shears IGR Pour-On for Sheep	0800
54279	Crusader Insect Growth Regulator for Sheep Dipping	0701
56368	Zenith Pour On Lousicide for Sheep	1203
Ivermectin		
45623	Jetamec Jetting Fluid Concentrate	0602
53127	Coopers Paramax Multi-Purpose Concentrate for Sheep	0702
Propetamphos		
39554	Nufarm Mules'n Mark II Blowfly Dressing	01
39887	Nufarm Seraphos 360 Dip and Jetting Fluid for Sheep	01
40138	Young's Deadmag Blowfly Strike Dressing Fluid	0302
51444	Ectomort Plus Lanolin Sheep Dip	0302
Temephos		
47568	Coopers Assassin Sheep Dip	0598
Triflumuron		
45636	Zapp Pour-On Lousicide for Sheep	1104
52466	Epic Pour-On Lousicide for Sheep	0704
53344	Virbac IGR Pour-On for Sheep and Lambs	1202
53823	Clipguard Pour-On Lousicide for Sheep	1004
55485	4Farmers Triflumuron 25 Pour On Lousicide for Sheep	0105
56254	WSD Command Pour-On Lousicide for Sheep	0504
56807	Exit Pour-On Lousicide for Sheep	1004
57928	Grow Force IGR Pour-On Lice Control for Sheep and Lambs	0605
Spinosad		
56734	Elanco AH0498 Extinosad Aerosol for Wounds	0804
56875	Elanco AH0492 Extinosad Lice, Fly and Maggot Eliminator	0403

Table 14 Label approval numbers to be cancelled as not containing adequate instructions

Product number	Product name	Label approval number
Alpha-Cypermethrin and Cypermethrin		
38354	Vanquish Long Wool Spray-On Lice Treatment and Blowfly Strike Preventive for Long Wooled Sheep and Unshorn Lambs	01 02
38355	Duracide Sustained Action Spray-On Lice Treatment for Shorn Sheep	01
47845	Outflank Off-Shears Pour-On Sheep Lice Treatment	01
Cypermethrin + Chlorfenvinphos		
46815	Coopers Blockade 'S' Cattle Dip and Spray	01 1200
Cyromazine		
39979	Vetrazin Spray-On Sheep Blowfly Treatment	0298 0500
49852	Vetrazin Liquid Sheep Blowfly Treatment	01
49995	Cyrazin Liquid Sheep Blowfly Treatment	0902
52669	Virbac Virbazine Liquid Sheep Blowfly Treatment	0101
52729	Cyrazin Spray on Sheep Blowfly Treatment	0700 1002
56440	Cyro-Fly 60 Spray-On Sheep Blowfly Treatment	0902
Deltamethrin		
36340	Coopers Clout-S Backline Lice Treatment	01 02 0103
55856	Arrest Lice Pour-On Treatment for Sheep	0602

Product number	Product name	Label approval number
Diazinon		
33867	Coopers Mulesing Powder Insecticide	01
38897	Virbac Mulesing and Fly Strike Powder	0101
42611	Virbac Kleen-Dok with Diazinon an Insecticidal Wound Dressing for Cuts and Abrasions in Sheep and Cattle	0498
46231	Coopers Fly Strike Powder Insecticide	01 02 03
45591	Di-Shield Sheep Dip & Jetting Fluid Cattle Goat and Pig Spray	01
46295	Coopers 4-in-1 Dip	01
51290	Eureka Gold OP Spray-On Off-Shears Sheep Lice Treatment	1298
Dicyclanil		
50005	Click Spray-On Blowfly Treatment	0899 0998
Dicyclanil + Diflubenzuron		
58306	Magik Spray-On Sheep Blowfly and Lice Treatment	0804
Diflubenzuron		
45968	Fleececare Insect Growth Regulator for Sheep Dipping and Jetting	01 02 03 1200 0701 17925
48741	Coopers Strike Insect Growth Regulator for Sheep Dipping and Jetting	01
50036	Backlash Pour On Lousicide for Sheep	0101
51359	Coopers Magnum IGR Pour-On Sheep Lice and Blowfly Destroyer	0100 0200 0201 0202 0402 0505 0603 0702
Ivermectin		
53127	Coopers Paramax Multi-Purpose Concentrate for Sheep	0501
Propetamphos		
40138	Young's Deadmag Blowfly Strike Dressing Fluid	0198
51444	Ectomort Plus Lanolin Sheep Dip	1198

Product number	Product name	Label approval number
Temephos		
47568	Coopers Assassin Sheep Dip	01 02 0498 18453
Triflumuron		
45636	Zapp Pour-On Lousicide for Sheep	01 0498 0499 0798 1003 1103
52466	Epic Pour-On Lousicide for Sheep	0502 0903
53344	Virbac IGR Pour-On for Sheep and Lambs	0101
53823	Clipguard Pour-On Lousicide for Sheep	0401 0503
55485	4Farmers Triflumuron 25 Pour On Lousicide for Sheep	0702
56254	WSD Command Pour-On Lousicide for Sheep	1002
56807	Exit Pour-On Lousicide for Sheep	0203 0603
Spinosad		
56734	Elanco AH0498 Extinosad Aerosol for Wounds	0104

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APPENDIX A. Sheep ectoparasiticide products included in the review[31]

Product number	Product name	Registrant	Registered uses
Alpha-Cypermethrin and Cypermethrin			
38354	Vanquish Long Wool Spray-On Lice Treatment and Blowfly Strike Preventive for Long Wooled Sheep and Unshorn Lambs	Schering Plough Pty Ltd	Controls body lice on sheep and lambs; prevents body strike
38355	Duracide Sustained Action Spray-On Lice Treatment for Shorn Sheep	Schering Plough Pty Ltd	Controls body lice off-shears
39065	WSD Spurt Off-Shears, Pour-On Sheep Lice Control	Rebop Holdings Pty Ltd	Controls body lice off-shears
39538	Cypercare Off-Shears Pour-On Sheep Body Lice Treatment	Virbac (Australia) Pty Ltd	Controls body lice off-shears
46245	Kleenklip Off-Shears High Volume Backline Treatment for Sheep Body Lice	Virbac (Australia) Pty Ltd	Controls body lice off-shears
47845	Outflank Off-Shears Pour-On Sheep Lice Treatment	Fort Dodge Australia Pty Ltd	Controls body lice off-shears
54370	4Farmers Cypermethrin 25 Off-Shears, Pour-On Sheep Lice Control	4Farmers Pty Ltd	Controls body lice off-shears

[31] This list includes products that were not included in the review at the start of the review but are subject to the outcomes of the review and recently discontinued products that are undergoing phase-out.
Products that were nominated at the start of the review and are directly affected by the outcomes of the review are identified with underscored product numbers.
Products that are no longer registered are identified with *italic* product numbers.

Product number	Product name	Registrant	Registered uses
Cypermethrin + Chlorfenvinphos			
46815	Coopers Blockade 'S' Cattle Dip and Spray	Schering Plough Pty Ltd	Controls cattle ticks, and buffalo flies on horses, deer, goats, sheep and working dogs
Cyromazine			
39979	Vetrazin Spray-On Sheep Blowfly Treatment	Novartis Animal Health Australasia Pty Ltd	Protects long wool sheep against fly strike
49852	Vetrazin Liquid Sheep Blowfly Treatment	Novartis Animal Health Australasia Pty Ltd	Protects long wool sheep from strike by blowflies
49995	Cyrazin Liquid Sheep Blowfly Treatment	Ancare Australia Pty Ltd	Protects long wool sheep from strike by blowflies
50179	Vital Crystal Cyromazine 500 Sheep Blowfly Treatment	Langey Holdings Pty Ltd	Protects long wool sheep from strike by blowflies
52107	Farmoz Cyromazine 500 SC Sheep Blowfly Treatment	Norbrook Laboratories Australia Pty Ltd	Controls long wool sheep from strike by blowflies
52552	Virbac Virbazine Spray-On Sheep Blowfly Treatment	Virbac (Australia) Pty Ltd	Protects long wool sheep against fly strike by blowflies
52669	Virbac Virbazine Liquid Sheep Blowfly Treatment	Virbac (Australia) Pty Ltd	Controls long wool sheep from strike by blowflies
52729	Cyrazin Spray on Sheep Blowfly Treatment	Ancare Australia Pty Ltd	Controls long wool sheep from strike by blowflies
52745	Venus Spray-On Sheep Blowfly Treatment	Norbrook Laboratories Australia Pty Ltd	Controls long wool sheep from strike by blowflies

Product number	Product name	Registrant	Registered uses
52967	Cyro-Fly 500 Blowfly Treatment for Sheep	Jurox Pty Ltd	Controls long wool sheep from strike by blowflies
53023	Venus Liquid Sheep Blowfly Treatment	Norbrook Laboratories Australia Pty Ltd	Controls blowfly strike in long wool sheep
53393	Jetrite Liquid Sheep Blowfly Treatment	Captec Proprietary Limited	Protects long wool sheep from strike by blowflies
54189	*Sprayrite Spray-On Sheep Blowfly Treatment*	Merial Australia Pty Ltd	Protects long wool sheep against fly strike
54685	Coopers Clout Blowfly Jetting/Dipping Liquid for Sheep	Schering Plough Pty Ltd	Controls long wool sheep from strike by blowflies
56440	Cyro-Fly 60 Spray-On Sheep Blowfly Treatment	Jurox Pty Ltd	Protects long wool sheep against fly strike
57930	*Grow Force Cyromazine Liquid Sheep Blowfly Treatment*	Joranimo Pty Ltd	Controls long wool sheep from strike by blowflies
58519	Young's Cyromazine Spray-On Sheep Blowfly Treatment	Novartis Animal Health Australasia Pty Ltd	Protects long wool sheep against fly strike
58810	Young's Cyromazine Liquid Sheep Blowfly Treatment	Novartis Animal Health Australasia Pty Ltd	Controls long wool sheep from strike by blowflies
Deltamethrin			
36340	Coopers Clout-S Backline Lice Treatment	Schering Plough Pty Ltd	Controls body lice off-shears and keds
55856	Arrest Lice Pour-On Treatment for Sheep	Intervet Australia Pty Ltd	Controls body lice on sheep off-shears, and lice on goats

Product number	Product name	Registrant	Registered uses
Diazinon			
33475	Coopers Di-Jet Sheep Dip/Jetting Fluid, Cattle and Pig Spray	Schering Plough Pty Ltd	Controls body lice, ked and blowflies on short wool sheep; lice and buffalo flies on cattle, lice on goats, and mange on pigs
33867	Coopers Mulesing Powder Insecticide	Schering Plough Pty Ltd	Controls fly strike at mulesing and lamb marking
37640	KFM Blowfly Dressing	Pharmtech Pty Limited	Treats blowfly strike on sheep
38874	Virbac Jetdip Sheep Jetting Fluid & Blowfly Dressing	Virbac (Australia) Pty Ltd	Controls sheep blowfly; protects sheep against body lice and ked; dressing for marking wounds
38897	Virbac Mulesing and Fly Strike Powder	Virbac (Australia) Pty Ltd	Treats fly strike; prevents fly strike in wounds in sheep and cattle
39572	WSD Diazinon for Sheep, Cattle, Goats and Pigs	Rebop Holdings Pty Ltd	Controls blowfly strike in sheep; controls and protects sheep against lice and ked; controls lice on cattle, pigs and goats
39573	WSD Fly Strike Powder to Control Flystrike and for Wound Dressing for Animals	Rebop Holdings Pty Ltd	Controls fly strike in sheep cattle and goats; wound dressing
39574	WSD Mulesing Powder Wound Dressing Following Mules Operation General Wound Dressing for Sheep, Cattle and Goats	Rebop Holdings Pty Ltd	General wound dressing for sheep, cattle and goats
42611	Virbac Kleen-Dok with Diazinon an Insecticidal Wound Dressing for Cuts and Abrasions in Sheep and Cattle	Virbac (Australia) Pty Ltd	Wound dressing for cuts and abrasions in sheep and cattle; protects against blowfly strike

Product number	Product name	Registrant	Registered uses
45591	Di-Shield Sheep Dip & Jetting Fluid Cattle Goat and Pig Spray	Jurox Pty Ltd	Controls blowfly strike, lice and ked on short wool sheep; lice and buffalo flies on cattle, lice on pigs and goats
46231	Coopers Fly Strike Powder Insecticide	Schering Plough Pty Ltd	Controls fly strike on sheep; general wound dressing
46295	Coopers 4-in-1 Dip	Schering Plough Pty Ltd	Controls lice, ked, itch mites and blowfly strike on short wool sheep
49854	Topclip Blue Shield Sheep Dip, Jetting Fluid and Blowfly Dressing	Novartis Animal Health Australasia Pty Ltd	Controls blowfly strike, lice and ked on sheep
50544	Diprite Constant Concentration Dipping for Sheep	Captec Proprietary Limited	Controls body lice and ked on short wool sheep
51290	Eureka Gold OP Spray-On Off-Shears Sheep Lice Treatment	Zagro Animal Health Pty Ltd	Controls body lice on sheep off-shears
Dicyclanil			
50005	Click Spray-On Blowfly Treatment	Novartis Animal Health Australasia Pty Ltd	Protects sheep with any length wool against fly strike; protection of mulesing and marking wounds against fly strike
Dicyclanil + Diflubenzuron			
58306	Magik Spray-On Sheep Blowfly and Lice Treatment	Novartis Animal Health Australasia Pty Ltd	Protects sheep against fly strike; controls and treats body lice on sheep off-shears or within 7 days of shearing

Product number	Product name	Registrant	Registered uses
Diflubenzuron			
45968	Fleececare Insect Growth Regulator for Sheep Dipping and Jetting	Intervet Australia Pty Ltd	Controls and treats body lice on short wool and long wool sheep; controls blowfly
48741	*Coopers Strike Insect Growth Regulator for Sheep Dipping and Jetting*	Schering Plough Pty Ltd	Controls and treats body lice on short wool sheep; controls blowfly
50036	*Backlash Pour On Lousicide for Sheep*	Intervet Australia Pty Ltd	Controls and treats body lice on sheep off-shears
51359	Coopers Magnum IGR Pour-On Sheep Lice and Blowfly Destroyer	Schering Plough Pty Ltd	Controls and treats body lice on sheep off-shears and unshorn lambs up to 3 months old; controls blowfly on long wool sheep
53113	Virbac Duodip Treatment for Sheep Body Lice and Sheep Blowfly	Virbac (Australia) Pty Ltd	Controls and treats body lice on short wool and long wool sheep; controls blowfly
53268	Diflu Off-Shears IGR Pour-On for Sheep	Schering Plough Pty Ltd	Controls and treats body lice on sheep off-shears
54279	Crusader Insect Growth Regulator for Sheep Dipping	Intervet Australia Pty Ltd	Controls and treats body lice on short wool sheep
56368	Zenith Pour On Lousicide for Sheep	Intervet Australia Pty Ltd	Controls and treats body lice on sheep off-shears

Product number	Product name	Registrant	Registered uses
Ivermectin			
45623	Jetamec Jetting Fluid Concentrate	Merial Australia Pty Ltd	Prevents and treats blowfly strike; treats biting lice on long wool sheep
53127	Coopers Paramax Multi-Purpose Concentrate for Sheep	Schering Plough Pty Ltd	Treats and protects against blowfly strike; treats biting lice on long wool sheep
Propetamphos			
39554	Nufarm Mules'n Mark II Blowfly Dressing	Pharmtech Pty Limited	Protects sheep against fly strike
39887	Nufarm Seraphos 360 Dip and Jetting Fluid for Sheep	Captec Proprietary Limited	Controls lice and keds on sheep; assists in controlling fly strike on sheep
40138	Young's Deadmag Blowfly Strike Dressing Fluid	Arysta Lifescience North America Corporation	Treats and protects against fly strike
51444	*Ectomort Plus Lanolin Sheep Dip*	Arysta Lifescience North America Corporation	Controls body lice on short wool sheep; assists in controlling fly strike
Temephos			
47568	Coopers Assassin Sheep Dip	Schering Plough Pty Ltd	Controls body lice on short wool sheep; treats body lice on long wool sheep

Product number	Product name	Registrant	Registered uses
Triflumuron			
45636	Zapp Pour-On Lousicide for Sheep	Bayer Australia Ltd	Controls body lice on sheep up to 7 days off-shears and on unshorn lambs up to 3 months old
52466	Epic Pour-On Lousicide for Sheep	Jurox Pty Ltd	Controls body lice on sheep up to 7 days off-shears and on lambs at foot
53344	Virbac IGR Pour-On for Sheep and Lambs	Virbac (Australia) Pty Ltd	Controls body lice on sheep up to 7 days off-shears and on unshorn lambs up to 2 months old
53823	Clipguard Pour-On Lousicide for Sheep	Novartis Animal Health Australasia Pty Ltd	Controls body lice on sheep up to 7 days off-shears and on lambs at foot
55485	4Farmers Triflumuron 25 Pour On Lousicide for Sheep	4Farmers Pty Ltd	Controls body lice on sheep up to 7 days off-shears and on lambs at foot
56254	WSD Command Pour-On Lousicide for Sheep	Rebop Holdings Pty Ltd	Controls body lice on sheep up to 7 days off-shears and on lambs at foot
56807	Exit Pour-On Lousicide for Sheep	Jurox Pty Ltd	Controls body lice on sheep up to 7 days off-shears and on lambs at foot
57928	*Grow Force IGR Pour-On Lice Control for Sheep and Lambs*	Joranimo Pty Ltd	Controls body lice on sheep up to 7 days off-shears and on unshorn lambs up to 2 months old

Product number	Product name	Registrant	Registered uses
Spinosad			
56734	Elanco AH0498 Extinosad Aerosol for Wounds	Elanco Animal Health	Controls lice on sheep in short and long wool and protects against flystrike
56875	Elanco AH0492 Extinosad Lice, Fly and Maggot Eliminator	Elanco Animal Health	Treats and protects against flystrike