Australian Pesticides &
Veterinary Medicines Authority

The reconsideration of approval of the active constituent Endosulfan, registrations of products containing Endosulfan and their associated labels.

Draft FINAL REVIEW REPORT
Summary Report

May 2004

Australian Pesticides &
Veterinary Medicines Authority

Canberra
Australia

This review report for the active constituent Endosulfan and products containing Endosulfan is published by the Australian Pesticides and Veterinary Medicines Authority. For further information about this review or the Pesticides Review Program, contact:

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FOREWORD

The APVMA (*1) is an independent statutory authority with responsibility for the regulation of agricultural and veterinary chemicals in Australia. Its statutory powers are provided in the *Agricultural and Veterinary Chemicals Code Act, 1994* (Agvet Codes).

The APVMA can reconsider the approval of active constituents, the registration of chemical products or the approval of labels for containers of chemical products at any time. This is specified in Part 2, Division 4 of the Agvet Codes.

The basis for the reconsideration is whether the APVMA is satisfied that continued use of the active constituent endosulfan and products containing endosulfan in accordance with the instructions for their use:

- would not be an undue hazard to the safety of people exposed to it during its handling; and/or
- would not be likely to have an effect that is harmful to human beings; and /or
- would not be likely have an unintended effect that is harmful to animals, plants or things or to the environment; and/or
- would not unduly prejudice trade or commerce between Australia and places outside Australia.

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 process for reconsideration 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 reviews, the APVMA works in close cooperation with advisory agencies including the Department of Health and Aging, the Department of Environment and Heritage, the National Occupational Health and Safety Commission, and State Departments of Agriculture as well as other expert advisors, 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. Under this program it is proposed that countries receiving these reports will not utilise them for registration purposes unless they are also provided with the raw data from the relevant applicant.

This document contains the draft Summary Report of *'The reconsideration of approval of the active constituent Endosulfan, registrations of products containing Endosulfan and their associated labels'* and relates to all products containing endosulfan. The review's findings and recommendations 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 the methods of assessment undertaken.

The draft review report containing the APVMA preliminary assessments (The NRA Review of Endosulfan, Volume I, August 1998) and the technical reports from its advisory agencies (Volume II) for all registrations and approvals relating to endosulfan are available from the APVMA website: http://www.apvma.gov.au/chemrev/chemrev.shtml.

(*1) Prior to March 2003, the APVMA was known as the National Registration Authority for Agricultural and Veterinary Chemicals (NRA). In this report, the name APVMA is generally used even when referring to the organisation prior to March 2003.

COMMENT FROM THE PUBLIC IS INVITED

The APVMA invites persons and organisations to submit their comments and suggestions on this draft review report directly to the APVMA. Your comments will assist the APVMA in preparing the final report.

The draft review report consists of a Review Summary which outlines the APVMA review process, gives information to the public about how to respond to the review, summarises the technical assessments from the reviewing agencies and outlines the proposed regulatory action to be taken in relation to the continued registration of endosulfan products. It also contains the full technical assessment reports from the National Occupational Health and Safety Commission, the APVMA Chemistry & Residues Program, and the Department of Health and Aging Office of Chemical Safety.

PREPARING YOUR COMMENTS FOR SUBMISSION

You may agree or disagree with or comment on as many elements of the 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 Review Summary or the technical report. This will help the APVMA 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: 30 JULY 2004

Your comments should be mailed to:

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GLOSSARY OF TERMS AND ABBREVIATIONS

AAAA	Australian Aerial Agricultural Association
ACAHS	Australian Centre for Agricultural Health & Safety
ADI	Acceptable Daily Intake
a.i.	Active Ingredient
ai/100L	active ingredient per 100 Litres
aPAD	Acute Population Adjusted Dose
ARfD	Acute Reference Dose
ATV	All Terrain Vehicles
BCF	Bioconcentration Factor
bw	Body weight
CAS	Chemical Abstracts Service
CNS	Central Nervous System
CP	Pressure control nozzles
cPAD	Chronic Population Adjusted Dose
C-PAS	Centre for Pesticide Application Safety
CRDC	Cotton Research & Development Corporation
CRP	Chemical Review Program
CXL	Codex Maximum Residue Level
d	Days
DFR	Dislodgeable Foliar Residue
EC	Emulsifiable concentrate
ECRP	Existing Chemical Review Program (APVMA)
EPA	US Environmental Protection Agency
ER	Oestrogen Receptor
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FOB	Functional Observation Battery
FQPA	Food Quality Protection Act
g	Gram
g ai/ha	grams of active ingredient per hectare
GAP	Good Agricultural Practice
HPA	Hypothalamic-pituitary-adrenal
HPG	Hypothalamic-pituitary-gonadal
HPT	Hypothalamic-pituitary-thyroid
HRs	Highest Residues
IPM	Integrated Pest Management
kg	Kilogram
L	Litre
LOAEL	Lowest Observed Adverse Effect Level
LOD	Limit of Detection
LOEL	Lowest Observable Effect Level
MFL	Maximum Feed Level
mg	Milligram
mg/kg	milligrams per kilogram
mL	Millilitre
M/L	Mixing/loading
M/L/A/C	Mixing/loading/application/cleaning

MOE	Margins of Exposure
MRL	Maximum Residue Limits
NEDI	National Estimated Dietary Intake
NESTI	National Estimated Short Term Intake
NOAEL	No Observed Adverse Effect Level
NOEC	No Observable Effect Concentration
NOEL	No Observable Effect Level
NOHSC	National Occupational Health & Safety commission
OCS	Office of Chemical Safety
OHS	Occupational Health and Safety
OP	Organophosphorus compound
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PADI	Provisional Acceptable Daily Intake
PF	Processing Factor
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	parts per million
PVC	Polyvinyl chloride
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RLEM	Red Legged Earth Mite
SHBG	Sex hormone–binding globulin
STMRs	Supervised Trial Median Residues
SUSDP	Standards for the Uniform Scheduling of Drugs and Poisons
TC	Transfer Coefficient
TGA	Therapeutic Goods Administration
TGAC	Technical Grade Active Constituent
ULV	Ultra-low Volume
US EPA	United States Environment Protection Authority
WHP	With Holding Period

EXECUTIVE SUMMARY

Introduction

Endosulfan is a broad-spectrum insecticide/acaricide, which has been registered in Australia for control of a large variety of insects and mites in horticultural and agricultural crops, including cotton, cereal, oilseeds, fruit, vegetables and other crops. It has been widely used in Australia for over 35 years. Endosulfan products are not registered for home garden use.

There are five product registrations all of which are for emulsifiable concentrates. All of these product registrations are currently under suspension, and instructions for use have been issued under specified conditions.

Alternative products are available for all use patterns, although endosulfan has a number of important advantages in that it is inexpensive, soft on beneficial insects, and provides a different chemistry useful in resistance management. It is expected that increasing use of genetically modified cotton will reduce reliance on pesticides such as endosulfan.

Previous Reconsideration Action

In November 1995, the APVMA announced its decision to reconsider approvals and registrations associated with endosulfan. The review was initiated because of concerns regarding possible health and environmental effects, and residues in commodities.

An interim report of this review was released in 1998 that recommended a number of changes to the registered uses for endosulfan. The interim report also required additional Occupational Health & Safety (OH&S) and residues data to be provided, and set targets for reduction in endosulfan levels in surface waters. Subsequently, the endocrine disruption potential for endosulfan was also reassessed. This draft Final Review Report, *The reconsideration of approval of the active constituent Endosulfan, registrations of products containing Endosulfan and their associated labels*, April 2004, considers the assessment of this additional information.

During the period 1998 to 2001, the APVMA implemented a range of changes to the registrations and label approvals of endosulfan products. These changes were implemented to address risks associated with protection of the environment, worker safety and residues in commodities. Some of the principal changes included:

- declaring endosulfan products to be restricted chemical products;
- requiring users of endosulfan to undertake specified training;
- restricting the number of applications for endosulfan per season.

Subsequently, following reports of endosulfan residues in beef as a result of spray drift, the APVMA imposed mandatory buffer zones, required neighbourhood notification before application to cotton, and ultimately cancelled the registration of ultra-low volume endosulfan products.

Further action by the APVMA resulted in additional restrictions on the use of endosulfan. These were given effect by suspending product registrations and label approvals, and issuing new instructions for the supply and use of the suspended products. The primary concerns were potential health effects and violation of domestic and international Maximum Residue Level (MRL).

Occupational Health and Safety Assessment

As an outcome of the interim report of the endosulfan review, additional worker exposure data was generated under Australian conditions for workers conducting a range of tasks. These involved

operations for treating nursery, orchard and broadacre crops by ground and aerial applications and re-entry to broadacre crops.

The evaluation of this data found that acceptable occupational exposure safety margins could be achieved for all registered nursery, orchard and broadacre uses, with a re-entry period of 2 days for use on cotton, 5 days for use on pecans and 3 days for all other uses. New requirements for personal protective equipment (PPE) for various tasks were specified.

Residues Assessment

In response to the requirements of the interim report, additional residues studies were submitted to assess dietary exposure and trade risks from endosulfan use. The initial findings from these studies led to interim action in 2002 to suspend existing endosulfan products, with new instructions for supply and use of the suspended products.

Following full assessment of the residues data, uses will be deleted on the basis either of no data being submitted, dietary exposure risk, or trade risk. This includes the late spray for many broadacre crops, and some uses for horticulture crops.

A key issue from the review is the potential for by-products of cotton (and legume vegetables) that have been treated with endosulfan to be fed to livestock and cause residue violations in the meat. In assessing these uses of endosulfan, two alternative approaches are considered in the draft report:

1. continue to permit uses, with a label restraint against uses where crops will or may be fed to livestock; or
2. delete these uses because of the risk of violative residues in meat.

During the public consultation period the APVMA will actively seek comment from key stakeholders on the two options, to help resolve this matter.

The APVMA will also seek assurances that, should uses on cotton be retained, appropriate and effective safeguards can and will be put in place to protect against violative residues in meat, and so protect Australia's meat trade.

Water quality monitoring

The interim report noted relatively high levels of endosulfan contamination in surface waters in cotton growing areas, so targets were set to reduce levels of contamination. Results of river monitoring have shown a significant reduction for endosulfan contamination since 1999, demonstrating that measures put in place by the APVMA and the cotton industry, along with other factors such as the introduction of genetically modified (insect resistant) cotton, have been effective in reducing endosulfan contamination.

Endocrine disruption

Whilst the interim report found no evidence of endocrine disruption caused by endosulfan, following a US EPA RED (Reregistration Eligibility Decision) report in 2002 that identified endosulfan as "a potential endocrine disruptor", the initial conclusions were reassessed. Following this reassessment, it was again concluded that the endocrine disrupting potential of endosulfan is not a significant risk to public health under the existing management controls and health standards.

Summary of review recommendations

As an outcome of the review, a number of uses would no longer be permitted, including some horticultural uses and the late spray uses for broadacre crops.

The proposed recommendations are that all product registrations for endosulfan will be affirmed, however, product labels will be varied by deleting uses that are no longer permitted, adding new label instructions and amending the maximum residue levels, withholding periods and safety directions for retained product uses.

It is proposed that there be further public consultation before finalising the decision on the continued use of endosulfan for cotton and legume vegetables.

Approvals for the active constituent endosulfan were affirmed as an interim outcome of the review in 1998.

1. INTRODUCTION

The APVMA has completed its review of the active constituent endosulfan, products containing endosulfan and the associated labels. The purpose of this document is to provide a summary of the most recent data evaluated (subsequent to the interim report, see section 2.1, which can be accessed on the APVMA website: http://www.apvma.gov.au/chemrev/chemrev.shtml.), and of the regulatory decisions reached as a result of the review of endosulfan.

1.1 REGULATORY STATUS OF ENDOSULFAN IN AUSTRALIA

Endosulfan is a broad-spectrum insecticide/acaricide that has been registered in Australia for control of a large variety of insects and mites in horticultural and agricultural crops, including cotton, cereal, oilseeds, fruit, vegetables and other crops. It has been widely used in Australia for over 35 years. Endosulfan products are not registered for home garden use.

Endosulfan is an organochlorine chemical, but unlike most other members of this class, it has relatively low persistence in the soil and in animal and human tissue. It also has the benefit of relatively low toxicity to many species of beneficial insects, which prevent population explosions of damaging pests, which in turn would require higher levels of harsher pesticides to control.

Prior to the APVMA review of endosulfan, approximately 900 tonnes of technical grade endosulfan was imported annually into Australia. The greatest use was in cotton (approximately 70%), followed by vegetables (approximately 20%). Since commencement of the review, endosulfan usage has decreased significantly as a result of interim measures put in place by the APVMA and industry. The introduction of transgenic Bt cotton (genetically altered) is also likely to have a continuing impact on the amount of endosulfan used by the cotton industry.

Current Product information

There are five endosulfan product registrations, all of which are for emulsifiable concentrates. All of these registrations are currently under suspension, and instructions for use have been issued for use under specified conditions.

Three of the products (32799, 45570, 45838) are included in the review. Two products (50004, 52163) were registered subsequent to announcement of the review, but are subject to the outcome as a condition of registration:

Product Number	Name of Product	Label Number(s)
32799 *	Nufarm Endosulfan 350 EC Insecticide	32799/0899 32799/0400 32799/1000 32799/0301 32799/0801
45570 *	Thionex 350 EC Insecticide Spray [Makhteshim-Agan (Australia) Pty Ltd]	45570/0299 45570/1099
45838 *	Endosan Emulsifiable Concentrate Insecticide [Crop Care Australasia Pty Ltd]	45838/0899 45838/0300 45838/0800
50004 #	Thiodan EC Insecticide [Bayer Cropscience Pty Ltd]	50004/0899 50004/1099 50004/0702
52163 #	Farmoz Endosulfan 350 EC Insecticide	52163/0899

* included in the review # registered subsequently, but subject to outcome of the review.

1.2 REASONS FOR ENDOSULFAN REVIEW

The review of endosulfan was initiated because of concerns from its use regarding possible health and environmental effects and residues in commodities. Since commencement of the review, and following release of the interim report in 1998, a number of changes were made to the registered uses for endosulfan.

The interim report also required additional OH&S and residues data to be provided, and set targets for reduction in endosulfan levels in surface waters. The potential for endosulfan being an endocrine disruptor has also been reassessed. This draft final report considers the assessment of this additional information.

1.3 SCOPE OF THE REVIEW

The initial scope of this review in 1995 covered the active approvals, product registrations and use patterns, and associated labels. The review was conducted to determine whether the APVMA could be satisfied that the continued use of products containing endosulfan in accordance with the instructions for their use would not be likely to have any unintended effects that would impact on occupational health and safety, public health, trade and the environment, and whether labels contain adequate instructions.

1.4 REGULATORY OPTIONS

The basis for a reconsideration of the registration and approvals for a chemical is whether the APVMA is satisfied that the requirements prescribed by the Agvet Codes for continued registration and approval are being met. In the case of endosulfan, these requirements are that the use of the active constituents and products in accordance with the instructions for its use:

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

The requirements for product labels are that the label contains adequate instructions. Such instructions include:

- the circumstances in which the product should be used;
- how the product should be used;
- the times when the product should be used;
- the frequency of the use of the product;
- the withholding period after the use of the product;
- the disposal of the product and its container;
- the safe handling of the product.

There are three possible outcomes to the reconsideration of endosulfan active constituents, products and associated labels. Based on the information reviewed the APVMA may be:

- satisfied that the actives, products and their labels continue to meet the prescribed requirements for registration and approval and therefore confirms the registrations and approvals.

- satisfied that the conditions to which the registration or approval is currently subject can be varied in such a way that the requirements for continued registration and approval will be complied with and therefore varies the conditions of registration or approval.
- not satisfied that the requirements for continued registration and approval continue to be met and suspends or cancels the registrations and/or approvals.

2 BACKGROUND

2.1 PREVIOUS REVIEW ACTION

Interim Report

In November 1995, the APVMA announced its decision to reconsider approvals and registrations associated with endosulfan, in the first cycle of the Existing Chemicals Review Program (ECRP). In June 1998, following a comprehensive review of endosulfan, the APVMA released its interim report "*The NRA Review of Endosulfan (August 1998)*".

Approvals for the active constituent endosulfan were affirmed as an interim outcome of the review in 1998. Following the interim report, endosulfan use was substantially restricted. Measures to address the safety of agricultural workers, the environment, and the need to verify residue limits were important outcomes of the review, and relevant label changes were required to take effect by 30 June 1999.

Some minor changes to public health standards were recommended, resulting in a reduction of the acceptable daily intake (ADI).

These controls were considered necessary for the continued use of endosulfan. Existing uses were allowed to remain on an interim basis while new data was generated to support uses in the longer term.

A summary of the changes and restrictions arising from the Interim Review are shown in Table 2.1.

TABLE 2.1:
Summary of APVMA regulatory actions for endosulfan determined in June 1998

Key Issues	Regulatory Actions
Control of access	• Endosulfan declared a restricted chemical. • Endosulfan products must not be supplied to a person who is not authorised. Authorised persons require training certification.
Environmental contamination of streams and rivers	• Targets set for reduction in endosulfan levels in surface waters in cotton growing areas. Agreed to as a 25% reduction in number of measurements in upper quartile of past stream concentration values. Continued use of endosulfan contingent upon meeting those targets by 30 June 2001. • Maximum of 2 sprays (or equivalent) per season limit, unless growers could contain irrigation water or storm runoff water (up to 25mm of rainfall) on their farms. • Cotton growers to follow the cotton industry *Best Management Practices Manual*, which focuses on reducing risks to the environment, workers and neighbours.

	• New label statement requiring auditable spray records be kept. • New label statements prohibiting application during irrigation, rain or during weather conditions likely to increase spray drift.
Insufficient worker exposure data	• Requirement for the generation of worker exposure data for certain agricultural uses of endosulfan, under Australian conditions, by 31 December 1999. • New label statement promoting use of enclosed cabs for ground spray applications. • New label statement specifying a 2-day re-entry period. • New label safety directions.
Insufficient residues data in commodities	• Requirement to generate residue data by 30 June 2000 to support existing uses.
Potential for meat residues	• Restrictions placed on orchard grazing and feeding treated crop products to cows producing milk for human consumption. • Labels changed to include recommended withholding periods for use of crop by-products or fodder as animal feed.

During the period 1998 to 2002, the APVMA implemented a range of additional interim changes to the registrations and label approvals of endosulfan products. These changes were implemented to address a number of immediate risks identified during the course of the review.

Endosulfan residue crisis in exported beef of late 1998 and early 1999

In November and December 1998, endosulfan residue problems in beef emerged in cotton growing areas. These problems were severe enough to affect Australia's reputation with its international trading partners and to threaten the viability of segments of the domestic beef industry.

As a result, in March 1999 the APVMA mandated additional changes to all labels to avoid undue prejudice to Australia's international beef trade. These changes, effective from 1 July 1999, were to apply only to use on cotton and were in addition to the changes already required as a result of the outcomes of the interim report. The most significant new restrictions imposed were as follows:

- An absolute limit of 3 sprays (or equivalent) of endosulfan per cotton crop per season;
- Endosulfan to be applied by air only during specified time windows (15 Nov. to 15 Jan. for EC, 1 Dec. to 15 Jan. for ULV);
- Aerial application restricted to crops over a specified height;
- Mandatory downwind buffer zones required unless neighbour gives written permission to waive buffer;
- Mandatory prior notification of neighbours in all directions surrounding the sprayed area;
- Use of high-volume, large-droplet-placement technology required for all EC applications whether by air or by ground.

Spray drift from ULV products

In March 2001, the APVMA cancelled all registrations and label approvals for ULV products because of further concern over contamination of livestock from spray drift and the resulting risk to Australia's export trade.

Further action arising from additional residues data

As discussed above, additional residues data were required as an outcome of the interim report. Following assessment of this additional data, two areas of immediate concern were identified and addressed. These related to human dietary risk from eating pears, Brussels sprouts or leafy vegetables, and prejudice to Australia's international meat trade arising from endosulfan residues.

As part of the actions to address these concerns, the APVMA suspended product registrations and label approvals of all (5) endosulfan products in September 2002, and undertook recall action. New instructions for use were issued to allow continued supply of suspended product that specified prohibited crop uses, new withholding period statement for pears and numerous feeding restraints.

2.2 OVERSEAS REGULATORY STATUS

North America

In the United States endosulfan is registered for similar use patterns as in Australia.

In 2002, the US EPA released a RED (Re-registration Eligibility Decision). Following an assessment of data, it was determined that endosulfan products pose occupational and ecological risks. However, the US EPA believes that these risks can be mitigated through measures that include deletion of some uses, reduction in maximum application rates, inclusion of buffer zones, all products to be restricted, use of closed mixing/loading systems, use of closed cabs for certain situations, and increases to re-entry intervals. The US EPA is also requiring additional data to confirm this decision.

Canada is also conducting a re-evaluation of endosulfan, which should be completed in 2006. Canada is closely monitoring the outcomes of US regulatory actions.

Europe

Endosulfan products are registered for use in a number of EU countries (including UK), but are either restricted or banned in some others. A re-evaluation of endosulfan products is currently in preparation by the EU.

JMPR

Endosulfan was previously evaluated by JMPR for residues and toxicology in 1993. A re-evaluation is proposed based on residues, for September 2005.

2.3 ALTERNATIVE PRODUCTS

Alternative products to endosulfan are available for all use patterns. However, endosulfan has a number of important advantages in that it is:

- inexpensive;
- soft on beneficial insects, thus minimising post-application population explosion of harmful insects;
- a different chemistry, useful for resistance management.

It is anticipated that increasing use of genetically modified cotton will reduce reliance on pesticides such as endosulfan in future.

3. RESIDUES & TRADE ASSESSMENT

3.1 INTRODUCTION

The 1998 endosulfan interim report identified requirements for additional residue data to support existing uses and MRLs. As an outcome of the interim report, temporary MRLs were recommended for a number of crops to allow additional data to be generated.

Interim regulatory action in conjunction with the temporary MRLs, included limiting the number of applications of endosulfan per season to all crops and introducing residue management strategies with regular surveillance and monitoring in targeted areas. Crop withholding period statements were developed together with animal management statements, to allow treated animal feed commodities to be used whilst managing residues in livestock.

The following additional data requirements were determined:

- *Animal feeds* – data for forages, fodder or hays of such plants as cereals (including sorghum and maize), pastures, canola, sunflowers, legume vegetables, potato, peanuts, and legume crops.
- *Human foods* – data for all commodities that were assigned a temporary MRL in the MRL Standard.
- *Processing studies* – cereals, fruits (citrus, apples and grapes), cotton and other oilseeds.
- *Animal commodities* – animal transfer studies in cattle and poultry, including analyses of milk and eggs, respectively.

Where the requested data were not submitted and MRLs could not be supported or established, the uses would be deleted.

Supplementary residues data received by the APVMA were evaluated and an interim residues report was completed in September 2002. Recommendations in the interim report led to the suspension of existing endosulfan products and new instructions were issued for the supply and use of suspended products. These instructions included prohibited crop uses, a new withholding period statement for pears and numerous feeding restraints. The suspension notice is attached in Residues Appendix 1.

In this report, the supplementary data received by the APVMA are reviewed and form the basis of residues conclusions for final regulatory action.

3.1.1 Current MRLs and Label Withholding Period Statements

The current MRLs for endosulfan are listed below:

Table 1[1]

Code	Food Commodity	MRL (mg/kg)
FI 0026	Assorted tropical and sub-tropical fruits – edible peel	T2
FT 0030	Assorted tropical and sub-tropical fruits – inedible peel	T2
FB 0018	Berries and other small fruits	T2
VB 0400	Broccoli	T2
VB 0041	Cabbages, head	T2
VB 0404	Cauliflower	T2
GC 0080	Cereal grains	T0.2
FC 0001	Citrus fruits	T2
OC 0691	Cotton seed oil, crude	T0.5
MO 0105	Edible offal (mammalian)	T0.2
PE 0112	Eggs	T*0.05
VC 0045	Fruiting vegetables, cucurbits	T2
VO 0050	Fruiting vegetables, other than cucurbits	T2
VP 0060	Legume vegetables	T2

[1] Maximum Residue Limits of agricultural and veterinary chemicals and associated substances in food commodities.

MM 0095	Meat (mammalian)[in the fat]	0.2
ML 0106	Milks [in the fat]	T0.5
SO 0088	Oilseed	T1
VA 0385	Onion, bulb	T0.2
FP 0009	Pome fruits	T2
PO 0111	Poultry, edible offal of	0.2
PM 0110	Poultry meat [in the fat]	0.2
VD 0070	Pulses	T1
GC 0649	Rice	T0.1
VR 0075	Root and tuber vegetables	T2
VA 0388	Shallots	T2
VS 0078	Stalk and stem vegetables	T2
FS 0012	Stone fruits	T2
DT 1114	Tea, Green, Black	T30
TN 0085	Tree nuts	T2

As part of the interim regulatory action in 1998, the MRL for leafy vegetables (including Brassica leafy vegetables was deleted and the MRL for Brassica (cole and cabbage) vegetables, head cabbages, flowerhead Brassica was deleted and replaced with individual entries for broccoli, cabbage and cauliflower. These changes were associated with concerns regarding short-term dietary exposures.

Table 4[2]

Code	**Animal Feed Commodity**	**MRL (mg/kg)**
	Primary feed commodities	0.3

The following withholding period statements and feeding restraints are present on existing product labels, specifically for residue management in crops and in particular livestock that are fed treated crops and crop fractions.

Withholding period statements and feeding restraints

Beetroot, cucurbits, green beans, green peas, tomatoes – ***DO NOT HARVEST FOR 2 DAYS AFTER APPLICATION***

Cape gooseberry, capsicums, carrots, eggplant, okra, onions, peanuts, potatoes, shallots, sweet corn, sweet potatoes, taro – ***DO NOT HARVEST FOR 7 DAYS AFTER APPLICATION***

Avocados, bananas, berry fruit, blueberries, cashews, citrus, currants and related fruit, custard apples, grapes, guavas, kiwifruit, longans, lychees, macadamias, mammey apples, mangoes, passion fruit, pawpaws, pecans, persimmons, pistachios, pome fruit, pomegranates, rambutans, raspberries, sapodillas, strawberries, tamarillos – ***DO NOT HARVEST FOR 14 DAYS AFTER APPLICATION***

Adzuki beans, canola (oilseed rape), cereals, chickpeas, cotton, cowpeas, faba beans, field peas, fodder crops (clover, chou moellier, lucerne, medics, peas), linseed, lupins, maize, mung beans, oilseeds, pastures, pigeon peas, safflower, sorghum, soybeans, sunflowers, vetch – ***DO NOT HARVEST FOR 4 WEEKS AFTER APPLICATION***

FOR ANIMAL FEEDS

[2] Recommended maximum residue limits for pesticides in animal feed commodities.

(INCLUDING PULSES, VEGETABLES, VEGETABLE AND FRUIT WASTES, FODDER AND FORAGE):

DO NOT RE-APPLY WITHIN 7 DAYS

DO NOT GRAZE ORCHARDS AFTER APPLICATION

Pasture Forage and Pasture Seed Crops – ***DO NOT GRAZE OR CUT FOR STOCKFOOD FOR 4 WEEKS AFTER APPLICATION. FOR FOLIAR APPLICATIONS, A 42 DAYS SLAUGHTER INTERVAL APPLIES.***

DO NOT FEED TREATED CROPS OR CROP PARTS (EXCEPT COTTONSEED/MEAL) TO LACTATING COWS PRODUCING MILK FOR HUMAN CONSUMPTION.

Where there has been at least 4 weeks since the last endosulfan application, the following slaughter intervals are still required to avoid Maximum Residue Limit violations.

Crop/Commodity	***Observed Crop Harvest WHP***	***Required Animal Management***
Cottonseed/meal	*4 weeks*	*Nil slaughter interval*
Apples & apple pomace	*4 weeks*	*42 day slaughter interval*
Grain legumes & pulse fodder/stubble	*4 weeks*	*42 day slaughter interval (foliar application only)*
Cereal grains	*4 weeks*	*Nil slaughter interval*
Cereal fodder/stubble	*4 weeks*	*42 day slaughter interval*
Pasture seed legumes	*4 weeks*	*42 day slaughter interval*
Tropical and sub-tropical fruits & fruit by-products	*4 weeks*	*42 day slaughter interval*
Legume vegetables	*4 weeks*	*42 day slaughter interval*
Other vegetables (e.g. leafy vegetables)	*4 weeks*	*42 day slaughter interval*
Citrus & citrus pulp	*4 weeks*	*42 day slaughter interval*

Note below that maize and sorghum fodder require at least an 8 week WHP combined with a 42 day slaughter interval to avoid Maximum Residue Limit violations. For certain commodities where the WHPs shown below have been observed, the following animal management measures are still required to avoid Maximum Residue Limit violations.

Crop/Commodity	***Observed Crop Harvest WHP***	***Required Animal Management***
Cotton trash	*Not applicable*	*Do not feed to animals*
Green beans, green peas	*2 days*	*Do not feed to animals*
Maize grain	*8 weeks*	*Nil slaughter interval*
Maize fodder	*8 weeks*	*42 day slaughter interval*
Other vegetables (beetroot, cucurbits and tomato)	*2 days*	*Do not feed to animals*
Peanut hay	*7 days*	*42 day slaughter interval*
Sorghum grain	*8 weeks*	*Nil slaughter interval*
Sorghum fodder	*8 weeks*	*42 day slaughter interval*

The following withholding periods and feeding restraints were introduced as part of the suspension of endosulfan products in September 2002:

Withholding periods and feeding restraints introduced in September 2002

Pears: Do Not Harvest for 28 Days After Application

Do Not Feed Apple Pomace, Citrus Pulp/Peel, Grape Marc/Pomace To Livestock

Do Not Feed Pea Vines or Bean Trash to Livestock

Do Not Feed Fodder, Stubble Or Hay of Pulse Crops (Adzuki Beans, Chickpeas, Cow Peas, Faba Beans, Field Peas, Lupins, Mung Beans, Navy Beans and Pigeon Peas) To Livestock

Do Not Feed Treated Cow Peas, Field Peas and Pigeon Peas to Livestock

Do Not Feed Cereal Grains to Livestock

Do Not Feed Straw, Fodder or Trash from Treated Cereal Crops To Livestock

Do Not Feed Sunflower Seed, Safflower Seed or Linseed to Livestock

Do Not Feed Fodder, Stubble or Trash from Oilseed Crops (Canola, Cotton, Linseed, Peanuts, Safflower, Soya Beans, Sunflowers) To Livestock

Do Not Feed Cotton Fodder, Stubble or Trash To Livestock

Do Not Cut for Stockfeed or Allow Livestock to Graze: vetch, lucerne (seed crops), medics (seed crops), clover (seed crops), chou moellier, forage cereals and pastures (all with heliothis use rates)

Do Not Feed Wrapper Leaves of Brassica and Cole Crops (Cabbage, Cauliflower and Broccoli) or Sweet Corn Trash to Livestock

Do Not Feed To Livestock Any Treated Commodity Mentioned Above Which Has Been Bailed or Used in Silage

3.1.2 Label Use Patterns

Crop use patterns as shown on revised interim labels are given in Residues Appendix 2.

3.2 DISCUSSION

In response to the interim regulatory requirements for endosulfan, metabolism studies, animal transfer studies, supervised crop trials, storage stability and processing studies have been submitted. The findings from those studies and associated recommendations are discussed in the following sections.

3.2.1 Citrus fruit

Data for oranges, mandarins and lemons were provided from trials conducted in Australia, Italy, Greece and Spain. Data for processed commodities such as juice and pomace were also submitted.

Registered use patterns in citrus allow spraying at concentrations ranging from 20 g ai/100L (spined citrus bug, bronze orange bug) to 70 g ai/100L or 735 g ai/ha (heliothis, citrus plant hopper, leaf hopper), with a 14 day withholding period. However, the citrus industry provided data for a lower spray concentration to better reflect current practices in the industry. Therefore the new 1× and 2× spray concentrations are 10.5 and 21 g ai/100L, with a proposed withholding period of 3 days.

Overseas data were generated using spray concentrations of 37.5 and 112.3 g ai/100L, which are in excess of the new citrus use pattern. These data are not suitable for establishment of an MRL, however the processing information can be used to determine processing factors (PF) for juice and pomace.

Data for oranges, mandarins and lemons were generated in Australia. The data corresponding to the proposed GAP are summarised below:

Commodity, Trial	Spray Conc.	WHP	Total residues (mg/kg)
Oranges, Vic	10.5 g ai/100L	3	0.049
	21 g ai/100L	3	0.22
Oranges, SA	10.5 g ai/100L	3	0.078
	21 g ai/100L	3	0.034 (pulp); 0.38 (peel)
Lemons, Vic	10.5 g ai/100L	3	0.17
	21 g ai/100L	3	0.70
Lemons, Qld	10.5 g ai/100L	3	0.033
	21 g ai/100L	3	<0.02 (pulp); 0.36 (peel)
Lemons, SA	10.5 g ai/100L	3	0.16∗
	21 g ai/100L	3	0.34
Mandarins, Qld	10.5 g ai/100L	3	0.11
	21 g ai/100L	3	0.18
Mandarins, SA	10.5 g ai/100L	3	0.071
	21 g ai/100L	3	0.14

∗ Level of 0.036 mg/kg present in untreated control sample.

Residues in citrus fruit range from 0.033 to 0.17 mg/kg at 3 days following application at the 1× spray concentration. Residues in citrus fruit are in rank order: 0.033, 0.049, 0.071, 0.078, 0.11, 0.16 and 0.17 mg/kg. An MRL of 0.3 mg/kg is recommended for citrus fruit with highest residues (HR) of 0.078, 0.11 and 0.17 mg/kg for oranges, mandarins and lemons, respectively and a supervised trial medium residues (STMR) of 0.078 mg/kg.

In the overseas trials, spray concentrations of 37.5 and 112.3 g ai/100L (3.6× or 10.7×) were employed. Endosulfan residues in pulp, peel, juice and pomace were reported. In nine overseas trials, there was a 6-fold difference between residues found in peel vs whole fruit. In two Australian trials however, the difference between peel and whole fruit was 2-fold.

Residues in juice were <0.02 mg/kg in three orange trials; the mean PF was 0.12. The mean PF for wet pomace was 2.3. To estimate the livestock exposure from feeding of dry pomace, an STMR-P of 0.45 mg/kg is calculated (0.08 mg/kg × 2.3 = 0.18 mg/kg wet wgt; 0.45 mg/kg dry weight). This figure is included in the livestock dietary burden table (section 2.18).

Using an HR of 0.17 mg/kg in whole fruit and the PF for pomace, residues in wet pomace would be 0.17 × 2.3 = 0.39 mg/kg or 0.97 mg/kg on a dry weight basis. An MRL of 2 mg/kg is recommended for citrus pulp and pomace, dry.

3.2.2 Pome fruit

The current use pattern for pome fruit is application at 66.5 g ai/100L with a withholding period of 14 days. Residues data were provided from trials conducted in Australia, Italy, France and Spain. Processing data for juice, cider and pomace were also submitted.

Overseas data for apples were generated using spray concentrations of 56.5 and 113 g ai/100L (0.8× and 1.7×). In the Australian trials, 1× and 2× spray concentrations were used on apples and pears. The data that are comparable to GAP are tabulated below:

Commodity, Trial	Spray Conc.	WHP	Total residues (mg/kg)
Apples, NSW	66.5 g ai/100L	14	0.29
		21	0.27
		14	0.38
Apples, Qld	66.5	14	0.53
Apples, Spain	56.5 g ai/100L	12	0.03

		21	<0.01
		28	<0.01
Apples, Spain	56.5 g ai/100L	12	0.05
		21	0.06
		28	<0.01
Apples, France	57 g ai/100L	13	<0.01
		21	<0.01
		28	<0.01
Apples, Italy	56.5 g ai/100L	14	0.23
		21	0.14
		28	0.11
Apples, Italy	56.5 g ai/100L	14	0.04
		21	0.08
		28	0.03
Pears, Vic	66.5 g ai/100L	14	0.79
		21	0.42
Pears, SA	66.5 g ai/100L	14	0.44
		21	0.37

Allowing for a ±30% difference in spray concentration at 14 days, the following residues correspond to GAP in rank order: <0.01, 0.03, 0.04, 0.05, 0.23, 0.29, 0.38, 0.44, 0.53 and 0.79 mg/kg. Based on the data at 14 days, the current temporary MRL of 2 mg/kg is appropriate with an HR of 0.53 mg/kg for apples[3] and 0.79 mg/kg for pears.

Applying the HR value for pears in the short-term dietary estimates, the intake exceeds the acute reference dose (ARfD) for the 2 – 6 year group and approaches the ARfD for the general population (99%). To refine the short-term estimate, the horticulture industry agreed to extend the withholding period for apples and pears from 14 days to 28 days.

The HR for apples at 28 days after treatment is 0.11 mg/kg, from trial data generated in Italy. For pears, the highest residues expected at 28 days would be 0.21 mg/kg, using extrapolation from Australian trial data.

It is recommended that the current temporary MRL of 2 mg/kg be amended to 1 mg/kg with a withholding period of 28 days. An STMR is not estimated for the group.

Residues in apple juice in a single Australian trial were 0.022 mg/kg and residues in cider from Italian trials were <0.01 mg/kg. The PFs for juice and cider were 0.06 and 0.04, respectively.

The mean processing factor for wet pomace, calculated from three trials including one Australian trial, is 2.1. Using a HR of 0.11 mg/kg for apples (28 days), residues in wet pomace will approximate 0.23 mg/kg. A processing factor of 5.8 is calculated in the Australian trial for dry pomace. Therefore applying the dry pomace factor to the HR gives a value of 0.64 mg/kg for dry pomace. An MRL of 1 mg/kg is recommended for apple pomace, dry.

3.2.3 Grapes

Currently, there is a temporary MRL of 2 mg/kg for berries and other small fruits, which corresponds to registered uses of endosulfan on grapes, currants, blueberries and strawberries. Overseas data were provided for grapes and processed commodities. The registered use pattern for grapes allows application at a spray concentration of 66.5 g ai/100L with a withholding period of

[3] Data from the National Residues Survey monitoring program indicated that total endosulfan residues found in apples ranged from 0.05 mg/kg to 0.26 mg/kg. These data were obtained from 1238 samples over the period of 1998 – 2003; various varieties were sampled. The limit of reporting was 0.05 mg/kg.

14 days. In trials conducted in Italy and Spain, concentrations of 113 g ai/100L were employed. As the spray concentrations in the studies do not correspond to GAP in Australia, the data do not support existing use patterns. Therefore, the use pattern for grapes should be deleted from all product labels. Similarly, as data were not provided for other berry fruit such as blueberries, currants and strawberries, these uses must also be deleted from product labels. It is recommended that the temporary MRL for berries and other small fruits be withdrawn from the MRL Standard.

3.2.4 Tropical and sub-tropical fruits – inedible peel

The Codex crop group for tropical fruits – inedible peel includes avocados, bananas, custard apples, kiwifruit, longans, lychees, mammey, mangoes, passionfruit, pawpaw, persimmon, pomegranate, rambutan, sapodilla and tamarillo, all of which are included on registered product labels. Supplementary residues data were generated recognising that there was no support for use on bananas, and that extrapolation would be made for minor crops from the data set provided. In addition, extended withholding periods of 28 days were requested for mangoes and persimmons, and a shorter withholding period of 7 days for lychees to better reflect current industry practices.

Australian residues data were provided for avocado, custard apples, mangoes, pawpaw, persimmon and lychees. GAP in Australia is application at spray concentrations of 52.5 – 70 g ai/100L with withholding periods of 14 or 28 days, depending on the fruit.

Residues data which correspond to GAP for the various fruits, are summarised below:

Commodity, Trial	Spray Conc.	WHP (days)	Total residues (mg/kg)
Avocado, Qld	70 g ai/100L	14	0.02
Avocado, Qld	70 g ai/100L	14	0.065
Custard apple, Qld	70 g ai/100L	14	0.09
Custard apple, Qld	70 g ai/100L	14	0.18
Mango, NSW	70 g ai/100L	28	0.09
Mango, Qld	70 g ai/100L	28	0.16
Mango, Qld	70 g ai/100L	28	0.22
Pawpaw, Qld	70 g ai/100L	14	0.13
Pawpaw, Qld	70 g ai/100L	14	0.053
Persimmon, Qld	70 g ai/100L	28	0.50
Persimmon, Qld	70 g ai/100L	28	0.72
Lychee, Qld	52.5 g ai/100L	7	0.95, 1.62①
Lychee, Qld	52.5 g ai/100L	7	0.84, 1.16①

① Two replicate samples combined and analysed.

The portion of the commodity to which the MRL applies is the whole commodity after removal of the stone or seed, but calculated on a whole fruit basis.

Looking at the data across the whole group, residues are in rank order: 0.02, 0.053, 0.065, 0.09 (2), 0.13, 0.16, 0.18, 0.22, 0.50, 0.72, 0.84, 0.95, 1.16 and 1.62 mg/kg. On the basis of the data provided, the temporary (T) MRL of T2 mg/kg is appropriate for the whole group, with respect to proposed use patterns. The highest residues for avocado, custard apple, mango, pawpaw, persimmon and lychee are 0.065, 0.18, 0.22, 0.13, 0.72 and 1.62 mg/kg, respectively. For the group, an STMR of 0.18 mg/kg is estimated. It should be noted that tamarillo is to be included in this group.

3.2.5 Bulb vegetables

The current MRLs for endosulfan on bulb vegetables are T0.2 mg/kg for onions and T2 mg/kg for shallots. These correspond to application at a maximum rate of 735 g ai/ha and withholding periods

of 7 days. As residues data for these crops (or any bulb vegetable) have not been provided, the existing use patterns and temporary MRLs will be deleted as they are no longer supported.

3.2.6 Brassica vegetables

Australian data were provided for broccoli, cauliflower, cabbage, and Brussels sprouts. Registered use patterns allow application at 735 g ai/ha or 66.5 g ai/100L with a withholding period of 2 days (cole crops). The horticulture industry has requested a withholding period of 7 days for Brassica vegetables. Data that correspond to GAP in Australia are summarised below:

Commodity, Trial	Spray Conc.	WHP (days)	Total residues (mg/kg)
Broccoli, Qld	66.5 g ai/100L	7	0.29
Broccoli, VIC	66.5 g ai/100L	7	0.17
Cauliflower, WA	66.5 g ai/100L	7	0.10
Cauliflower, VIC	66.5 g ai/100L	7	0.016
		7	0.094
Cabbage, Qld	66.5 g ai/100L	7	0.098
Cabbage, VIC	66.5 g ai/100L	7	0.031
		7	0.026
Brussels sprouts, SA	66.5 g ai/100L	7	1.9
Brussels sprouts	6.5 g ai/100L	7	0.14

Residues in Brassica at day 7 are in rank order: 0.016, 0.026, 0.031, 0.094, 0.098, 0.10, 0.14, 0.17, 0.29 and 1.9 mg/kg. Highest residues in broccoli, cauliflower and cabbage are 0.29, 0.1 and 0.098 mg/kg, respectively. The highest residue of 1.9 mg/kg in Brussels sprouts was found following application at 1.8× the maximum rate; scaling for rate, residues of 1.05 mg/kg are estimated at 7 days. Taking into consideration the high value, and only one other data point at GAP for Brussels sprouts, it is recommended that the Brussels sprouts use pattern be removed from product labels. On the basis of the data provided for broccoli, cabbage and cauliflower, MRLs of 1 mg/kg are recommended for broccoli, head cabbage and cauliflower. An STMR of 0.096 mg/kg is estimated for the chronic dietary exposure for broccoli, cauliflower and cabbage.

3.2.7 Cucurbits

Endosulfan is registered for use on cucurbits, with application at 66.5 g ai/100L and a withholding period of 2 days. Residues data were provided from trials conducted in Australia, Italy and Spain. In the overseas trials in melons, residues were determined in the pulp, peel and whole fruit. The horticulture industry requested that the current withholding period be extended from 2 days to 7 days. Data corresponding to Australian GAP are summarized below:

Commodity, Trial Site	Spray Conc. (g ai/100L)	WHP (days)	Total residues (mg/kg)
Musk melon, Italy	56.5	7	<0.15 (whole fruit)
			<0.15 (pulp)
			0.29 (peel)
Musk melon, Italy	56.5	7	0.19 (whole fruit)
			<0.15 (pulp)
			0.49 (peel)
Rockmelon, VIC	66.5	7	0.23
Cucumber, NSW	66.5	7	0.12
Cucumber, Qld	66.5	7	0.094
Zucchini, NSW	66.5	7	0.088
Zucchini, Qld	66.5	7	0.037
Zucchini, Qld	66.5	7	0.08
Zucchini, WA	66.5	7	0.025

Using ±30% allowance in the spray concentration, Italian data in melons can be compared to the Australian spray concentration of 66.5 g ai/100L. Residues in the edible portion of the musk melon were <0.15 mg/kg in all of the overseas trials, at spray concentrations ranging 1 – 2.8× the Australian spray concentration. The level of 0.08 mg/kg may be used in the estimates of dietary exposure, both short-term and chronic.

Residues in cucurbits at 7 days after application, are in rank order: 0.025, 0.037, 0.080, 0.088, 0.094, 0.12, <0.15, 0.19 and 0.23 mg/kg. An MRL of 0.5 mg/kg is recommended for cucurbits with a withholding period of 7 days. The HRs in rockmelon, cucumber and zucchini are <0.15 (pulp) or 0.23 (whole fruit), 0.12 and 0.088 mg/kg, respectively and the STMR is 0.094 mg/kg for the group.

3.2.8 Fruiting vegetables

Australian data were provided for capsicum, tomato, eggplant and sweet corn as being representative members of the crop group, which also includes okra and cape gooseberry. The current use pattern is application at 66.5 g ai/100L or 735 g ai/ha and withholding periods of 2 days for tomatoes and 7 days for cape gooseberries, capsicums, eggplant, okra and sweet corn.

The horticulture industry has requested a withholding period of 3 days for capsicums and 14 days for tomatoes.

In the residue trials the application rates employed were 1× and 2× the maximum application rate, with sampling intervals up to 14 days. The data that correspond to GAP (proposed) are summarised below:

Commodity, Trial Site	Rate (g ai/ha)	WHP (days)	Total residues (mg/kg)
Capsicum, Qld	735	3	0.16
Capsicum, Qld	735	7	0.089
Capsicum, Vic	735	7	0.037
Capsicum, SA	735	3	0.40
Tomatoes, Qld	735	14	<0.02
Tomatoes, Qld	735	14	<0.02
Tomatoes, Vic	735	14	0.038
Tomatoes, NSW	735	14	0.020
Eggplant, NSW	735	7	<0.02
Eggplant, Qld	735	7	0.055
Eggplant, Vic	735	7	<0.02
Eggplant, Qld	735	7	<0.02
Sweet corn, Qld	735	7	<0.02
Sweet corn, Vic	735	7	<0.02
Sweet corn, NSW	735	7	<0.02

Residues that correspond to GAP are in rank order: <0.02 (8), 0.02, 0.038, 0.055, 0.16 and 0.40 mg/kg. The HRs for capsicum, tomato, eggplant and sweet corn are 0.40, 0.038, 0.055 and 0.02 mg/kg, respectively, with an STMR of 0.02 mg/kg. An MRL of 1 mg/kg is recommended for the fruiting vegetables group.

In relation to sweet corn fodder/trash, the following restraint was included as part of the interim regulatory action for endosulfan:

- *Do Not Feed Sweet Corn Trash To Livestock.*

On registered product labels, there had previously been no directions regarding the feeding of sweet corn fodder or trash to livestock. As data specifically for sweet corn fodder or trash were not provided, some extrapolation can be made from sorghum forage and trash. The use pattern for

sorghum is detailed in section 2.14 under cereal crops, where application is at 735 g ai/ha with a withholding period of 4 weeks. Endosulfan residues in sorghum forage/fodder ranged from 3 to 79 mg/kg in samples taken at 26 to 35 days after two applications. As the withholding period for sweet corn is 7 days, it is possible that residues in sweet corn fodder/trash may be even higher than the levels found in sorghum forage/fodder at 26 to 35 days.

As there was no previous feeding restraint regarding sweet corn fodder/trash and it is typical practice for sweet corn fodder to be used as a livestock feed, it is recommended that the sweet corn use pattern be deleted from product labels, as the likely exposure to livestock from sweet corn fodder and trash may be at levels that are unacceptable in relation to existing animal commodity MRLs. Deletion of the use pattern does not result in a change to the MRL or STMR for the crop group.

3.2.9 Leafy vegetables

The Codex classification for leafy vegetables includes Brassica leafy vegetables and crops such as chard (silverbeet), chinese cabbage, choi sum, leafy lettuce varieties (cos lettuce, endive, rocket), cress, japanese greens (mizuna, indian mustard, komatsuna), head lettuce, spinach, pak choi, bok choi and a variety of other salad greens. Australian residues data were provided for bok choi, silverbeet, and leafy lettuce, which are considered representatives of the crop group.

In addition to the data that were generated in Australia there were several published reports of endosulfan residues in leafy vegetables, which are summarised in Residues Appendix 3. These include JMPR data (1989), review articles and information available from published papers.

The current registered uses of endosulfan on leafy vegetables (cole crops and leaf vegetables), silverbeet and spinach include application at 735 g ai/ha or 66.5 g ai/100L with withholding periods of 2 days for cole crops and silverbeet and 7 days for spinach. There is no specific withholding period statement for other leafy crops, where the use pattern is listed as *cabbages, cauliflower & other cole crops & leaf vegetables* on some product labels. For the purposes of data interpretation, the withholding period closest to label directions is taken as being nil or 0 days.

The data that correspond to GAP are summarised below:

Commodity, Trial Site	Spray conc. (g ai/100L)	WHP (days)	Total residues (mg/kg)
Bok choi, Vic	66.5	0	3.4
Bok choi, Qld	66.5	0	29
Silverbeet, Vic	66.5	0	6.1
Silverbeet, Qld	66.5	0	18
Leafy lettuce, Vic	66.5	0	3.4
Leafy lettuce, Vic	514 g ai/ha	0	16
Leafy lettuce, NSW	66.5	0	16
Leafy lettuce, NSW	66.5	0	6.5
Leafy lettuce, Qld	66.5	0	1.54

There is a large variation in the residues present in the different crops, with levels ranging 1.54 – 29 mg/kg. As there is no clear withholding period statement for leafy vegetables, the 0 day data are taken as being reflective of the levels that would be found at harvest in some members of the crop group. The residues are in rank order: 1.54, 3.4 (2), 6.1, 6.5, 16 (2), 18 and 29 mg/kg.

Using the mean 0 day values from overseas data for the various leafy crops and scaling for the Australian application rate, estimated endosulfan residues in chard, spinach, leaf lettuce, head lettuce, endive and cos lettuce ranged from 7.9 mg/kg to 20 mg/kg. This range of values is

comparable to the 0 day data from the Australian trials in silver beet and leafy lettuces. The published data support the findings in the Australian trials.

Based on the data reviewed, an MRL of 40 mg/kg would be recommended for leafy vegetables, with HRs of 18 mg/kg for silverbeet, 29 mg/kg for bok choi and 16 mg/kg for leafy lettuce. As there is a large variation in residues, an STMR cannot be estimated for the crop group.

A longer withholding period has been considered to determine if residues would comply with the current temporary MRL of 2 mg/kg. However, using the 14 day data, the acute reference dose is still exceeded for both the 2 – 6 year age group and the general population. Based on the short-term estimate of intake for both the 2 – 6 year subpopulation and the general population, it is recommended that the leafy vegetables use patterns should be deleted from all product labels, as the estimated dietary exposure is unacceptable using current methods of assessment (section 2.21). Action was taken to withdraw registered uses of endosulfan on leafy vegetables as part of the suspension of products in September 2002.

3.2.10 Legume vegetables

Residues data were provided for green peas and green beans from trials conducted in Italy, France and Australia. In the overseas trials, samples of green plant material were collected to give an indication of residues that may be present in animal feed commodities, such as pea vines. Processing data were also generated with residues being determined in canned peas.

Current use patterns allow application at 735 g ai/ha with a withholding period of 2 days. The horticulture industry has requested that the withholding period be extended to 7 days for both crops. Data that correspond to proposed GAP are summarised below:

Commodity, Trial Site	Rate (g ai/ha)	WHP (days)	Total residues (mg/kg)
Green beans, Qld	735	7	0.15
Green beans, Tas	735	7	<0.02
Green beans, Vic	735	7	0.092
Green peas, Qld	735	7	0.082
Green peas, Qld	735	7	0.12
Green peas, Vic	735	7	0.37
Plant material, France	749	7	1.65 (6.6 dry wgt)∗
Plant material, France	780	7	2.2 (8.8 dry wgt)
Plant material, Italy	780	7	1.24 (4.9 dry wgt)
Plant material, Italy	750	7	2.67 (10.7 dry wgt)
Pea hay, Qld	735	7	3.1 (12.4 dry wgt)

∗ Using 25% DM for green material.

Data for green peas and beans that correspond to GAP are in rank order: <0.02, 0.082, 0.092, 0.12, 0.15 and 0.37 mg/kg. The HR for green peas is 0.37 mg/kg and for green beans is 0.092 mg/kg. An MRL of 1 mg/kg is recommended for legume vegetables with a withholding period of 7 days; an STMR of 0.11 mg kg is estimated for the group.

In relation to animal feed commodities, the highest residues found in plant material were 12.4 mg/kg on a dry weight basis, with values ranging from 6.6 to 12.4 mg/kg. The current primary feed commodity MRL in Table 4 of the MRL Standard is 0.3 mg/kg. As an interim measure, the following recommendation was made as part of the suspension of endosulfan products:

- *Do Not Feed Treated Pea Vines or Bean Trash to Livestock*

On registered product labels, there are directions regarding the feeding of green beans and green peas; crop by-products such as pea vines and bean hay are however not specifically mentioned. The directions regarding green beans and green peas are:

- *Do Not Feed To Animals*

Although it is recognised that green peas and beans are primarily grown for human consumption, it is claimed that pea hay and other legume hays and vines are routinely cut and fed to livestock or grazed by livestock following harvest. Due to this potential exposure and the associated trade implications, two alternative approaches can be considered for the use of endosulfan on legume vegetables:

1. continue to permit the use, with the following label restraint:

- **This Product Must Not Be Used On Crops That Will Or May Be Fed To Livestock.**

2. delete the uses.

These options are discussed more fully in section 3.2.21

3.2.11 Pulse crops

Endosulfan is registered for use on a number of pulse crops including adzuki beans, chickpeas, cow peas, faba beans, field peas, lupins, mung beans, navy beans and pigeon peas. In all cases, there are two specific use patterns and application timings. The first is an early pre-emergent application for control of red legged earth mite (RLEM) and blue oat mite at rates of 175 – 350 g ai/ha. The approximate interval between application and harvest would range between 140 and 200 days, depending on the crop.

The second application is at a later stage of crop growth, at a maximum rate of 735 g ai/ha and is primarily for control of heliothis and other pests including loopers, corn earworms and green vegetable bugs. The withholding period for the later application is 28 days. Associated with the late stage application is a slaughter interval of 42 days for livestock that may be fed stubble, hay or fodder resulting from crops that have been treated with endosulfan. This slaughter interval is to allow any residues in animal commodities to fall below the domestic MRLs.

Australian data were generated for chickpeas, cow peas, faba beans, field peas, lupins and navy beans, as representatives of the pulse crop group. Trials were designed to reflect residues resulting from both use patterns, the early mite treatment and the late stage heliothis treatment. In many of the trials, four replicate samples were analysed separately, and these are individually tabulated to give an indication of the variation between replicate plots, especially in the trash/fodder samples.

Data that correspond to GAP (mite and heliothis treatment) are summarised below:

Commodity, Trial Site	Rate (g ai/ha)	WHP (days)	Total residues (mg/kg)
Navy beans, Qld	735	41	0.031, 0.036, 0.046, 0.053
Navy beans, Qld	735	26 (1 spray)	0.012, 0.018
		26 (2 sprays)	<0.015, 0.040
		33 (2 sprays)	0.026, 0.051
Faba beans, NSW	350	196	<0.015, <0.015
	350 + 735	60	0.027, 0.028, 0.028, 0.1
Cow peas, Qld	735	28	0.30, 0.31, 0.32, 0.35
		35	0.16 (2), 0.22, 0.26
Cow peas, Qld	735	28	0.24, 0.27, 0.32, 0.35
		35	0.14 (2), 0.16, 0.19
Field peas	350	157	<0.015, <0.015
	350 + 735	49	0.006 (2), 0.007, 0.011

Lupins	350	203	<0.015, <0.015
	350 + 735	49	0.023, 0.055
Chickpeas	350	142	<0.015, 0.006
	350 + 735	38	0.12, 0.15, 0.20, 0.21
Navy bean trash/stubble	735	28	6.1, 12.7, 15, 16.1
Navy bean trash/stubble	735	26 (1 spray)	2.4, 6.3
		26 (2 sprays)	1.3, 1.8
		33 (2 sprays)	0.7, 1.4
Faba beans	350	196	0.034, 0.035
Cow pea trash/stubble	735	28	23, 29, 35, 37
		35	25, 30, 31, 46,
Cow peas trash/stubble	735	28	20, 25, 29, 47
		35	26 (2), 32, 33
Field pea forage	350	47	<0.1, <0.1
Field pea straw	350	157	0.035, 0.047
	350 + 735	49	0.32, 0.37, 0.40, 0.48
Lupin forage	350	61	<0.1, <0.1
Lupin straw	350	203	<0.1, <0.1
	350 + 735	49	0.19, 0.24
Chickpea forage	350	38	0.17, 0.22, 0.27, 0.29
Chickpea straw	350	157	0.06, 0.17
Chickpea straw	350 + 735	49	2.2, 4.3, 4.5, 9.4

LOD = 0.005 mg/kg in grain; LOQ = 0.1 mg/kg in grain, forage and straw

Residues in pulses are below the current temporary MRL of 1 mg/kg, with a 28 day withholding period. Although residues in cow peas at 28 days are above the primary feed commodities MRL of 0.3 mg/kg, current residues management advice indicates that a 42 day slaughter interval applies to livestock that may be fed treated pulses, therefore a feeding restraint for pulses is not required.

Residues in forage, stubble, straw and trash range from <0.1 to 47 mg/kg across the crop group. The current primary feed commodity MRL of 0.3 mg/kg is clearly exceeded for a number of those feed commodities. Applying an additional 42 days slaughter interval for livestock is only appropriate to those feed commodities in which residues are <2 ppm. The highest residues were found in cow pea fodder, where a slaughter interval of 70 days (on clean feed) would be required for livestock that would be exposed to fodder from treated crops.

As it is common agricultural practice to allow livestock to graze forage, straw and stubble of treated pulse crops, it is considered that a feeding restraint on product labels would be contrary to common practices. In addition, as a slaughter interval of 42 days on clean feed is not sufficient to allow endosulfan residues in animal commodities to fall below the current animal commodity MRLs, it is recommended that the late use pattern for control of heliothis and other pests (application at 735 g ai/ha with a 28 day withholding period) be deleted from all product labels. The early mite control treatment can be supported, and therefore on the basis of the data provided, residues in pulses are in rank order: 0.006 and <0.015 (7) mg/kg. An MRL of *0.1 mg/kg is recommended for pulses, with a nil withholding period for harvest.

Endosulfan residues in pulse forage (field peas, lupins and chickpeas) range from <0.1 to 0.29 mg/kg for samples taken at 38 to 61 days after treatment. The highest residues of 0.29 mg/kg dry weight were found in chickpea forage at 38 days after treatment. The data support an MRL of 0.5 mg/kg for pulse forage with a grazing withholding period of 42 days. This recommendation is made recognising that residues in forage should decline to below the current primary feed commodities MRL (0.3 mg/kg) within 42 days after treatment.

Endosulfan residues in pulse straw and stubble ranged from <0.1 mg/kg to 0.17 mg/kg for samples taken at harvest (157 to 203 days after treatment). An MRL of 0.3 mg/kg is recommended for pulse straw and fodder with a withholding period similar to that for harvest of the grain, i.e. nil.

3.2.12 Root and tuber vegetables

Current GAP for root and tuber vegetables (potato, carrot, beetroot, sweet potato, taro) allows application at 735 g ai/ha with withholding periods of 2 days for beetroot and 7 days for carrots, potatoes, sweet potatoes and taro. Taro is found on only two registered product labels[4].

The horticulture industry has requested that the withholding periods for all root and tuber vegetables be extended to 14 days.

Data that correspond to proposed GAP are summarised below:

Commodity, Trial Site	Rate (g ai/ha)	WHP (days)	Total residues (mg/kg)
Beetroot, Qld	735	14	0.20
Carrot, SA	735	14	0.06
Carrot, SA	735	14	0.095
Carrot, WA	735	14	0.037
Potato, Vic	735	14	<0.02
Potato, Qld	735	14	<0.02
Potato, WA	735	14	<0.02
Sweet potato, Qld	735	14	<0.02

Residues in root vegetables are in rank order: <0.02 (4), 0.037, 0.06, 0.095 and 0.2 mg/kg. An MRL of 0.5 mg/kg is recommended for root vegetables with a withholding period of 14 days for all root vegetables. The HRs for beetroot, carrot, potato and sweet potato are 0.2, 0.095, 0.02 and 0.02 mg/kg, respectively. An STMR of 0.028 mg/kg for the crop group is estimated for chronic intake purposes.

3.2.13 Stalk and stem vegetables

The current registered use pattern for celery is 66.5 g ai/100L with a withholding period of 2 days. This use is only found on one product label[5]. Australian data were provided for celery and rhubarb to allow consideration of a group MRL. The horticulture industry has requested withholding periods of 7 days for celery and rhubarb. As there is no use pattern for rhubarb, the proposed GAP only is considered.

The data that correspond to GAP are summarised below:

Commodity, Trial Site	Rate (g ai/ha)	WHP (days)	Total residues (mg/kg)
Celery, Qld	735	7	0.59
Celery, Vic	735	7	0.26
Rhubarb, Qld	735	7	0.059
Rhubarb, Qld	735	7	0.34

Residues in celery at 7 days after application are 0.26 and 0.59 mg/kg. These levels are below the temporary MRL of 2 mg/kg for stalk and stem vegetables.

The data that correspond to proposed GAP are in rank order: 0.059, 0.26, 0.34 and 0.59 mg/kg. The HRs for celery and rhubarb are 0.59 and 0.34 mg/kg, respectively. There are an insufficient number

[4] Thiodan EC Insecticide and Farmoz Endosulfan 350EC Insecticide.
[5] Nufarm Endosulfan 350EC Insecticide.

of data points to estimate an STMR for the group. On the basis of the data provided, an MRL of 1 mg/kg is recommended for stalk and stem vegetables with a withholding period of 7 days.

3.2.14 Cereal crops

Use of endosulfan on cereals includes two specific application timings, an early pre-emergent application for control of RLEM at 175 or 350 g ai/ha and applications at a later stage of crop growth for control of armyworm at 525 g ai/ha and heliothis at a rate of 735 g ai/ha. The use patterns for sorghum and maize differ from other cereal crops, as the only registered uses in these two crops are for heliothis control at 735 g ai/ha. The withholding period in all cases is 4 weeks for harvest.

In the residue trials, samples from four replicate plots following two applications were analysed separately (as for pulses) and these are individually tabulated to give an indication of the variation between replicate plots, especially in the fodder/trash material. Data that correspond to GAP (heliothis control) for sorghum are summarised below:

Commodity, Trial Site	Rate (g ai/ha)	WHP (days)	Total residues (mg/kg)
Sorghum, NSW	735	26	0.55, 0.78, 0.88, 1.1
		31	0.60, 0.66, 0.74, 0.94
Sorghum, NSW	735	29	0.42, 0.44, 0.56, 0.87
		35	0.27, 0.31 (2), 0.34
Sorghum, Qld	735	27	0.31, 0.37, 0.43, 0.44
		32	0.25, 0.34, 0.39, 0.51
Sorghum, NSW	735	27	1.5, 1.6, 1.7, 2.1
		34	0.88, 0.9, 1.0 (2)
Sorghum fodder/trash	735	26	30, 43, 55, 79
		31	22, 26, 39, 47
Sorghum fodder/trash	735	29	7, 15, 23, 31
		35	12, 13, 15, 21
Sorghum fodder/trash	735	27	5, 6 (2), 7
		32	3 (3), 5
Sorghum fodder/trash	735	27	47, 49, 55, 63
		34	16, 28, 36, 43

The data for sorghum can be extrapolated to maize; data for sorghum fodder can be extrapolated to maize and sweet corn fodder.

The registered uses of endosulfan on sorghum and maize are for control of heliothis, sorghum midge, sorghum head caterpillar and peach moth, and application timings are typically from head-emergence onwards. The data for sorghum clearly show that residues in grain at 28 days after application are greater than the current temporary MRL of 0.2 mg/kg for cereal grains. In the sorghum trials sampling intervals ranged from 26 to 51 days after application, and in the majority of the trials, residues in sorghum were above the temporary MRL for cereal grains and the primary feed commodities MRL, even at 51 days after application.

Registered labels offer contradictory advice with respect to sorghum and maize grain and corresponding fodder/stubble/trash. The residue management statements advise that a withholding period of 8 weeks would be required for grain used for livestock feed with a nil slaughter interval. However in the crop listing, sorghum, maize and other cereals may be harvested after 4 weeks for human consumption.

Residues in sorghum fodder range from 3 to 79 mg/kg in samples taken at 26 to 35 days after two applications. The data clearly show that residues far in excess of the primary feed commodity MRL of 0.3 mg/kg may be present in sorghum fodder at 4 to 5 weeks after application. If livestock were

exposed to the highest level of 79 mg/kg, approximately 80 to 90 days on clean feed would be required for residues in meat (fat) to fall below the domestic MRL of 0.2 mg/kg. The interim recommendation for sorghum and maize fodder as part of the suspension of endosulfan products was:

- *Do Not Feed Treated Sorghum or Maize Fodder to Livestock; and*
- *If livestock have been fed treated sorghum or maize grain or fodder, animals must be kept on clean feed for at least 90 days before slaughter.*

As discussed above in section 2.11 (pulse crops), it is common practice to feed sorghum, maize and their crop parts to livestock; sorghum is predominantly grown for livestock feed. As a feeding restraint would be contrary to common livestock grazing and feeding practices and a slaughter interval of 90 days is considered impractical, the use patterns for sorghum and maize should be deleted from product labels.

Data that correspond to GAP for other cereal grains, except sorghum and maize are summarised below:

Commodity, Trial Site	Rate (g ai/ha)	WHP (days)	Total residues (mg/kg)
Barley, Vic	350	158	0.008, 0.01
	350 + 735	42	0.66, 1.0, 1.1, 1.3
Barley, NSW	350	189	0.009, 0.05
	350 + 735	53	0.55, 0.46, 0.62, 0.72
Wheat, WA	350	203	<0.005 (2)
	350 + 735	49	<0.005 (2)
Wheat, NSW	350	130	<0.005 (2)
	350 + 735	35	<0.005, 0.046, 0.048, 0.099
Barley forage	350	70	0.079, 0.083
Barley straw	350	158	0.21, 0.22
Barley straw	350	158	0.1, 0.36
Barley straw	350 + 735	42	4.3, 5.1, 5.7, 6.4
Barley straw	350 + 735	42	1.6, 2.4, 2.9, 4
Wheat forage	350	61	<0.005 (2)
Wheat straw	350	203	<0.005, <0.005
Wheat straw	350	130	0.03, 0.03
Wheat straw/trash	350 + 735	49	0.24, 0.32
Wheat forage	350	55	0.25, 0.29
Wheat straw	350 + 735	35	0.39, 0.81, 1.4, 1.6

LOD = 0.005 mg/kg; LOQ = 0.1 mg/kg in grain, forage and straw.

The data for barley and wheat can be extrapolated to other cereal grains such as oats, rye and triticale. The withholding period for cereal grains is 28 days. The results show that residues in grain following the late application for heliothis control are greater than the current temporary MRL of 0.2 mg/kg at 28 days after application and are greater than the primary feed commodities MRL of 0.3 mg/kg. However, for the pre-emergent mite treatment, residues comply with the current MRL.

The residues management advice on registered labels is again contradictory in relation to cereal grains, and a withholding period of 4 weeks with a nil slaughter interval is indicated. The barley data indicate that a slaughter interval of up to 20 days on clean feed may be required for livestock that may be fed barley grain from treated crops.

Residues in barley and wheat straw/fodder (heliothis treatment rates) are greater than the primary animal feed commodities MRL of 0.3 mg/kg at intervals longer than 4 weeks. Label advice is required for livestock that are exposed to fodder or straw from treated crops. If animals were exposed to the highest levels of 6.4 mg/kg in barley straw, approximately 50 days on clean feed would be required for residues in fat to comply with the current animal commodity MRLs.

Residues data indicate that current use patterns (critical GAP heliothis control) for cereals require a slaughter interval for livestock in addition to the crop withholding periods, in order that the animal commodity MRLs are not violated. As it is common practice to feed cereal grains and their straw/hay to livestock, it is recommended that the late stage applications for heliothis control and other pests should be deleted from product labels. The use patterns that will remain are early pre-emergent applications for mite control. On the basis of that use pattern only, the temporary cereal grains MRL of 0.2 mg/kg may be amended to 0.1 mg/kg with a nil withholding period for harvest.

Residues in wheat and barley forage range from <0.1 mg/kg to 0.29 mg/kg at intervals of 55 to 70 days after treatment. On the basis of the data provided, a grazing withholding period of 8 weeks is recommended together with an MRL of 0.5 mg/kg for cereal forage. Residues in wheat and barley straw ranged from <0.1 to 0.36 mg/kg at intervals ranging 158 to 203 days after application. An MRL of 0.5 mg/kg is recommended for cereal straw and fodder, with a nil withholding period for harvest.

3.2.15 Tree nuts

Endosulfan is registered for use on cashews, macadamias, pecans and pistachios. The current use pattern is 52.5 g ai/100L or 525 g ai/ha and a withholding period of 14 days for the nuts mentioned above. The horticulture industry has requested that the withholding period for macadamias be reduced to 2 days.

Residues in macadamias at 2 days after application were <0.01 mg/kg in three trials conducted in NSW and Qld. The temporary MRL of 2 mg/kg adequately covers the current use patterns for cashews, macadamias, pecans and pistachios. On the basis of the data provided, an MRL of 0.05 mg/kg is recommended for tree nuts, with a withholding period of 2 days for macadamias and 14 days for cashews, pecans and pistachios.

3.2.16 Oilseeds

For oilseeds (canola, cotton, linseed, peanuts, soy beans, safflower, sunflowers), there are two specific application timings of endosulfan. One is an early pre-emergent application for control of RLEM and blue oat mite at rates of 175 – 350 g ai/ha and the other is application at a later stage of crop growth for heliothis control at rates of 735 g ai/ha. The withholding period for peanuts is 7 days, and 28 days for other oilseeds.

The use patterns for cotton and peanuts only include the late heliothis application, whereas for the other oilseed crops, both early and late applications are permitted.

For cotton, registered labels have a specific page entitled ‘Conditions of Use on Cotton’. In the conditions of use, application timings (aerial application) are limited to between 15 November to 15 January in NSW and 1 November to 31 December in Qld, with a maximum of 3 sprays at 735 g ai/ha. These timings would indicate that the period between final application and harvest would approximate 8 to 10 weeks.

The residue management section of product labels lists only cotton seed and meal (4 week withholding period with a nil slaughter interval for livestock), cotton trash and peanut hay . For cotton seed and meal, there is a direction that cotton trash must not be fed to livestock.

For peanut hay, there is a 7 day withholding period with a 42 day slaughter interval for livestock that may be fed treated hay. As data for peanuts and peanut hay were not provided to enable an assessment of the residues and trade situation, the uses should be deleted from all endosulfan product labels.

Data that correspond to GAP are summarised below:

Commodity, Trial Site	Rate (g ai/ha)	WHP (days)	Total residues (mg/kg)
Canola	350	203	<0.005, <0.005
	350	211	<0.005, <0.005
	350	188	<0.005, <0.005
Cotton, NSW	735	27	0.007, 0.037, 0.047, 0.055
	735	41*	0.009, 0.029, 0.042, 0.080
Soya beans, Qld	735	28	0.018, 0.020, 0.033, 0.042
Sunflowers, NSW	735	29	0.12, 0.21, 0.28, 0.31
		34	0.16, 0.18, 0.23, 0.51
Canola forage	350	61	<0.005, <0.005
	350	47	0.23, 0.25
	350	98	0.09, 0.10, 0.11
	350	79	0.04, 0.05
Canola straw	350	203	0.006, 0.01
	350	211	0.008, <0.005
	350	188	0.05, 0.05
Cotton lint	735	27	0.069, 0.14, 0.19, 0.33
	735	41*	0.024, 0.066, 0.084, 0.10
Soya bean fodder/trash	735	28	1.5, 3.0, 3.2, 4.4
Sunflowers fodder/trash	735	29	9, 12, 13, 15
		34	39, 62, 59, 83

LOD = 0.005 mg/kg; LOQ = 0.1 mg/kg in seed, forage and straw/trash. * Closest interval in trials in relation to 'Conditions of use on cotton'.

In the canola trials, samples of seed and straw/trash were taken at 49 and 54 days after application at 735 g ai/ha, which do not strictly correspond to the critical GAP, therefore those data have not been included in the above table.

Endosulfan residues in cotton seed, soy beans and sunflowers were below the current temporary MRL of T1 mg/kg. The highest levels found were 0.51 mg/kg in sunflower seed.

Residues in fodder and trash of soy beans and sunflowers range from 1.5 to 83 mg/kg. As the levels clearly exceed the primary feed commodities MRL of 0.3 mg/kg, the following interim recommendation was made, noting there was no label direction in relation to feeding of oilseed fodders and trash:

- *Do Not Feed Fodder, Stubble or Trash from Treated Oilseeds (Canola, Cotton, Linseed, Peanuts, Safflower, Soya beans, Sunflowers) to Livestock*

The levels of endosulfan that are found in soybean fodder and sunflower trash would require a slaughter interval of greater than 42 days for any livestock that may have been fed treated commodities. As an interim measure, it was recommended that any livestock that may have been fed any oilseed fodder or trash must be kept on clean feed for 90 days before slaughter.

Cotton fodder

Residues in cotton fodder are not tabulated, as the control samples in one relevant trial were contaminated, therefore the data must be interpreted with care. The levels of endosulfan in cotton fodder ranged 1 to 12 mg/kg, at intervals of 27 and 41 days after application.

As feeding of cotton fodder, stubble and trash is not considered to be Good Agricultural Practice (GAP), the following feeding restraint was re-emphasised as part of the 1998 interim recommendations for the endosulfan review:

- *Do Not Feed Cotton Forage, Stubble, or Trash to Livestock*

The use of endosulfan for cotton production has previously been linked to residues in beef, for example, from spray-drift, contaminated feed and poor management practice. However, significant measures have been put in place by the APVMA and the cotton industry aimed at preventing endosulfan contamination in meat commodities, with a high level of success.

Never-the-less, the risk of residues in trade for the meat industry remains from the feeding of cotton fodder, stubble and trash, particularly in drought situations.

In assessing the use of endosulfan in cotton, two alternative approaches can be considered:

1. continue to permit the use of endosulfan on cotton, with the following label restraint:

- **This Product Must Not Be Used On Crops That Will Or May Be Fed To Livestock.**

2. delete the uses of endosulfan on cotton.

These options are discussed more fully in section 3.2.21

The oilseeds data (as with pulses and cereals) indicate that endosulfan residues in fodder, straw and trash following application at 735 g ai/ha (heliothis control) were clearly greater than the primary feed commodity MRL of 0.3 mg/kg and slaughter intervals ranging 20 to 90 days on clean feed would be required if livestock were exposed to such levels for prolonged periods. As a 90 day slaughter interval is not considered to be practical, it is recommended that the late stage application for heliothis control (735 g ai/ha) be deleted from product labels for oilseeds (except cotton).

The current temporary MRL of 1 mg/kg is appropriate for the remaining uses on oilseeds, which include mite treatment only. A nil withholding period for harvest is recommended in relation to the above MRL for canola, linseed, soybeans, safflower and sunflowers. For cotton, the withholding period is 28 days. As the oilseed MRL of 1 mg/kg will also accommodate the existing cotton seed oil MRL of T0.5 mg/kg, the oil MRL is not required.

Forage data were generated for canola only, at the timings and rates applicable for mite control. Residues ranged <0.1 to 0.25 mg/kg at intervals of 47 to 79 days after application. On the basis of the canola forage data, an MRL of 0.5 mg/kg is recommended for oilseed forage with a grazing withholding period of 8 weeks. This should allow sufficient time for residues in other oilseed forages to decline to below the maximum feed level of 0.3 mg/kg.

Similarly with straw and fodder of oilseeds, data for canola were generated at the 350 g ai/ha rate and mite application timings. On the basis of the data provided an MRL of *0.1 mg/kg is recommended for oilseed straw and fodder with a nil withholding period for harvest/grazing.

3.2.17 Pastures and related crops

Use patterns for clover and medic seed crops, lucerne seed crops, pastures, chou moeiller and vetch are found on a number of product labels. Residues data for pastures were requested as part of the interim regulatory action in 1998, however no new data were generated.

In the 1998 APVMA review of endosulfan, data from the 1989 JMPR were evaluated against registered use patterns[6]. The data were from single applications ranging from 210 to 530 g ai/ha or 0.3 to 0.7× the maximum application rate in Australia. As the data did not correspond to GAP in Australia, additional data were requested.

[6] Page 55 of the APVMA Review of Endosulfan.

As new data supporting the existing use patterns have not been provided, the APVMA cannot be satisfied that pastures and related crops will not contain residues at unacceptable levels. Therefore, it is recommended that all use patterns relating to control of pests on pastures, clover and medic crops, lucerne, chou moeiller and vetch must be deleted from all registered labels.

3.2.18 Animal feed commodities and animal commodity MRLs

A list of animal feed commodities and residues therein is given in Table 1. The data are taken from residue trials described in section 8.

Table 1: Livestock dietary burden estimates from Australian residues data (Cattle)

Commodity	HR/STMR-P (mg/kg)	Livestock diet (%)	Residues in feed (ppm)
Citrus pulp	0.45①	20	0.09
Apple pomace	0.64	20	0.13
Pulses	0.016	100	0.016
Pulse forages	0.29	100	0.29
Pulse straw/fodder	0.17	100	0.17
Cereal grains	0.015	100	0.015
Cereal forage	0.29	100	0.29
Cereal straw/fodder	0.36	100	0.36
Oilseed forage	0.25	100	0.25
Oilseed straw/fodder	0.05	100	0.05

① PF × STMR in residue trials.

It should be noted that residues data were generated for representatives of particular crop groupings, therefore there are other feed commodities from related crops for which data were not provided, but for which valid extrapolation can be made. For example, the data for sorghum fodder can be extrapolated to maize and sweet corn fodder. Similarly, the data for navy beans and cow peas can be extrapolated to other pulse crops such as mung beans, faba beans, field peas, chickpeas, lupins, adzuki beans and pigeon peas. The sunflower data can be extrapolated to safflower and the data for sunflower and canola can be extrapolated to linseed. Similarly the barley straw data can be extrapolated to wheat, oats, rye and triticale.

The current animal commodity MRLs of T0.2 mg/kg in edible offal, 0.2 mg/kg in meat (mammalian)[in the fat] and T0.5 mg/kg in milk (in the fat) are based on a maximum feed level of 0.3 ppm[7]. Existing labels included crop harvest and grazing withholding periods, together with a 42 day slaughter interval for livestock that may graze or be fed a number of commodities treated with endosulfan (see section 8**).** This withhold from slaughter period was to allow residues in livestock (specifically fat) to decline to below the domestic MRL.

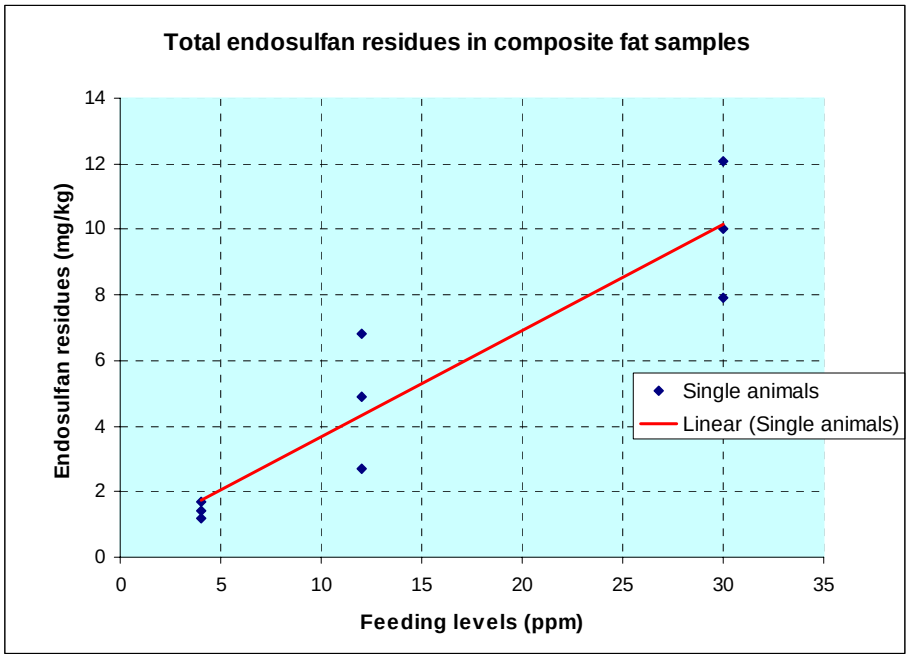
With the recommended deletion of late stage applications in broadacre crops except cotton (specifically application at 735 g ai/ha with a 28 day withholding period), the dietary burden table is significantly different to that previously considered in the interim report. The greatest exposure to grazing livestock is from cereal straw and fodder, following application for mite control.

For all feed commodities considered, the exposures approach the maximum feed level of 0.3 mg/kg, with levels ranging from 0.015 to 0.36 mg/kg. However, on the basis of the estimates presented in the dietary burden table, a maximum feed level of 0.4 mg/kg is appropriate. In addition, as MRL recommendations have been proposed for individual animal feed commodities, it is recommended that the current primary feed commodities entry of 0.3 mg/kg be deleted from Table 4 of the MRL Standard.

[7] *The NRA review of Endosulfan (Aug 1998)*; Agricultural Assessment. Prelim report *Endosulfan Uptake Study* 1996.

Following dosing for 28 days at a feed level of 4 ppm, maximum residues of 0.07 mg/kg in muscle, 1.7 mg/kg in composite fat, 0.98 mg/kg in liver, 0.08 mg/kg in kidney and 0.08 mg/kg in whole milk, were found. The mean levels (n = 3) of total endosulfan were 0.04 mg/kg in muscle, 1.4 mg/kg in composite fat, 0.7 mg/kg in liver, 0.07 mg/kg in kidney and 0.07 mg/kg in whole milk. The scatter of results for composite fat is shown in figure 3.1.

Figure 3.1.



At higher feed levels, the scatter or variation observed between single animals is greater than that found at the lowest feed level of 4 ppm.

Scaling the residues in fat (highest single animal result) for exposure at a level of 0.4 ppm, residues of 0.17 mg/kg would be expected. This is still within the current MRL of 0.2 mg/kg for meat (mammalian)[in the fat]. Applying the same principle to muscle and edible offal, residues of 0.1 and 0.008 mg/kg are estimated for liver and kidney, respectively, and 0.007 for muscle. It is recommended that the current temporary MRL of 0.2 mg/kg for edible offal (mammalian) be made a permanent MRL.

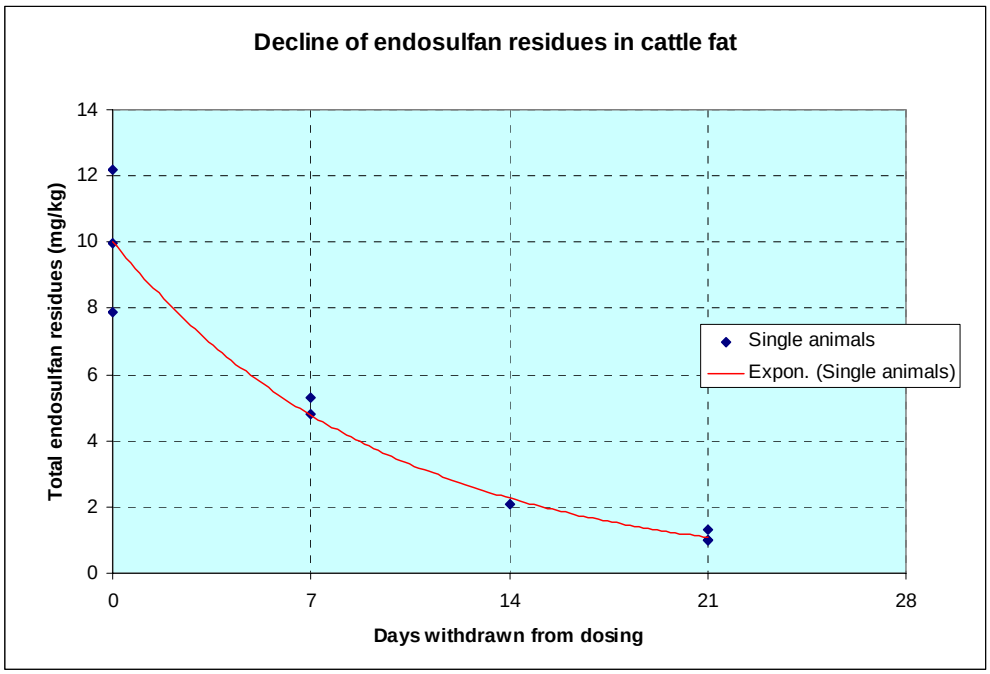
Maximum residues of 0.08 mg/kg were present in whole milk following dosing at 4 ppm for 28 days, which is scaled to 0.008 mg/kg for a maximum feed level of 0.4 mg/kg. After 7 days of dosing, total endosulfan levels appeared to plateau in milk, with an occasional spike at a later sampling point (see section 4.2.1). On the basis of the data for milk, the current temporary entry of 0.5 mg/kg for milk [in the fat] should be amended to 0.02 mg/kg for whole milk.

Residues were determined in cream following dosing at 12 ppm for 9 days, with levels ranging from 0.81 to 1.42 mg/kg. Maximum endosulfan residues in milk following dosing at 12 ppm were 0.22 mg/kg. A mean concentration factor of 4.7 is estimated from these results.

Depuration of residues in muscle, fat, liver and kidney were determined as part of the cattle transfer study. The depletion of endosulfan residues in fat is shown in figure 3.2.

Using the depuration data from the transfer study in dairy cattle (section 9**),** a half-life of 7 days is calculated in fat. It should be noted however, that the fat samples in the transfer study were analysed as a composite (subcutaneous, omental and perirenal) and therefore the time taken to deplete in individual fat depots cannot be ascertained. Due to differences in individual fat depots and to allow for variation in animals, a half-life of 10 days is considered to be appropriate.

Figure 3.2.



For poultry, a conservative maximum feed level (MFL) of 0.2 ppm is estimated from residues present in oilseeds, cereal grains and pulses. In the poultry metabolism study provided (section 3.1), hens were dosed orally for 12 days at levels ranging 10 to 12 ppm in the feed. Scaling the radioactive residues present for a maximum feed level of 0.2 ppm, endosulfan residues (α- and β-endosulfan and endosulfan sulfate) of 0.016 and 0.014 mg/kg would be present in fat, 0.008 mg/kg would be present in skin, 0.008 mg/kg would be present in eggs and 0.003 mg/kg would be present in liver. On the basis of the metabolism study, MRLs of 0.02 mg/kg, 0.05 mg/kg and *0.01 mg/kg are recommended for eggs, poultry meat [in the fat] and poultry offal.

3.2.19 Processing and storage stability

Storage stability data are described in section 8 for both crop and animal matrices. The residues data provided for crops and animal commodities are adequately covered by the storage intervals in the stability studies and therefore the reported residues in supervised trials reflect residues found after treatment.

Processing data were provided as part of the residues studies. These are described in the individual studies in section 8**.**

3.2.20 Trade considerations

The following export data were extracted from *Australian Commodity Statistics 2003*, published by the Australian Bureau of Agriculture and Resource Economics, Canberra.

Export value – Livestock: Australian exports of sheep meat, on average over the last decade, were 227±15 kt mutton and 88±27 kt lamb per year, being valued at over $1000m pa. Australia

also exported live sheep to the Middle East, with the main markets for the $400m pa trade being Kuwait, Jordan, Saudi Arabia and the UAE. These accounted for more than 75% of the live sheep market in 2002. Australia's main customers for the sheep meat trade in 2002 are shown in the following table.

Market	Trade Value ($m) (2002)		
	Mutton	Lamb	Live sheep
Chinese Taipei	48.9		
Japan	51.1	40.7	
Malaysia	22.9		
Singapore	23.2		
PNG	6.6	15.7	
European Union	41.1	85.7	
South Africa	17.6	1.2	
USA	64.7	218.2	
United Arab Emirates		31.6	30
Saudi Arabia	77.5		127
Jordan			39
Kuwait			101
TOTAL (all markets)	**520**	**566**	**395**

Furthermore, Australia exports significant amounts of sheep offal, both chilled and frozen, and valued at over $40m pa. The main markets for sheep offal are China, Hong Kong and Singapore.

Australian exports of beef and veal are valued at over $4.0bn, with live cattle exports totalling around $580m.for the year 2002. The main markets for these products are as follows:

Market	Trade Value ($m) (2002)	
	Beef and veal	Live cattle
Chinese Taipei	152.3	
Japan	1237.7	11.2
South Korea	320.4	
Philippines	36.1	65.8
Malaysia / Singapore	91.4	45.1
PNG	9.8	
European Union	53.5	
Canada	320.2	
USA	1593.6	
Egypt		94.9
Indonesia	46.1	254.0
TOTAL (all markets)	**4003**	**580**

Export value – Cereal grains: Australia exports large quantities of cereal grains, with exports in 2002-2003 of coarse grains totalling $1.015bn and of wheat totalling $3bn. The main markets for Australian wheat were Egypt, Iran, Iraq, Yemen, Indonesia, Japan, S. Korea and Malaysia. Main markets for the coarse grains could not be determined.

Export value – Cotton products: Cottonseed, cottonseed oil and cottonseed meal are also exported by Australia. Whilst specific data were not available, estimates of their value are $210m, $600,000 and $460m respectively.

MRLs: MRLs have been set for endosulfan in cereal grains and cattle and sheep commodities in most countries worldwide and in Codex. They can be summarised as follows:

Commodity	MRL (mg/kg)					
	Current Australian	Proposed Australian	Codex	USA	EU	Canada
Cereal grains	T0.2	0.1			0.05	None
Wheat grain			0.2 (3)	0.1 (N)		
Wheat straw		0.5		0.2 (N)		
Primary feed commodities	0.3	0.3	1			
Edible offal (mammalian)	T0.2	0.2		0.2	0.1	0.2 (F)
Meat (mammalian)[in the fat]	0.2	0.2	0.1	0.2	0.1	0.2
Cottonseed		1	1	1	0.3	
Cottonseed oil, crude	T0.5	0.5	0.5			

Note: *(F) indicates in the fat.*
(3) indicates at Step 3 of the Codex process.

Japan has no MRLs listed for endosulfan on their web site.

MRLs - Cereal Grains: The main markets for wheat are the Middle East and Asia, where there appear to be no MRLs established. The proposed Codex MRL for wheat is the same as that of Australia. There should be no prejudice to trade for wheat exports, once the proposed MRL is established. However, the lack of a Codex MRL in the past has not prejudiced trade in the past for these main markets and this is not expected to alter in the future.

MRLs - Cottonseed: The Australian MRL for cottonseed is included in the oilseed MRL of 1 mg/kg, which is the same as that of Codex and the USA. The current crude cottonseed oil MRL is the same as that of Codex, however it will be deleted, as residues in oil will be accommodated by the oilseed MRL. As the main markets were not indicated in the export data, the presence of MRLs in those markets is unknown. However, trade in the past has not been prejudiced by the presence of these MRLs for endosulfan and this is not expected to alter in the future.

MRLs - Cattle and Sheep: The Australian MRL for meat fat is twice that of the Codex value. Australia's main markets are in North America, Asia and the Middle East. Most Asian countries that have not established MRLs for endosulfan adopt either the Codex value or the EU value of 0.1 mg/kg. There have been past incidents in Asia particularly when shipments of meat have been rejected for exceeding the Codex MRL and this difference could be seen to prejudice Australia's trade to these markets.

Export trade in meat is drawn from both grazed animals and from feedlot cattle. The source of endosulfan residues could be from the pastures grazed (either from spray drift or from treatment for red-legged earth mite), from forage crops or supplementary feeds. Silage, cut fodder and hays could also be sources of endosulfan for export animals. Animal feed commodities that produce residues above 0.4 mg/kg endosulfan (the proposed primary feed commodity MRL) should be restricted from feeding to cattle and sheep. With this restraint, residues in meat fat from feeding endosulfan below 0.4 mg/kg in the feed should not exceed the MRL of 0.2 mg/kg in the fat.

3.2.21 Meat trade implications from Animal feed commodities

A number of broadacre crops for which endosulfan is registered are used as animal feed commodities, potentially resulting in endosulfan meat residue violations.

For those crops grown primarily or substantially for livestock feed it is proposed that some endosulfan uses no longer be permitted, where they present an undue risk to trade and alternative risk mitigation measures are unlikely to be complied with. This includes some uses for cereal crops, oil seed crops (except cotton and peanuts) and pulse crops.

Cotton and legume vegetables are not grown primarily for feed purposes. The feeding of cotton fodder, stubble and trash to livestock is not considered to be GAP, however, cotton production has previously been linked to endosulfan residues in beef, as a result of contaminated feeds, spray drift and other poor management practices.

In assessing the use of endosulfan in cotton (and legume vegetables), two alternative approaches can be considered:

1. continue to permit these uses with the following label restraint:

- **This Product Must Not Be Used On Crops That Will Or May Be Fed To Livestock.**

2. delete these uses because of the risk of violative residues in meat.

Alternative approach: option 1

Under option 1, the current uses of endosulfan on cotton (and legume vegetables) would continue to be permitted, provided that the crops and by-products are not intended for use as livestock feed and the following label statement is used:

- *This product must not be used on cotton or legume vegetables that will or may be fed to livestock.*

Significant measures have been put in place by the APVMA and the cotton industry to ensure good agricultural management practice aimed at, amongst other things, preventing violative endosulfan residues in meat commodities, with a high level of success.

Whilst acknowledging the risk to meat producers, there is a need for all parties to take responsibility for minimising the risks under their control. On this basis, it can be argued that cotton growers should not lose an important use pattern because of the potential actions of others in not following the label, which reflects GAP. In particularly because cotton is not specifically grown as a feed commodity.

Adoption of this approach would present potential risks for violative meat residues in trade if GAP were not complied with.

Alternative approach: option 2

Option 2 assumes that feeding restraints may not prove effective and, consequently, uses of endosulfan on cotton (and legume vegetables) would be deleted to prevent the risk of violative residues in meat.

It has been claimed that cottonseed, processed by-products, fodder and trash have been used as a source of feed, particularly in drought periods, and advice received from State Departments of Agriculture has been that feeding prohibitions are very difficult to enforce because of traceability problems and because livestock producers will continue to ignore such restraints.

It could be argued that those feeding cotton fodder, stubble and trash to livestock may not be aware of the label restraints.

Outcome

The issue of use on cotton (and legume vegetables) has still to be determined. During the public consultation period the APVMA will actively seek comment from key stakeholders on the two options to help resolve this matter. The APVMA will also seek assurances that, should uses on

cotton be retained, appropriate and effective safeguards can and will be put in place to protect against violative residues in meat, and so protect Australia's meat trade.

3.2.22 Adoption of Codex MRLs for meat

The Australian MRL for meat fat (0.2mg/kg) is based on GAP for Australian production. The APVMA has considered the implications for endosulfan use patterns if the existing Codex MRL for meat fat (0.1mg/kg) were adopted to replace the current Australian MRL.

The existing primary feed commodity MRL of 0.3 mg/kg is the limit against which all of the livestock feeds have been assessed. Information from a new feeding study and existing data, show that the limit can be revised to 0.4 mg/kg, which corresponds to residues of 0.17 mg/kg in meat fat. If the Codex MRL of 0.1 mg/kg were adopted, residues in feeds must be below 0.23 mg/kg.

On this basis, the pre-emergence mite treatments for pulses, cereals and oilseeds would need to be deleted due to the levels present in pulse forages, wheat forage and barley straw, and canola forage. This would result in all broadacre uses of endosulfan having to be withdrawn for feedstock commodities, irrespective of trade considerations.

For these reasons, the replacement of the Australian for the Codex MRL is not proposed.

3.2.23 Dietary exposure

The ADI and ARfD for endosulfan are 0.006 and 0.02 mg/kg bodyweight/day, respectively. At the time of publication of the 1998 Endosulfan interim report the National Estimated Daily Intake (NEDI) was equivalent to 339% of the ADI. This estimate was based on temporary MRLs and used available refinements. It is recognised that the NEDI is a conservative estimate of chronic exposure and that excursions above the ADI may be allowed (Residues Appendix 4). Using the supplementary residues data that have been submitted, the NEDI is now equivalent to 27% of the ADI.

The ARfD for endosulfan was set by the TGA in December 2000. The dose is 0.02 mg/kg bodyweight, based on a NOEL of 2 mg/kg bodyweight/day and a 100-fold safety factor from a developmental study in rats. The LOEL was 6 mg/kg bodyweight/day.

In 1998, at the time of publication of the endosulfan review, acute or short-term dietary exposures were not routinely considered in Australia, as the methodology was still under development[8]. The National Estimated Short Term Intake (NESTI, Residues Appendix 2) is calculated using the supplementary residues data corresponding to registered use patterns. For the 2 to 6 year subpopulation, the acute reference dose was exceeded for pears (3.6-fold), leafy vegetables (20 to 27 fold) and Brussels sprouts (1.3 fold). For the 2 years + group (general population), the acute reference dose was exceeded for leafy vegetables (17 to 20-fold); pears approach the acute reference dose.

Short-term dietary intake must not exceed the acute reference dose. To reduce the exposure from residues in pears, the interim regulatory action recommended extension of the withholding period from 14 days to 28 days, to allow residues to decline to acceptable levels:

- *Pears: Do Not Harvest For 28 Days After Application*

In addition, the suspension of endosulfan products included the following recommendation, as the use patterns may pose an unacceptable dietary risk:

[8] JMPR first reported short-term estimates of dietary intake in 1999.

- *Do Not Use On Leafy Vegetables and Brussels sprouts*

The revised short-term dietary exposure ranges from 0 to 82% of the acute RfD for the 2 to 6 years age group and from 0.1 to 71% of the acute RfD for the 2 years and above age group (see Residues Appendix 4).

3.3 CONCLUSIONS FROM RESIDUES ASSESSMENT

The following conclusions were determined following assessment of the residues data. (These conclusions are further considered in conjunction with OHS conclusions in formulating the final recommendations, shown in section 7).

3.3.1 Use patterns

Residues data not provided
For the following crops, residues data were required but were not provided to the APVMA. Consequently, on the basis that the APVMA cannot be satisfied that the continued use of endosulfan for these uses would not be an undue hazard to the safety of people using anything containing its residues, the following use patterns are not supported:

- bananas;
- berries and other related fruit such as grapes and currants;
- bulb vegetables, namely onions and shallots;
- pastures, chou moeiller, vetch, lucerne, clover and medic crops;
- peanuts.

Short-term dietary concerns were highlighted
For the following crops short-term dietary concerns were highlighted. Consequently, on the basis that the APVMA cannot be satisfied that the continued use of endosulfan for these uses would not be an undue hazard to the safety of people using anything containing its residues, the following use patterns are not supported:

- leafy vegetables, silverbeet, spinach and cole crops (except broccoli, cabbage (head) and cauliflower);
- Brussels sprouts.

Crops produced primarily or substantially for livestock feed
For the following crops, that are produced either for livestock feed only or are grown and used for human food and for livestock feed, risks from residues in trade were shown to be unacceptable. Consequently, on the basis that the APVMA cannot be satisfied that the continued use of endosulfan for these uses would not unduly prejudice trade or commerce between Australia and places outside Australia, the following use patterns are not supported:

- for the control of heliothis and other pests at the rate of 735 g ai/ha (2.1 L product/ha) in pulse crops, cereal crops and oilseed crops (except cotton). This includes the use patterns for, maize and sorghum. The use pattern for sweet corn should be deleted from all product labels.

Crops produced primarily for purposes other than livestock feed
The following crops are produced primarily for purposes other than livestock feed:

- legume vegetables (green beans and green peas);
- cotton.

The issue of endosulfan uses on these crops has still to be determined. During the public consultation period the APVMA will actively seek comment from key stakeholders to help resolve this matter. The APVMA will also seek assurances that, should uses on cotton be retained,

appropriate and effective safeguards can and will be put in place to protect against violative residues in meat, and so protect Australia's meat trade.

3.3.2 New label instructions

In addition to the labelling requirements as defined in the Agvet Labelling Code (2001) and the interim report for the review of endosulfan (1998), the following instructions must also be included.

The following livestock feeding restraints must be included on all product labels:

- **This Product Must Not Be Used On Cotton or Legume Vegetables That Will Or May Be Fed To Livestock (*1)**
- **Do Not Feed Vegetable Wastes or Wrapper Leaves of Treated Vegetable Crops to Livestock**

(*1) Subject to final regulatory decision for uses on cotton and legume vegetables.

3.3.3 MRLs

The following amendments to the MRL Standard are proposed:

Table 1

Endosulfan

Code	Food	MRL (mg/kg)	
		Current	Proposed
FI 0026	Assorted tropical and sub-tropical fruits – edible peel	T2	–
FT 0030	Assorted tropical and sub-tropical fruits – inedible peel	T2	2
FB 0018	Berries and other small fruits	T2	–
VB 0400	Broccoli	T2	1
VB 0041	Cabbages, head	T2	1
VB 0404	Cauliflower	T2	1
GC 0080	Cereal grains	T0.2	0.1
FC 0001	Citrus fruits	T2	0.3
OC 0691	Cotton seed oil, crude	T0.5	–
MO 0105	Edible offal (mammalian)	T0.2	0.2
PE 0112	Eggs	T*0.05	0.02
VC 0045	Fruiting vegetables, cucurbits	T2	0.5
VO 0050	Fruiting vegetables, other than cucurbits	T2	1
VP 0060	Legume vegetables	T2	1
MM0095	Meat (mammalian) [in the fat]	0.2	0.2
ML 0106	Milks [in the fat]	T0.5	–
ML 0106	Milks	–	0.02
SO 0088	Oilseed	T1	1
VA 0385	Onion, bulb	T0.2	–
FP 0009	Pome fruits	T2	1
PO 0111	Poultry, edible offal of	0.2	*0.01
PM 0110	Poultry meat [in the fat]	0.2	0.05
VD 0070	Pulses	T1	*0.1
GC 0649	Rice	T0.1	–
VR 0075	Root and tuber vegetables	T2	0.5
VA 0388	Shallots	T2	–

VS 0078	Stalk and stem vegetables	T2	1
FS 0012	Stone fruits	T2	–
DT 1114	Tea, Green, Black	T30	–
TN 0085	Tree nuts	T2	0.05

Table 4

Code	Animal Feed Commodity	MRL (mg/kg)	
		Current	Proposed
-	Primary Feed Commodities	0.3	–
AB 0226	Apple pomace, dry	–	1
-	Cereal forage (green)	–	0.5
-	Citrus pulp and pomace, dry	–	2
-	Forage of pulse crops (green)	–	0.5
-	Forage of oilseed crops	–	0.5
AS 0081	Straw and fodder (dry) of cereal grains	–	0.5
-	Straw and fodder (dry) of oilseeds	–	*0.1
-	Straw and fodder (dry) of pulse crops		0.3

3.3.4 Withholding periods

The following withholding period statements are proposed in relation to the above MRLs:

Citrus fruit: Do Not Harvest For 3 Days After Application
Pome fruit: Do Not Harvest For 28 Days After Application
Avocado, Custard Apple, Kiwifruit, Mammey, Passionfruit, Pawpaw, Pomegranate, Rambutan, Sapodilla, Tamarillo: Do Not Harvest For 14 Days After Application
Mango, Persimmon: Do Not Harvest for 28 Days After Application
Lychees, Longans: Do Not Harvest For 7 Days After Application
Broccoli, Cabbage, Cauliflower: Do Not Harvest For 7 Days After Application
Cucurbits: Do Not Harvest For 7 Days After Application
Capsicum: Do Not Harvest For 3 Days After Application
Tomatoes: Do Not Harvest For 14 Days After Application
Cape gooseberry, Eggplant, Okra: Do Not Harvest For 7 Days After Application
Green Beans, Green Peas: Do Not Harvest For 7 Days After Application
Beetroot, Carrot, Potato, Sweet Potato, Taro: Do Not Harvest For 14 Days After Application
Celery, Rhubarb: Do Not Harvest For 7 Days After Application
Cashews, Pecans, Pistachios: Do Not Harvest For 14 Days After Application
Macadamias: Do Not Harvest For 2 Days After Application
Pulse Crops (Adzuki beans, Chickpeas, Cow peas, Faba beans, Field peas, Lupins, Mung beans, Navy beans, Pigeon peas):Harvest: Nil; **Grazing:** Do Not Graze Or Cut For Stockfood For 6 Weeks After Application.
Cereals (Barley, Oats, Rye, Triticale, Wheat): Harvest: Nil; **Grazing:** Do Not Graze Or Cut For Stockfood For 8 Weeks After Application
Oilseeds: Canola (Rapeseed), Linseed, Soya beans, Safflower, Sunflowers): Harvest: Nil; **Grazing:** Do Not Graze Or Cut For Stockfood For 8 Weeks After Application
Cotton: Do Not Harvest For 28 Days After Application (*2)

(*2) Subject to final regulatory decision for uses on cotton.

3.3.5 Outcome

The outcome of these conclusions is that, based on residues assessment, some uses would be deleted. These include late spray (heliothis) for broadacre and a number of horticultural uses (see Table 7.1).

However, it is proposed to seek further public comment before finalising the regulatory decision for uses on cotton and legume vegetables.

4. OH&S WORKER EXPOSURE ASSESSMENT SUMMARY

4.1 INTRODUCTION

Following the 1998 APVMA interim report of the review of endosulfan, based on the available data, concerns were raised with regard to exposure for workers during certain use and re-entry activities. The OH&S risk assessment was largely carried out using surrogate exposure data.

The interim report noted that the major use of endosulfan in Australia, at that time, was in cotton production, representing approximately 70% of use, and vegetables, accounting for 20%, with the remaining 10% divided between oilseeds, pome and stone fruits, exotic fruits and other crops, such as pulses and ornamentals. Label instructions permit the use of endosulfan in cereal crops, tobacco, and nursery crops. Endosulfan was noted to be an integrated pest management (IPM) tool in both horticulture and broadacre crops.

Current (suspended) labels include instructions for application by ground and by air, with endosulfan being applied aerially in significant quantities since the major crop is cotton. Ground applications are either by boom spray, airblast, airshear or knapsack with hand wand/nozzle.

Information available at the time of the interim report indicated that workers involved in crop tending and harvest activities could become contaminated with endosulfan product residues. Poisoning incidents reported overseas indicated that field workers may also experience health effects when re-entering endosulfan treated areas and it was identified that re-entry restrictions are needed on current endosulfan product labels.

Consequently, the APVMA decided that certain uses of endosulfan should continue on a temporary basis until additional worker exposure data were obtained. An interim re-entry period of 2 days (for field and orchard crops and for greenhouses) was recommended until new Australian data was generated. Existing guidance on safe flagging procedures was also identified for upgrading.

Due to the apparent lack of suitable studies (available in Australia or overseas) the APVMA required worker exposure data to be generated under actual Australian use conditions in order to generate specific data/information on the extent and circumstances of exposure to endosulfan in occupational settings. Work practices that were identified by the APVMA for further assessment were:

- Mixer/loaders in ground and aerial applications
- Manual flaggers for aerial applicators
- Orchard ground spray applicators (including re-entry)
- Broadacre ground spray applicators (including re-entry)
- Greenhouse workers
- Workers using hand-directed spray applicators.

The requisite worker exposure studies were conducted by the Australian Centre for Agricultural Health and Safety (Moree) and the Centre for Pesticide Application Safety (Gatton). The studies were based on a protocol approved by the APVMA and NOHSC, and in accordance with standards prescribed by the New England Health Research and University of Sydney Research ethics committees. All studies used the same formulation of endosulfan containing 350 g ai/L, which was considered representative of each of the products under review.

Assessment of the additional data was conducted by the National Occupational Health and Safety Commission (NOHSC).

4.2 FINDINGS

Recent findings, based on *in-vitro* human studies, have led to calculation of lower dermal absorption values for endosulfan than had previously been determined for the interim report. These revised values have impacted on issues identified in the interim report. They are reflected in all conclusions from new studies and ensuing recommendations in this report.

4.2.1 Orchard applications

Issues identified in interim report

Results (from available data and modeling) from the interim assessment indicated:

- Unacceptable MOE for M/L/A for high volume ground rig spraying of large areas (>20 ha/d). This finding was irrespective of:
    - Use of tractors with enclosed cabs, and/or
    - Wearing of extra layer of protective clothing, and/or
    - Use of closed mixing systems

- Unacceptable MOE for M/L/A for low volume ground rig spraying (mist blower[9]) of small and large areas (study range ~5 to 20 ha/d), using tractors without cabs. These risks were reduced to acceptable levels for small areas only (~ 5 ha/d) by:
    - Wearing of extra layer of protective clothing, or
    - Use of tractors with enclosed cabs

- Unacceptable MOE for M/L/A for hand-spraying (knapsack) of large areas. These risks were reduced to acceptable levels by:
    - Wearing of extra layer of protective clothing

Conclusions from new studies

With regard to Mixer/Loader (M/L) and Application (A), endosulfan (using ground air assist application with and without the use of closed cabins, ground air-shear spray and ground boom oscillating spray), acceptable MOE were determined for workers handling up to 40 kg ai/day and a work rate of 30 ha/day, when exposures for individual tasks were considered separately. MOE were acceptable for applicators with and without the use of head / face protection. Thus although required for M/L (due to acute inhalation risks), respirators are not required during application of the diluted product.

MOE for combined exposures (M/L/A/C) were acceptable for air assist with cabin, air shear with cabin, and oscillating boomspray applications only.

MOE for combined exposures (M/L/A/C) were unacceptable for air assist applications without cabins, where head / face exposure was included in the determination (ie, where workers were not wearing a respirator / hat).

Acceptable MOE were determined for cleaning down (C) operations following mixing/loading and spraying.

No hand spraying, aerial application or re-entry studies were carried out for orchard applications.

[9] Surrogate for airblast spraying

Proposed outcomes:

The APVMA can be satisfied that continued use of endosulfan products containing 350 g/L in EC formulations in accordance with current label instructions, would not be an undue hazard to the safety of workers.

It is recommended, however, that the label instructions be amended as follows:

Safety directions

MixerLoader

Waterproof or cotton overalls done up to the neck and wrist, elbow-length PVC gloves, full face-piece respirator (or half face-piece respirator plus goggles) and water-resistant footwear/boots worn beneath overalls.

Application

Waterproof or cotton overalls done up to the neck and wrist, elbow-length PVC gloves and water-resistant footwear/boots worn beneath overalls.

Precautionary statement:

For workers applying endosulfan using air assist equipment, a closed cabin is required. If an open cabin is used, a full or half face-piece respirator and washable cotton hat should be worn in addition to the PPE recommended for Applicator.

Re-entry interval: Refer to Section 4.2.4

4.2.2 Nursery crop applications

Issues identified in interim report

Results (from available data and modeling) from the interim assessment indicated:

- Unacceptable MOE for hand spraying of ornamentals. This finding was based on an application rate of 0.1 kg/ha per day.
- Risk for workers using hand-held equipment for greenhouse treatment could not be identified due to lack of measured or predicted (modeled) exposure data.

Conclusions from new studies

Studies were carried out for mixing/loading, hand-held spraying and cleaning down associated with nursery crops. It was not clear from the studies whether high or low-pressure systems were used.

Acceptable MOE were determined for workers mixing/loading and cleaning down operations, where up to 0.5 kg endosulfan was handled per day.

Combined M/L/A and cleaning down exposure provided acceptable MOE for workers carrying out all activities.

MOE determined from dermal exposure data for applicators with and without the use of head / face protection were acceptable. Thus although required for M/L (due to acute inhalation risks), respirators are not required during application of the diluted product.

No application or re-entry studies were carried out for greenhouses and no re-entry studies were carried out for outdoor nursery crops.

Proposed outcomes:

The APVMA can be satisfied that continued use of endosulfan products containing 350 g/L in EC formulations in accordance with current label instructions, would not be an undue hazard to the safety of workers.

It is recommended, however, that the label instructions be amended as follows:

Safety directions

Mixer/Loader

Waterproof or cotton overalls done up to the neck and wrist, washable cotton hat, elbow-length PVC gloves, full face-piece respirator or half face-piece respirator plus goggles and water-resistant footwear/boots worn beneath overalls.

Application

Waterproof or cotton overalls done up to the neck and wrist, elbow-length PVC gloves and water-resistant footwear/boots worn beneath overalls.

Re-entry interval: Refer to Section 4.2.4

Note: The above recommendation applies to outdoor applications.

4.2.3 Broadacre applications

Issues identified in interim report

No measured exposure data were available in the interim report (APVMA 1998). Results (from modeling data) indicated:

- *Unacceptable* MOE for M/L/A for low volume boomspray (0.5 –2.1 L product in 100-400 L water) of areas (~50 ha/d). This finding was irrespective of:
    - Use of tractors with enclosed cabs
- *Acceptable* MOE for Applicators for low volume (0.5 L product in 400 L water) boomspray of areas (~50 ha/d).

Conclusions from new studies (Broadacre crops / aerial application)

Studies were carried out for mixing/loading endosulfan for aerial application and exposure to support workers (markers etc) using vehicles (including ATVs) and cleaning down operations.

Mixer/loader exposures were determined for bulk, mini-bulk and small containers in open and closed systems for aerial application of broadacre crops. The total endosulfan handled/day was 1470 kg ai based on an application rate of 2.1 L/ha and work rate of 2000 ha/day.

Acceptable MOE were determined for mixer/loaders using open/remote or closed base systems for aerial application.

Acceptable MOE were determined for aerial applicators (pilots), and support workers in vehicles and ATVs

MOE determined from dermal exposure data for applicators and support workers with and without the use of head / face protection were acceptable. Thus, although required for mixer/loaders, respirator and hat are not required during application of the diluted product.

Acceptable MOE were determined for workers conducting cleaning down activities.

Conclusions based on PHED data (Broadacre crops / ground application)

PHED data for ground application (boom spray) were recalculated using a 10% dermal absorption factor. Acceptable MOE were determined for workers open mixing/loading endosulfan for treatment of broadacre crops by ground application, only when wearing gloves.

Acceptable MOE were determined for workers using open cab for ground application of endosulfan to broadacre crops, with and without then use of gloves.

Acceptable MOE were determined for workers open pour mixing and ground boom open cab application (combined activity) to broadacre crops, only when wearing gloves.

Although acceptable MOE were determined for M/L and applicators from combined dermal and inhalation exposure, a respirator is required for all workers handling both the undiluted and diluted (spray) product, due to acute inhalation risks.[10]

Proposed outcomes:

The APVMA can be satisfied that continued use of endosulfan products containing 350 g/L in EC formulations in accordance with current label instructions, would not be an undue hazard to the safety of workers.

It is recommended, however, that the label instructions be amended as follows:

Safety directions

Mixer/Loader:
Waterproof or cotton overalls done up to the neck and wrist, elbow-length PVC gloves, full face-piece respirator (or half face-piece respirator plus goggles) and water-resistant footwear/boots worn beneath overalls.

Application (ground rig only):
Waterproof or cotton overalls done up to the neck and wrist, washable cotton hat, elbow-length PVC gloves, full face-piece respirator (or half face-piece) and water-resistant footwear/boots worn beneath overalls.

Precautionary statement

For aerial application, support workers/markers should be protected by enclosed cabs.

Re-entry interval: Refer to Section 4.2.4

[10] This report has been amended on May 31, 2004. To include requirements for respirators in broadacre applications.

4.2.4 Re-entry exposure

Issues identified in interim report

No information was provided by the registrants for the 1998 report on worker exposure during re-entry.

Clarke and Churches (1992) investigated re-entry exposure to cotton chippers in NSW. The total potential skin exposure was 12.2 mg/hr seven hours after endosulfan spraying to a 30 cm high crop and 19.8 mg/hr twenty-four hours after endosulfan spraying to a 50 cm high crop (NRA 1998).

A re-entry period of 24 hours was identified as inadequate. Results from this study indicated that a re-entry period would need to consider crop height.

In the absence of data, an interim re-entry period of 2-3 days was proposed pending submission and assessment of further information.

Conclusions from new studies

Re-entry exposure data was submitted for cotton crops only, for both ground and aerial application. MOE for other crops (as identified in labels) were extrapolated from cotton DFR data. TC (with and without PPE) determined from measured DFR data, dosimetry data, and generic TC for low and medium exposure were used to calculate the MOE and determine re-entry intervals for cotton, and for other crops using the extrapolated cotton DFR data.

No measured exposure data were provided for workers re-entering treated areas on day 0 and day 1. Data were only provided from day 2 onwards, with acceptable MOE being determined from day 2. Using the study TC and generic TC for low exposure for cotton chipping and crop checking acceptable MOE were obtained from day 0 onwards. Therefore:

i) as no measured data were provided for day 0 and day 1;
ii) as exposure sturdy data provided on day 2; and
iii) as DFR data provided acceptable MOE on Day 2;

a 2 day re-entry interval for workers entering treated cotton areas, and a 3 day re-entry period for all other crops, except pecans, (as identified from extrapolating endosulfan exposure study data) were recommended. A 5 day re-entry period was indicated for pecans.

There are no PPE requirements following the re-entry interval.

Proposed outcomes:

The following re-entry statements are to be included on the labels:

Cotton: "Do not allow re-entry into treated areas, within 48 hours of spraying".

Pecans: "Do not allow re-entry into treated areas, within 5 days of spraying".

All other crops: "Do not allow re-entry into treated areas, within 72 hours of spraying".

4.3 CONCLUSIONS FROM OH&S ASSESSMENT

The following conclusions were determined following the assessment of OHS studies. (These conclusions are further considered in conjunction with residues conclusions in formulating the final recommendations, in section 7).

4.3.1 Use patterns

Satisfactory data from measurement or modelling

Acceptable worker exposure levels can be achieved for the use of endosulfan in nursery, orchard and broadacre use patterns. Consequently, on the basis that the APVMA can be satisfied that the continued use of endosulfan for these uses would not be an undue hazard to the safety of people exposed to it during its handling, it is concluded that the following use patterns should continue to be permitted:

- nursery use applications.
- orchard use; ground rig applications.
- broadacre use applications; aerial applications and ground rig applications.

No suitable data provided

Uses of endosulfan for turf and hides were deleted from labels following the interim report on the basis that no information was provided and these uses were not supported by the states. However, these uses still remain in two current labels and are to be deleted as an outcome of the review.

4.3.2 New label instructions

In addition to the labelling requirements as defined in the Agvet Labelling Code (2001) and the interim review of endosulfan (1998), the following instructions must also be included:

- **Re-entry:**
  Cotton: "Do not allow re-entry into treated areas, within 48 hours of spraying".
  Pecans: "Do not allow re-entry into treated areas, within 5 days of spraying".
  All other crops: "Do not allow re-entry into treated areas, within 72 hours of spraying".

4.3.3 Safety directions

The following amended safety instructions are proposed:

Personal protective equipment:

For all Orchard, Nursery, Horticulture, and Broadacre use the following must be worn:

Mixer/Loader: Waterproof or cotton overalls done up to the neck and wrist, washable cotton hat, elbow-length PVC gloves, full face-piece respirator (or half face-piece respirator plus goggles) and water-resistant footwear/boots worn beneath overalls.

For all Orchard, Nursery, Horticulture, applications the following must be worn:

Application: Waterproof or cotton overalls done up to the neck and wrist, washable cotton hat, elbow-length PVC gloves and water-resistant footwear/boots worn beneath overalls.

For Broadacre application (Groundrig only) the following must be worn:[11]

Application: Waterproof or cotton overalls done up to the neck and wrist, washable cotton hat, elbow-length PVC gloves, full face-piece respirator (or half face-piece) and water-resistant footwear/boots worn beneath overalls.

[11] This report has been amended on May 31, 2004. The inclusion of respirator requirements for broadacre applications can be found at section 4.2.3

Precautionary statement:

Orchard applications: for workers applying endosulfan using air assist equipment, a closed cabin is required. If an open cabin is used, a full face-piece respirator should be worn.

Orchard applications: do not apply at a rate of more than 1400L of diluted spray per hectare.

Broadacre applications: for aerial application, support workers/markers should be protected by enclosed cabs.

4.3.4 Outcome

The outcome from the OH&S evaluation is that any uses of endosulfan for turf and hides that remain on labels are to be deleted. Other use patterns will be retained as indicted in section 7.1.

5. WATER QUALITY MONITORING

5.1 INTRODUCTION

The APVMA interim report of the endosulfan review (1998) concluded that, although well retained once in the soil, endosulfan contaminates the broader environment through spray drift, volatilisation and particle transport. This may occur aerially and, more importantly, by storm runoff leading to riverine contamination. The major metabolite, endosulfan sulphate, retains the toxicity of endosulfan and persists in soil and sediments.

Particular problems occurred with storm runoff into rivers, as endosulfan has high aquatic toxicity. For example, there have been a number of reported fish kills in NSW and Queensland between the mid 1970s and 1995. Whilst agricultural chemicals are not the only cause of fish kills, and despite difficulties in determining exact causes, cotton pesticides, in particular endosulfan, have been most often implicated as causing the majority of those fish kills (Bowmer *et al.* (1995); Napier *et al.* (1998)).

Pesticide monitoring in cotton growing areas of NSW during the cotton season consistently found endosulfan at concentrations above ANZECC guidelines (ANZECC and ARMCANZ 2000) in at least 50% of samples through the 1990s. Despite limited information, it was believed that a comparable situation existed in Queensland rivers.

Whilst there were indications at the time of the interim report that the situation may have been improving, contamination levels were unacceptably high. A number of measures were put in place by the APVMA to address these problems, including tighter controls and restrictions on use. The cotton industry introduced a Best Management Practice Manual, with guidelines to promote adoption of improved agricultural practices. Amongst other things, the aim of these measures was to minimise the impact of pesticides on riverine environments.

The APVMA interim report concluded that the cotton industry needed to demonstrate improved practices and reduced environmental contamination. The report required that:

> "*Trends in environmental contamination and total quantity used will be re-evaluated by 30 June 2001 to determine whether endosulfan use should be continued*".

As an interim outcome of the review, data was required to be submitted in relation to this requirement and, in addition, the report specified other requirements aimed at reducing environmental impacts from endosulfan use.

To measure the effectiveness of measures taken to protect the waterways in cotton regions, an evaluation has been conducted of river monitoring data provided by the then Department of Land and Water Conservation (Muschal (2000a); Muschal (2000b). This, together with other related information (Mawhinney, 2003) provides the basis of the following discussion.

5.2 DISCUSSION

Water quality is largely determined by land use, geology, climate, riparian vegetation and stream flow. Agricultural activities have a number of impacts on water quality including the levels of pesticides in waterways.

5.2.1 Water Monitoring in Rivers of NSW

The Central and North West Regions Water Quality Program (CNWRWQP) was jointly funded by the then Department of Land and Water Conservation and the water users of the Macintyre, Gwydir, Namoi and Macquarie Valleys. The project commenced in the early 1990s and focused on

the impacts of agriculture on water quality. Amongst other things, the levels of pesticides were monitored, at a number of sites, over a ten-year period.

Spray drift, vapour transport and runoff are the main pathways for pesticide transport into river systems. Spray drift and vapour both contribute low level but almost continuous inputs to the riverine ecosystem during the peak spraying season. The likelihood of pesticide drift is influenced by weather conditions, the method of application, equipment used and crop structure. Runoff tends to provide occasional high concentrations of pesticide contamination. Pesticides in runoff can be dissolved in the water, bound within sediments or adsorbed on to suspended particles.

The number and percentage of samples containing endosulfan contamination in the Namoi, Gwydir and Macintyre Valleys in each sampling year are given in Table 5.1. The number of samples includes all sampling sites across each valley, not just those located in the main cotton growing areas.

Table 5.1: No. & % endosulfan detections across the Namoi, Gwydir and Macintyre Valleys (1991/92 - 2001/02)

Year	No. Samples	Endosulfan
1991/92	296	174 (59%)
1992/93	299	194 (65%)
1993/94	210	137 (65%)
1994/95	281	135 (48%)
1995/96	291	169 (58%)
1996/97	395	207 (52%)
1997/98	404	196 (49%)
1998/99	400	182 (46%)
1999/00	413	126 (31%)
2000/01	438	76 (17%)
2001/02	290	14 (4.8%)

No results subsequent to 2001/02 available

The most commonly detected insecticide was endosulfan, with approximately 50% or more of samples containing residues of endosulfan during 1991-1999. The highest levels of contamination occurred in the periods 1991-94, coinciding with the rapid expansion of the cotton industry and a relatively low awareness of best practice methods compared to today's standards.

In 1998-1999 endosulfan residues were detected in cattle. This led to the introduction of greater restrictions on endosulfan use, and further emphasis on the cotton industries best management strategy. These two factors resulted in a dramatic reduction in endosulfan in the three valleys during 2000-2001 and 2001-2002.

In 2001-02, for the first time since pesticide monitoring commenced in 1990, no endosulfan residues were detected in the Namoi Valley (118 samples collected). This compares to previous years ranging from 32% (1991–92), peaking at 49% (1993–94), to 8% (2000–01). Endosulfan concentrations in the Gwydir River catchment in 2001–2002 were the lowest detected since 1991, although endosulfan and/or metabolites were detected at 9 out of 70 (13%) locations. This compares to previous detections ranging from 80% (1991–92) to 29% (2000–01). Furthermore, in recent years endosulfan concentrations fell below the ANZECC guidelines value for 99% ecosystem protection across all three valleys.

It was noted that this reduction may be due to a combination of factors including the implementation of best agricultural management practices, and a lack of runoff during 2001–02.

A report of the Mid-Lower Lachlan River Pesticide Study (NSW Department of Land & Water Conservation, June 2002) detected endosulfan in 35% of samples measured. However, it should be noted that the analytical procedures used were qualitative only, and not confirmed, and the majority of detections were at or slightly above the limit of detection. For this reason, whilst these results cannot be ignored, any conclusions to be drawn from this study are limited.

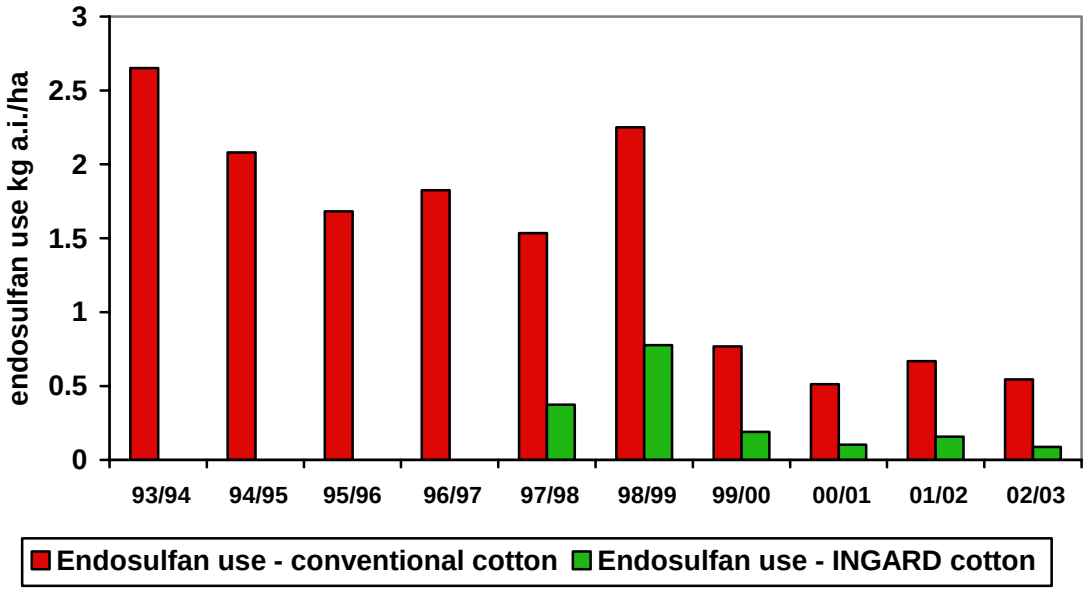
5.2.2 Endosulfan Usage

The figure below shows usage rates for endosulfan in Australia for the periods 1993-2003 (personal communication, B Pike, 2003. Data collected the annual Market Survey of Cotton Consultants Australia).

For the years up to 2000, use includes ultra-low volume (ULV) formulations plus emulsifiable concentrate (EC) formulations. Since 2000, only EC has been used. Usage has been converted to kg active ingredient /ha. For all years EC use has been generally consistent between 0.5 and 1 kg ai/ha.

INGARD (genetically modified cotton) was grown in 1996/97 but no specific data is available. It was noted that data for the limited area of Bollgard cotton in trials in 2001-02 indicated a reduction of only 30% endosulfan usage compared to INGARD. Endosulfan is a very good aphicide and it does not flair mites so it has a definite place in managing Bollgard as well.

Fig 5.1. Endosulfan usage rates in Australia



5.3 WATER QUALITY REFERENCES

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Napier G.M., Fairweather P.G. and Scott A.C. (1998). *Record of fish kills in inland waters of NSW and Queensland in relation to cotton pesticides*. WETLANDS (*Australia*), **17**: 60-71.

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6. ENDOCRINE DISRUPTION

6.1 INTRODUCTION

The APVMA interim report on the review of endosulfan (1998) assessed a comprehensive toxicity data package. The major hazard associated with endosulfan was the high acute toxicity through exposure by ingestion, skin contact or inhalation. It was found that endosulfan does not persist for long periods in the tissues or organs of animals, and it was concluded that endosulfan was unlikely to bioaccumulate in humans.

There was no increase noted in the incidence of cancer arising from high concentrations and long exposure periods to endosulfan in the diet. It was also concluded that endosulfan was not likely to have any harmful effects on reproduction or cause birth defects. Endosulfan was not found to cause damage to genetic material and there was no evidence of disruption to the endocrine hormonal system.

In examining the issue of whether endosulfan is a xenoestrogen, the interim report concluded that toxicology studies did not indicate that endosulfan induces any functional aberrations that might result from disruption of endocrine homeostasis. However, a US EPA RED (Reregistration Eligibility Decision), finalised in 2002, identified endosulfan as "a potential endocrine disruptor".

Subsequent to the interim report, the APVMA decided to re-examine the issue of endocrine disruption for endosulfan. In doing so, the objective was to:

1) examine the US EPA RED report and attendant information regarding endosulfan, and identify and clarify variations from previous conclusions reported in the interim report;
2) specifically re-examine the issue of possible endocrine disruption caused by endosulfan.

In conducting this re-examination, the conclusions of the interim report relating to the chronic, developmental and reproductive studies have been reconsidered, together with the relevant findings of the US EPA RED report. Additionally all of the published literature relevant to the endocrine disrupting potential of endosulfan to the end of April 2003 has been evaluated.

6.2 DISCUSSION

Definition and mechanisms

Several definitions for *endocrine disruptor* have been proposed.

The OECD (1998) defines an endocrine disruptor as "an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations. A potential endocrine disruptor is an exogenous substance or mixture that possesses properties that might be expected to lead to endocrine disruption in an intact organism, or it progeny or (sub)populations".

The working definition used in the final report of the US EPA Endocrine Disruptor Screening and Testing Advisory Committee (1998) for an endocrine disruptor is "an exogenous chemical or mixture that alters the structure or function(s) of the endocrine system and causes adverse effects at the level of the organism, its progeny, populations or subpopulations of organisms, based on scientific principles, data, weight-of-evidence, and the precautionary principle". The National Research Council of the USA has adopted the term *hormonally active agents*, in place of the term *endocrine disruptor chemicals* (1999).

Australian and US EPA policy relating to Endocrine Disruptor Effects

Australian agencies consider that endocrine disruption is not considered to be an adverse end-point *per se*, but rather is a mode or mechanism of action potentially leading to other toxicological or eco-toxicological outcomes, for example, reproductive, developmental, carcinogenic or ecological effects. These effects are routinely considered in reaching regulatory decisions (at least for pesticides, food additive chemicals and high production volume industrial chemicals for which the required toxicology database is extensive). This position is quite similar to the US EPA position.

The US EPA view of endocrine disruption has resulted from changes in its underlying legislation. The US EPA is required to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring oestrogen, or other such endocrine effects as the Administrator may designate." Consequently, the US EPA has broadened its definition of endocrine disruption to include the androgen and thyroid hormone systems, in addition to the oestrogen hormone system, and also included the evaluation of potential effects in wildlife.

The Australian vs USA position on endosulfan as an endocrine disruptor

The APVMA interim report on endosulfan stated that:

- "Several recent studies have reported that endosulfan, alone or in combination with other pesticides, may have oestrogenic binding capability, and possibly potential for perturbation of the endocrine system. To date, the available studies show only very weak binding to hormone receptors *in vitro*, and the evidence for any relevance to adverse physiological effects *in vivo* is extremely limited"; and that
- "Long term bioassays, and reproductive and developmental toxicology studies in experimental animals, do not indicate that endosulfan induces any functional aberrations which might result from disruption of endocrine homeostasis."

The US EPA RED stated that:

- "Exposure to endosulfan has resulted in both reproductive and developmental effects in non-target animals. Endosulfan exposure resulted in impaired development in amphibians, reduced cortisol secretion in fish, impaired development of the genital tract in birds and reduced hormone levels and sperm production and produced testicular atrophy in mammals. Additionally, endosulfan has been demonstrated to bind to the human oestrogen receptor and exhibit significant estrogenic activity. Whether the toxicity endpoints are a result of endocrine disruption is not known. However, it is clear that organisms treated with endosulfan did exhibit some toxic effects that have historically been associated with endocrine disrupting chemicals, for example, developmental and reproductive."

Both reports suggested that more information was needed.

Hence the main difference between the Australian and US EPA is primarily definitional. The APVMA report suggested that endosulfan does not appear to be significantly endocrine disruptive in mammals whereas the US EPA RED proposes that the weight of evidence from all studies (including amphibians, fish and birds) supports the designation of endosulfan as a potential endocrine disruptor.

6.3 CONCLUSIONS

From this assessment, it was determined that the overall conclusions and regulatory recommendations of both regulators are very similar.

The APVMA and US EPA reviews of endosulfan evaluated comparable databases and adopted similar regulatory approaches on most issues. The specific issue of whether endosulfan should be categorised as an endocrine disruptor remains as one significant difference between the two agencies. However, this arises mainly from the US EPA inclusion of data from all endocrine systems as well as potential effects in wildlife. Both agencies state that further testing of endosulfan using validated assays would be valuable and might help to further characterise effects related to endocrine disruption.

The APVMA evaluation reported the endocrine-related effects seen in test animals, particularly testicular toxicity, but noted that these appear to arise from homeostatic disturbance resulting from systemic toxicity. The APVMA report concludes that endosulfan binding to the oestrogen receptor is insignificant and considers that the regulatory endpoint chosen is adequately sensitive and protective against potential endocrine disruption by endosulfan.

The US EPA evaluation noted the effects seen in test animals and argued additionally that effects seen in amphibians, fish, birds and hormone receptor studies are indicative of potential endocrine disruption.

It is concluded from the APVMA re-examination of possible endocrine disruption caused by endosulfan that, from a public health perspective, there are no compelling reasons to change the conclusions of the APVMA interim report on the endocrine disrupting potential of endosulfan. While the effects seen in wildlife indicate that endosulfan may have endocrine disrupting potential in some species, the overall weight of evidence is that endosulfan has limited endocrine disrupting potential in mammals. Furthermore, while endosulfan may be relatively persistent in the environment and is capable of long-range transfer, it does not appear to bioaccumulate. The endocrine disrupting potential of endosulfan is not a significant risk to public health under the risk management controls and health standards established by the recent review.

7. REVIEW RECOMMENDATIONS

In addition to the interim outcomes of the review announced in 1998 and subsequent actions taken by the APVMA, and following evaluation of supplementary information, the conclusions discussed below were determined.

7.1 USE PATTERNS

Summary of the overall conclusions for the Review are summarised in Table 7.1.

TABLE 7.1 SUMMARY OF PROPOSED REGULATORY ACTION – USE PATTERNS

Use Pattern (label)	No data	Residues		OHS	Recommendation
		dietary expose	trade risk		
ORCHARDS:					
Citrus fruits, pome fruits, assorted tropical / subtropical fruits (inedible peel), tree nuts (excluding Banana):	-	-	-	-	Retain
Bananas:	**X**	-	-	-	Delete
BROADACRE:					
Pasture, chou moeiller, vetch, lucerne, clover and medic crops:	**X**	-	-	-	Delete
Pulse crops (*current uses*):	-	-	**X**	-	Delete
or Pulse crops (*pre-emergent use only*):	-	-	-	-	Retain (*1)
Cereal crops (excluding sorgum and maize) (*current uses*):	-	-	**X**	-	Delete
or Cereal crops (excluding sorgum and maize) (*pre-emergent use only*):	-	-	-	-	Retain (*1)
Sorgum and Maize	-	-	**X**	-	Delete
Oilseed crops (excluding cotton and peanuts) (*current uses*):	-	-	**X**	-	Delete
or Oilseed crops (excluding cotton and peanuts) (*pre-emergent use only*):	-	-	-	-	Retain (*1)
Cotton (recommended *2):	-	-	-	-	Retain (label restraint)
or Cotton (alternative *2):	-	-	**X**	-	Delete
Peanuts:	**X**	-	-	-	Delete
Legume vegetables (recommended *2):	-	-	-	-	Retain (label restraint)
or Legume vegetables (alternative *2)	-	-	**X**	-	Delete
HORTICULTURE:					
Berries & other related fruit:	**X**	-	-	-	Delete
Bulb vegetables:	**X**	-	-	-	Delete
Leafy vegetables:	-	**X**	-	-	Delete
Cole vegetables (except Broccoli, cabbage (head) and cauliflower):	-	**X**	-	-	Delete
Broccoli, cabbage (head) and cauliflower:	-	-	-	-	Retain

Brussel sprouts:	-	**X**	-	-	Delete
Fruiting vegetables, other than curcurbits (excluding sweet corn):	-	-	-	-	Retain
Cucurbits:	-	-	-	-	Retain
Sweet corn:	-	-	**X**	-	Delete
Root & tuber vegetables:	-	-	-	-	Retain
Stalk and stem vegetables:	-	-	-	-	Retain
Stone fruit	-	-	-	-	(*3)
OTHER: Native trees & shrubs, direct seeding:	-	-	-	-	Retain
Nursery and ornamental crops:	-	-	-	-	Retain
Tobacco:	-	-	-	-	Retain
Hides:	**X**	-	-	-	Delete (*4)
Lawn/turf:	**X**	-	-	-	Delete (*4)

X potential risk from some use patterns

*(*1) subject to the deletion of all use patterns except for the pre-emergent use to control Redlegged earth mite and blue oat mite.*

*(*2) Subject to final regulatory decision – use on cotton and legumes to be retained, with label restraint on feeding to livestock.*

*(*3) Stone fruit currently not on label, but were assessed in the report. Apricots had dietary concerns.*

*(*4) As a result of review outcome 3.# from the interim Endosulfan Report (August 1998). Worker exposure data/support for these use patterns was not provided for assessment.*

7.2 AMENDMENTS TO STANDARDS

7.2.1 Confirmation of Maximum Residue Levels

The following amendments to the MRL Standard are proposed:

Changes to Table 1 of the MRL Standard for Endosulfan

Code	Food	MRL (mg/kg)	
		Current	Proposed
FI 0026	Assorted tropical and sub-tropical fruits – edible peel	T2	–
FT 0030	Assorted tropical and sub-tropical fruits – inedible peel	T2	2
FB 0018	Berries and other small fruits	T2	–
VB 0400	Broccoli	T2	1
VB 0041	Cabbages, head	T2	1
VB 0404	Cauliflower	T2	1
GC 0080	Cereal grains	T0.2	0.1
FC 0001	Citrus fruits	T2	0.3
OC 0691	Cotton seed oil, crude	T0.5	–
MO 0105	Edible offal (mammalian)	T0.2	0.2
PE 0112	Eggs	T*0.05	0.02
VC 0045	Fruiting vegetables, cucurbits	T2	0.5
VO 0050	Fruiting vegetables, other than cucurbits	T2	1
VP 0060	Legume vegetables	T2	1
ML 0106	Milks [in the fat]	T0.5	–
ML 0106	Milks	–	0.02
MM0095	Meat (mammalian) [in the fat]	0.2	0.2
SO 0088	Oilseed	T1	1
VA 0385	Onion, bulb	T0.2	–
FP 0009	Pome fruits	T2	1
PO 0111	Poultry, edible offal of	0.2	*0.01
PM 0110	Poultry meat [in the fat]	0.2	0.05
VD 0070	Pulses	T1	*0.1
GC 0649	Rice	T0.1	–
VR 0075	Root and tuber vegetables	T2	0.5
VA 0388	Shallots	T2	–
VS 0078	Stalk and stem vegetables	T2	1
FS 0012	Stone fruits	T2	–
DT 1114	Tea, Green, Black	T30	–
TN 0085	Tree nuts	T2	0.05

Changes to Table 4 of the MRL Standard for Endosulfan

Code	Animal Feed Commodity	MRL (mg/kg)	
		Current	Proposed
-	Primary Feed Commodities	0.3	–
AB 0226	Apple pomace, dry	–	1
-	Cereal forage (green)	–	0.5
-	Citrus pulp and pomace, dry	–	2
-	Forage of pulse crops (green)	–	0.5
-	Forage of oilseed crops	–	0.5
AS 0081	Straw and fodder (dry) of cereal grains	–	0.5
-	Straw and fodder (dry) of oilseeds	–	*0.1
-	Straw and fodder of pulse crops	-	0.3

7.2.2 Withholding periods

The following withholding period statements are recommended in relation to the above MRLs:

Citrus fruit: Do Not Harvest For 3 Days After Application
Pome fruit: Do Not Harvest For 28 Days After Application
Avocado, Custard Apple, Kiwifruit, Mammey, Passionfruit, Pawpaw, Pomegranate, Rambutan, Sapodilla, Tamarillo: Do Not Harvest For 14 Days After Application
Mango, Persimmon: Do Not Harvest for 28 Days After Application
Lychees, Longans: Do Not Harvest For 7 Days After Application
Broccoli, Cabbage, Cauliflower: Do Not Harvest For 7 Days After Application
Cucurbits: Do Not Harvest For 7 Days After Application
Capsicum: Do Not Harvest For 3 Days After Application
Tomatoes: Do Not Harvest For 14 Days After Application
Cape gooseberry, Eggplant, Okra: Do Not Harvest For 7 Days After Application
Green Beans, Green Peas: Do Not Harvest For 7 Days After Application
Beetroot, Carrot, Potato, Sweet Potato, Taro: Do Not Harvest For 14 Days After Application
Celery, Rhubarb: Do Not Harvest For 7 Days After Application
Cashews, Pecans, Pistachios: Do Not Harvest For 14 Days After Application
Macadamias: Do Not Harvest For 2 Days After Application
Pulse Crops (Adzuki beans, Chickpeas, Cow peas, Faba beans, Field peas, Lupins, Mung beans, Navy beans, Pigeon peas):Harvest: Nil; **Grazing:** Do Not Graze Or Cut For Stockfood For 6 Weeks After Application.
Cereals (Barley, Oats, Rye, Triticale, Wheat): Harvest: Nil; **Grazing:** Do Not Graze Or Cut For Stockfood For 8 Weeks After Application
Oilseeds: Canola (Rapeseed), Linseed, Soya beans, Safflower, Sunflowers): Harvest: Nil; **Grazing:** Do Not Graze Or Cut For Stockfood For 8 Weeks After Application
Cotton: Do Not Harvest For 28 Days After Application (*2)

(*2) Subject to final regulatory decision for uses on cotton.

7.2.3 Label directions

In addition to the labelling requirements as defined in the Agvet Labelling Code (2001) and the interim review of endosulfan (1998), the following instructions must also be included:

- **Re-entry:**
  Cotton: "Do not allow re-entry into treated areas, within 48 hours of spraying".
  Pecans: "Do not allow re-entry into treated areas, within 5 days of spraying".
  All other crops: "Do not allow re-entry into treated areas, within 72 hours of spraying".

Note: The above recommendation applies to outdoors and greenhouse applications.

The following livestock feeding restraints must be included on all product labels:

- **This Product Must Not Be Used On Cotton or Legume Vegetables That Will Or May Be Fed To Livestock (*1)**
- **Do Not Feed Vegetable Wastes or Wrapper Leaves of Treated Vegetable Crops to Livestock**

(*1) Subject to final regulatory decision for uses on cotton and legume vegetables

7.2.4 Safety directions

The following amended safety instructions are proposed:

Personal protective equipment:

For all Orchard, Nursery, Horticulture, and Broadacre use the following must be worn:

Mixer/Loader: Waterproof or cotton overalls done up to the neck and wrist, washable cotton hat, elbow-length PVC gloves, full face-piece respirator and water-resistant footwear/boots worn beneath overalls.

For all Orchard, Nursery, Horticulture, applications the following must be worn:

Application: Waterproof or cotton overalls done up to the neck and wrist, washable cotton hat, elbow-length PVC gloves and water-resistant footwear/boots worn beneath overalls.

For Broadacre application (Groundrig only) the following must be worn:[12]

Application: Waterproof or cotton overalls done up to the neck and wrist, washable cotton hat, elbow-length PVC gloves, full face-piece respirator (or half face-piece) and water-resistant footwear/boots worn beneath overalls.

Precautionary statement:

Orchard applications: for workers applying endosulfan using air assist equipment, a closed cabin is required. If an open cabin is used, a full face-piece respirator should be worn.

[12] This report has been amended on May 31, 2004. The inclusion of respirator requirements for broadacre applications can be found at section 4.2.3

Orchard applications: do not apply at a rate of more than 1400L of diluted spray per hectare.

Broadacre applications: for aerial application, support workers/markers should be protected by enclosed cabs.

7.3 PROPOSED REGULATORY ACTIONS

1. As an outcome of these evaluations it is proposed that for endosulfan:

    a. All product labels be varied by:

        - deleting the uses, as specified in section 7.1;
        - amending MRLs and associated withholding periods as specified in sections 7.2.1 and 7.2.2;
        - adding new safety instructions as specified in sections 7.2.3 and 7.2.4.

    b. All product registrations under consideration, as listed in section 1.1, be affirmed.

    c. Registrants of products registered subject to outcome of the review, as listed in section 1.1, be required to comply with the outcomes of the review.

2. The issue of use on cotton and legumes has still to be determined.