# The NRA review of

# ENDOSULFAN

## August 1998

## VOLUME 1

National Registration Authority for Agricultural and Veterinary Chemicals

**Existing Chemicals Review Program**

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# FOREWORD

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) is an independent statutory authority with responsibility for the regulation of agricultural and veterinary chemicals.

The NRA's Existing Chemicals Review Program (ECRP) systematically examines agricultural and veterinary chemicals registered in the past to determine whether they continue to meet current standards for registration. Chemicals for review are chosen according to pre-determined, publicly available selection criteria. Public participation is a key aspect of this program.

In undertaking reviews, the NRA works in close cooperation with advisory agencies including the Department of Health and Family Services (Chemicals and Non-Prescription Drug Branch), Environment Australia (Risk Assessment and Policy Section), National Occupational Health and Safety Commission (Chemical Assessment Division) and relevant State Departments.

The NRA has a policy of encouraging openness and transparency in its activities and community involvement in decision-making. The publication of evaluation documents for all ECRP reviews is a part of that process.

The NRA also makes these reports available to the regulatory agencies of other countries as part of bilateral agreements or as part of the OECD *ad hoc* exchange program. 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.

The summary provides a brief overview of the review of endosulfan that has been conducted by the NRA and its advisory agencies. The review's findings are based on information collected from a variety of sources, including data packages and information submitted by registrants, information submitted by members of the public, questionnaires sent to key user/industry groups and government organisations, and literature searches.

The information and technical data required by the NRA 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. Details of required data are outlined in various NRA publications.

Other publications explaining the NRA's requirements for registration can also be purchased or obtained by contacting the NRA. Among these are: *Ag Manual: The Requirements Manual for Agricultural Chemicals; Vet Manual: The Requirements Manual for Veterinary Chemicals* and the *Agricultural Requirements Series*.

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# BRIEF OVERVIEW

Endosulfan is an insecticide which has been widely used in Australia for over 30 years. The agricultural industry and State agricultural authorities advise that endosulfan is extremely important to agriculture, and for some crop/pest situations there are no alternatives at all or none which work as well.

Endosulfan is an organochlorine chemical, but unlike most other members of this class, it largely disappears from soil in 3 to 6 months and does not remain in the bodies of animals or humans. Numerous scientific studies have not found any evidence of involvement in cancer, birth defects, damage to genetic material, disruption of the endocrine hormone system or other long term affects due to chronic, low level exposure. However, endosulfan has a high acute or immediate toxicity to humans which is a matter of concern for agricultural workers. In addition, endosulfan is quite toxic to fish and other aquatic organisms.

Although endosulfan concentrations in surface waters in areas of intensive use routinely exceed ANZECC criteria recommended to protect aquatic ecosystems, there is not yet clear evidence that endosulfan is causing long term harm to the general environment or biological communities. However, it is known that during parts of each year in the rivers and creeks of these regions, endosulfan reaches concentrations which are lethal to important species of native fish and native macroinvertabrates when tested under laboratory conditions. Regular attainment of such concentrations of endosulfan in regional surface waters is not acceptable on an ongoing basis. Concern over this problem is increased by predictions of some authorities that acreage of cotton, the main user of endosulfan, is likely to increase significantly in the next few years in some regions.

A simple ban of endosulfan could lead to other problems. This is because endosulfan has relatively low toxicity to many species of beneficial insects, mites and spiders (that is, ones which prey upon or parasitise damaging insect pests). Other chemicals, necessarily substituted for endosulfan, would kill beneficial insects leading to population explosions of damaging pests which in turn would require more frequent sprays of harsher chemicals than if endosulfan had been used in the first place. In addition, because endosulfan is from a different chemical class than almost all other available insecticides, its use is very important for slowing the development of insecticide resistance to the other chemicals. Loss of endosulfan would, therefore, also lead to more insecticide use due to increasing resistance among insect pests. The net result is greater overall danger to agricultural workers and to the environment.

To address the above concerns, the National Registration Authority has taken steps to manage the use of endosulfan on an interim basis while more data on worker safety and commodity residues are developed to determine specific requirements in those areas necessary for ongoing use. In addition, the NRA has taken steps designed to reduce the inappropriate use of endosulfan and to reduce the amount of endosulfan which is carried off farms into creeks and rivers. The results of environmental monitoring and an assessment of use patterns over the next three years will be examined to determine whether endosulfan can continue to be used.

# SUMMARY


## Background information on endosulfan

Endosulfan is an organochlorine insecticide, but unlike other organochlorines such as dieldrin and chlordane, it does not persist for years in the environment. It is fat soluble and will produce residues in animal fat while animals continue to consume feed containing endosulfan residues. However, endosulfan does not accumulate in the body in the way other organochlorine chemicals do and when animals are taken off contaminated feed, any significant residues present in the body drop by half about every 7 to 14 days depending upon the species.

Endosulfan is a broad spectrum insecticide/acaricide which is registered in Australia for control of a large variety of insects and mites in ranges of horticultural and agricultural crops. Among the pest/crop combinations for which this insecticide is registered are aphids, thrips, beetles, foliar feeding larvae, mites, cutworms, *Helicoverpa* spp, bugs, whiteflies and leafhoppers on citrus, pome and small fruits, fibre and forage crops, grains, nuts, oilseeds, pulses, ornamentals, tobacco and vegetables. It is not used in animal production. This use profile is similar to its use in other countries such as the USA and southern European countries.

Large quantities of endosulfan are used in Australia every year with approximately 900 tonnes of technical grade endosulfan being imported annually for formulation into products for use in agriculture and horticulture. This amount of technical material is formulated into some 2.9 million litres of insecticide concentrate, by far the greatest percentage of which is used in cotton (approximately 70%), followed by vegetables (approximately 20%). Almost equal quantities of ultra low volume (ULV) and emulsifiable concentrate (EC) formulations are applied in cotton since there are significant quantities applied by aircraft. However, it is possible that use of ULV formulations may diminish over time in favour of EC formulations because of a reduced potential for drift of spray off target with larger droplets.

## Use of endosulfan in agriculture

State agricultural authorities and growers emphasised the importance of endosulfan to successful farming operations and identified many crops for which continued availability of endosulfan was considered to be necessary. It is considered to be especially suited to use in Integrated Pest Management (IPM) and resistance management strategies because it has proved to be ‘soft’ on beneficial, insects and it is one of the few remaining effective organochlorine insecticides which can be used as a rotation in resistance management strategies.

The introduction of transgenic Bt cotton (genetically altered by inclusion of a gene to produce a *Bacillus thuringiensis* (Bt) toxin) will have an initial impact on the amount of endosulfan required in the cotton industry. However, experts agree that endosulfan will continue to be essential for the viability of the cotton industry because of factors such as the risk of resistance developing to Bt, the emergence of new pests and the possible need to use chemicals when the cotton plants are older and not producing the same levels of Bt toxin. In addition, research into use of transgenic cotton to guarantee its usefulness in cotton production is continuing.

Endosulfan use has been implicated in a number of environmental incidents, particularly related to fish kills in cotton growing areas, and has also been found to result in isolated residue detections in beef. These issues have prompted the respective industries to instigate strategies to minimise the impact of such incidents. Although there are encouraging signs that the strategies have significantly reduced the impact of endosulfan use by these industries, further development of these strategies is being undertaken.

The cotton industry has devoted significant resources to developing best management practice farming methods to reduce off-farm movement of endosulfan and indications to date are that these strategies have resulted in reduced levels of environmental endosulfan.

The cattle industry has expended considerable research effort in examining the fate of residues in cattle and use of endosulfan on crops which may be used for stock foods and also the environmental fate of endosulfan. A campaign to heighten grower awareness of the difficulty and strategies to use to avoid violative residues has also been conducted and contributed to the reduction in residue detections in meat and other cattle products.

The use of endosulfan on commodities which may be used as stock foods is an important consideration because endosulfan will build up in the fat of cattle while animals continue to be exposed to feed containing high levels of endosulfan. An export slaughter interval (ESI) of 42 days has therefore been established to give producers a guide as to the time necessary for residues to drop below the Maximum Residue Limit (MRL) if cattle are taken off feed containing endosulfan. This figure is approximately equivalent to four half lives for endosulfan in cattle.

In relation to its use in stock food commodities, this research has resulted in the MRL for primary feed commodities being raised to 0.3 mg/kg and the discovery that residues of endosulfan on plant tissue which is no longer actively growing decay much more slowly than they do on actively growing plant tissue.

These activities have led to a significant reduction in the incidence of endosulfan detections in beef, but have also highlighted the need for changed practices in relation to feeding crops/produce treated with endosulfan to cattle.

## Community concerns

Considerable concern has been expressed by members of the community in a number of cotton growing areas of New South Wales (NSW), particularly Gunnedah, regarding the possible health and environmental effects of pesticide (including endosulfan) spraying associated with cotton production.

## Toxicology and Public Health Assessment

During the course of the review, a comprehensive toxicological data package was assessed. The major hazard associated with endosulfan is the high acute toxicity of the compound when exposure occurs by ingestion, skin contact, or inhalation. When laboratory animals are exposed to endosulfan, some of the signs of poisoning include drooling, hyperactivity, difficulty in breathing, diarrhoea, tremors, hunching and convulsions. Endosulfan does not persist for long periods in the tissues or organs of animals, and passes relatively quickly from the body after animals are exposed to this compound. From animal data, it is concluded that endosulfan does not bioaccumulate in humans.

When endosulfan is repeatedly given to laboratory animals, the main effects are seen in the kidneys, and these effects depend on the dose of endosulfan, and the length of time that endosulfan is administered. For example, ageing laboratory rats normally suffer from a high rate of progressive chronic glomerulonephrosis, a condition that results in degeneration of the kidneys. However, when rats are exposed to relatively high levels of endosulfan in the diet for their entire lifetime, this condition worsens.

When rats and mice are exposed to relatively high levels of endosulfan in the diet for long periods, there is no increase in the incidence of cancer as a result of this exposure. In addition, endosulfan does not have any harmful effects on reproduction in experimental animals, and does not cause damage to genetic material. When endosulfan is given to rats during pregnancy, there is some delayed physical development in offspring, but only at the high doses of endosulfan that also caused harmful effects to the mothers. Endosulfan does not cause birth defects in animals exposed during pregnancy. There is also no evidence that endosulfan disrupts the endocrine hormonal system.

In Australia, endosulfan is not registered for use in or around the home, and so the most likely exposure to endosulfan for the public is via residues in food, via incidental exposure (including spray drift) or poisoning. Endosulfan is currently in the restrictive Schedule 7 of the *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP), and this is appropriate for a compound with the acute toxicity potential of endosulfan. Based on the current restricted uses of endosulfan, it is considered that there should be no harmful effects on public health from the continued use of endosulfan in Australia, and endosulfan residues are estimated to be very low in Australian diets.

In Australia, the current Acceptable Daily Intake (ADI) is 0.007 mg/kg/day, based on a no observed effect level (NOEL) of 0.7- 0.75 mg/kg/day, and using a 100-fold safety factor. The ADI for humans is considered to be a level of intake of a substance that can be ingested daily over an entire lifetime without any appreciable risk to health.

As a result of this review, some minor changes to public health standards are recommended. It is proposed that the acceptable daily intake (ADI) for endosulfan be 0.006 mg/kg/day, based on the lowest NOEL estimated in animal studies of approximately 0.6 mg/kg/day, and using a 100-fold safety factor.

## Occupational Health and Safety Issues

The OHS risk assessment concludes that some restrictions on endosulfan use are required to reduce the level of risk to workers. This conclusion is based on a quantitative risk assessment using measured and predicted worker exposure and a qualitative risk assessment for uses where worker exposure data is not available.

Limited measured worker exposure data were submitted for consideration during the review. These studies, together with predictive exposure modelling, indicated that in many of the situations encountered in Australian agriculture, exposure could be high.

The OHS risk assessment indicates that there is a need to develop Australian worker exposure data for a number of agricultural uses in order to verify that current practices are adequately safe or to determine how to modify those practices to ensure safety. Work practices for which data are needed are:

- Mixer/loaders in ground and aerial applications
- Orchard ground spray applicators
- Broadacre ground spray applicators
- Manual flaggers for aerial applications
- Greenhouse workers
- Workers using hand directed spray applicators

The endosulfan use pattern and limited worker exposure data indicate that workers involved in crop tending and harvest activities could become contaminated with endosulfan product residues. Poisoning incident reporting overseas indicates that field workers may experience health effects when re-entering endosulfan treated areas. Re-entry restrictions are needed on current endosulfan product labels. An interim re-entry period of 2 days is therefore to be introduced, until new Australian data can be generated and analysed for field and orchard crops and for greenhouses.

There is also a need for the introduction of better engineering controls for packaging and dispensing of the concentrate, preferred use of enclosed cabs, additional personal protective equipment such as waterproof clothing and respirator and strengthened training requirements. Human flagging in aerial operations is not acceptable, unless flaggers are protected by engineering controls such as cabs. Existing guidance on safe flagging procedures requires upgrading.

Specification of low volume spraying parameters is not normally done on labels, and this is a serious limitation to defining worker exposure and risk.

Endosulfan and the products under review are hazardous substances and are covered by regulations to control workplace hazardous substances.

The existing safety directions for endosulfan need to be upgraded to include sufficient personal protective equipment requirements for all products.

## Environmental aspects of endosulfan use

From an environmental perspective, endosulfan has high aquatic toxicity and although well retained once within the soil, it contaminates the broader environment through spray drift, volatilisation and particle transport, both aerially on dust and more importantly by storm runoff leading to riverine contamination. The major metabolite, endosulfan sulfate, retains the toxicity of endosulfan and persists in soil and sediment.

Pesticide monitoring in the cotton growing areas of NSW during the season has consistently found endosulfan at concentrations above the ANZECC guideline of 0.01 μg/L in at least 50% of samples through the 1990s. [By comparison, the Canadian guideline is 0.02 μg/L and the current US EPA guidelines for protection of freshwater organisms are 0.22 μg/L (acute) and 0.056 μg/L (chronic). However, the US National Academy of Sciences recommends a more stringent criterion of 0.003 μg/L.] There are indications that the situation may be improving in recent seasons, but contamination remains at unacceptably high levels. Particular problems occur with storm events that produce surface runoff, when total endosulfan levels in excess of 1 μg/L are likely to prevail in rivers for a day or two. The limited information available suggests a comparable situation in Queensland rivers.

Laboratory testing has determined that acute LC50s for Australian native fish can be as low as 0.2 μg/L, and that some native invertebrate species are acutely sensitive at concentrations below 1 μg/L. Consideration of exposure and effects information indicates that acute impacts of endosulfan on fish are likely during the spray season. Isolated fish kill incidents have been reported after the release from cotton farms of both stormwater runoff and irrigation tailwater polluted with endosulfan. More subtle chronic effects on aquatic fauna are also considered possible given the frequency with which endosulfan breaches environmental guidelines and the high acute to chronic ratio determined for this substance. Low level aquatic exposure, particularly to the sulfate metabolite, persists throughout the year.

Endosulfan residues in the soil appear to exert protracted adverse impacts on earthworm populations and are likely to similarly affect sensitive soil arthropods.

## Proposed Changes

From the data, it is apparent that the availability of endosulfan cannot be continued without significant modifications to use patterns, labels, maximum residue limits and limitations on use. Research programs such as the Minimising the Impact of Pesticides on the Riverine Environment Research and Development Program are likely to result in greatly improved management practices.

In order to enable agricultural industries to continue to have access to endosulfan, a restricted use regime will be necessary. Such a regime should be seen as providing an opportunity to develop practices which address the environmental and worker safety concerns which have been identified relating to the use of endosulfan.

Therefore, in brief, the NRA is requiring that:

- Endosulfan be classed as a Restricted Chemical and supply and use be restricted to Farmcare accredited personnel (or equivalent) and/or licensed operators.
- Labels be modified with restraints to require record keeping, to limit use unless storm runoff can be contained on farm and for cotton, to require that practices follow the cotton industry Best Management Practices Manual.
- Trends in environmental contamination and total quantity used will be re-evaluated by 30 June 2001 to determine whether endosulfan use should be continued. #
- Worker exposure data for a variety of Australian agricultural practices to be supplied by 31/12/1999 to establish acceptable use patterns. #
- Worker exposure data for greenhouse use and greenhouse re-entry period be provided by 30/06/1999. #
- Data to establish safe re-entry periods for crops to be supplied by 31/12/1999. #
- Agricultural practices be improved to minimise off-target movement, including the use of buffer zones. The cotton industry's Best Management Practices Manual exemplifies this approach.
- Labels be modified by the addition of a re-entry period of two days and a statement recommending use of enclosed tractor cabs for ground application.
- To minimise environmental contamination, labels be modified by the inclusion of environmental warning statements.
- Worker/operator training be upgraded for those using this chemical. #
- Existing guidance on safe flagging procedures be upgraded by industry. Human flagging in aerial operations is not acceptable, unless flaggers are protected by engineering controls such as cabs. #
- Current MRLs which are not supported by adequate data be given temporary status from 30 June 1998 until 31 December 2000 or until appropriate supporting data are submitted. MRLs which are not supported by adequate data on 31 December 2000 should be deleted**. #**
- Further limitations in relation to the feeding of crops and crop residues which have been treated with endosulfan be included on labels
- All product registrants and TGAC approval holders be required to produce material safety data sheets for their respective TGACs and products. #

**# Data are required to be submitted in relation to these review outcomes.**

**PLEASE NOTE:**
**Full details of the review outcomes (including a table which indicates data required) are presented in Section 1, part 7 beginning on page 42 of this review**.

## ABBREVIATIONS AND ACRONYMS

| | |
|---|---|
| **ac** | Active Constituent |
| **ADI** | Acceptable Daily Intake (for humans) |
| **ai** | Active Ingredient |
| **ANZECC** | Australia and New Zealand Environment and Conservation Council |
| **Bt** | *Bacillus thuringiensis* |
| **ChE** | Cholinesterase |
| **d** | Day |
| **EC** | Emulsifiable Concentrate |
| **EC50** | Concentration at which 50% of the test population are affected. |
| **EEC** | Estimated Environmental Concentration |
| **GAP** | Good Agricultural Practice |
| **h** | Hour |
| **ha** | Hectare |
| ***in vitro*** | Outside the living body and in an artificial environment |
| ***in vivo*** | Inside the living body of a plant or animal |
| **IPM** | Integrated Pest Management |
| **kg** | Kilogram |
| **L** | Litre |
| **LC50** | Concentration that kills 50% of the test population of organisms |
| **LD50** | Dosage of chemical that kills 50% of the test population of organisms |
| **LOEL** | Lowest Observable Effect Level |
| **m** | Metre |
| **mg** | Milligram |
| **µg** | Microgram |
| **mL** | Millilitre |
| **MOE** | Margin of Exposure |
| **MRL** | Maximum Residue Limit |
| **MSDS** | Material Safety Data Sheet |
| **NDPSC** | National Drugs and Poisons Schedule Committee |
| **NHMRC** | National Health and Medical Research Council |
| **NOEL** | No Observed Effect Level |
| **NOHSC** | National Occupational Health and Safety Commission |
| **OP** | Organophosphate |
| **POEM** | Predictive Operator Exposure Model |
| **ppb** | Parts per Billion |
| **PPE** | Personal Protective Equipment |
| **ppm** | Parts per Million |
| **RBC** | Erythrocyte |
| **SUSDP** | Standard for the Uniform Scheduling of Drugs and Poisons |
| **TGAC** | Technical Grade Active Constituent |
| **WHP** | Withholding Period |
| **WSA** | Worksafe Australia |

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## SUMMARY OF ASSESSMENTS & REVIEW OUTCOMES

# 1. CHEMISTRY ASSESSMENT

## 1.1 Chemistry Aspects

The chemistry aspects (manufacturing process, quality control procedures, batch analysis results and analytical methods) of endosulfan TGACs were evaluated and found acceptable.

## 1.2 Endosulfan Technical Grade Active Constituent

Technical endosulfan consists of a mixture of two stereoisomers, alpha-endosulfan stereochemistry 3α, 5aβ, 6α, 9α, 9aβ-, comprises 64 to 67% of the technical grade; beta-endosulfan stereochemistry 3α, 5aα, 6β, 9β, 9aα-, comprises 29-32% of the technical grade.

**Microcontaminants**

There are not expected to be other compounds of toxicological significance (sulfotep, N-nitrosamines, halogenated dibenzo-p-dioxins or halogenated dibenzofurans and PCBs) in endosulfan TGACs due to the raw materials and synthetic chemistry route used.

# 2. TOXICOLOGICAL ASSESSMENT

The toxicological database for endosulfan, which consists primarily of toxicity tests conducted using animals, is quite extensive. In interpreting the data, it should be noted that toxicity tests generally use doses which are high compared to likely human exposures. The use of high doses increases the likelihood that potentially significant toxic effects will be identified. Toxicity tests should also indicate dose levels at which the specific toxic effects are unlikely to occur. Such dose levels as the No-Observed-Effect-Level (NOEL) are used to develop acceptable limits for dietary or other intakes at which no adverse health effects in humans would be expected.

## 2.1 Toxicokinetics and Metabolism

Following oral administration of endosulfan, either via single dose or dietary administration, elimination of the parent compound and its metabolites is extensive and relatively rapid in a range of species of experimental animals. In rats and mice, recovery of radiolabelled test material was generally greater than 85% of the administered dose, with a majority of this excretion occurring within a few days of administration. Excretion in rodents was mainly in the faeces, with a smaller amount excreted in the urine. Similarly, elimination of endosulfan was extensive in goats (>90%), with about 50% recovered in the faeces and 40% in the urine.

Dermal absorption was reported to be as high as 46% in rats, and about 20% in Rhesus monkeys.

In mice, endosulfan and its sulfate and diol metabolites were the major faecal excretion products, with the diol metabolite excreted in the urine, while in rats, biliary excretion was extensive (up to 50%), and there was little enterohepatic circulation from the bile. There is no appreciable toxicological concerns associated with bioaccumulation of endosulfan residues in body tissues, with only trace amounts of endosulfan residues found in most tissues, including the fat, of most species.

## 2.2 Acute Studies

Endosulfan has high acute toxicity in experimental animals, with wide variation in the LD50 of endosulfan depending on the route of administration, species, chemical specification of the test material, dosing vehicle and sex of the animal. Females were generally more sensitive to the acute toxicity effects of endosulfan than males, often by one order of magnitude or more. In many older toxicity studies, the chemical identity of the test material, including impurities, stabilisers and metabolites, was often poorly characterised. The oral LD50 for endosulfan in rats ranged from 9.6 to 160 mg/kg, and in mice from 13.5 to 35 mg/kg. However, the lowest oral LD50 for rats, using technical endosulfan known to conform to current FAO specifications, was 22.7 mg/kg. Similarly the lowest dermal LD50 in rabbits was 106 mg/kg, and in rats was 290 mg/kg, but the lowest dermal LD50 using current FAO specification endosulfan was 500 mg/kg in female rats, and >4000 mg/kg in male rats. In a 4-hour, whole body inhalational study the lowest LC50 was 13 mg/m$^3$ in female rats. The clinical signs of intoxication include piloerection, salivation, hyperactivity, respiratory distress, diarrhea, tremors, hunching and convulsions. The isomers of endosulfan also show acute oral toxicity profiles similar to that of technical endosulfan.

The acute toxicity of formulations containing endosulfan was dependent upon the concentration of the active ingredient in the end-use products, and were similar to those seen following administration of the active ingredient. Like endosulfan, the toxicity of the metabolites varies depending upon vehicle and species used. In general, the toxicities of the metabolites were similar to the parent compound, except for endosulfan diol which has low acute oral toxicity in the mouse.

Endosulfan was not an eye irritant in rabbits, while the 33.7% emulsifiable concentrate formulation of endosulfan was a severe eye irritant to rabbits. Endosulfan was a slight skin irritant in rabbits, while the emulsifiable concentrate formulation containing 33.7% endosulfan was a moderate skin irritant to rabbits. Endosulfan was not a skin sensitiser to guinea pigs.

Phenobarbital administration proved to be an effective therapeutic measure against an absolute lethal dose of endosulfan in rats, with reductions in the clinical signs of intoxication and in the mortality rate. Diazepam did not have a therapeutic effect against endosulfan intoxication in rats.

## 2.3 Short Term Studies

In dermal studies in rats, signs of toxicity included mortality, tremors, and hypersalivation, with the severity of these findings increasing with the endosulfan dose. In one study, no treatment-related effects were seen at 9 mg/kg/day, while at the next dose level (27 mg/kg/day) no clinical signs or mortality were seen in males, but there was significant mortality in females (5/6 animals), also in the absence of clinical signs. In another study, no adverse effects were seen at 12 mg/kg/day, but clinical signs and mortality were seen at the next dose level (48 mg/kg/day).

Rats were exposed to endosulfan in a 29-day inhalation toxicity study, but apart from a transient non-dose related increase in creatinine and decrease in SGOT levels in high dose females, no treatment-related changes in clinicochemical parameters was noted. No pathomorphological changes were seen in any of the test animals. The NOEL for toxicity was 2.0 $mg/m^3$ .

### Sub Chronic Studies

In 13-week dietary studies in rats, a range of treatment related effects were observed. In one study, increased kidney weight and granular pigment formation in kidney proximal tubular cells were seen at doses of approximately 3.85 mg/kg/day, with a NOEL for this effect of approximately 1.92 mg/kg/day. In another study, convulsions, increased salivation, decreased survival and increased serum lipids were seen at about 7.3 mg/kg/day, with the NOEL for these effects of about 2.13 mg/kg/day.

In a 12-month interim report of a lifetime dietary study in mice there were no apparent treatment related clinical signs or deaths, and the NOEL was 4.1 mg/kg/day in males and 4.7 mg/kg/day in females, based on histological findings in the liver and lymphatic system at doses of 13.5 to 42 mg/kg/day.

## 2.4 Long Term Studies

When mice were administered endosulfan technical via the diet for 78 weeks, no treatment related neoplastic lesions were seen in the study. Similarly, in a combined dietary chronic toxicity/carcinogenicity study in mice, where endosulfan was administered at doses up to 2.86 mg/kg/day for up to 24 months, no increase in the incidence of neoplastic or non-neoplastic lesions was observed. The NOEL for this latter study was approximately 0.84 mg/kg/day in males and 0.97 mg/kg/day in females, based on decreased body weights in males (24-month sacrifice) and decreased organ weights (liver, ovaries, lung) in males and females at the 12 and /or 18 month interim sacrifices at 2.51 mg/kg/day in males and 2.86 mg/kg/day in females.

There was no evidence of increased carcinogenicity findings in dietary studies where endosulfan was administered to rats at up to 5 mg/kg/day for up to 2 years. The NOEL for long term studies in rats was approximately 0.6 mg/kg/day, based upon the reduced body weights and pathological findings of progressive glomerulonephrosis (degeneration of the kidneys) at 2.9 mg/kg/day in a 2-year study. In a 78-week study where endosulfan was administered to rats at very high doses (up to about 40 mg/kg/day), treatment related non-neoplastic changes in the kidneys of male and female rats and the testes of males were observed at the low doses of 10 to 20 mg/kg/day.

No increase in incidence of neoplastic or non-neoplastic lesions were observed in Beagle dogs treated with endosulfan at up to 2.3 mg/kg/day for one year. Based on clinical signs (tonic contractions, and increased sensitivity to noise and optical stimuli) and reductions in body weights, the NOEL for this study was 0.65 mg/kg/day for males, and 0.57 mg/kg/day for females. When endosulfan was administered orally, via gelatin capsules, to adult mongrel dogs at dose levels up to 0.75 mg/kg/day for one year, no adverse effects were seen. Initially, a dose of 2.5 mg/kg/day was used, but the animals displayed severe clinical signs at this dose level, and the treatment was discontinued.

## 2.5 Reproduction Studies

In a dietary reproduction study in rats, where endosulfan was given to rats for two generations at doses of up to 5.72 mg/kg/day for males and 6.92 mg/kg/day for females, no effects on reproductive parameters or treatment related abnormalities being seen at any dose level tested in this study. The NOEL was approximately 1.0 mg/kg/day, based on an increase in liver and kidney weights at approximately 6 mg/kg/day.

## 2.6 Developmental Studies

When endosulfan was administered to pregnant rats during organogenesis at doses up to 6 mg/kg/day, no treatment related birth defects were observed. Signs of maternotoxicity (including decreased body weights, convulsions, hypersalivation, hyperactivity) were observed at doses of 2 and/or 6 mg/kg/day. Accompanying this maternotoxicity was evidence of delayed development and/or an isolated low incidence of skeletal variations at 6.0 mg/kg/day. Based on these effects, the NOEL for developmental toxicity was 2 mg/kg/day. The NOEL for maternotoxicity was 0.66 mg/kg/day based on decreases in body weight gain at 2 mg/kg/day and decreased body weight gain and clinical signs at 6 mg/kg/day.

When endosulfan was administered to rabbits during organogenesis at dose levels of up to 1.8 mg/kg/day, the high dose was associated with signs of maternotoxicity including noisy and rapid breathing, hyperactivity and convulsions. Endosulfan did not produce any teratogenic or developmental effects even in the presence of maternotoxicity. The NOEL for maternotoxicity was 0.7 mg/kg/day based on clinical signs seen at 1.8 mg/kg/day.

## 2.7 Genotoxicity Studies

Endosulfan was negative for genotoxicity in a wide range of assays, both *in vitro* (with and without metabolic activation) and *in vivo.*

## 2.8 Other studies

### Immunotoxicology

Isolated studies report a reduced ability of rats to mount an immune response to an antigen following subchronic exposure to endosulfan. The tests used for estimation of immune status, with the exception of the specific antibody response to tetanus toxoid, were less than ideal, and the absence of other immunotoxicological findings in the large number of bioassays conducted with endosulfan suggests that endosulfan does not have an adverse functional effect on the immune status of laboratory animals.

### Testicular Effects

In a long term rat study, exposure to endosulfan at a high dose (20 mg/kg/day) resulted in testicular atrophy, characterised by degeneration and necrosis of the germinal cells lining the seminiferous tubules. In addition, decreases in sperm count, along with increases in the incidence of sperm abnormalities, have been reported in the open literature, again at high doses of endosulfan in rodents. These effects may be related to the frank toxicity of endosulfan, and the functional significance of these findings is unclear, as reproductive and developmental studies in a number of species did not reveal any effect on reproduction indices (such as fertility) nor any increase in the incidence of defects or abnormalities in offspring. Given the high doses at which these effects were reported, it would appear that these effects are of limited significance to humans.

### Endocrine Effects

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 the endocrine hormone system.

## 2.9 Effects in Humans

In general, characterisation of the dose of endosulfan in poisoning cases has been poor. The lowest reported dose that resulted in death in humans was 35 mg/kg body weight, and deaths have also been reported after ingestions of approximately 295 and 467 mg/kg, with death occurring within 1 h of administration in some cases. Intensive medical treatment within one hour of endosulfan administration was reportedly successful at doses of 100 and 1000 mg/kg, with clinical signs in these patient consistent with those seen in laboratory animals, dominated by tonoclonic spasms. In a case where the dose was 1000 mg/kg, neurological symptoms requiring anti-epileptic therapy, which resulted from anoxia during treatment, were still reportedly required one year after endosulfan exposure.

## 2.10 Conclusions for Public Health Standards

### Poisons scheduling

Endosulfan is currently in the restrictive Schedule 7 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP), and this is appropriate for a compound with the acute toxicity potential of endosulfan. There are provisions for appropriate safety directions on the product label aimed at limiting exposure, and first aid instructions in the event of poisoning. Endosulfan is not registered for domestic use.

### No Observed Effect Level / Acceptable daily intake

The proposed acceptable daily intake (ADI) is 0.006 mg/kg/day, based on the lowest NOEL estimated in animal studies of approximately 0.6 mg/kg/day, and using a 100-fold safety factor. This NOEL was derived from a range of effects (including decreased body weights and kidney pathology) observed in a variety of studies (namely a 78-week dietary study in mice, a 1-year dietary study in dogs, developmental study in rats and 2-year dietary study in rats).

# 3. OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT

## 3.1 Existing Regulatory Controls for Occupational Health and Safety

### Hazardous Substances

Endosulfan is listed in the National Occupational Health and Safety Commission (NOHSC) List of Designated Hazardous Substances, with the cut-off concentrations, at 3.0% - Harmful, 25.0% - Toxic and 20.0% - Irritant. The following risk and safety phrases have been allocated to endosulfan:

| | |
|---|---|
| R24/25 | Toxic in contact with skin and if swallowed |
| R36 | Irritating to eyes |
| S28 | After contact with skin, wash immediately with plenty of.............[material to be specified by the manufacturer] |
| S36/37 | Wear suitable protective clothing and gloves |
| S44 | If you feel unwell, contact a doctor or Poisons Information Centre immediately (show the label where possible) |

Endosulfan products under review contain endosulfan at 350 g/L (35% EC products) or 240 g/L (24% ULV products) and are hazardous substances. Hazardous substances come under the controls for workers specified in NOHSC Control of Workplace Hazardous Substances. Hydrocarbon solvents make up a large proportion of the endosulfan product formulations.

### Atmospheric Monitoring

There is a NOHSC Exposure Standard for endosulfan of 0.1 $mg/m^3$ time weighted average with a skin notation indicating that absorption through the skin may be a significant source of exposure.

## 3.2 Toxicity and Contamination Relevant to Occupational Exposure

After single doses, endosulfan has high acute oral, dermal and inhalation toxicity in experimental animals. It is a slight eye and skin irritant but not a skin sensitiser. Skin contamination with 2.7 g of endosulfan, 7.7 mL of 35% EC product or 11.3 mL of 24% ULV product is needed for an average 60 kg worker to receive a dose equivalent to the dermal $LD_{50}$ on abraded skin in animals. The equivalent volume of working strength solution needed is 3.9 L at the maximum high volume endosulfan concentration of 0.07%. Volumes would be higher by a factor of 2.4 if the skin were not abraded.

Experimental dermal absorption studies for endosulfan were available for rats and monkeys (*in vivo*) and rats and humans (*in vitro*). The most relevant value for the occupational health and safety (OHS) risk assessment is 29%, derived from comparisons of rat and human data. This selection accounts for the most likely exposure time and levels of skin contamination found in end users.

The toxicology review has concluded that the oral NOEL for endosulfan is approximately 0.6 mg/kg/d based on a 78-week dietary study in mice, 1-year dietary study in dogs and developmental study in rats. In a 13 week dietary study in rats, the toxicology review concluded the NOEL to be 1.92 mg/kg/d based on increases in kidney weights and granular formation in kidney proximal tubule cells, at the next dose of 3.85 mg/kg/d.

Endosulfan is used on a seasonal basis. For OHS risk assessment the 13-week dietary study in rats is considered relevant. The NOEL for OHS assessment is therefore 1.92 mg/kg/d. Lowest-observed-effect-levels (LOEL) in this study was 3.85 mg/kg/d.

Taking into account dermal absorption of 29% (see below), this approximates a dermal dose of 6.6 mg/kg. This dose is close to the NOEL of 9 mg/kg/d achieved in the 30 day dermal rat study.

The dermal $LD_{50}$ of endosulfan is 45 mg/kg. For an acute toxic exposure, an average 60 kg worker would need to become contaminated on the skin with 2.7 g of endosulfan, 7.7 mL of EC formulation at 350 g/L or 11.3 mL of ULV formulation at 240 g/L, to reach the dermal $LD_{50}$. The amount of working strength solution needed to reach the dermal $LD_{50}$ will be 3.9 L of EC spray solution at the maximum high volume concentration of 0.07% endosulfan. Low volume spraying can result in high end use concentrations of endosulfan. For instance 0.74% endosulfan is possible with low volume (100 L/ha) spraying to vegetable and broadacre crops. In this case the amount of working strength solution needed to reach the dermal $LD_{50}$ is 0.4 L. The maximum concentration of endosulfan in EC aerial spraying solution is 7.4%. The volume of working strength solution needed to reach the dermal $LD_{50}$ is 40 mL. These calculations do not include a safety factor.

To estimate the repeat dose toxic potential, the oral NOEL of 1.92 mg/kg bw/d and percutaneous absorption of 29% is used. The amount of skin contamination needed to exceed this dose for an average 60 kg worker is 397 mg endosulfan, 1.1 mL of 35% EC, 1.6 mL of 24% ULV, or 567 mL, 54 mL and 5.4 mL working strength solution at 0.07%, 0.74% and 7.4% endosulfan, respectively. These calculations do not include a safety factor.

The LOEL in the study used to derive the NOEL is 3.85 mg/kg bw/d. This corresponds to skin contamination with 797 mg endosulfan, 2.3 mL of the 35 % EC product or 3.3 mL of the 24% ULV product.

Biomarkers for endosulfan have been used to only a limited extent to monitor exposure in workers. Studies have monitored urinary excretion of endosulfan and endosulfan-diol metabolite for endosulfan sprayers. No Biological Exposure Index (BEI) has been set for endosulfan.

The amounts of endosulfan workers may be exposed to during spraying operations and re-entry were estimated, to assess the likelihood of toxic effects. The rat subchronic and developmental NOEL and dermal absorption factor were considered against estimated exposures, to determine whether or not the risk was acceptable. The findings appear in later sections of this summary.

### 3.3 Reported Endosulfan Effects

The published scientific literature for endosulfan includes reports of poisoning following deliberate ingestion and adverse health effects in workers during use and at re-entry. The lowest dose proving fatal in humans after deliberate ingestion is 35 mg/kg bw. This would theoretically correspond with skin contamination of 20.3 mL of a 35% EC product.

Data obtained from the California Department of Food and Agriculture reporting system for workers over 1976-1987 (inclusive) implicates exposure to endosulfan alone in 42 incidents where medical advice was sought. None of the exposures was fatal. Most reports (approximately 40%) concerned exposure to field residues, with a small number concerning mixer/loaders, applicators and manufacture/formulation workers. The health effects reported included systemic toxicity and eye and skin irritation. The contribution of endosulfan-related reports to the overall workplace injuries was small.

There is only limited information on health effects experienced by endosulfan end users in Australia. One report on pesticide exposure and work practices in the New South Wales horticulture industry, found that growers did not adopt adequate safety precautions. Many growers felt that pesticides had at some time affected their health, however it was outside the scope of the report to investigate the links between health effects and any particular chemical. Despite anecdotal reports of overspraying of field workers by aerial sprayers, only one published incident involving an endosulfan product was available. In this case, oversprayed cotton chippers experienced respiratory effects, eye irritation and headaches.

Due to the lack of reporting systems in Australia, this reporting rate cannot be assumed to be an accurate representation of the extent of health effects or overspraying incidents experienced by field workers.

## 3.4 Endosulfan Use Pattern in Australia

### Handling Prior to End Use

Most endosulfan products are formulated in Australia using imported endosulfan. Formulators may be exposed to technical grade endosulfan and the formulated products.

Transport and storage workers handle only packaged technical grade active constituent or product so should not become contaminated with endosulfan unless the packaging is damaged.

EC products are available in 1 L, 5 L, 20 L and 200 L containers; ULV products are available in 200 L and 1000 L containers.

### Handling by End Users

Endosulfan use patterns considered in the OHS report come from product labels and NRA Performance Questionnaires. Use patterns are diverse, reflecting the variety of crops, application equipment, size of treatment areas and spraying frequency of endosulfan across Australia. The most common application methods are airblast and boom sprayers and aerial spraying. Endosulfan may be hand sprayed on small crop areas and for ornamentals and nursery uses. There are minor miscellaneous uses on some product labels. Home garden products are not available.

Across crop types, endosulfan EC labels indicate high volume or low volume ground spraying or both. Most high volume working strength sprays uses fall within a maximum endosulfan concentration of 0.07%. Low volume working strength sprays result in endosulfan concentrations of approximately 0.7%, however this would be higher in very low volume sprays believed to be used in orchards. In aerial spraying, EC formulations are most commonly applied at 735 g endosulfan/ha at a maximum end use concentration of 7.4%.

The use pattern of all ULV products is similar. They are applied undiluted by aerial spraying over large areas of broadacre crops at 360-750 g endosulfan/ha.

The NRA Performance Questionnaires revealed a wide range in numbers of hectares that could be treated per hour in ground or aerial spraying. For example, in broadacre crops, ground sprayers covered 8-50 ha/hr and aerial sprayers covered 100-400 ha/hr. Small scale users were not surveyed.

Use pattern information is used to estimate worker exposure under Australian conditions. Table 1 on the following page summarises the main crop categories, spraying pattern and sources of operator exposure data. Exposure data was derived from measured worker exposure studies conducted in orchards and in broadacre applications from the Pesticide Handler Exposure Database (PHED Version 1.1). Predicted exposures were calculated from the UK Predictive Operator Exposure Model (POEM) and were used to estimate worker risk for uses lacking actual exposure data.

**Table 1: Endosulfan spraying (35% EC): use rate and sources of worker exposure data by crop**

| Crop | Measured worker exposure (1) | Predictive Operator Exposure Model (2) | Spraying pattern (3) |
|---|---|---|---|
| Fruit & nut trees | high volume - airblast;<br>low volume - mistblower; high volume - hand-held | high volume & low volume - air-blast; electrostatic (air-blast as default) | high volume;<br>low volume |
| Vegetables, peanuts, berries & ornamentals | none submitted | high volume & low volume - boomspray; hand-held low | high volume;<br>low volume;<br>aerial (vegetables) |
| Vines | high volume - airblast;<br>low volume - mistblower; high volume - hand-held (none submitted - orchard studies used as surrogate) | high volume - air-blast | high volume;<br>low volume |
| Tobacco | high volume - airblast; high volume - hand-held (none submitted - orchard studies used as surrogate) | high volume - air-blast | high volume |
| Broadacre (4) including cereals, legumes, oilseeds, cotton & peanuts | none submitted | low volume - boomspray | low volume;<br>aerial |
| Turf | none submitted | high volume boomspray | high volume |
| Greenhouse | none submitted | none | high volume;<br>low volume |

(1) Hoechst Schering AgrEvo Pty Ltd submitted data
(2) Conducted for the occupational health and safety risk assessment
(3) from product labels and NRA Performance Questionnaires
(4) PHED data submitted by Hoechst for ground and aerial spraying

## 3.5 Occupational Exposure and Risk

Workers may be exposed to endosulfan when mixing/loading, applying spray, cleaning up spills and maintaining equipment. In addition re-entry workers such as crop checkers, manual weeders and harvesters may contact endosulfan residues on treated foliage. Inhalation of vapours from the concentrate is unlikely because endosulfan has low vapour pressure. The main routes of occupational exposure will be through skin contamination while performing routine tasks. Sprayers may also inhale spray mist.

Farm-based operators or contractors may use endosulfan products. The frequency and duration of use are dependent upon crop type, area to be treated and number of repeat applications. Contractors are likely to receive the most intense exposure. Assessment of exposure and risk was complicated by the diversity of use patterns, compared with the limited end use scenarios with measured or predicted exposure data.

### Ground Spraying—Measured Worker Exposure

Studies were available for orchard uses by airblast, mistblower and hand held motorised knapsack equipment. These were used to assess the risk of endosulfan use in orchards (fruit and nut trees) and extrapolated to cover vines and tobacco. Findings revealed the significant contribution of applicator exposure to overall exposure and risk. The incorporation of a closed cab for applicators in any of the above crop categories significantly increased the assurance of acceptable risk for continued repeated use of endosulfan. Cabs with open windows substantially add to risk. Risk is also increased as the area treated per day is increased. Risk to mixer/loaders was lower than to applicators. (See detailed results and analysis in Section 5.)

Studies from the Pesticide Handlers Database (PHED Version 1.1) jointly developed and used by Canada and the United States were evaluated for risk of endosulfan use by groundboom applicator to broadacre crops with either open or closed cabs and mixer/loaders with either open or closed systems. Results from this analysis indicate that margins of safety are acceptable for applicators using open or closed cabs.

### Ground Spraying—Predicted Worker Exposure

Numerous end use scenarios were tested through POEM for a typical 35% EC product, with combinations of application rates, equipment, treatment areas and spraying times reflecting the use pattern. Scenarios covered the broad crop categories as in Table 1. POEM was used to supplement measured worker exposure studies (fruit and nut trees, vines and tobacco) or provide exposure data for end use scenarios with no measured data (vegetables, peanuts, berries, ornamentals, and turf).

The application methods tested were:

- boomspray, i.e. Vehicle mounted (with cab) hydraulic nozzles (V-Nozzle);
- airblast, ie Vehicle mounted (without cab) air-assisted, high volume (V-500) and low volume (V-100); and

- knapsack, ie hand held outdoors rotary disc atomisers: low level application (H-RDA-low).

Only a minority of end use scenarios had acceptable predicted exposure and risk for mixer/loaders, applicators and mixer/loaders/applicators (M/L/A). For example, complete elimination of mixer/loader exposure resulted in acceptable risk for short time high volume air-blast application to fruit and nut trees, boomspray application to berries, ornamentals and vegetables (one or two hectares over two hours) and boomspray high volume turf application (fifty hectares over six hours). For certain other uses, the addition of further controls on exposure such as enclosed mixing, extra personal protective clothing (PPE), enclosed cabs or, on occasion, restrictions over the area covered or time spent spraying, resulted in acceptable risk. (See Section 6 for detailed analysis and results.)

**Greenhouse Spraying**

There were no measured or predicted exposure data available to enable a risk assessment for workers spraying endosulfan inside greenhouses.

**Aerial Spraying—Qualitative Assessment**

There were no measured exposure studies available for workers involved in the aerial spraying of endosulfan and it was not possible to predict exposure using POEM. Hundreds of hectares of broadacre crops and vegetables may be treated per day by air. Operators may be involved in repeated operations using undiluted ULV products or diluted EC products containing a high concentration of endosulfan. Considering the extensive use of endosulfan, the 200 L or 1000 L bulk loading containers would be most frequently used. Incorporation of an automated transfer system from the container to a premix tank or plane should enable more effective exposure control than with open pour and mixing systems. For aerial spray operations, closed mixing/loading systems are used in most workplaces. In addition, mixer/loaders are likely to have received special training in chemical handling. Spray pilots are protected from direct spray contamination when located inside the plane. PHED data indicates that the risk to pilots is acceptable. Overall risk to mixer/loaders and pilots should be acceptable.

Flaggers involved in aerial spraying may become contaminated with spray mist. The chances of this type of exposure are high and cannot be quantified. PHED data indicates that the risk to flaggers in aerial operations is high. Therefore the risk to human flaggers is considered unacceptable, unless they are protected by engineering controls such as cabs.

### Other Uses

There were no measured or predicted exposure data available to enable a risk assessment for workers using endosulfan for any other uses such as treatment of hides, post-harvest treatment dipping of export pineapples and pot plant earthworm treatments.

### Re-entry

No information was available on worker exposure during re-entry. Official reports of endosulfan overspraying or direct contamination from treated crop foliage for workers in Australia are limited. One review investigating re-entry exposure to cotton chippers in New South Wales indicated that a re-entry period would need to consider crop height as well as whether or not foliar residues were dry. The risk was unacceptable for workers re-entering at 24 hours, the only time measured in the study. One NRA Performance Questionnaire reported that certain hand weeders in tomato crops could be affected by fumes for a couple of days after endosulfan product application. In overseas reports, the California Department of Food and Agriculture mandatory reporting system found that exposure to field residues made up a high proportion of the total end user incident reports involving endosulfan alone.

There is currently no re-entry period on endosulfan product labels. In the absence of data, an interim re-entry period of 2 days will be required until data is generated to allow determination of a suitable permanent re-entry period.

## 3.6 Conclusions

The OHS risk assessment concludes that restrictions on endosulfan use are required to reduce the level of risk to workers. This conclusion is based on a quantitative risk assessment using measured and predicted worker exposure and a qualitative risk assessment for uses where worker exposure data are not available.

Very limited measured worker exposure data (three studies in orchards and PHED data for certain ground and aerial broadacre applications) were submitted for consideration during the review. These studies, together with predictive exposure, indicate that in many of the situations encountered in Australian agriculture, exposure could be high.

The OHS risk assessment indicates that there is a need to develop Australian worker exposure data for a number of agricultural uses in order to verify that current practices are adequately safe or to determine how to modify those practices to ensure safety. Work practices for which data are needed are:

- Mixer/loaders in ground and aerial applications
- Orchard ground spray applicators
- Broadacre ground spray applicators
- Manual flaggers for aerial applications
- Greenhouse workers
- Workers using hand directed spray applicators

The endosulfan use pattern and limited worker exposure data indicate that workers involved in crop tending and harvest activities could become contaminated with endosulfan product residues. Poisoning incident reporting overseas indicates that field workers may experience health effects when re-entering endosulfan treated areas. Re-entry restrictions are needed on current endosulfan product labels. An interim re-entry period of 2 days is therefore to be introduced, until new Australian data can be generated and analysed for field and orchard crops and for greenhouses.

There is also a need for the introduction of better engineering controls for packaging and dispensing of the concentrate, preferred use of enclosed cabs, additional personal protective equipment such as waterproof clothing and respirator and strengthened training requirements. Human flagging in aerial operations is not acceptable, unless flaggers are protected by engineering controls such as cabs. Existing guidance on safe flagging procedures requires upgrading.

Specification of low volume spraying parameters is not normally done on labels, and this is a serious limitation to defining worker exposure and risk.

Endosulfan and the products under review are hazardous substances and are covered by regulations to control workplace hazardous substances.

The existing safety directions for endosulfan need to be upgraded to include sufficient personal protective equipment requirements for all products.

## 4. ENVIRONMENTAL ASSESSMENT

### Environmental Exposure

The main sources of information on levels of endosulfan in the Australian environment are the annual reports on pesticide monitoring generated under the Central and North West Regions Water Quality Program. The reports cover areas of irrigated agriculture within the Border, Gwydir, Macquarie and Namoi valleys in NSW, with monitoring of surface waters typically conducted over the summer cropping season (September to April).

Endosulfan is a widespread environmental contaminant in these areas, particularly during the cotton season. Significant contamination of waterways occurs downstream of cotton areas and has sometimes been attended by fish kills. Total endosulfan levels exceed, frequently by one and occasionally by two orders of magnitude, the ANZECC guideline of 0.01 µg/L for protection of aquatic life. By comparison, the Canadian guideline is 0.02 µg/L and the current US EPA guidelines for protection of freshwater organisms are 0.22 µg/L (acute) and 0.056 µg/L (chronic). However, the US National Academy of Sciences recommends a more stringent criterion of 0.003 µg/L.

In contrast to the water quality monitoring results described above for the cotton growing areas of northern New South Wales, results obtained in non-cotton growing areas show a different pattern. Sampling programs in the Murrumbidgee Irrigation Area of southern New South Wales have shown a substantial decreasing trend over the last three years in endosulfan contamination. During the 94/95 season, the ANZECC guideline was frequently exceeded with total endosulfan at times reaching levels in the range of 1 μg/L in the MIA drainage system. However in the years since then, detection of endosulfan has decreased substantially to be within or near the ANZEC guideline. The improvement is thought to be due to a decline in tomato production in the area, a move to closed systems for remaining tomato production and to an improvement in the management of endosulfan use in citrus.

During dry seasons, transport through the atmosphere is the main mode of riverine contamination with the more volatile isomer α-endosulfan being the dominant form. During wet years, both isomers may be detected in waterways as a result of runoff from sprayed areas, at significantly higher levels than when conditions are dry. In some parts of Australia, such as the upper Namoi valley, expansion of dryland cotton production on to flood prone land has exacerbated problems of riverine pollution associated with storm runoff. Such pollution continues after the spray season, with late summer storms washing soil contaminated with endosulfan sulfate into waterways. Low level contamination of waterways appears to persist through to the next season but limited investigations have found no evidence of build up from season to season.

Volatilisation from sprayed areas appears to contribute to a general low level aquatic contamination by endosulfan in areas where it finds widespread use, notably in cotton growing areas. From the environmental perspective, the export of endosulfan vapours from treated areas is undesirable. Ways of reducing the atmospheric vapour burden in critical areas need to be considered.

Most instances of serious aquatic contamination appear to arise through export of endosulfan residues in storm runoff. Residues can also enter drainage systems with irrigation tailwaters, to be subsequently mobilised into waterways by heavy rains. Sediment carried by tailwaters contains higher concentrations of endosulfan than the soil from which it is eroded as smaller particles containing higher proportions of surface sorbed endosulfan tend to be transported preferentially in overland flow. Because endosulfan tends to largely volatilise from soils in the one or two days following application and to undergo significant degradation in moist alkaline soils within a week, losses with runoff can be reduced by timing applications to avoid storm runoff situations, and by irrigating only after soil residues have subsided. The planting of a wheat cover crop prior to cotton also appears to have promise as a technique for reducing off-target contamination by runoff, although this practice may not be practical in NSW since the wheat could not be harvested before the beginning of the cotton season.

Exclusion of endosulfan residues from Australian waterways in areas of intensive endosulfan use is not possible with current technology and use patterns. Research into pesticide fate from the point of application on crops to potential discharge in rivers, and impacts on aquatic fauna, is approaching completion under the Minimising the Impact of Pesticides on the Riverine Environment Research and Development Program, findings from which have been particularly important in developing best management practice guidelines which now appear in the cotton industry's Best Management Practices Manual, the latest version of which was published in December 1997.

## 4.1 Environmental Chemistry and Fate

### Hydrolysis

Two tests submitted by the principal registrant indicate that endosulfan is hydrolytically stable at acidic pH but hydrolyses to endosulfan diol with a half-life of a few weeks at pH 7 and a few hours at pH 9. A literature study that took precautions to avoid volatilisation found hydrolytic half-lives at neutral pH in the order of months rather than weeks, but results may have been confounded by solubility limitations.

### Photolysis

Endosulfan appears photostable in solution, apart from some photoisomerisation of the β isomer to the α, and photodegrades only slowly on soil surfaces. There is no evidence that photolysis occurs on leaf surfaces. Photoisomerisation also occurs in the gas phase, as does hydrolysis and, to a limited extent, mineralisation. Estimated atmospheric half-lives are in the order of a week.

### Metabolism

A broad range of microorganisms isolated from agricultural soils are capable of degrading endosulfan. In general, fungi oxidise endosulfan to the sulfate, the major breakdown product in soils, and bacteria hydrolyse it to the diol, which is also an abiotic breakdown product under alkaline conditions. Microbial mineralisation is very inefficient.

Endosulfan degrades relatively rapidly in short term tests, with a few weeks to a couple of months required to reduce soil concentrations by 50% in the three soils tested. Corresponding times for breakdown of the sulfate metabolite are in the range of 4-6 months, and for total toxic residues (parent isomers and sulfate metabolite) about 4 months. Endosulfan also forms significant amounts of nonextractable residues in soils.

Short term tests on an Australian soil (alkaline grey cracking clay) found significant volatilisation, particularly of the α isomer from wet soils, and oxidation of up to 20% of applied α-endosulfan to the sulfate over the course of a week. The β isomer does not appear to undergo this conversion. Sulfate formation appears to be suppressed in dry soils.

Half-lives obtained from longer term studies on five soils are about 3-4 months for both parent isomers combined, with the α isomer typically dissipating about ten times faster. Projected half-lives for total residues are in the range of 9 months to 2 years, extending to over 6 years in one soil.

The diol degrades further in long term studies to a range of products with endosulfan lactone and a polar unknown predominant, significant production of non-extractable residues, and release of 18% of applied radiolabel as carbon dioxide over the course of a year.

Persistence of endosulfan increases in anaerobic soils, where the sulfate metabolite can revert to parent endosulfan. Anaerobic half-lives of parent endosulfan in the two soils studied are about 4-5 months, with similar results for the sulfate metabolite.

Microbial oxidation to the sulfate is also prominent in aquatic environments, followed by hydrolysis to the diol which can be fairly rapid in alkaline systems. The half-life for total toxic residues appears to be about 2 weeks in the single aquatic system (German river water with sediment) for which reliable results are available. Toxic residues partition to sediment over the course of a few weeks with a significant fraction becoming non-extractable.

**Mobility**

Endosulfan is strongly sorbed and immobile in soils. Soil organic carbon partition coefficients from four soils and a sediment obtained from runoff water are in the order of $10^4$ for endosulfan parent isomers and the sulfate metabolite, with the β isomer sorbing slightly more strongly than the α. Endosulfan diol has low mobility in soil with soil organic carbon partition coefficients in the order of $10^3$.

Leaching studies on two soil columns confirm that aged samples of endosulfan and metabolites should not leach through soil, with most retained in the surface 10 cm and less than 2% recovered from leachate.

Endosulfan is, however, mobile in the environment by virtue of its volatility. Significant amounts volatilise from soil and leaf surfaces, particularly soon after application. The α isomer is more volatile than the β isomer, which in turn is more volatile than the sulfate. Wind tunnel experiments found volatilisation half-lives for technical endosulfan of about a day from foliage and 3 days from soil. Deposition of volatilised endosulfan to water is favoured by high water/air partition coefficients. Endosulfan is a regional rather than global pollutant as its volatility appears too low to enable widespread global distribution, although detections have occurred in snowpack in the Canadian Arctic.

**Field Dissipation**

Early studies in Asia and South Africa indicate large declines in endosulfan residues in soil and water in the few days following application. Endosulfan sulfate persists longer than parent isomers.

The significance of early volatilisation losses is reflected in field trials on bare ground in Germany, in which between 17 and 38 days were required for residues to decline by 50%, but extending to between 182 and 425 days for 90% dissipation. The α isomer declined more rapidly than the β isomer. Volatilisation does not appear to contribute significantly to losses of the sulfate metabolite, which declines according to pseudo first order kinetics with a half-life in the order of 6 months.

A multi-year study in a Dutch apple orchard found soil residues to be continually present, with a residue plateau in the 5 cm surface soil layer at the start of each season of about 100-200 µg/kg, mainly as the sulfate. Accumulation above this plateau was not apparent, even after four years, but the use pattern appears less intense than in Australia. Residues were mainly confined to the surface 5 cm of soil.

Studies on tomatoes in Georgia, USA involved three applications by boom spray, each at 1.1 kg/ha endosulfan, at fortnightly intervals, with monitoring of soil dissipation, spray drift, runoff, and contamination of two ponds occupying about 10% the area of the crop and receiving runoff from it. The half life for total toxic residues was about 2 months. Small spray drift losses (less than 1% of applied at 5 m downwind, including a volatilisation component) were associated with concentrations in the pond of 0.1-0.3 µg/L. Peak concentrations in runoff water were about 200 and 80 µg/L at the two sites, with respective peak concentrations in the receiving ponds of 1.3 and 0.6 µg/L and sediment concentrations of 50 and 99 µg/kg. Residues dissipated rapidly from water, with a 75% reduction from peak levels over a few days. Sediment residues dissipated to undetectable levels over about 3-6 months, with the β isomer predominant soon after runoff occurred, but the sulfate the main contaminant in later samples.

Studies on vegetables in Kentucky found reductions in runoff losses but increased leaching tendencies when turf was grown between rows. Endosulfan was found at significant levels in deeper soil and water from the vadose zone under these conditions. These results appear to reflect preferential flow through macropores under established groundcover.

Studies on cotton in South Carolina and California involving application at more than twice the rate used in Australia found half-lives in soil in the order of 1-3 months for the α isomer and 2-4 months for the β isomer. Half-lives for total toxic residues were about 2 months in South Carolina and 5 months in California. Losses with irrigation tailwater were very small, remaining well below 1% of applied.

Studies conducted in the cotton growing areas of NSW and Queensland confirm the importance of transport through the atmosphere with around 70% of applied endosulfan lost mainly to volatilisation within 7 days after application. Particularly rapid losses occur in the first two days, especially when temperatures are high. The more volatile α isomer is lost more rapidly through volatilisation, and its formation by photoisomerisation appears to enable loss of the β isomer. Aerial transport losses include spray drift, which may approach 10% of applied at a distance 200-400 m downwind from the target. Losses with tailwater are typically in the order of 1-2%, with typical concentrations of 5-15 µg/L early in the season declining to 2-3 µg/L late in the season, although more than 10% of applied may be exported during large storms. For the alkaline clay soils where cotton is typically grown, residues approaching 10% of applied may be expected after a month, mainly in the soil, reducing to about 1% after a year. However, persistence can increase markedly in acidic soils and particularly when soils are dry. The balance (25-30%) is assumed to degrade.

Soil residues largely dissipate between seasons, but sulfate residues typically persist at levels in the range of 100-200 µg/kg in the surface 2.5 cm and the parent compound can also persist as residues, particularly the β isomer. Residues can also be found in silt at the tailwater outlet, at higher levels than in the soil from which they are transported. Residues in irrigation tailwater are mainly in the dissolved phase but partition to sediment with a half-life in the order of a week when ponded. Significant off-target movement of endosulfan sorbed to soil and suspended sediment occurs during major storms.

An early trial at Narrabri found total toxic residues of 620 µg/kg in the surface 10 cm soil layer, containing 65% sulfate and 20% β endosulfan. This equates to about half the theoretical residue from a single application to bare ground. Only a single application 12 months before sampling had occurred in the two years before these residues were discovered, indicating that the ready breakdown of endosulfan that occurs in most soils is by no means a consistent outcome, with dry conditions in particular favouring residue carryover from season to season.

Although volatilisation is the main route by which off-target movement occurs, it occurs gradually and off-target deposition via this route over short timeframes is some 200 times lower than can occur from spray drift. Off site contamination by dust movement is also relatively insignificant. Processes that can move large quantities of endosulfan in a short time, namely spray drift and especially storm runoff, appear to be the main contributors to major aquatic contamination incidents involving endosulfan. There is an urgent need to minimise export of endosulfan from cotton farms during major storms. For farms that do not retain storm runoff, irrigation and crop protection operations need to be carefully timed so that irrigation only occurs when soil residues are low. Other management techniques outlined in the recently released Best Management Practices Manual also appear to have promise for reducing export of endosulfan residues, particularly in erosion prone areas.

**Bioaccumulation**

Information submitted indicates that endosulfan bioconcentrates in fish, particularly as its sulfate metabolite, but that residues depurate rapidly in clean water. Bioconcentration factors vary with species but appear to be in the order of 1000 over short timeframes (96 hours), increasing over longer timeframes. The β isomer appears to undergo preferential metabolism in fish, and tends to enter waterways only through spray or runoff contamination. Endosulfan residues in fish are mainly found as the α isomer and sulfate metabolite. Residues in fish from cotton farm dams are about 5-50 times higher than in fish taken from rivers downstream of cotton areas.

**Conclusion**

Hydrolysis and photolysis appear to be minor pathways for degradation of endosulfan, although hydrolysis is favoured by alkaline conditions and some photodegradation is likely to occur in the vapour phase. The main mode of degradation in the environment is microbial metabolism to endosulfan sulfate, which retains the toxicity of endosulfan.

Parent endosulfan isomers and sulfate metabolite appear moderately persistent in soils, although dissipation in the field is generally rapid in the few days following application because of the volatility of α-endosulfan. Endosulfan contaminates terrestrial and aquatic compartments through vapour transport in regions in which it is used, but the vapour pressure appears too low to enable long range atmospheric transport.

Laboratory studies indicate that endosulfan and its sulfate metabolite are non-leachers, but some leaching through the vadose zone is evident in field studies, apparently because of preferential flow through macropores. Vapour transport is of concern in the field situation as both calculation and experiment indicate that transfer across water surfaces can give rise to concentrations that are relatively low but in excess of water quality objectives (0.01 µg/L). Such aquatic contamination occurs generally throughout areas where endosulfan is used, notably in cotton. Isolated but more serious pollution incidents also occur when runoff water enters waterways, or when rivers are contaminated directly by spray drift. Concentrations in irrigation or stormwater leaving the cotton field frequently exceed 10 µg/L, particularly early in the cotton season, and can give rise to acute impact in receiving waters.

Although endosulfan largely degrades over the course of a year in soils and aquatic sediments to which it partitions, low levels are carried over from season to season and aquatic and soil organisms have no relief from exposure. This is of particular concern for the aquatic environment given indications that endosulfan is bioaccumulative, although bioaccumulation capacity is limited by the ready elimination of residues from fish.

## 4.2 Environmental Effects

### Avian Toxicity

Test results indicate that endosulfan is moderately to highly toxic to bobwhite quail, Japanese quail and mallard ducks under conditions of acute oral exposure, and slightly to moderately toxic through the diet. Dietary toxicity appears to be balanced by repellent effects. Reproductive performance is impaired in quail and ducks under conditions of prolonged exposure to endosulfan in the diet at concentrations in the order of 100 parts per million. Endosulfan does not appear to give rise to avian incidents under field use as no such incidents have been reported.

### Aquatic Toxicity

Test results indicate endosulfan to be very highly toxic to aquatic fauna. Fish are killed by acute exposure to concentrations in the order of 1 µg/L, with a number of species more sensitive. The most sensitive native species tested is bony bream (96 hour LC50 = 0.2 µg/L). As endosulfan is a hydrophobic substance, its toxicity is thought to be moderated in turbid waters through sorptive interactions. However, evidence for this from the field is equivocal, and experimental attempts at confirmation have been unsuccessful.

Tests have mainly been conducted on the parent isomers as a mixture. Endosulfan sulfate is generally assumed to be of comparable toxicity but few results are available.

Aquatic invertebrates appear generally to be acutely susceptible to concentrations in the order of 100 µg/L, although considerable variation is evident. Cladocerans appear relatively insensitive, with acute and chronic endpoints of a few hundred parts per billion typical. An exception is *Ceriodaphnia dubia*, for which no effect concentrations in local reproductive testing over at least three broods were 3.3 µg/L at $20^{o}$C, decreasing to 0.1 µg/L at $30^{o}$C. The acute EC50 for this species was 2.4 µg/L at $30^{o}$C, increasing to 166 µg/L at $15^{o}$C. Sedimentary worms avoid sediment contaminated with endosulfan at levels of 50 µg/kg and above, and suffer 50% mortality in acute tests when exposed to dissolved concentrations of 100 µg/L. Estuarine crustacea and Australian freshwater mayfly nymphs appear to be as susceptible as fish, with acute endpoints of about 1 µg/L and below. No information is available regarding the chronic sensitivity of these organisms, but high acute to chronic ratios have been determined for daphnids.

Endosulfan appears highly toxic to algae, although these organisms can absorb endosulfan and metabolise it to the diol.

Overseas field studies confirm that fish kills are likely to occur when aquatic concentrations reach about 1 µg/L. Fish kills were documented following runoff from tomato fields into small ponds, but most of the fish in the ponds remained unaffected. Drift studies have shown that mortality of fish exposed in shallow water can occur 200 m downwind of the crop.

Biological monitoring in Australia finds that macroinvertebrate community structure is changed downstream from cotton areas during the season, with reduced diversity and abundance of sensitive species. A correlation can be made between on-farm impacts and endosulfan exposure, although physical factors such as turbidity appear better correlated with impacts in natural waterways during the dry seasons in which biomonitoring has been performed. Monitoring indicates that aquatic contamination exceeds water quality objectives (0.01 µg/L), frequently by one and occasionally by two orders of magnitude, raising the likelihood of biological impact. Although this aspect requires further study, populations of sensitive sediment dwelling organisms colonise upstream sites in significantly larger numbers during summer than at sites downstream from cotton production.

### Terrestrial Non-Target Invertebrates

Endosulfan is toxic to bees in the laboratory but appears generally to be without significant impact in the field, even when applied when bees are actively foraging.

Endosulfan is moderately toxic to earthworms in the laboratory, and there is evidence for protracted suppression of earthworm populations in the field at typical application rates.

Residues of endosulfan on foliage are toxic to predatory insects and mites, but the toxicity does not appear to persist beyond 1 day, allowing repopulation to occur from unsprayed areas.

Endosulfan exerts persistent adverse effects on soil arthropods, consistent with its use to control red legged earth mite.

Endosulfan residues do not appear to impair microbial processes in the soil, although some microbial species appear to be susceptible.

### Plants

Endosulfan has not been shown to be significantly toxic to plants in normal usage in a broad variety of crops, but some isolated reports of phytotoxic effects exist.

## 4.3 Prediction of Environmental Hazard

The following assessment of environmental hazard deals mainly with cotton, as this crop is the main consumer of endosulfan and use patterns are comparable to other cropping situations. Specific comment is also provided for higher rate uses, such as orchard applications.

### Terrestrial Hazard

Simple calculations indicate that application of endosulfan should not present a hazard to birds, even at the high rates that may be used in some orchards. In contrast, even the lower rate used in crops such as cotton appears from calculation and field experience to represent a potential hazard for soil dwelling invertebrates, including earthworms, and for bees. A hazard is also apparent to beneficial parasitic and predatory insects, although the limited persistence of endosulfan allows repopulation to occur and is said to reduce this hazard relative to other broad spectrum insecticides (organophosphates and synthetic pyrethroids) such that endosulfan is included in IPM programs for a number of crops.

In general, the hazard will largely dissipate between applications because of the volatility of endosulfan. Soil dwelling organisms are an exception. These organisms appear to be impacted by the sulfate metabolite, which increases in concentration in the soil with multiple applications through the season, and protracted suppression of earthworm populations has been demonstrated. Even though acute hazard to most organisms will be of relatively short duration, further insults with repeat spraying will retard population recovery.

## Aquatic Hazard

Endosulfan enters riverine environments through aerial and waterborne pathways. Aerial transport involves spray drift and vapour transport, as well as minor movement on dust particles, while waterborne transport occurs in dissolved and sorbed phases when storm runoff or irrigation tailwaters leave the farm. Highest concentrations in waterways arise through spray drift and runoff, but only in localised areas. Vapour transport is comparable in overall importance, but occurs throughout regions where endosulfan is used and does not contaminate water to such high levels. Transport on dust appears relatively insignificant.

Use on cotton consumes over 70% of all endosulfan used in Australia, and areas of intensive cotton cultivation are generally the areas of greatest risk for stream contamination of endosulfan. Some orchard uses may cause local problems where higher application rates and airblast equipment producing high volumes of fine spray are used. High application rates per hectare to larger tree crops may lead to exposure of the ground surface. Since avocados and macadamias are commonly grown close to native habitat, it is especially important to avoid off-target impacts in these areas.

However, in terms of the total amount of endosulfan reaching surface waters in the environment of areas at risk, movement of endosulfan out of treated crop areas into streams and rivers is a more serious problem with field crops than with orchards. The principal reason is that orchards are smaller plantings and much more geographically dispersed than are crops such as cotton and its common rotation crops which in some areas dominate watershed regions.

In addition, the application of endosulfan to tree crops directs the spray or mist upward into the canopy of the trees whereas when spraying field crops, the spray is directed downward resulting in more endosulfan reaching the soil surface. Moreover, the ground under most orchard canopies is covered with mulch, grass or some other ground cover which greatly restricts transport of soil particles out of the orchard into streams while the opposite is the case with most field crops.

Aquatic hazard is estimated by comparing the estimated environmental concentration in 15 cm water with toxicity data. The ratio of concentration to toxicity is generally known as Q (for quotient). Calculated values for Q in the table below are based on a toxic end-point of 1 µg/L, and would not be sufficiently protective of more sensitive species. However, they illustrate the severity of the problem.

| Spray drift (%) | 10% | 5% | 1% | 0.5% | 0.1% |
|---|---|---|---|---|---|
| Concentration (µg/L) | 47 | 24 | 4.7 | 2.4 | 0.47 |
| Quotient, Q | 47 | 24 | 4.7 | 2.4 | 0.47 |

According to methodology used by the US EPA for its reregistration program, a Q of less than 0.1 indicates that risk to aquatic organisms is minimal. A potential acute risk is indicated where Q falls between 0.1 and 0.5, but may be mitigated by restricted use classification. Higher Q values indicate high acute risk and a need for further use restrictions or special review. More detailed analysis is required for chronic exposure situations, such as presented by endosulfan during the spray season. Clearly, the aquatic risks of endosulfan are of concern.

While the hazard will largely dissipate between applications, further insults with repeat exposures will retard population recovery. Populations of sediment dwelling organisms appear to be particularly vulnerable, given the sensitivity of some species in the laboratory and the impacts apparent in the field. There is also likely to be more prolonged exposure of such organisms as endosulfan and its toxic sulfate metabolite partition to sediment and appear to persist there.

Aquatic contamination can also arise via vapour transport. Model calculations indicate that vapour transport can lead to aquatic contamination in excess of water quality objectives (0.01 µg/L), and this prediction has been confirmed by experiment. Therefore, to achieve water quality objectives during the spray season, measures to reduce the atmospheric vapour burden in critical areas need to be considered.

Experience gained through use of endosulfan confirms that both drift and runoff are hazardous to aquatic life. Isolated fish kills have been reported after the release from cotton farms of both stormwater runoff and irrigation tailwater polluted with endosulfan. Fish kills have also been thought to be caused by spray drift or overspray. Monitoring of sediment dwelling organisms through the summer months indicates major perturbations to populations of sensitive aquatic invertebrates in rivers downstream from Australian cotton growing areas, but no clear case has been established to implicate endosulfan, or other pesticides, as a causal factor. Other unmeasured factors may be responsible for the changes observed. However, given widespread aquatic exposure and toxic properties, the use of endosulfan, particularly on the scale that occurs in cotton, would appear to incur widespread impacts on aquatic ecosystems. Even if the vapour transport of endosulfan is reduced, there will still be an urgent need to avoid situations conducive to spray drift and runoff.

The hazards of endosulfan are exacerbated by poor agricultural practices. These include opportunistic expansion of dryland cotton farming into marginal areas, such as flood prone land in the upper Namoi. Of particular concern is the tendency for dryland farmers in this region to continue to spray when rain is forecast, in some cases only hours before heavy rain and notwithstanding low pest pressure, and for irrigated cotton growers to irrigate shortly after spraying. These poor practices incur excessive and unnecessary environmental impacts, and need to be stopped if the advantages of endosulfan to crop production are to be retained.

## 4.4 Conclusions

Endosulfan is used in high volumes, particularly in cotton, and has high aquatic toxicity. Although well retained once within the soil, endosulfan contaminates the broader environment through spray drift, volatilisation and particle transport, both aerially on dust and more importantly by storm runoff leading to riverine contamination. The α isomer largely volatilises in the few days following application, while the β isomer can persist in the soil. Both isomers metabolise in soils to endosulfan sulfate, which retains the toxicity of endosulfan and persists in soil and sediment.

Pesticide monitoring in the cotton growing areas of NSW during the season has consistently found endosulfan at concentrations above the ANZECC guideline of 0.01 µg/L in at least 50% of samples through the 1990s. [By comparison, the Canadian guideline is 0.02 µg/L and the current US EPA guidelines for protection of freshwater organisms are 0.22 µg/L (acute) and 0.056 µg/L (chronic). However, the US National Academy of Sciences recommends a more stringent criterion of 0.003 µg/L.] There are indications that the situation may be improving in recent seasons, but contamination remains at unacceptably high levels. Particular problems occur with storm events that produce surface runoff, when total endosulfan levels in excess of 1 µg/L are likely to prevail in rivers for a day or two. The limited information available suggests a comparable situation in Queensland rivers.

Laboratory testing has determined that acute LC50s for Australian native fish can be as low as 0.2 µg/L, and that some native invertebrate species are acutely sensitive at concentrations below 1 µg/L. Consideration of exposure and effects information indicates that acute impacts of endosulfan on fish are likely during the spray season. Isolated fish kill incidents have been reported after the release from cotton farms of both stormwater runoff and irrigation tailwater polluted with endosulfan. More subtle chronic effects on aquatic fauna are also considered possible given the frequency with which endosulfan breaches environmental guidelines and the high acute to chronic ratio determined for this substance. Low level aquatic exposure, particularly to the sulfate metabolite, persists throughout the year.

Endosulfan residues in the soil appear to exert protracted adverse impacts on earthworm populations and are likely to similarly affect sensitive soil arthropods.

Barring other considerations, a rapid phase-out of endosulfan might be warranted on environmental grounds. However, there are reasons to be cautious in implementing such an outcome. An abrupt phase-out would likely lead to an increased use of other toxic chemicals. Furthermore, the Minimising the Impact of Pesticides on the Riverine Environment Research and Development Program is approaching completion. The publication of a Best Management Practices Manual (published December 1997) for the cotton industry under the auspices of this program is likely to result in greatly improved management practices that will ease the immediate problem and may allow endosulfan to continue to be used on a reduced scale.

Where use has been identified as essential, management of adverse environmental impacts at present requires that endosulfan be used more responsibly and in smaller volumes, rather than not at all. The number of applications per crop per season should be therefore restricted to the minimum necessary to maintain the crop. Additionally, time intervals between applications should be as long as possible, determined by monitoring of pests, to give populations of aquatic species maximum time to recover. Greater control over the use of endosulfan may be possible if it were to be made a Restricted Chemical Product.

In order to minimise environmental impact, labels need to be improved to offer clear guidance to users regarding appropriate application methods, and improved management practices developed and implemented to avoid contamination of aquatic areas through drift or runoff. All labels should carry the following restraints:

- DO NOT apply under meteorological conditions or from spraying equipment which could be expected to cause spray to drift onto wetlands, natural surface waters, neighbouring properties or other sensitive areas.

- DO NOT apply to waterlogged soil or while water remains in furrows.

- DO NOT apply if heavy rains or storms that are likely to cause surface runoff are forecast within two days of application unless stormwater can be captured.

- DO NOT irrigate while spraying, or for at least two days after application.

There is also a need to alert users to the volatility problem by advising against application during periods of high temperature.

**Minimising Drift**

Some growers have expressed a preference for using ground rigs early in the season as this enables spray to be directed at the crop, thereby reducing application rates and the potential for off-target contamination. Ground rigs should be the preferred application method whenever it is possible to reduce overall rates through band application techniques and should especially be used whenever possible near sensitive areas. Wide swath ULV applications should be avoided because of their increased propensity to drift from the site of application compared with conventional methods. Placement applications using large droplets should be the preferred method for aerial application, particularly near sensitive areas. Application of endosulfan, particularly by aircraft, should not occur in high winds or when the air is highly turbulent, under temperature inversion or in calm conditions, or when winds are light and variable. Spray should only be released when aircraft are flying straight and level. Growers should consider planting trees along boundaries to help intercept any spray drift that may occur.

Buffer zones should be observed adjacent to environmentally sensitive areas such as waterways downwind of the crop. An example of appropriate strategies in relation to use of buffer zones can be found in the cotton industry's Best Management Practices Manual (p AP-10), the latest version of which was published in December 1997.

**Minimising Runoff**

Control measures also need to be improved with respect to runoff. For irrigated agriculture, irrigation efficiency should be improved in order to minimise contamination of drains by tailwater. As one component, drainage recirculation systems should be installed to capture irrigation tailwater and at least, until better information is available, the first flush of storm runoff. This is particularly important for dryland cotton farmers, as many are completely unable to contain contaminated stormwater. Cotton production is currently expanding into risky areas such as floodways, from which heavy rains can wash large quantities of contaminated soil into waterways. Planning authorities need to consider whether expansion of dryland cotton production into such marginal areas, as has occurred recently in the upper Namoi valley for example, is appropriate.

Application of pesticides should not occur while irrigating, and should be delayed after irrigation has occurred. Endosulfan should not be applied where soils are waterlogged, and irrigation should be withheld for 48 hours after application unless tailwater can be captured. The objective should be to irrigate only when pesticide residues in the soil reach their minimum level. Neither application nor irrigation should be contemplated if heavy rains or storms are expected. Failure to observe these basic precautions will lead to increased environmental contamination, and will inevitably strengthen the case for withdrawal of pesticides such as endosulfan which are known to contaminate the environment and impact adversely on non-target species, particularly when not used responsibly.

Older high volume application methods which lead to runoff, for example in orchards, should be discouraged given their inefficiency compared with low volume techniques.

### Agricultural Best Practice

Findings from the Minimising the Impact of Pesticides on the Riverine Environment Research and Development Program have been particularly important in developing best management practice guidelines which now appear in the cotton industry's Best Management Practices Manual, the latest version of which was published on 31 December 1997. These guidelines should be circulated widely within the industry and to other industry organisations to help promote the adoption of improved agricultural practices.

### Water Quality Guidelines

The current ANZECC water quality guideline for protection of aquatic life is 0.01 µg/L, derived by applying an assessment factor of 50 to the lowest acute LC50 for native Australian fish. The guideline has been criticised as unrealistically low given that it is frequently exceeded by one and occasionally by two orders of magnitude during the cotton season without causing noticeable fish kills. It is also hard to measure endosulfan at such low levels, which are around the limit of detection.

Outstanding questions concerning the persistence of endosulfan (including its toxic sulfate metabolite) in aquatic sediment and its effects on resident biota need to be addressed before consideration can be given to relaxing the water quality guideline.

### Further Development of IPM and Resistance Management Strategies

 

In light of the environmental risks identified and its agronomic importance, use of endosulfan should be minimised and phased out if better alternatives become available.

The registration status of endosulfan in Australia needs to be revisited, say in 3 years, in order to establish whether measures identified in this review have been effective in addressing environmental concerns associated with the use of endosulfan. The success of best management practice agricultural techniques in reducing environmental contamination by endosulfan would also be evaluated, with a view to determining whether some limited uses where endosulfan has particular performance advantages may be retained. Significant overseas regulatory or scientific developments should also trigger such review.

In the interim, industries need to manage the use of endosulfan in a more responsible way, and demonstrate improved practices and reduced environmental contamination. Endosulfan will be under close scrutiny, and any ongoing environmental problems will inevitably strengthen calls for its phase out, particularly in crops where it is applied frequently using inefficient application methods.

## 5. AGRICULTURAL ASSESSMENT

### 5.1 Efficacy

Information contained in the performance questionnaires from all sectors of the rural industry surveyed in relation to this chemical indicated that it was still efficacious for the purposes claimed. In fact, in orchard IPM situations, some growers advised that they had actually reduced their rates and frequency of use but were achieving the same level of control as when they had first used the chemical. This phenomenon could be attributable to a number of factors including use of more efficient application equipment (low volume application equipment, electrostatic sprayers as opposed to high volume boom sprayers) and better timing of sprays based on pest monitoring to achieve maximum effect on pest populations. It was also noted that label rates were in some cases being converted to rates per hectare for the purposes of using low volume equipment.

Registrants indicated that they did not have any information on any reduction in efficacy and had not received any complaints from growers in relation to failure to control nominated pests using this chemical.

However, three State agricultural authorities indicated that they had been requested to investigate a number of complaints in relation to poor efficacy. As a general comment, both the Queensland Department of Primary Industries and NSW Agriculture noted that efficacy drops off in very hot weather. They also noted that there are ongoing resistance problems with *Helicoverpa armigera*.

In Queensland, the Department of Primary Industries has investigated complaints in relation to poor efficacy against *Helicoverpa armigera* in grain legumes. In all cases the problem was due to hard water used in tank mixes.

The Northern Territory Department of Primary Industries and Fisheries indicated that complaints of lack of efficacy against cucumber moth had been investigated. They found that the chemical had been applied to large larvae when they had moved to sheltering sites under the fruit (rockmelons) and contact with the spray was therefore reduced. In other investigations it had been noted that spray application was a difficulty in that concentrations in the applied spray were low and there was poor coverage of the crops.

**Alternatives**

For many of the use situations listed, there are no alternatives available or registered. For example, in beans, solanaceous vegetables and cucurbits, endosulfan is the only chemical available for control of various species of pests, while there are no alternatives to endosulfan for control of fruit spotting bug in tropical and sub-tropical fruits

Endosulfan is particularly useful for IPM because it is ‘soft’ on beneficials and, although in some cases there are alternatives in terms of insecticides which will control particular pests, advice from entomologists indicates that use of these chemicals inevitably results in flares (rapid population increase) of other pests later in the season. This effectively increases the overall pesticide requirement for the crop. For example, use of synthetic pyrethroids in avocados to control fruit spotting bugs results in severe scale problems later in the production cycle requiring treatment with more pesticide. In addition, some of the organophosphate alternatives have exhibited phytotoxicity in some crops.

At present, therefore, there are no alternatives which can take the place of endosulfan in IPM systems. Although developmental work in the use of new insecticide groups, pheromones and microbiological/biological insecticides is proceeding, full scale utilisation of these alternatives is some years off. Use of parasites in grain legumes is also being examined in Queensland, but this research will only be targeting one of the pod sucking bugs which affect these crops and is unlikely to eliminate the need for pesticides in the immediate to medium future. In addition, use of a combination of salt with lower endosulfan concentrations has shown promise in bug control overseas but is yet to be proven in Australia.

Similarly, in terms of resistance management strategies, there are no alternatives because endosulfan is one of the last remaining organochlorine insecticides, and the only one registered in these situations.

Advice from State departments indicate that insecticides with new chemistry which could take the place of endosulfan in resistance management strategies are under development, but it will be three to five years before these are readily available for major crops and somewhat longer before they are available to producers of minor crops.

Of interest in this area is the introduction of transgenic Bt cotton in 1996/97. This cotton has been genetically modified to produce a *Bacillus thuringiensis* toxin during its growth. However, entomologists still consider use of endosulfan will be required, both to spray ‘refugia’ blocks of conventional cotton and to spray transgenic cotton as toxin production drops off late in the growing season. Further research is being undertaken to secure the usefulness of the present transgenic cotton technology.

Endosulfan is considered to be an essential chemical by a number of State departments of agriculture for use as a bare earth treatment in the control of red legged earth mite for a number of crops. However, it is noted that bifenthrin and imidacloprid have recently been registered for this use in some crops and registration may be extended to cover other crops as well.

**Use Patterns**

As indicated above, endosulfan’s major use patterns are either in resistance or integrated pest management strategies.

By far the major use for endosulfan in Australia is for control of *Helicoverpa spp* and, to a lesser extent, aphids and whitefly in cotton. It is used in this context in accordance with the Insecticide Resistance Management Strategy (Cotton pests and pest management). This strategy involves only spraying small, susceptible *Helicoverpa* larvae in response to monitoring of pest populations, thus limiting the number of sprays of endosulfan per season. In addition, it is not recommended that it be sprayed consecutively, but alternated with insecticides from different chemical groups. Advice in relation to use in the 1996-97 season is that the number of endosulfan sprays has been halved to an average of 2.5. However, it is emphasised that this is an average figure only and numbers of sprays in local areas were significantly higher (eg Bourke 6.6 sprays).

In a similar manner, when it is used in integrated pest management, it is only applied in response to monitoring for pest populations and economic threshold levels. In some cases it has been difficult to establish monitoring techniques and threshold levels. However, in these cases spraying is carried out based on an experienced assessment of need, rather than a program basis.

## 5.2 Trade

### Exports

Endosulfan is considered essential by growers and State departments of agriculture for the production of a number of Australia’s major export crops.

Advice from the Queensland Department of Primary Industries and NSW Agriculture is that this chemical is presently essential for the continued viability of the cotton industry in Australia. In spite of the introduction of transgenic Bt cotton which produces a *Bacillus thuringiensis* toxin, entomologists are of the opinion that endosulfan with a modified use pattern will still be required for the cotton industry for a number of years to come. This industry has an export value approaching $1 billion.

Production of Australia's major fruit crops such as pome fruit, citrus and avocados would also be seriously affected by any removal or restriction of availability of endosulfan. The chemical is considered to be essential by State agricultural authorities and growers alike for IPM programs for production of these fruit crops.

The viability of smaller horticultural industries which are in their infancy would also be threatened by limitations on the availability of endosulfan. The Queensland Department of Primary Industries advises that these crops are being established using integrated pest management as the major pest control option. Use of endosulfan in IPM in these programs is critical to their success. Although these industries only have a total value of some $20 million at present, the potential export earnings are considerably greater in the medium to long term.

**Use**

Endosulfan is widely used in IPM and resistance management strategies in many crops but has a particularly important role in cotton production. Other significant usage areas are grain legumes, oilseeds, vegetables and fruit.

An estimate of the relative distribution of use of endosulfan products by crop/crop grouping is contained in the following table:

***Estimate of endosulfan usage by crop/crop grouping****

| Crop/Crop Grouping | % of product used in crop |
|---|---|
| Cotton | 72 |
| Vegetables | 20.5 |
| Oilseeds | 3 |
| Pome & Stone Fruit | 2 |
| Exotic Fruit | 2 |
| Other | < 0.5 |

Information was also received during the review that approximately 900 tonnes of technical endosulfan are imported annually into Australia which would result in a quantity of formulated product of the order of 2.9 million litres assuming similar amounts of EC and ULV formulations are manufactured. Using the figures above, approximately 2.1 million litres of endosulfan concentrate would be used in cotton in Australia, with slightly more than half of this quantity being used in NSW and the remainder being used in Queensland.

It should be noted in relation to these estimates that seasonal factors play a major role in determining pest prevalence, pest complexes and areas planted and needing to be sprayed. Consequently, there can be significant variation from year to year in the amount of endosulfan used.

Crops appearing on currently registered product labels have been listed in the following table:

***Crops/Situations in which endosulfan is registered***

| | | | |
|---|---|---|---|
| Canola (Rapeseed) | Avocadoes | Soybeans | Cape Gooseberry |
| Carrots | Bananas | Safflower | Capsicums |
| Cashews | Berry Fruit - Currants & related fruits | Pecans | Carambolas |
| Chou Moellier | Blueberries | Yellow Mombins | Carobs |
| Citrus | Cabbages, Cauliflower & other Crucifers & Leaf Vegetables | Sunflower | Cassia-Round Leafed |
| Clover & Medic Seed Crops | Casimoras | Pomegranates | Cereal Crop & Pasture |
| Cucurbits | Celery | Sesame | Cereals |
| Duboisia | Chickpeas, Cowpeas, Pigeon Peas, Adzuki Beans, Faba Beans, (Broad Beans) | Spinach | Cotton |
| Durians | Custard Apples | Sweet Corn | Grapes |
| Egg Plant | Granadillas | Sweet Potato | Green Beans |
| Green Peas, Peas, Snow Peas | Grass Seed Crops & Legume Pasture Seed Crops | Stone Fruit | Jaboticabas |
| Field Peas | Guavas and/or persimmons | Tamarillos | Lawns |
| Hides | Kiwifruit | Tobacco | Loquats |
| Leeks | Lablab beans | Tomatoes | Lucerne Seed Crops |
| Lima Beans | Linseed | Red Beet | Mangosteens |
| Lychees | Longans | Rhubarb | Okra |
| Navy Beans, Mung Beans | Low Chill Stone Fruit | Sapodillas | Pecan Nuts |
| Nursery Crops | Lupins | Spinach | Pineapples |
| Oilseeds | Macadamia Nuts | Taro | Potatoes |
| Ornamentals | Maize | Tea trees | Rambutans |
| Peanuts | Mammy apples | Strawberries | Rape |
| Pistachios | Mangoes | Vetch (Common) | Rollinias |
| Pome Fruit | Onions | Tea | Shallots |
| Raspberries | Passion Fruit | Wildflowers and Proteas | Sorghum |
| Rosella | Pawpaw | Turf | |

Possession and use of endosulfan is also permitted by the NRA in certain circumstances such as minor and/or emergency uses and for trial purposes. Current permits which have been issued by the NRA for endosulfan are presented in the following table:

***Permits issued for endosulfan****

| Crops | Pests | States |
|---|---|---|
| Vetch | *Helicoverpa spp*., Cowpea aphid | NSW only |
| Black sapote | Fruit spotting bug | Qld only |
| Carrots | Rutherglen bug | Tas only |
| Soybeans, Mungbeans, Adzuki beans, Navy beans, peanuts | Evaluate efficacy against green vegetable bug, brown bean bug, redbanded shield bug & green mirid | Qld |
| Pawpaws | Cutworm | Qld only |
| Strawberries | western flower thrips | All States |
| Cotton (Pre-squaring only) | *Helicoverpa spp* | NSW |

*Note: These crops may appear on registered labels but not for rates, pests etc nominated in permits. Permits may also be for trial purposes.

**Residue Detections**

Residue detections have been made by the National Residue Survey in many export commodities some examples of which are listed in the following table:

***Residues of endosulfan detected in export commodities by the National Residue Survey***

| **Commodity** | **% of samples with endosulfan residues** |
|---|---|
| Apples* | 4 |
| Capsicums* | 30 |
| Celery* | 25 |
| Citrus* | 3.5 |
| Dried vine fruits* | 2 |
| Lettuce* | 3 |
| Tomatoes* | 2.5 |
| Melons* | 15 |
| Raspberries* | Not Available |
| Fresh Grapes* | 1 |
| Beef** | 0.03 |

* Period 1/1/89 - 31/12/93
** Period 1989 - 23/6/97
Notes:

1. The NRS does not currently analyse export vegetables.
2. The NRS targeted survey of endosulfan residues in beef (17/7/95 - 23/6/97) showed 1.25% of samples with endosulfan residues (0.5% of samples above the Australian MRL)

Although none of these detections was above the respective Australian MRL, there were occasional detections up to half MRL in vegetable crops such as celery and lettuce which would bring the residues into the order of those represented by the Codex MRL of 0.1 mg/kg. It is emphasised that such detections represented less than 0.5% of samples.

## 5.3 Residues

Endosulfan is only used in crop protection and not for veterinary purposes. Contamination in animal tissues is expected to result mainly from feeding crops or crop parts that have been either treated with, or contaminated by the spray drift of, endosulfan.

Metabolism studies on both animals and plants showed that the metabolite endosulfan sulfate is the major residue in both plant and animal tissues. The sulfate also has a significantly longer half life than the alpha and beta isomers and is usually the only isomer detected in animal fat. The half-life of total residues would vary between 3 and 14 days in both plants and animals in the range of 1 -10 mg/kg, especially for broad-leaf plants. The half life in leaves of cereals including sorghum and maize appears to be much longer at a later stage of growth, as residues in both sorghum and maize were detected even months after endosulfan application. Also, elimination in animal tissues is longer at low concentrations (around 0.1 mg/kg). Residues in harvested crops or dead materials do not appear to degrade.

Recent incidents involving animal MRL violations in Australia were partly associated with misuse of endosulfan, as the crops were harvested 10 days after spray when the residues could be as high as 10 mg/kg, while the WHP was 28 days. In addition, the development of new analytical techniques in the early 90’s has enabled easy quantitation of endosulfan sulfate in plant and animal tissues.

The grazing WHP of 28 days does not appear to be consistently sufficient to allow decline of residues to levels that are consistent with existing animal commodity MRL’s. This period of time is more consistent with primary food commodities (e.g. grains) than that required for grazing.

As a remedy to the incidents, a withdraw from slaughter interval of 42 days was introduced in early 1996 to all beef producers. A label warning was also required to be attached to each label produced after 1995, indicating the risk of feeding animals with crops treated with endosulfan. The slaughter interval of 42 days accommodates the maximum feeding level of endosulfan at about 5 mg/kg (dry weight).

Cattle transfer studies with biopsied samples undertaken in 1996 have made it possible to set a MRL of 0.3 mg/kg for Primary feed commodity. The feeding level of 0.3 mg/kg would provide substantial safety to the feeding of livestock with resulting satisfactory residue levels in animal commodities. To eliminate the need of the 42 day withdraw from slaughter period, the feeding level must be at or lower than 0.3 mg/kg.

For primary animal feed commodities, it is considered necessary to maintain the slaughter interval of 42 days if the current use patterns of endosulfan products are to be continued. The data available confirm that a single application of endosulfan to crops could result in residues much higher than 0.3 mg/kg in fodder of treated crops (dry weight) at a WHP of 28 days.

Alternatively, use patterns could be adjusted so that plant residues would be at or below 0.3 mg/kg. However, the appropriate pest management will determine use patterns and some current uses of endosulfan may be discontinued due to incompatibility with animal commodity residues.

Primary animal feed commodities are generally derived from pastures (for cattle, sheep and goat) and cereals (grains for cattle, poultry and pigs; hays for cattle and sheep). Other crops or crop parts, especially fodder of legume vegetables, can also be fed to animals. According to the cattle transfer studies, any crops or crop parts contaminated with residues above 0.3 mg/kg, when fed continuously for 10 days, will result in residues exceeding the MRL of 0.2 mg/kg in meat [in the fat]. Crops or crop parts that fall into both categories, i.e., with residues above 0.3 mg/kg and likely to be fed for over 10 days, are represented by the majority of the crops including vegetables specified on the draft label. Commodities of fruit species may not be fed to animals to a great extent, but processed parts of some fruits containing high residues are likely to be fed to some animals.

The residue data provided on crops by registrants were not normally generated in line with the current Australian use patterns (rate of application, application number and WHP). Much of the data was produced overseas. Cattle transfer studies are considered valid and significant in making decisions on the MRL of Primary animal feeds. However, valid data are not available for other animal species or milks, although the primary problems have been related to cattle. A solution to the cattle issues will undoubtedly resolve outstanding /potential difficulties with goats and sheep.

## 5.4 Conclusions

Endosulfan is very widely used in Australian agriculture and horticulture and is an integral part of many spray programs recommended by State departments of primary industries/agriculture.

Of particular importance is its use in integrated pest management (IPM) programs and resistance management strategies. It would appear that there are many of these programs which are dependent on the continued availability of endosulfan and in some cases, the viability of whole industries would be threatened if the current level of access to this chemical were lost. State agricultural authorities indicate that the chemical is required for control of various pests in a number of major crops/crop groupings such as cotton and vegetables.

It has particular advantages for use in IPM, the major one being that it is ‘soft’ on pollinators, predators and parasites. In terms of its use in resistance management strategies, its importance is due to the fact that it represents a whole class of insecticides (organochlorines) and therefore, because it is in a chemical group unrelated in mechanism to other insecticides, it adds another distinct group into any rotation strategy in which it is used. Some experts have commented that loss of this group could make some resistance management strategies unworkable.

In some of the cases where endosulfan has been identified as essential by agricultural authorities and growers, it was recognised that there are alternative chemicals registered for use in the respective crops. However, the point was made that other chemicals (eg synthetic pyrethroids) caused flares of secondary pests, which in turn required the use of more insecticide sprays overall than if endosulfan had been used in the first place. Without endosulfan, IPM and resistance management in these crops may no longer be workable and a return to program spraying may be necessary.

Although it was recognised that alternative chemicals/chemical groups (eg pheromones, microbial pesticides) and strategies such as more efficient monitoring of pests and biological/cultural controls may be able to replace chemicals such as endosulfan in the long term, State departments agreed that endosulfan is essential for at least the next 3-5 years.

In relation to use of this chemical in orchards, the recommendation of high volume rates per 100L of water without a guide as to the amount of water to be used per hectare is a difficulty in common with other older chemicals. Growers are not able to calculate a standard rate per hectare to use through the low volume equipment now commonly used in orchards. There can therefore be a considerable variation in the amounts of chemical applied per hectare.

"Rates of use and spray application in orchards is a complex matter which is not chemical specific and which is subject to ongoing research and investigation. The outcomes of this research will impact on the labelling for all chemicals used in orchards, including endosulfan."

Significant difficulties were identified in relation to the management of residues of endosulfan produced in both plants and animals as a result of endosulfan use.

Residue data were not available at all in many cases, and for those in which data were available, they were not acceptable because of inconsistencies in use pattern or methodology. Current MRLs are not therefore able to be supported on a continuing basis without submission of residue data generated from trials conducted according to NRA standards.

Difficulties were particularly acute in relation to the presence of endosulfan residues in beef and milk.

There are some data available which suggest that the current management strategy of a 28 day grazing/fodder withholding period followed by a 42 day slaughter interval may not be sufficient to comply with the current beef MRL. However, monitoring by State agricultural authorities, coupled with analysis of feed and fodder by large scale producers indicates that this use pattern is practical for the industry. It has been found in a significant number of cases, that residue violations are the result of smaller producers opportunistically buying crop, cannery or fruit and vegetable market wastes as cattle feed. Further research may be warranted in this area.

In general, there were no problems reported with the efficacy of endosulfan, although it was clearly recognised that there were significant levels of resistance in some pests to this chemical. Similarly, it was recognised that there were some difficulties with the chemical and the various formulations in heatwave conditions and appropriate strategies (such as applying at night, late in the evening or early in the morning) were being adopted to overcome these difficulties.

# 6. OVERALL DISCUSSION AND CONCLUSIONS

In determining the outcomes of the endosulfan review the NRA has to be satisfied that the registration and approval of endosulfan meets current regulatory requirements. The main findings of the review are as follows:

## Essential Uses of Endosulfan in Agriculture

Continued availability of endosulfan is essential for the production of a number of Australia's major and developing export crops because of its particular suitability for use in IPM and resistance management strategies. In particular, production of cotton, pulses, pome and stone fruit, citrus and tropical and sub-tropical fruits would probably not be feasible without use of endosulfan.

However, this availability cannot be continued without modifications to use patterns, labels, maximum residue limits and limitations on use.

## More Residue Data Required

It has been found during the course of the review that many of the current MRLs for endosulfan are not supported by adequate data and are probably the result of adoption of old Codex MRLs. However, no information on use patterns for these MRLs is available. A specific management program that takes into account the likely residues in animal feeds is proposed to ensure that residues in animal (especially cattle) commodities are not likely to exceed Australian MRLs or relevant international MRLs important in trade.

## Toxicology and Public Health Issues

A comprehensive toxicological data package on endosulfan has been assessed in this review and it has been found that endosulfan has high acute toxicity when administered via oral, dermal, and inhalational routes of exposure, with clinical signs of acute intoxication including piloerection, salivation, hyperactivity, respiratory distress, diarrhea, tremors, hunching and convulsions.

Long-term dietary studies in rodents indicated that endosulfan was not carcinogenic, lacked genotoxicity in a range of tests, and had no adverse effect on reproductive parameters. While evidence of delayed development was seen in rats, this was associated with maternotoxicity, and no treatment related teratogenicity was observed in any studies.

In rats, the kidney appears to be the main target for endosulfan toxicity in a number of studies. Renal effects seen include increases in kidney weights and granular pigment formation in shorter-term administration, and progressive chronic glomerulonephrosis or toxic nephropathy after long term exposure to endosulfan. These findings, however, need to be seen in light of the fact that such renal effects are common in aging laboratory rats and also occur at a high incidence in non-exposed control animals.

Long term bioassays, and reproductive and developmental toxicology studies in experimental animals have found no evidence that endosulfan induces any functional aberrations which might result from disruption of the endocrine hormone system.

The absence of immunotoxicological findings in the large number of bioassays conducted with endosulfan suggests that endosulfan does not have an adverse functional effect on the immune status of laboratory animals.

**Occupational Health and Safety Issues**

The OHS risk assessment concludes that restrictions on endosulfan use are required to reduce the level of risk to workers. This conclusion is based on a quantitative risk assessment using measured and predicted worker exposure and a qualitative risk assessment for uses where worker exposure data are not available.

Very limited measured worker exposure data (three studies in orchards and PHED data for certain ground and aerial broadacre applications) were submitted for consideration during the review. These studies, together with predictive exposure modelling (POEM), indicate that in many of the situations encountered in Australian agriculture, exposure could be high.

The OHS risk assessment indicates that there is a need to develop Australian worker exposure data for a number of agricultural uses in order to verify that current practices are adequately safe or to determine how to modify those practices to ensure safety. Work practices for which data are needed are:

- Mixer/loaders in ground and aerial applications
- Orchard ground spray applicators
- Broadacre ground spray applicators
- Manual flaggers for aerial applications
- Greenhouse workers
- Workers using hand directed spray applicators

The endosulfan use pattern and limited worker exposure data indicate that workers involved in crop tending and harvest activities could become contaminated with endosulfan product residues. Poisoning incident reporting overseas indicates that field workers may experience health effects when re-entering endosulfan treated areas. Re-entry restrictions are needed on current endosulfan product labels. An interim re-entry period of 2 days is therefore to be introduced, until new Australian data can be generated and analysed for field and orchard crops and for greenhouses.

There is also a need for the introduction of better engineering controls for packaging and dispensing of the concentrate, preferred use of enclosed cabs, additional personal protective equipment such as waterproof clothing and respirator and strengthened training requirements. Human flagging in aerial operations is not acceptable, unless flaggers are protected by engineering controls such as cabs. Existing guidance on safe flagging procedures requires upgrading.

Specification of low volume spraying parameters is not normally done on labels, and this is a serious limitation to defining worker exposure and risk.

Endosulfan and the products under review are hazardous substances and are covered by regulations to control workplace hazardous substances.

The existing safety directions for endosulfan need to be upgraded to include sufficient personal protective equipment requirements for all products.

**Environmental Concerns**

From an environmental perspective, endosulfan has high aquatic toxicity and although well retained once within the soil, it contaminates the broader environment through spray drift, volatilisation and particle transport, both aerially on dust and more importantly by storm runoff leading to riverine contamination. The major metabolite, endosulfan sulfate, retains the toxicity of endosulfan and persists in soil and sediment. Pesticide monitoring in the cotton growing areas of NSW during the season has consistently found endosulfan at concentrations above the ANZECC guideline of 0.01 µg/L in at least 50% of samples through the 1990s. [By comparison, the Canadian guideline is 0.02 µg/L and the current US EPA guidelines for protection of freshwater organisms are 0.22 µg/L (acute) and 0.056 µg/L (chronic). However, the US National Academy of Sciences recommends a more stringent criterion of 0.003 µg/L.] There are indications that the situation may be improving in recent seasons, but contamination remains at unacceptably high levels. Particular problems occur with storm events that produce surface runoff, when total endosulfan levels in excess of 1 µg/L are likely to prevail in rivers for a day or two. The limited information available suggests a comparable situation in Queensland rivers.

Laboratory testing has determined that acute LC50s for Australian native fish can be as low as 0.2 µg/L, and that some native invertebrate species are acutely sensitive at concentrations below 1 µg/L. Consideration of exposure and effects information indicates that acute impacts of endosulfan on fish are likely during the spray season. Isolated fish kill incidents have been reported after the release from cotton farms of both stormwater runoff and irrigation tailwater polluted with endosulfan. More subtle chronic effects on aquatic fauna are also considered possible given the frequency with which endosulfan breaches environmental guidelines and the high acute to chronic ratio determined for this substance. Low level aquatic exposure, particularly to the sulfate metabolite, persists throughout the year.

Endosulfan residues in the soil appear to exert protracted adverse impacts on earthworm populations and are likely to similarly affect sensitive soil arthropods.

From the data, it is apparent that the availability of endosulfan cannot be continued without significant modifications to use patterns, labels, maximum residue limits and limitations on use. Research programs such as the Minimising the Impact of Pesticides on the Riverine Environment Research and Development Program are likely to result in greatly improved management practices.

## Community Concerns

Some members of several communities in cotton growing areas have expressed concern over their potential exposure, not only to endosulfan, but to all of the various chemicals used in cotton production. There is fear that low level exposure, which might arise from spray drift, from volatilisation of chemicals into community air and from chemicals carried on dust particles, may lead over time to allergies or other harmful health effects.

Responding to that concern, State authorities have been monitoring some additional aspects of possible exposure in areas of intensive use such as by sampling rainwater tanks and by sampling domestic properties where contamination is suspected.

However, monitoring and measuring the adverse health effects of a range of different pesticides on a community is extremely difficult in view of the uncertainty of exposure, the variety of long term effects reported, the time that must pass between exposure and development of symptoms, other unknown interfering risk factors and the necessity to acquire sufficient numbers to provide meaningful statistical data.

Pilot programs are now being organised between Commonwealth organisations and local Divisions of General Practice to report all suspected cases of adverse reactions to pesticides. Efforts are also under way to improve the investigation of adverse health occurrences in rural communities by public health services and other agencies. Although these steps are to be encouraged, it is acknowledged that for human health questions, the most valid and useful information about adverse impacts of pesticides, their formulations and mechanisms of exposure come from studies of workers who regularly handle pesticides.

In the case of endosulfan, this review found no evidence for low level toxicity or for involvement in cancer, birth defects, genotoxicity, endocrine disruption or other adverse health effects due to low level, long term exposure (See Section 5). However, it is still appropriate to be alert to the larger question of cumulative community exposure to a range of different pesticides in areas of intensive use. The primary role of the NRA in this context is to register only chemicals which can be used safely, to promote responsible chemical use and to promote practices which reduce chemicals reaching beyond their intended place of use.

## Development of Review Outcomes

In a draft released for public comment on 22 December 1997, the NRA proposed recommendations which addressed the major issues identified by the review. During the public consultation phase, newly obtained data filled some of the data gaps relative to worker safety (see Section 5), one of the major issues. However, issues concerning the safety of the environment, the safety of agricultural workers and the need to verify residue limits are still paramount in the outcome of this review.

The main concerns arising from public comment to the draft review and the changes made between the draft recommendations and the final Review Outcomes are described and explained in Attachment 1 to this section following the final Review Outcomes.

In preparing its final Review Outcomes which are presented next in Part 7, the NRA has incorporated appropriate controls to protect the environment, farm workers and other people. These controls are necessary for the continued use of endosulfan. Existing uses have been allowed to remain on an interim basis while new data is generated to support those uses in the longer term.

It should be noted, however, that as a result of this review, endosulfan will be under a substantially more restricted registration regime than was previously the case. The additional measures taken by the NRA are designed to reduce contamination of the environment and to protect agricultural workers and other members of the community while at the same time allowing endosulfan to continue to be used.

## 7. ENDOSULFAN REVIEW OUTCOMES

| IMPORTANT NOTICE | Key Date |
|---|---|
| **Certain Review Outcomes require the development of additional data as specified below. These data will be eligible for data protection (as appropriate) in accordance with Part 3 of the Agvet Code. Those choosing to submit such data must confirm a commitment to do so (and submit a plan for generating the data) by 31 December 1998. If no such commitment is provided by that date, then the use related to that data requirement may be cancelled.** | **31 December 1998** |

Those outcomes marked with # require the submission of further data, plans, standards or label changes as specified in the following table:

| Review Outcome | Due Date | Requirement |
|---|---|---|
| 2 | 30/11/1998<br>30/06/2001 | • Development of plan for monitoring environmental contamination.<br>• Demonstration of reductions in environmental contamination |
| 3 | 30/06/1999<br>31/12/1999 | • Worker exposure data in greenhouses<br>• Worker exposure data in industries which require continued use of endosulfan |
| 4 | 30/06/2000 | • Residue data |
| 5 | 30/06/2000 | • Residue data |
| 8 | 31/12/1999 | • Re-entry data (Exposure of workers to in-crop residues) |
| 12 | 30/06/1999 | • Material Safety Data Sheets |
| 16 | 30/06/1999 | • Upgraded guidance on safe flagging procedures |
| 17 | 30/06/1999 | • All TGACs required to demonstrate compliance with the NRA standard. |
| 1,8,9,10,11,13,14 | 30/06/1999 | • All changes and amendments to labels |

**Restrictions on use**

*Environmental concerns raised as a result of the review necessitate that endosulfan can only be used according to new limitations designed to reduce environmental contamination.*

*It is therefore recommended that:*

| Review Outcome | Key Date |
|---|---|
| **1.#** The following additional limitations must be included on all labels immediately following the statement "NOT TO BE USED FOR ANY PURPOSE OR IN ANY MANNER CONTRARY TO THIS LABEL UNLESS AUTHOR-ISED UNDER APPROPRIATE LEGISLATION" | **30 June 1999** |

**THIS PRODUCT CAN ONLY BE USED IF RECORDS OF SPRAYS ARE KEPT IN ACCORDANCE WITH GUIDELINES OF FARMCARE ACCREDITATION OR ANOTHER GUIDELINE ACCEPTABLE TO THE NATIONAL REGISTRATION AUTHORITY. RECORDS OF SPRAYS WILL BE SUBJECT TO AUDIT BY AUTHORISED INSPECTORS.**

**EXCEPT FOR ORCHARD CROPS, ALL OTHER CROPS (INCLUDING COTTON) ARE LIMITED TO A MAXIMUM OF 2 SPRAYS OF THIS PRODUCT PER CROP PER GROWTH SEASON (OR EQUIVALENT OF 2 SPRAYS IN ACTIVE INGREDIENT PER HECTARE) UNLESS IRRIGATION TAILWATER AND STORM RUN-OFF WATER CAN BE CAPTURED ON FARM (FOR ISOLATED RAINFALL EVENTS UP TO AT LEAST 25MM OF RAINFALL).**

**IN ADDITION TO THE LIMITATION ABOVE, WHEN USED ON COTTON THIS PRODUCT MUST BE USED IN ACCORDANCE WITH THE LATEST (AT TIME OF USE) AUSTRALIAN COTTON INDUSTRY BEST MANAGEMENT PRACTICES MANUAL. BEST MANAGEMENT PRACTICES WHICH SPECIFICALLY CONCERN IRRIGATION DO NOT APPLY TO NON-IRRIGATED COTTON.**

| | Review Outcome | Key Date |
|---|---|---|
| **2.#** | Endosulfan may be further restricted or withdrawn if demonstrable reductions in its release to the environment are not achieved. Reductions will be assessed principally against measured endosulfan concentrations in surface waters of regions the NRA considers to be at risk. For other areas, reductions in the quantity of endosulfan used will be accepted as evidence of reduced environmental exposure. Acceptable baselines and reduction targets will be established by the NRA in consultation with respective State authorities responsible for water quality. Plans defining such baselines and targets are to be completed by **30 November 1998** and monitoring results will be assessed by the NRA by **30 June 2001**. | **30 November 1998** |

*Occupational health and safety (OH&S) concerns raised as a result of the review necessitate that certain uses of endosulfan can only continue on a temporary basis until additional worker exposure data is obtained. Because of the acute toxicity of the chemical, worker exposure data generated under actual Australian conditions is required for these uses.*

*It is therefore recommended that:*

| | **Review Outcome** | **Key Date** |
|---|---|---|
| **3.#** | The following requirements will be met: | |
| • | Worker exposure data for greenhouse workers must be generated by **30/06/1999**. Unless worker exposure data are provided for occupational health and safety assessment and the risks to workers are shown to be acceptable to the NRA, use in greenhouses will be discontinued from **31/12/1999**. In addition, studies designed to determine a safe re-entry period for greenhouses are to be accomplished within the same time frame. | **30 June 1999** |
| • | Certain other industries which require use of endosulfan for work practices specified below must generate worker exposure data by **31/12/1999** to enable the NRA to establish permanent acceptable use patterns for the respective industries. Those uses which are not supported by worker exposure data will be withdrawn on **30/06/2000**. Work practices which require Australian data are:<br>▪ Mixer/loaders in ground and aerial applications<br>▪ Orchard ground spray applicators<br>▪ Broadacre ground spray applicators<br>▪ Manual flaggers for aerial applications<br>▪ Workers using hand directed spray applicators | **31 December 1999** |

**Residues** (Note: Additional recommendations which impact on residues are included under ‘Labelling’)

*Residue and trade concerns raised as a result of the review necessitate that certain uses of endosulfan can only continue in the long term if data supporting maximum residue limits (MRLs) are provided to the NRA.*

*It is therefore recommended that:*

| | Review Outcome | Key Date |
|---|---|---|
| **4.#** | Residue trial data for uses currently without adequate Australian data (See Recommendation 5 below) must be submitted to the NRA for evaluation by **30/06/2000**. | **30 June 2000** |

Uses which are not supported by adequate MRL data will be removed as from **31/12/2000**.

All residue trials should be conducted in accordance with Residue Guidelines which have been published in the NRA Gazette. Residue trials must address the maximum treatment regimes.

The following data are considered essential:

- Animal feeds - Forages, fodder or hays of such plants as cereals (including sorghum and maize), pastures, canola, sunflower, legume vegetables, potato, peanuts, and legume crops for pulse production.
- Human food – All commodities which have been assigned a temporary MRL in the table above.
- Processing studies - Cereals, fruits (citrus and apple), cotton and other oilseeds and grapes.
- Animal commodities: Animal transfer study in cattle including milk analysis and poultry feeding studies including analysis of eggs.

| | Review Outcome | Key Date |
|---|---|---|
| **5.#** | It is recommended that the current MRLs in Table 1 of the MRL Standard, be amended as follows: | **30 June 2000** |

The following MRLs are to be deleted:

| Code | Food | MRL (mg/kg) |
|---|---|---|
| VR 0577 | Carrot | 0.2 |
| MO 0812 | Cattle, Edible offal of | 0.2 |
| MM 0812 | Cattle meat [in the fat] | 0.2 |
| GC 0080 | Cereal grains | 0.2 |
| VD 0526 | Common bean [navy bean] | 1 |
| OC 0691 | Cotton seed oil, crude | 0.5 |
| PE 0112 | Eggs | 0.05* |
| | Fruits | 2 |
| VO 0050 | Fruiting vegetables, other than cucurbits | 2 |
| MO 0814 | Goat, edible offal of | 0.2 |
| MM 0814 | Goat meat [in the fat] | 0.2 |
| VD 0545 | Lupin (dry) | 1 |

| | | |
|---|---|---|
| ML 0106 | Milks [in the fat] | 0.5 |
| VD 0536 | Mung beans (dry) | 1 |
| SO 0088 | Oilseed | 1 |
| VA 0385 | Onion, Bulb | 0.2 |
| SO 0697 | Peanut | 1 |
| VR 0589 | Potato | 0.2 |
| PO 0111 | Poultry, Edible offal of | 0.2 |
| PM 0110 | Poultry meat [in the fat] | 0.2 |
| GC 0649 | Rice | 0.1 |
| MO 0822 | Sheep, edible offal of | 0.2 |
| MM 0822 | Sheep meat [in the fat] | 0.2 |
| VD 0541 | Soybean (dry) | 1 |
| VO 0447 | Sweet corn (corn-on-the-cob) | 0.2 |
| VR 0508 | Sweet potato | 0.2 |
| DT 1114 | Tea, Green, Black | 30 |
| TN 0085 | Tree nuts | 2 |
| VO 0448 | Tomato | 2 |
| | Vegetables [except carrot; common beans; lupin (dry); mung bean (dry); onion, bulb; potato; soybean (dry); sweet corn (corn-on-the-cob); sweet potato] | 2 |

* the limit of analytical quantitation

The following MRLs are to be set:

| Code | Food | MRL (mg/kg) |
|---|---|---|
| FT 0005 | Assorted tropical and sub-tropical fruits - edible peel | T2 |
| FT 0006 | Assorted tropical and sub-tropical fruits - inedible peel | T2 |
| FB 0004 | Berries and other small fruits | T2 |
| VB 0040 | Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas | T2 |
| GC 0080 | Cereal grains | T0.2 |
| FC 0001 | Citrus fruits | T2 |
| OC 0691 | Cotton seed oil, crude | T0.5 |
| | Curcurbits | T2 |
| PE 0112 | Eggs | T*0.05 |
| VO 0050 | Fruiting vegetables, other than cucurbits | T2 |
| VL 0013 | Leafy vegetables (including Brassica leafy vegetables) | T2 |
| VP 0034 | Legume vegetables | T2 |
| 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 0002 | Pome fruits | T2 |

| | | |
|---|---|---|
| PO 0111 | Poultry, Edible offal of | T0.2 |
| PM 0110 | Poultry meat [in the fat] | T0.2 |
| VD 0070 | Pulses | T1 |
| GC 0649 | Rice | T0.1 |
| VR 0075 | Root and tuber vegetables | T2 |
| VA 0388 | Shallots | T2 |
| VS 0017 | Stalk and stem vegetables | T2 |
| FS 0003 | Stone fruits | T2 |
| DT 1114 | Tea, Green, Black | T30 |
| TN 0085 | Tree nuts | T2 |

* - the limit of analytical quantitation
T - temporary MRL

**IMPORTANT NOTE: The temporary MRLs above will be withdrawn on 31/12/2000 unless data are submitted to support these MRLs by 30/06/2000.**

| | Review Outcome | Key Date |
|---|---|---|
| **6.** | The Table 4 MRL of 0.3 mg/kg for Primary animal feed should remain. Unless strategies are established to accommodate residues higher than 0.2 mg/kg in meat (mammalian)[in the fat], or residue data are generated for individual animal feed commodities, the MRL should stay unchanged.<br><br>In relation to any future applications for registration, it is strongly recommended that residue data on any likely animal feeds [forage, fodder or hay, processed wastes from raw commodities such as citrus pulp, apple pomace, cotton meal, cotton seed, rice hull, vegetable wastes], be generated by addressing the maximum treatment regimes (ie. application rate, number of applications, and intervals between re-applications). The time course of the residue decline should be demonstrated in all trials. | **Not Applicable** |
| **7.** | All future Australian residue data should be submitted by registrants or applicants to Codex Alimentarius Commission for review, so that Codex MRLs for endosulfan can encompass Australian use patterns. It is noted that endosulfan has been scheduled for periodic review by Codex in 2000. | **December 31 1999** |

 

## Labelling

| | Review Outcome | Key Date |
|---|---|---|
| **8.#** | An interim re-entry period of two days is required on labels by **30/06/1999**. Collection and assessment of Australian re-entry data for different crop types will enable an appropriate permanent re-entry period to be confirmed. Protocols for development of re-entry information must be acceptable to the NRA. Data showing the likely exposure of workers to in-crop residues for different crop types/situations must be submitted by appropriate industries by **31/12/1999**. In the case of crop types for which no data is provided or can be extrapolated, those crops will be subject to a 3 day re-entry period after the deadline of **31/12/1999**. In the case of crop types where data was provided, a decision will be made by **30/06/2000**. The following label statements are required: | **30 June 1999**<br><br>**31 December 1999**<br><br>**30 June 1999** |

**Re-entry period**

**Do not allow entry for 2 days after treatment unless wearing cotton overalls buttoned to the neck and wrist and elbow length PVC gloves. Clothing must be laundered after each day's use.**

**Hand weeders:**
**Do not allow entry into treated areas for 2 days after treatment. After this period, it is recommended to wear shoes or boots, socks, long trousers, long sleeved shirt, gloves and hat.**

| | Review Outcome | Key Date |
|---|---|---|
| **9.#** | A statement promoting the preferred use of enclosed vehicle cabs for ground spraying equipment over reliance on personal protective equipment is to be included on the label below the Safety Directions as follows: | **30 June 1999** |

**To minimise exposure, a vehicle equipped with an enclosed cab should be used for ground spraying operations when practicable.**

| | | |
|---|---|---|
| **10.#** | In order to minimise environmental impact, all labels will be required to carry the following precautions: | **30 June 1999** |

**DO NOT apply under meteorological conditions or**

**from spraying equipment which could be expected to cause spray to drift onto wetlands, natural surface waters, neighbouring properties or other sensitive areas.**

**DO NOT apply if heavy rains or storms that are likely to cause surface runoff are forecast within two days of application.**

**DO NOT apply when irrigating or for at least two days after irrigation, or to waterlogged soil or while water remains in furrows unless tailwater can be captured.**

| | Review Outcome | Key Date |
|---|---|---|
| **11.#** | Withholding periods (WHPs) for uses which are currently less than two days will be increased to two days. These uses include:<br><br>Beetroot, Chou Moullier, cole crops, cucurbits, green beans, field and green peas, leaf vegetables, silver beet, stalk vegetables, tomatoes and turnip. | **30 June 1999** |
| | All other current withholding periods (WHPs) for human food, including pulses and leafy vegetables, should remain. Pulses, brassica and leafy vegetables, when treated for human consumption only, shall not be deemed different from other human food commodities in this regard. The establishment of a grazing WHP shall depend on the maintenance of the slaughter interval of 42 days and/or on the feasibility of not feeding crops of concern. The following label statements are required: | **30 June 1999** |

**FOR HUMAN FOODS**

**SEE THE CROP HARVEST WITHHOLDING PERIODS (WHPS) SPECIFIED IN THE INSTRUCTION TABLE.**

**FOR ANIMAL FEEDS ( INCLUDING PULSES, VEGETABLES, VEGETABLE AND FRUIT WASTES, FODDER AND FORAGE):**
**DO NOT RE-APPLY WITHIN 7 DAYS.**
**DO NOT GRAZE ORCHARDS AFTER APPLICATION.**
**DO NOT FEED TREATED CROPS OR**

**CROP PARTS (EXCEPT COTTONSEED/MEAL) TO LACTATING COWS PRODUCING MILK FOR HUMAN CONSUMPTION.**

A grazing WHP of four weeks plus 42 days slaughter interval should be observed for legumes, vegetables and any other crops intended for forage except for maize and sorghum as noted next. A grazing WHP of eight weeks plus 42 days slaughter interval should be observed for maize and sorghum forage.

Where processed commodities such as apple pomace, citrus pulp or fruit peels in a cannery are traditionally traded as animal feeds, exchanges of information on crop and animal produce residues between farmers and processors should be actively promoted and facilitated by grower organisations and government agencies.

The following crop harvest WHPs and withhold from slaughter intervals are to be included in Label Instructions as shown below: **30 June 1999**

| Crop/Commodity | Crop Harvest WHP | Animal Management |
|---|---|---|
| Cottonseed/meal | 4 weeks | Nil slaughter interval |
| Apples & Pomace | 4weeks | 42 day slaughter interval |
| Grain legumes & Pulses and Fodder/stubble | 4weeks | 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 (eg tomato, leafy vegetables) | 4 weeks | 42 day slaughter interval |
| Citrus & citrus pulp | 4 weeks | 42 day slaughter interval |

The following crop/commodities are special cases which require different treatment to avoid violations of animal MRLs. The following information is to be included on labels as shown below: **30 June 1999**

| Crop/Commodity | Crop Harvest WHP | Animal Management |
|---|---|---|
| Cotton trash | Not Applicable | Do not feed to animals |
| Legume vegetables | 2 day | Do not feed to animals |
| Maize grain | 8 weeks | Nil slaughter interval |
| Maize fodder | 8 weeks | 42 day slaughter interval |
| Other vegetables (eg tomato, leafy vegetables) | 2 day | Do not feed to animals |
| Sorghum grain | 8 weeks | Nil slaughter interval |
| Sorghum fodder | 8 weeks | 42 day slaughter interval |

**Health**

| | Review Outcome | Key Date |
|---|---|---|
| **12.#** | All product registrants and TGAC approval holders are required to produce Material Safety Data Sheets for their respective TGAC and products by 30/06/1999. | **30 June 1999** |
| **13.#** | The First Aid and Safety Directions as revised will appear on the label as follows: | **30 June 1999** |

***EC and ULV all strengths***

| | |
|---|---|
| 100 | Very dangerous |
| 130 131 132 133 | Poisonous if absorbed by skin contact, inhaled or swallowed |
| 207 162 | Will damage eyes |
| 161 164 | Will irritate the skin |
| 210 211 | Avoid contact with eyes and skin |
| 220 222 223 | Do not inhale vapour or spray mist |
| 279 280 281 282 290 291 294 298b 301 (or 297 300) | When opening the container, preparing the spray and using the prepared spray wear protective waterproof clothing, elbow-length PVC gloves, water resistant footwear and full-facepiece respirator (or goggles and half facepiece respirator) |
| 340 341 343 | If product or spray in eyes, wash it out immediately with water |

| | |
|---|---|
| 340 342 | If product on skin, immediately wash area with soap and water |
| 350 | After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water |
| 360 361 363 364 366 | After each day's use, wash gloves, goggles, respirator and if rubber wash with detergent and warm water and contaminated clothing |

**Supply and Use**

| | Review Outcome | Key Date |
|---|---|---|
| **14.#** | In order to limit supply and use to suitably trained persons, endosulfan will be included in the Agricultural and Veterinary Chemicals Code Regulations as a restricted chemical product, and labels will be altered accordingly by the inclusion of the following wording:<br><br>**RESTRICTED CHEMICAL PRODUCT - ONLY TO BE SUPPLIED TO OR USED BY AN AUTHORISED PERSON**<br><br>It is proposed that 'authorised persons' will be those who have obtained Farmcare Australia accreditation or another accreditation acceptable to the NRA or who are licensed spraying contractors. | **30 June 1999** |
| **15.** | Suppliers must obtain proof from purchasers that they are authorised to possess and use endosulfan before supplying endosulfan. | **30 June 1999** |
| **16.#** | Existing guidance on safe flagging procedures needs to be upgraded by industry by **30/06/1999**. Human flagging in aerial operations is not acceptable unless flaggers are protected by engineering controls such as cabs. | **30 June 1999** |
| **17.#** | The NRA will adopt the FAO compositional standard for this chemical. All TGACs will be required to comply with this standard (Regulation 42 concerning standards) by **30/06/1999**. | **30 June 1999** |

| | **Review Outcome** | **Key Date** |
|---|---|---|
| **18.** | In order to better manage spray drift, a spray drift minimisation strategy is to be employed at all times. The strategy envisaged is exemplified by the cotton industry's treatment of buffer zones in their recently published *Australian Cotton Industry Best Management Practices Manual*, December 1997. Adoption of in crop buffer zones or other protective measures which accord with the confirmed findings of current research should be actively promoted by representative grower organisations. | **30 June 1999** |

**Compliance**

| | | |
|---|---|---|
| **19.** | The NRA and relevant State departments will monitor the supply and restricted use regime to ensure the restrictions are being complied with. | **Ongoing** |

## Advice to Users and Industry

1. All feedlots and/or abattoirs for beef export should monitor residues in animal feed and animal produce. Where it is impractical to have an on-site laboratory, monitoring could be contracted to other laboratories.

2. Packaging and mixing/loading mechanisms should be improved to avoid the use of open pour methods and minimise worker exposure to the concentrate.

3. Industries are encouraged to use ground application whenever possible near sensitive areas to minimise the potential for drift of chemical off target.

4. Industries are encouraged to use ground application during early crop stages when band spraying is feasible to minimise the amount of endosulfan applied per hectare and reduce the amount falling on the soil surface.

5. Continued research into comparing ULV and EC formulations with regard to drift and run-off potential should be pursued to help minimise off-farm movement of endosulfan.

6. Use of endosulfan at high temperatures (above 30° C) should be avoided whenever possible due to increased volatility losses into the atmosphere at higher temperatures.

7. Training requirements for the safe handling of pesticides in aerial spraying applications, especially regarding the potential for spray drift and other unintended off-target deposition, should be strengthened.

## 8. PROTECTION STATUS OF SUBMITTED DATA

Many of the studies contained in the bibliographies of the full review report have been judged by the NRA as being protected registration information in accordance with Part 3 of the Agvet Code. A full list of those studies identified as protected can be obtained separately from the NRA. Requests for this list should be addressed to:

Manager, Chemical Review
National Registration Authority
PO Box E240
KINGSTON ACT 2604

## ATTACHMENT 1: Summary of Public Response to the Draft Endosulfan Review

After substantial and continuous consultation with the public, industry and State agricultural authorities, the NRA released a draft endosulfan review report on 22 December 1997 for public comment. This release was widely advertised and notices were sent to all who had expressed interest in or who had participated in the review to that point. The draft review was published on the NRA website and printed copies were available upon request. A period of over two months was given to receipt of all comments and submissions from the community.

The NRA received considerable response during the public comment phase. This summary describes the principal issues brought out in responses to the draft review. Public comment specifically addressed the proposed review recommendations contained in the draft.

Approximately 150 submissions were received, the great majority of which came from individual growers, grower organisations and commodity organisations. Four submissions were received from groups representing community and environmental concerns and two submissions were received from producers of endosulfan.

Detailed submissions were received from organisations representing industries producing the following commodities: apples and pears, avocadoes, canola, cotton, custard apples, flowers, fruits and vegetables (in general), grains, macadamia nuts, oilseeds (in general), ornamental plants, peanuts, processed seed, soybeans, stonefruit, subtropical fruits, sunflowers and tobacco.

Several issues dominated the concerns expressed by the community and industry. Those issues and others are presented below with the most frequently raised issues first. Text entries describing the public concerns are in normal type font. The responses of the NRA to those concerns or the manner in which the NRA addressed those issues are shown in *italic font*.

### Limitations on Frequency of Application

1. The most frequently raised issue was the proposed limitation of 2 sprays per crop per season. Endosulfan users and user representatives said that a limitation to two sprays per season would not be adequate to protect crops because the severity of insect pest pressures is variable. While 2 sprays might be adequate for some crops in some areas in some years, growers objected that such a situation would be uncommon and that the limitation would force them to use other, harsher chemicals (when available) to save their crops during more common pest/crop situations. It was argued that any alternative chemicals which could be used would kill all beneficial insects whereas endosulfan use allows significant seed populations to survive. Loss of the beneficial insects, especially early in the season, would result in much greater insect and mite problems later in the season leading to the use of more pesticides than would be needed if endosulfan was not restricted in this way. For some crops such as avocados and macadamias, the 2 spray limit for endosulfan was considered to be entirely unworkable at any time due to especially difficult pests such as the fruit spotting bug and the simultaneous need to maintain populations of beneficial insects in the orchards.

*The two spray limit was proposed as a means of limiting endosulfan exposure to agricultural workers. The issue of efficacy alone could not take precedence over the issue of worker safety. However, since the draft was circulated, new data has been obtained from the Pesticide Handlers Exposure Database (PHED) which is used in the United States and Canada. This data provides part of the information needed to relieve some of the concern over the occupational health and safety issues for some uses. There continues to be a need to generate worker exposure data for certain uses under Australian conditions, but endosulfan can be used on an interim basis until that data is obtained and analysed. Use of endosulfan will be withdrawn for any uses for which data is not provided by the dates specified in the review outcomes. (See Review Outcome numbers 3, 8, 9 and 16)*

2. Related to the issue above was the proposed requirement that growers could use more than 2 applications per crop per season in the context of an IPM or resistance management program provided that those extra sprays were applied by licensed application contractors. Many respondents informed the NRA that licensed contractors did not exist in most areas and that where some did exist, their numbers were not sufficient to service the needs of growers in the region. In particular, for a number of crops, the time window for spraying was critically short, related to local weather conditions and local insect population pressures and that even if contractors did exist in reasonable numbers, they could not possibly treat all crops requesting their service in such short periods of time. Growers also argued that paying contractors was an unnecessary and an unreasonable expense when they had already invested in expensive spray equipment, taken chemical safety training courses and were themselves the most highly motivated of all to protect both their own safety and the safety of their crops.

   *The NRA accepted the information and arguments above as reasonable. There was, however, still a need to address the issue of safety to people actually applying pesticides. That issue is partly dealt with in the response to point 1 above. In addition, it could be addressed by better chemical safety training for all those who work with and apply pesticides, since the original logic behind the requirement to use licensed contractors was that those contractors would be highly trained in and specially equipped for safety. Therefore, the use of endosulfan will be restricted to people who have obtained adequate training in the use of pesticides. See further discussion of this issue in point 8 below.*

**Essential Uses**

3. A concern also raised frequently was the proposal to limit endosulfan to “essential uses” as defined in the draft proposal. Those industries which had been left out of the essential use category objected that the availability of endosulfan was crucial to their need as well. Those industries which were included as essential uses in some states but excluded in other states argued that they should be included in all states.

   *The concept of limiting endosulfan to “essential uses” was introduced as a means of reducing the overall amount of endosulfan used and thereby reducing both the risk to* *agricultural workers and reducing the amount of endosulfan which might contaminate the general environment. However, since the circulation of the draft report for public comment, new data has been reviewed which partially reduces the high level of concern formerly held over the issue of worker safety (see response under point 1 above). Therefore the distinction of essential uses has been removed from the review outcomes and endosulfan will be available to all industries subject to other restrictions which are designed to reduce the amount of endosulfan contaminating the general environment. (See especially Review Outcomes numbers 1, 2 and 10.)*

## Re-entry Period

4. The imposition of a 3-day re-entry period caused much comment It was argued that a number of industries have used a shorter re-entry period for years without any apparent problem. For example, the cotton industry typically observes a 2-day re-entry period and in some vegetable crops which may at times be harvested daily, one day is standard. In addition, orchardists pointed out that walking under trees to check the efficacy of a spray application had a very different exposure potential compared, for example, to walking through a closed canopy of a waist high field crop.

   *The perception that no problems with 1 or 2-day re-entry periods have become apparent in the last decade or more is not of itself adequate to guarantee the safety of the practice. The fact that no adverse incident reporting system has been in place and that toxic symptoms due to endosulfan exposure may be misinterpreted as due to other causes could prevent recognition of a problem.*

   *The NRA has data from one study which indicates that one day is not a safe re-entry period in cotton 50 cm tall. More comprehensive data and data from other crop situations are required. In Review Outcome number 8, the NRA has therefore required exposure data relevant to re-entry to be submitted by 31/12/1999. The studies must be done according to protocols acceptable to the NRA.*

   *In the interim, while data is being generated and analysed, a 2-day re-entry period will be in force for all crops. In the case of crop types for which no data is provided, those crops will be subject to a 3 day re-entry period after the deadline of 31/12/1999. In the case of crop types where data was provided, a decision will be made by 30/06/2000.*

   *Those crops which in the past have had a withholding period of one day will have their withholding period increased to 2 days to be consistent with the interim re-entry period.*

## Worker Exposure Data Requirements

5. The call for Australian worker exposure data was objected to by some respondents on the grounds that new studies would be expensive and that endosulfan had been in use for over 30 years with no pronounced worker safety problems becoming evident. Some respondents stated that the POEM modelling method cited in the review was too conservative and based on inadequate data or data not appropriate for Australian conditions. Objections also stated that there was not enough time given to complete

new studies.

*The NRA recognises that worker exposure studies are costly and take time to complete. However, because of the toxicity of endosulfan and the potential hazard to agricultural workers, the NRA must be satisfied that risks to workers are acceptably low. The recently acquired data from a database (PHED) used in the United States and Canada (see the response under point 1 above) went only part of the way to answer questions over worker safety.*

*The NRA will still require studies which conform to scientific principles and protocols to ensure that current questions of safety can be resolved. It is expected that the studies can be accomplished in the time allowed and that most of the studies can be done on a cooperative basis between industries for similar practices and between States, commodity organisations and registrants. Many of the studies will also be able to be used to support practices with other chemicals which may come under question in the future.*

## Greenhouse Use

6. The proposal to stop use of endosulfan in greenhouses until worker exposure data could be generated to show that greenhouse applications were safe was thought to be unreasonable and overly restrictive by not giving industry time to respond. Moreover, some questioned the concern over greenhouse use claiming no obvious problems had emerged in the past.

   *While the NRA presently does not have studies showing that greenhouse use is safe to workers, acute exposure problems have not emerged from long standing practices and a very short term continuation of use could be justified. Therefore, the NRA has changed its earlier position and will now allow the use of endosulfan in greenhouses to continue until data is generated which clearly demonstrates the level of hazard to workers. This continuation of use will only be allowed until 31/12/1999 and data must be provided for analysis by 30/06/1999. Furthermore, the studies must also include a protocol to establish a safe re-entry period in greenhouses.*

## Residue Data Requirements

7. The proposed requirement that industry provide residue data to fill existing data gaps caused concern among producers mainly for two reasons. Some simply objected that generating the new data would be expensive and that it was not needed in view of the fact that for many commodities, endosulfan violations had not been a serious problem. Others objected because small industries would not have the funds necessary to generate the data and because chemical companies would decide that small industries, as a future market, could not justify the cost of generating residue data for those industries. Therefore, it was argued that endosulfan would be lost to many of the smaller commodity uses. Finally, there were some who believed that not enough time had been allowed to generate the data while community groups argued that industry should not be given as much time as allowed.

*Because endosulfan is an old chemical, various MRLs were set before current health practices were defined and often without the benefit of specific supporting data. Without actual data to support MRLs for endosulfan, there is no way to be sure that current MRLs are set at appropriate levels for current use practices. From a trade standpoint, the NRA cannot allow such unsupported uses to continue indefinitely, and therefore data is required.*

*Certain States have indicated that they will support studies for many of the small industries operating within their borders. Commodity organisations and state agricultural authorities may be able to cooperate to produce the required studies within the time frame set by the NRA.*

*Performing modern studies to generate dependable and informative data to enable realistic and safe MRLs to be set is time consuming. The NRA has chosen a time frame which it considers to be minimal but achievable.*

## Restricted Chemical Status

8. The proposal to make endosulfan a "restricted chemical" was not generally questioned. However, the proposal to limit its purchase only to licensed contractors or to those who have completed a specific chemical safety training course was cause for concern. Almost all supported the call for better and more uniform chemical safety training but believed that a number of suitable courses existed and that the NRA should recognise those training programs which are at least as comprehensive as the Farmcare Australia course. One submission suggested that the NRA should design and administer a course specific to endosulfan users.

*The Farmcare Farm Chemical User Training Program has achieved a nationwide recognition. However, the NRA realises that other training programs are available and will recognise those training programs following suitable evaluation by the NRA. The NRA believes that a course specific to endosulfan would not be more beneficial to user and community safety than the more general type of program.*

## Environmental Exposure

9. Some respondents objected to the proposed withdrawal of endosulfan unless scientific arguments or data were presented supporting its use or unless a strategy was adopted making continued availability dependent upon reductions in environmental exposure. Their objections were based upon the grounds that there is no evidence that endosulfan is harming the environment. By contrast, several other respondents believed that endosulfan is so dangerous and pervasive in the environment, that it should be more stringently restricted or banned at once.

*Although endosulfan concentrations in some areas routinely exceed ANZECC criteria recommended to protect aquatic ecosystems, there is not yet clear evidence that endosulfan is causing long term harm to the general environment or biological* *communities in surface waters of those areas. However, it is known that during parts of each year in the rivers and creeks of regions where endosulfan is used intensively, it reaches concentrations which are lethal to important species of native fish and native macroinvertabrates when tested under laboratory conditions. Regular attainment of such concentrations of endosulfan in regional surface waters is not acceptable on an ongoing basis. Concern over this problem is increased by the predictions of some authorities that acreage of cotton, the main user of endosulfan, is likely to increase significantly in the next few years in some of these regions. In addition, endosulfan has been found at very low levels in rainwater tanks (for human drinking water) near areas of intensive use.*

*The NRA therefore considers it to be necessary to achieve a reduction in environmental contamination of endosulfan consistent with its legislative obligations in this area. Review Outcomes numbers 1, 2 and 10 are especially intended to lower environmental contamination. In particular, under Review Outcome number 1, endosulfan may be further restricted or withdrawn if satisfactory reductions in environmental levels are not achieved by 30 June 2001.*

## Aerial and Ground Application

10. Another issue of concern related to the problem of aerial spray drift and the recommendation that ground application be encouraged over aerial application. One submission argued that endosulfan should be banned from all aerial spraying and be limited to ground application or at the very least aerial spraying should be heavily curtailed. In a related separate issue, it was suggested that notification of neighbours be made mandatory before spraying with endosulfan could commence.

    *Although spray drift is typically a lesser problem with ground application as compared with aerial spraying, the broader issue is more complex. For example, from the standpoint of overall worker safety, ground application requires the exposure of many more individuals to pesticides during mixing, loading and application than does aerial application due to the vastly greater number of hectares per person per unit time which can be treated by air. The aerial application industry is also self-regulated and regulated by all State governments in terms of licensing, record keeping, standards and practices. In addition, the aerial industry uses newer technologies such as closed mixing and loading systems and such as the global positioning system (GPS) to accurately position sprays and provide a reliable record of application. By comparison, individuals who apply by ground have far fewer restrictions and oversights and generally do not have affordable access to technology which is as advanced or as highly maintained and inspected.*

    *The NRA encourages ground application where it would be more efficacious, where band spraying could be used to reduce overall chemical use or in sensitive areas where spray drift may result in serious consequences. However, the NRA also recognises that aerial spraying has distinct advantages in some applications and in certain situations is the only method which is practicable.*

*Ongoing improvements in technology and practices promise to reduce the problem of spray drift from both aerial and ground application methods. The Aerial Agricultural Association of Australia and the cotton industry as exemplified in the recently published Australian Cotton Industry Best Management Practices Manual are actively pursuing ways to improve the effectiveness and safety of pesticide application.*

*The separate issue of notification of neighbours before spraying operations is essentially a control of use issue administered by State governments. However, it is encouraged by the NRA and is built into the Review Outcomes for all cotton uses by means of the requirement to follow cotton best management practices. (See Review Outcome number 1.) In addition it is recommended for all applications under Review Outcome number 18.*

11. A respondent suggested that the proposed label precaution, which warns against spraying under unfavourable “meteorological conditions” which might be expected to cause spray drift, should specify the meteorological conditions in detail on the label.

*The NRA notes that only people who are licensed application contractors who are required to have extensive training and experience or individuals who have completed a chemical safety training course specified by the NRA are allowed to purchase and use endosulfan. These people will have been trained as to the specific meteorological conditions to avoid and will understand the precaution as stated.*

## Other Issues

12. A few respondents objected to the requirement to maintain an interval of 10 days between endosulfan applications as this requirement could seriously conflict with the need to spray pests. If endosulfan could not be used, a different chemical would necessarily be used which would kill beneficial insects and disrupt IPM programs. Resistance management programs would also be disrupted.

*The 10 day spray interval applied only to crops intended to be used as animal feed. The format of presentation in the draft report may not have been clear, making it easy to misinterpret the intent of the statement. As indicated earlier, there is not adequate data to support existing MRLs. However, limited information indicates that feeds, fodders and wastes intended for animal consumption often have higher residue levels than foods intended for human use. Since release of the draft report, a re-evaluation of the limited data has determined that the spray interval could be reduced to 7 days Maintenance of a 7 day spray interval in commodities intended for animal feed is a necessary precaution to help prevent endosulfan residue violations in animals. Such violations could threaten international trade.*

13. One submission warned against the possibility that a “black market” for endosulfan might develop if those who were legally able to purchase the chemical could buy more than they needed for their own use in order to sell it to others who had no access to legal purchase.

*The NRA believes that the restraints under the declaration of endosulfan as a restricted chemical (see Review Outcome numbers 14 and 15) and the requirement to maintain an auditable spray record (see Review Outcome number 1) will work to prevent any legal purchaser from obtaining enough chemical undetected to make onselling of endosulfan worth the risk of penalty.*